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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
	7	11660030		2023-05-30	BULLINGTON GREGORY J	
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	Art Unit	OPAP
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	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

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Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-12-20
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/783,088	**08/26/2024 08:25:09 PM Z ET**	**069366-0580418_KUR2C06US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	2051	FILED BY	Trent Tercenio
PATENT CENTER #	66927842	FILING DATE	07/24/2024
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 77

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
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069366-0580418_KUR2C06US_PTO_IDS-Form-C.pdf	5	Information Disclosure Statement (IDS) Form (SB08)	1293 KB
069366-0580418_KUR2C06US_PTO_IDS-Form-B.pdf	9	Information Disclosure Statement (IDS) Form (SB08)	1318 KB
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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27500 7590 11/28/2022

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 11/28/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	069366-0572168_KUR4002US	6468

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH PASSIVE FLUID CONTROL JUNCTION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	02/28/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

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III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

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Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	069366-0572168_KUR4002US	6468

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH PASSIVE FLUID CONTROL JUNCTION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	02/28/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-573000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	069366-0572168_KUR4002US	6468

27500 7590 11/28/2022

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 11/28/2022

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/819,033	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 11/04/2022.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-23 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. 11/16/2022.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Terminal Disclaimer

2. The terminal disclaimer filed on 11/17/2022 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 17/094692, 17/538990, 11311219, 9820682, 10143412, 11185266 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

3. Authorization for this examiner's amendment was given in an interview with BENJAMIN F. HUDSON on 11/06/2022.

Claim 5 should be amended as follow:

5. (Currently Amended) The device in accordance with claim 1, wherein the junction includes one or more passive structures configured to inhibit ~~a~~ **the** return to the inlet path of any of the first portion of blood received by the chamber.

Allowable Subject Matter

4. Claims 1-23 are allowed.

5. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Eldridge et al (4,207,870) teaches a device comprising; an inlet path;

an outlet path; a chamber connected to the inlet path; and a sampling channel connected between the inlet path and the outlet path, the sampling channel being configured to convey subsequent amounts of blood between the inlet path and the outlet path after the first amount of blood is received by the sequestration chamber.

The prior art does not teach, disclose and/or fairly suggest a chamber connected with the inlet path by a junction and being configured to receive a first portion of blood through the inlet path, the junction being configured to inhibit a return to the inlet path of any of the first portion of blood received by the chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Examiner-Initiated Interview Summary	**Application No.** 16/819,033	**Applicant(s)** ROGERS et al.		
	Examiner MAY A ABOUELELA	**Art Unit** 3791	**AIA (First Inventor to File) Status** Yes	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
MAY A ABOUELELA	Primary Examiner	Telephonic
BENJAMIN F. HUDSON	Attorney of Record	

Date of Interview: 16 November 2022

Issues Discussed:

35 U.S.C. 112

Applicant and Examiner discussed the claims set mailed on 11/04/2022. Applicant and Examiner discussed the claim language with respect to the applied prior art and the disclosure. Applicant and Examiner discussed proposed claim amendments represented by the Examiner to overcome 112 rejection for claim 5. The Applicant has authorized the Examiner to amend the claims.

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	KURIN4CIP	6468

158174 7590 08/04/2022

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
08/04/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficeaction@appcoll.com
jsnolan1@hotmail.com
kurin@virtualipsupport.com

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No. 16/819,033	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 03/13/2020.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☑ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 06/01/2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 06/24/2020, 07/03/2020 and 09/18/2020. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

4. Claim 11 is objected to because of the following informalities: the phrase "in inlet port" in line 2 should be amended to read –an inlet port--. Appropriate correction is required.

5. Claim 11 is objected to because of the following informalities: the phrase "the vent further being further configured to" in line 8 should be amended to read –the vent further being configured to--. Appropriate correction is required.

6. Claim 12 is objected to because of the following informalities: the phrase "it" in line 3 should be amended to read –air--. Appropriate correction is required.

7. Claim 13 is objected to because of the following informalities: the phrase "a return" in line 2 should be amended to read –the return--. Appropriate correction is required.

8. Claim 18 is objected to because of the following informalities: the phrase "a patient" in line 4 should be amended to read –the patient--. Appropriate correction is required.

9. Claim 18 is objected to because of the following informalities: the phrase "at subsequent" in line 8 should be amended to read –a subsequent--. Appropriate correction is required.

10. Claim 19 is objected to because of the following informalities: the phrase "a return" in line 3 should be amended to read –the return--. Appropriate correction is required.

Claim Interpretation

11. The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word "means," but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform

the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

Limitation "closure mechanism" in claim 12, the claim does not recite enough structure that corresponds to the claimed "closure mechanism", however the specification disclose (the closure mechanism 3710 is a raised portion that is raised from an outer surface of the housing, par.215, the closure mechanism simply defines a surface to interface with another object, such as a human fingertip, a cotton swab, a piece of tape, or any other object, to seal any vents, apertures, openings, holes, par.216, closure mechanism in the form of a cap 3180 to enclose and/or seal air-permeable blood barrier and/or air vent, par.219).

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

12. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-20 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claim 18 recites the limitation "the patient needle" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "the sample needle" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s)

because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 7-13 of co-pending Application No.17/094692, claims 1-20 of co-pending Application No.17/538990, claims 1-20 of U.S Patent Application

No.11311219, claims 1-16 of U.S Patent Application No. 9820682, claims 1-23 of U.S Patent Application No.10143412, and claims 1-2 of U.S Patent Application No. 11185266. Although the claims at issue are not identical, they are not patentably distinct from each other because the copending and patent applications and the instance application are claiming a common subject matter including: a blood sequestration device comprising; an inlet path; an outlet path; a sequestration chamber connected with the inlet path by a junction and being configured to receive a first portion of blood through the inlet path, the first blood portion is inhibited to return to the inlet path; and a sampling channel connected between the inlet path and the outlet path, the sampling channel being configured to convey subsequent amounts of blood between the inlet path and the outlet path.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 16/819,033	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
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*	B	US-9138572-B2	09-2015	Zeytoonian; Paul	A61M39/26	1/1
*	C	US-8568371-B2	10-2013	Siopes; William	A61M39/26	251/903
*	D	US-8540663-B2	09-2013	Davey; Christopher T.	A61M1/30	604/93.01
*	E	US-8523826-B2	09-2013	Layton, Jr.; Russell K.	A61M39/16	604/533
*	F	US-20160174888-A1	06-2016	Berthier; Erwin	A61B5/150503	600/573
*	G	US-8197420-B2	06-2012	Patton; Richard G.	A61B5/150503	600/573
*	H	US-4057050-A	11-1977	Sarstedt; Walter	A61B5/150351	604/125
*	I	US-20050240161-A1	10-2005	Crawford, Jamieson William McLean	A61B5/150572	604/264
*	J	US-20040147855-A1	07-2004	Marsden, Stewart	A61B5/150496	600/576
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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

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*	B	US-20030105414-A1	06-2003	Leong, Alvin Tan Chee	A61B5/15003	600/576
*	C	US-5749857-A	05-1998	Cuppy; Michael J.	A61M25/0606	604/161
*	D	US-9060724-B2	06-2015	Bullington; Gregory J.	A61B5/150221	1/1
*	E	US-9204864-B2	12-2015	Bullington; Gregory J.	A61B10/0096	1/1
*	F	US-20020004647-A1	01-2002	Leong, Alvin Tan Chee	A61B5/1545	604/168.01
*	G	US-3817240-A	06-1974	Ayres; Waldemar A.	A61B5/150221	600/584
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*	G	US-9022951-B2	05-2015	Bullington; Gregory	A61B5/150244	600/576
*	H	US-6569117-B1	05-2003	Ziv; David	A61M39/02	604/246
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*	D	US-20070083162-A1	04-2007	O'Reagan; James	A61M39/26	604/167.03
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16819033
Filing Date	2020-03-13
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	
Attorney Docket Number	KURIN4CIP

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4444203	A	1984-04-24	Engelman	
	2	6398743	B1	2002-06-04	Halseth et al.	

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	1	20070083162	A1	2007-04-12	O'Reagan et al.	

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	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	
	Attorney Docket Number	KURIN4CIP

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	Examiner Name	
	Attorney Docket Number	KURIN4CIP

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/JSN/	Date (YYYY-MM-DD)	2020-09-18
Name/Print	James Scott Nolan	Registration Number	53,393

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Doc description: Information Disclosure Statement (IDS) Filed

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	1	4349035	A	1982-09-14	Thomas et al.	
	2	5401262	A	1995-03-28	Karwoski et al.	

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	3	20180353117	A1	2018-12-13	Magnolia Medical Technologies, Inc.	

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	Art Unit	3791
	Examiner Name	
	Attorney Docket Number	KURIN4CIP

	1							

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	1	International Search Report and Written Opinion dated 19 June 2020, for PCT application no. PCTUS2020/023617.	

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	Filing Date	2020-03-13
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	
	Attorney Docket Number	KURIN4CIP

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See attached certification statement.

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Signature	/JSN/	Date (YYYY-MM-DD)	2020-07-01
Name/Print	James S. Nolan	Registration Number	53,393

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(Not for submission under 37 CFR 1.99)

Application Number	16819033
Filing Date	2020-03-13
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	
Attorney Docket Number	KURIN4CIP

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	10010282	B2	2018-07-03	Rogers et al.	
	2	10143412	B2	2018-12-04	Rogers et al.	
	3	3648684	A	1972-03-14	Barnwell et al.	
	4	3741197	A	1973-06-26	Sanz et al.	
	5	3817240	A	1974-06-18	Ayres	
	6	3874367	A	1975-04-01	Ayres	
	7	3886930	A	1975-06-03	Ryan	
	8	4056101	A	1977-11-01	Geissler et al.	

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	9	4057050	A	1977-11-08	Sarstedt	
	10	4106497	A	1978-08-15	Percarpio	
	11	4154229	A	1979-05-15	Nugent	
	12	4207870	A	1980-06-17	Eldridge	
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	15	4813433	A	1989-03-21	Downey	
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	17	5520193	A	1996-05-28	Suzuki et al.	
	18	5749857	A	1998-05-12	Cuppy	
	19	6569117	B1	2003-05-27	Ziv et al.	

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	20	8070725	B2	2011-12-06	Christensen	
	21	8197420	B2	2012-06-12	Patton	
	22	8523826	B2	2013-09-03	Layton Jr.	
	23	8535241	B2	2013-09-17	Bullington et al.	
	24	8540663	B2	2013-09-24	Davey et al.	
	25	8568371	B2	2013-10-29	Siopes et al.	
	26	8603009	B2	2013-12-10	Tan et al.	
	27	8864684	B2	2014-10-21	Bullington et al.	
	28	9022951	B2	2015-05-05	Bullington et al.	
	29	9060724	B2	2015-06-23	Bullington et al.	
	30	9138572	B2	2015-09-22	Zeytoonian et al.	

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	31	9155495	B2	2015-10-13	Bullington et al.	
	32	9204864	B2	2015-12-08	Bullington et al.	
	33	9820682	B2	2017-11-21	Rogers et al.	

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	1	20020004647	A1	2002-01-10	Leong	
	2	20030105414	A1	2003-06-05	Leong	
	3	20030208151	A1	2003-11-06	Kraus et al.	
	4	20040054333	A1	2004-03-18	Theeuwes et al.	
	5	20040073171	A1	2004-04-15	Rogers et al.	
	6	20040147855	A1	2004-07-29	Marsden	

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	7	20050004524	A1	2005-01-06	Newby et al.	
	8	20050005635	A1	2005-01-13	Metais	
	9	20050007524	A1	2005-01-13	Luo et al.	
	10	20050240161	A1	2005-10-27	Crawford	
	11	20070088279	A1	2007-04-19	Shue et al.	
	12	20080145933	A1	2008-06-19	Patton	
	13	20080167577	A1	2008-07-10	Weilbacher et al.	
	14	20080319346	A1	2008-12-25	Crawford et al.	
	15	20090227953	A1	2009-09-10	Tan et al.	
	16	20100010372	A1	2010-01-14	Brown et al.	
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	18	20130317391	A1	2013-11-28	Bullington et al.	
	19	20140039348	A1	2014-02-06	Bullington et al.	
	20	20140107564	A1	2014-04-17	Bullington et al.	
	21	20140155782	A1	2014-06-05	Bullington et al.	
	22	20140276578	A1	2014-09-18	Bullington et al.	
	23	20150246352	A1	2015-09-03	Bullington et al.	
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	26	20160174888	A1	2016-06-23	Berthier et al.	
	27	20160361006	A1	2016-12-15	Bullington et al.	
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	29	20170020428	A1	2017-01-26	Rogers et al.	
	30	20170065733	A1	2017-03-09	Bullington et al.	
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	32	20180177445	A1	2018-06-28	Rogers et al.	
	33	20180353117	A1	2018-12-13	Bullington et al.	
	34	20190159711	A1	2019-05-30	Rogers et al.	

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	1	1665986	EP	B1	2009-06-03	Bennett et al.		
	2	3324845	EP	A1	2018-05-30	Rogers et al.	Equivalent to WO2017/019552	
	3	3562397	EP	A1	2019-11-06	Rogers et al.	Equivalent to WO2018/125929	

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	4	3622890	EP	A1	2020-03-18	Rogers et al.		
	5	3622890	EP	A1	2019-10-01	Bobby E. Rogers		X
	6	2012016496	JP	A	2012-01-26	Akiyama et al.		☐
	7	2019534792	JP	A	2019-12-05	Seilinger et al.		☐
	8	2020000340	JP	A	2020-01-09	Omura et al.		☒
	9	5789869	JP	B2	2015-10-07	Suzuki, Tatsutoshi et al.		☒
	10	5825146	JP	B2	2015-12-02	Karasawa et al.		☒
	11	5867238	JP	B2	2016-02-24	Najiyanto et al.		☒
	12	6643474	JP	B2	2020-02-12	Rogers, et al.		☒
	13	H08257018	JP	A	1996-10-08	Higaki et al.		☒
	14	H09504726	JP	A	1997-05-13	Desecki et al.		☐

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	15	S5825146	JP	A	1983-02-15	Jiyosefu		☒
	16	S5867238	JP	A	1983-04-21	Edowaado et al.		☐
	17	2011162772	WO	A1	2011-12-29	Fischel et al.		☐
	18	2013181352	WO	A1	2013-12-05	Bullington et al.		☐
	19	2017019552	WO	A1	2017-02-02	Rogers et al.		☐
	20	2018125929	WO	A1	2018-07-05	Rogers et al.		☐
	21	9605875	WO	A1	1996-02-29	Desecki et al.		☐

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	1	BULLINGTON, et al, Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in Provisional Application No. 62/517,681, dated 6/9/2017, 131 pages	
	2	Communication Under Rule 71(3) EPC dated 22 April 2020 for EP application no. 17840467.9	

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	3	European Patent Application No. EP19200766.4 extended European Search Report dated December 2, 2019, 11 pages.	
	4	European Patent Office; Communication pursuant to Article 94(3) EPC; dated October 31, 2018.	
	5	Examination Report No. 1 dated 29 April 2020, for Australian Patent Application No. 2016297849.	
	6	International Search Report and Written Opinion for PCT/US16/43709, Dated October 19, 2016.	
	7	International Search Report/Written Opinion for PCT/US17/68569 dated 25 April 2018.	
	8	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application number JP2018-523384, dated July 23, 2019.	

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Name/Print	James S. Nolan	Registration Number	53393

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ROYAUME UNI

Date 26.07.2023

Reference	Application No./Patent No.
KUR-002EP3	23155927.9 - 1122 / 4215114
Applicant/Proprietor	
Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the European search report (R. 61 EPC) or the partial European search report/ declaration of no search (R. 63 EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

The following have been approved:

☐ Abstract ☐ Title

☒ The Abstract was modified and the definitive text is attached to this communication.

The following figure(s) will be published together with the abstract: 23B

Refund of search fee
If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued once the date of publication of the European search report has been mentioned in the European Patent Bulletin (R. 69(1), R. 70(2) EPC).

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The examination is being carried out on the **following application documents**

Description, Pages

1-35 as originally filed

Claims, Numbers

1-16 filed in electronic form on 20-02-2023

Drawings, Sheets

1/50-50/50 as originally filed

Reference is made to the following document; the numbering will be adhered to in the rest of the procedure.

D1 WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29)

1. The amendments filed with the letter dated 20-02-2023 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 123(2) EPC. The amendments concerned are the following: claims 1-16 relate to a device while the application as filed as well as in particular paragraphs [0051],[0125],[0126] relate to a blood sequestration device.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claim 1 is not new within the meaning of Article 54(1) and (2) EPC.

D1 discloses a device (10) comprising:
an inlet port (14);
an outlet port (42);
a chamber (22) connected with the inlet port (14) and configured to receive a first portion of blood the chamber (22) including an air permeable material (30) that seals at least partially upon contact with a portion of the first portion of blood (see p.7 l.172-174); and
a sampling channel (36) having a proximal end connected with the inlet port (14, see fig. 1) and a distal end connected with the outlet port (42, see fig.1).

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

3. Dependent claims 2-16 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to novelty and/or inventive step.

3.1 The features of claims 2,9,10,13,15 are merely some straightforward possibilities which the skilled person would select, depending on the circumstances, without exercising inventive skill, in order to solve the problem posed.

3.2 The subject matter of claim 3 is already known from D1 (p.7 l.172-174).

3.3 The subject matter of claim 4 is already known from D1 (p.7 l.188,189).

3.4 The subject matter of claim 5 is already known from D1 (fig. 1).

3.5 The subject matter of claims 6,7 is already known from D1 (p.5 l.2).

3.6 The subject matter of claim 8 is already known from D1 (p.4 l.25: adsorbing material 24).

3.7 The subject matter of claims 11,12,14 is already known from D1 (fig.1).

3.8 The subject matter of claim 16 is already known from D1 (fig.2).

4. The applicant **should bring the description into conformity** with the claims on file (Article 84 EPC). In particular should features that are present in the independent claim(s) not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment" and so forth, but be clearly identified as forming part of the invention. **This applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. recitation of superseded claims be removed or adapted to the wording of the new claims. Please also note that no method is claimed.

5. To meet the requirements of Rule 42(1)(b) EPC, the document D1 should be identified in the description and the relevant background art disclosed therein should be briefly discussed, observing that references to the prior art introduced after filing must be purely factual.

6. In order to meet the requirements of Rule 43(1) EPC, the independent claim should be properly cast in the two-part form, with those features which in combination are part of the prior art being placed in the preamble (see Guidelines F-IV, 2.2).Arguments in support of inventive step should be presented in an accompanying letter.

If the applicant is of the opinion that a two-part form of claim would be inappropriate he is invited to provide reasons in his reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of the independent claim are known from the prior art (see Guidelines F-IV, 2.3.2).

7. The vague and imprecise statements used in the description at paragraph [0128] imply that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 84 EPC) when used to interpret them (see the Guidelines, F-IV, 4.4). These statements should therefore be amended to remove this inconsistency.

8. "Incorporation by reference" is not an option in the European procedure; the description thus requires amendments in this respect at paragraph.

9. The unit inch expressed in paragraphs [0084],[0090],[0105] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex 2). The present expression should, however, be retained in parentheses after the replacement expression.

10. Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage**, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).**

11. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant should **clearly identify the amendments made**, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (**see Guidelines H-IV**).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

12. Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

13. Amendments should be made by filing replacement pages. Unnecessary recasting of the description should be avoided. An amended abstract is not required. The applicant should also take account of the requirements of Rule 50(1) EPC. According to Rule 50(1) in conjunction with Rule 49(8) EPC, amendments shall be typed or printed. Handwritten amendments may only be made in documents other than those replacing application documents (Rule 50(2) EPC); they may, for example, be used to fulfil the requirements of Rule 137(4) EPC (identifying amendments and indicating basis for them).

14. In order to expedite the procedure, the applicant is requested to deal with all of the raised objections and to **perform all necessary amendments along with the first response to this communication**.

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EUROPEAN SEARCH REPORT

Application Number
EP 23 15 5927

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29) * the whole document *	1-16	INV. A61B5/15 A61B5/153 A61B5/154
A	WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHEL LLOYD [US]; BR) 29 December 2011 (2011-12-29) * paragraph [0070] * * figure 15 * * abstract *	1-16	
A	US 2009/227953 A1 (TAN CHEE LEONG [SG] ET AL) 10 September 2009 (2009-09-10) * the whole document *	1-16	
A	JP H08 257018 A (NISSHO KK) 8 October 1996 (1996-10-08) * abstract; figures *	1-16	
A	US 4 416 291 A (KAUFMAN JOSEPH [US]) 22 November 1983 (1983-11-22) * column 5, line 40 - line 52; figure 7 *	1-16	TECHNICAL FIELDS SEARCHED (IPC) A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	18 July 2023	Coja, Michael

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

1

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 23 15 5927

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

18-07-2023

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		AU 686450 B2	05-02-1998
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		US 4416291 A	22-11-1983
		ZA 822891 B	30-03-1983
		ZA 822892 B	30-03-1983

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

Information on Search Strategy

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

EP 23 15 5927

TITLE: BLOOD SAMPLE CONTAMINANT SEQUESTRATION DEVICE

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: A61B5/15, A61B5/153, A61B5/154

EXAMINER: Coja, Michael

CONSULTED DATABASES: EPODOC, WPI, COMBI, TXT+

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150389, A61B5/150473, A61B5/150572, A61B5/153, A61B5/154, A61B5/150251

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

EPO FORM P04A42

JOURNAL OF CLINICAL MICROBIOLOGY, Mar. 1998, p. 657–661 Vol. 36, No. 3
0095-1137/98/$04.00+0
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Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems To Detect Bloodstream Infections

R. ZIEGLER,[1] I. JOHNSCHER,[1] P. MARTUS,[2] D. LENHARDT,[1] AND H.-M. JUST[1]*

Institut für Klinikhygiene, Medizinische Mikrobiologie und Klinische Infektiologie, Klinikum Nürnberg, 90419 Nürnberg,[1] and Institut für Medizinische Statistik und Dokumentation, Universität Erlangen-Nürnberg, 91054 Erlangen,[2] Germany

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A 20-ml blood sample was collected from adult patients with suspected bloodstream infections and distributed equally into the four volume-controlled bottles of a blood culture set consisting of aerobic and anaerobic BACTEC Plus/F bottles and aerobic and anaerobic BacT/Alert FAN bottles. All bottles were incubated in their respective instruments for a standard 5-day protocol or until the instruments signalled positivity. Samples in all bottles with negative results by these instruments were terminally subcultured. A total of 8,390 blood culture sets were obtained during the study period, of which 4,402 (52.5%) met the study criteria. Of these, 946 (21.5%) were positive either by instrument signal or by additional terminal subculture of all negative bottles and yielded growth of microorganisms. Five hundred eighty-nine (13.4%) blood culture sets were considered to have recovered 663 clinically significant organisms. When both the BACTEC and the BacT/Alert systems were used, 465 positive sets were detected; BACTEC alone detected 52 positive sets and BacT/Alert alone detected 72 ($P = 0.09$). No differences were found between the two systems in microbial recovery rate from blood cultures obtained from patients on antibiotic therapy. Significantly more members of the family *Enterobacteriaceae* ($P < 0.01$) were detected from patients without antimicrobial therapy by BacT/Alert than by BACTEC. The false-negative rates were 0.20% for BACTEC and 0.32% for BacT/Alert. A significantly higher false-positive rate was found for BACTEC ($P < 0.0001$). Both systems were comparable for the time to detection of microorganisms. However, gram-positive bacteria were detected faster by BACTEC and *Enterobacteriaceae* were detected faster on average by BacT/Alert. We concluded that both systems are comparable in their abilities to recover aerobic and anaerobic organisms from blood cultures and a terminal subculture might not be necessary for either of the two systems. The increased positivity rate when using an anaerobic bottle in a two-bottle blood culture set is due to the additional blood volume rather than to the use of an anaerobic medium.

Due to the high morbidity and mortality associated with bacteremia (7), the rapid detection and subsequent identification of microorganisms from blood remain critical services of the clinical microbiology laboratory. Numerous blood culture methods are available, and selecting the optimal system for the diagnostic laboratory is an important and often difficult task (15). Many remarkable improvements have been made in an attempt to reduce the time to isolate pathogens from blood. Advancements in the use of liquid media linked with automation technology have enhanced the ability of laboratories to provide faster blood culture results. Two continuously monitored noninvasive blood culture systems, the BACTEC 9240 (Becton Dickinson, Heidelberg, Germany) and the BacT/Alert (Organon Teknika, Eppelheim, Germany), are in widespread use. The main advantages of the two systems over previous generations of blood culture instruments include full automation once the bottles are loaded, a shorter time to detection of blood pathogens, considerable labor savings, and improved laboratory workflow. The BacT/Alert and the BACTEC 9240 systems monitor the growth of organisms by checking for elaboration of CO_2 with a colorimetric and a fluorescent sensor, respectively.

New aerobic and anaerobic media were developed by the manufacturers to remove a variety of growth inhibitors from patients' blood, to enhance the recovery of fastidious organisms, and to improve the detection of bacteremia and fungemia in patients receiving antimicrobial therapy. BACTEC Plus/F medium consists of soybean-casein digest broth, primary supplements, and two types of resin, a nonionic absorbing resin and a cation-exchange resin. FAN medium (BacT/Alert) is a brain heart infusion broth base containing Ecosorb, a proprietary substance that contains adsorbent charcoal, Fuller's earth, and other components.

A number of studies comparing the two systems have been carried out, but to our knowledge, none of them compared the supplemented aerobic and anaerobic BACTEC Plus/F media with the supplemented aerobic and anaerobic BacT/Alert FAN media in one controlled clinical trial.

This study was conducted to compare the performances of the two blood culture systems, BACTEC 9240 and BacT/Alert, in terms of microbial recovery, time to detection, and false-positive and false-negative rates, thereby indicating the performance of the aerobic and anaerobic BACTEC Plus/F resin media and the aerobic and anaerobic BacT/Alert FAN media.

MATERIALS AND METHODS

Patient population. This monocenter study was conducted from August 1995 through February 1997 in a 2,500-bed acute-care community hospital which provides a full range of medical and surgical care. The hospital cares for an appreciable number of transplant, immunosuppressed patients, as well as patients presenting common community-acquired infections. Blood cultures were obtained from all adult patients with suspected bacteremia during the study

* Corresponding author. Mailing address: Institut für Klinikhygiene, Medizinische Mikrobiologie und Klinische Infektiologie, Klinikum Nürnberg, Flurstr. 17, 90419 Nürnberg, Germany. Phone: (49) 911 398 2522. Fax: (49) 911 398 3266.

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period and processed in the hospital-related Institute of Microbiology and Hygiene.

Study design. Blood culture sets were prepared for the purposes of the study; each set contained four volume-controlled and randomized bottles, one each containing aerobic and anaerobic BACTEC Plus/F media and aerobic and anaerobic BacT/Alert FAN media. Written instructions for obtaining a blood culture, the required amount of blood, and the order of inoculation of the bottles for clinicians were included. In respect of the patient and with the agreement of the ethical commission of our hospital, a 20-ml amount of blood for one blood culture set was considered the maximum to obtain from a single venipuncture. This amount was distributed equally into each of the four bottles. The inoculum volume was determined in the microbiology laboratory by weight. Sets in which any one of the bottles did not contain a minimum of 3 ml of blood or in which the volume difference between two bottles was more than 3 ml were considered noncompliant and excluded from the study but processed for the bene@ of the patient.

On arrival in the laboratory, all bottles were placed in their respective instruments for a 5-day incubation time at 35°C and monitored in accordance with the manufacturers' recommendations. FAN aerobic bottles were vented before incubation.

Bottles indicated as positive by the instrument as well as bottles positive on arrival were Gram stained. Based on the Gram stain result, aliquots of the bottles were subcultured onto adequate media (chocolate agar incubated at 35°C in a 5% CO_2-enriched atmosphere or blood agar with aerobic and anaerobic incubation at 35°C). All microorganisms were identi@ed by standard microbiologic procedures. All false-positive bottles (i.e., bottles that were smear and subculture negative after instrument signal) were replaced into the instrument during the 5 days of protocol. A terminal blind subculture onto chocolate agar and blood agar (aerobic and anaerobic incubation as described above) was performed for all negative bottles. False-negative bottles had no positive signal by the instrument, but growth occurred on the terminal subculture.

Statistical methods. The following data of all blood cultures were entered in a computer database: collection time, loading time, blood volume of each bottle, detection of growth by each bottle, growth on subculture and identity of microorganisms recovered, antimicrobic therapy, and the detection time for each positive bottle. Detection time of a microorganism was de@ed as the time between loading a blood culture bottle into the instrument and the time when a positive signal occurred followed by growth on subculture. For comparison of detection times, only clinically signi@ant isolates recovered in both systems were taken into account. If both bottles of one system recovered the same organisms, the shorter time to detection was taken into account for comparison. The clinical importance of isolated microorganisms was determined after consultation with the patient's physician in accordance with published criteria (6, 10, 16, 18). Statistical analysis was done for blood cultures meeting the study criteria. Only isolates classi@d as being clinically signi@ant were taken into account. Sensitivities were calculated in two manners. For comparison of the two systems, the common denominator of positive cultures was determined by all four terminal blind subcultures. For evaluating the usefulness of terminal subcultures in clinical routines, the detection rate of each system was determined with reference only to the related terminal subculture. The common denominator for the determination of both the false-positive and the false-negative rates for each system was the total of 4,402 compliant sets of the study. The main scienti@ goal of the study was the comparison of the sensitivities and speci@ities of both systems. For these two analyses, the Bonferroni correction was used. All other analysis on subgroups of patients or isolates must be considered explorative without protection against the error of multiple testing. All comparisons were evaluated by McNemar's test ($\alpha = 0.05$, two-sided) by using the statistical package SPSSWIN.

RESULTS

A total of 8,390 blood culture sets were obtained during the study period. Of these, 4,402 (52.5%) met the study criteria; of these, 946 (21.5%) yielded growth of 1,083 bacteria or fungi. Five hundred eighty-nine (13.4%) compliant sets, positive by either instrument signal or terminal subculture only, detected 663 bacteria or fungi that were considered clinically signi@ant. Three hundred @fty-seven (8.1%) sets recovered only organisms classi@ed as contaminants.

Of the 589 positive blood culture sets with signi@ant isolates, 508 (86.3%) were positive by BACTEC 9240 and 523 (88.8%) sets were positive by BacT/Alert. BACTEC alone detected 52 (8.8%) positive sets, and BacT/Alert alone detected 72 (12.2%). With reference to the terminal blind subcultures of both systems, BACTEC and BacT/Alert showed sensitivity rates of 86.3 and 88.8% respectively. With reference to the system-related terminal subculture, the BACTEC instrument demonstrated a detection rate of 98.3% and the BacT/Alert instrument gave one of 97.4%.

TABLE 1. Comparative yields of clinically important bacteria and fungi in BACTEC Plus/F and FAN aerobic and anaerobic culture sets

Microorganism	No. of organisms detected by:			*P*
	BACTEC only	BacT/Alert only	Both systems	
Gram-positive bacteria	30	34	228	NS[a]
Staphylococcus aureus	11	14	124	
Staphylococcus epidermidis	2	2	9	
Viridans group streptococcus	2	5	18	
Enterococcus spp.	6	7	32	
Streptococcus pneumoniae	6	4	33	
Beta-hemolytic streptococci	3	1	9	
Listeria monocytogenes		1	3	
Enterobacteriaceae	21	45	187	<0.01
Escherichia coli	14	25	101	
Klebsiella spp.	3	12	27	
Enterobacter/Citrobacter spp.	2	5	31	
Salmonella spp.			6	
Proteus/Providencia/Morganella	1	1	11	
Serratia/Hafnia spp.	1	2	11	
Non-*Enterobacteriaceae*	18	13	36	NS
Haemophilus spp.		2	1	
Pseudomonas aeruginosa	7	7	8	
Stenotrophomonas maltophilia	3		6	
Neisseria meningitidis		1	1	
Acinetobacter spp.	8	3	18	
Other			2	
Anaerobic bacteria	6	3	4	NS
Clostridium perfringens	1	1	1	
Bacteroides spp.	3	2	2	
Candida spp.	5	6	14	NS
All microorganisms	80	101	482[b]	

[a] NS, not signi@ant.
[b] For some species with a single isolate, data were not depicted separately but were included in the total

Nine false-negative blood cultures occurred with the BACTEC instrument (three *Candida* species and single isolates of *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Listeria monocytogenes*, *Enterobacter agglomerans*, *Pseudomonas aeruginosa*, and *Pseudomonas stutzeri*) and 14 false negatives occurred with the BacT/Alert instrument (four *P. aeruginosa*, three *Acinetobacter* species, two *Stenotrophomonas maltophilia*, two *Candida* species, and single isolates of *Streptococcus sanguis*, *Escherichia coli*, and *Proteus mirabilis*).

The false-negative rates for the systems were 0.20% for BACTEC and 0.32% for BacT/Alert.

A signi@antly higher false-positive rate was found for BACTEC, 6.2%, than for BacT/Alert, 1.4% ($P < 0.0001$).

The comparative yields of bacteria and fungi from the two systems are indicated in Table 1. Of the 663 clinically signi@cant organisms from compliant sets, 482 (72.7%) were recovered from both systems, 80 (12%) were recovered by BACTEC only, and 101 (15.2%) were recovered by BacT/Alert only. The differences observed in the recovery of bacteria reached statistical signi@cance only for the *Enterobacteriaceae* group. The BacT/Alert system detected signi@antly more *Enterobacteriaceae* than the BACTEC system did ($P < 0.01$). A similar trend

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TABLE 2. Comparative speed of detection of clinically signi@cant organisms when both systems were positive and detection time was provided for both systems ($n = 421$)

Microorganism	Time to detection (h)		n	P
	BACTEC	BacT/Alert		
Staphylococcus aureus	8.4	11.2	124	<0.001
Viridans group streptococcus	4.0	6.6	18	<0.01
Enterococci	5.1	19.5	32	<0.05
Streptococcus pneumoniae	5.1	6.2	33	<0.05
Escherichia coli	7.6	6.9	101	<0.05
Klebsiella spp.	8.9	5.8	27	NS[a]
Enterobacter spp.	7.8	7.5	31	<0.05
Pseudomonas aeruginosa	15.4	20.7	8	NS
Acinetobacter spp.	6.9	10.2	18	<0.01
Mean values	9.0	10.4	482[b]	<0.05

[a] NS, not signi@cant.
[b] For some species with fewer than 10 isolates, data were not depicted separately but were included in the mean time to detection.

was seen in the recovery of yeasts from blood cultures obtained from patients without antibiotic therapy. For all other organisms, there were no signi@cant differences in the number of positive cultures between systems, neither by organism group nor by species.

Of all compliant blood culture sets, 41.9% (1,807 sets) were obtained from patients receiving antimicrobial therapy. Of the 589 positive compliant sets with signi@cant isolates, 35.5% (208) were obtained from patients receiving antibiotics. There were no signi@cant differences in isolation rates between the two systems for patients receiving antibiotics. The BacT/Alert system detected signi@cantly more *Enterobacteriaceae* than the BACTEC system did ($P < 0.01$) from patients without antibiotic therapy.

The times to detection of several bacterial groups were compared for the two systems (Table 2). Gram-positive bacteria were detected signi@cantly faster by the BACTEC system, whereas *Enterobacteriaceae* on average were recovered faster by the BacT/Alert system. There was no difference between the two systems in the cumulative percentage of positive cultures after 24, 48, and 72 h of incubation. Within the @rst 24 h, BACTEC detected 89.8% and BacT/Alert detected 89.6% of the positive cultures; after 48 h, 95.7 and 96.9% were detected by BACTEC and BacT/Alert, respectively; and after 72 h, 99.0 and 99.4% were detected by the two systems, respectively. The average times to detection were 9.0 h for the BACTEC system and 10.4 h for the BacT/Alert system ($P < 0.05$). The signi@cant difference in average time to detection between both systems was caused by the higher detection rate within the @rst 6 h of the BACTEC instrument (50.7% detected by BACTEC and 45.8% by BacT/Alert).

Delayed entry was de@ned as a time difference of >12 h between blood sample collection and placement of a blood culture bottle into the respective instrument. More than half of the compliant positive blood cultures had a transportation time of >12 h due to the fact that our new hospital building is separated from the laboratory. Delayed entry had no effect on the sensitivity of the BacT/Alert instrument, but for the BACTEC system, the detection rate was signi@cantly lower for blood cultures with delayed entry than for those with no delay ($P = 0.0097$). Differences also occurred in detection of the *Enterobacteriaceae* group: BacT/Alert recovered signi@cantly more *Enterobacteriaceae* from blood cultures with delayed entry than BACTEC did ($P = 0.0062$) when the subgroup of patients not receiving antibiotic therapy was considered.

The data of the two systems allow not only a system-versus-system comparison but also a comparison of the two media, i.e., resin aerobic versus FAN aerobic media and resin anaerobic versus FAN anaerobic media (Table 3). No signi@cant differences were seen between the aerobic media nor between the anaerobic media of the two systems in terms of detection rate. A comparison of the aerobic and anaerobic media of each system showed signi@cant differences. The false-positive rate was signi@cantly higher for both resin media than for the FAN media. The false-negative rates for both anaerobic media (4.7% for resin and 3.9% for FAN) were higher than those for the aerobic media (1.7% for resin and 2.2% for FAN).

Anaerobic bacteria causing septicemia were recovered from 13 compliant blood culture sets. Both systems detected four, the BACTEC system alone detected six, and the BacT/Alert system alone detected three anaerobic bacteria.

DISCUSSION

This monocenter-controlled evaluation compared the performances of the supplemented aerobic and anaerobic BACTEC resin media, under identical conditions of observation against the supplemented aerobic and anaerobic BacT/Alert FAN media in a clinical trial. Simultaneous inoculation of all four bottles from a single blood culture also enabled a system-versus-system comparison of the BACTEC 9240 and the BacT/Alert instruments. To our knowledge, no data have been published yet on this subject. In the past, several studies have evaluated the performance of the BACTEC (20) and BacT/Alert (2, 11) instruments, comparing either the two nonsupplemented media (19), the resin medium and the standard BacT/Alert medium (1, 9, 13), or the aerobic resin medium and the aerobic FAN medium (4, 8, 14). Outcomes have been quite different: the BACTEC system detected signi@cantly more gram-positive cocci and the BacT/Alert system recovered signi@cantly more *Enterobacteriaceae* in a @rst comparison (19) of the two nonsupplemented media.

Auckenthaler et al. (1) as well as Smith et al. (13) compared BACTEC resin medium to standard BacT/Alert medium, and both groups reported a better performance in terms of microbial recovery, false-positive rate, and detection time for the resin medium. A comparison of aerobic resin medium with aerobic FAN medium in a recent multicenter (4) study has demonstrated equal results. The previous single-center study by Pohlman et al. (8) showed a better recovery rate for *Entero-*

TABLE 3. Detection of positive cultures and false-positive signals by aerobic and anaerobic media

Medium	No. of positive cultures			No. of false-positive signals[b]
	Total	Detected by instrument[a]	Detected by terminal subculture	
Aerobic resin	466	456	10	185
Aerobic FAN	489	476	13	54
Anaerobic resin	448	420	28	116
Anaerobic FAN	429	406	23	11

[a] Values for aerobic resin versus aerobic FAN media and for anaerobic resin versus anaerobic FAN media are not signi@cantly different. Values for aerobic resin versus anaerobic resin media and aerobic FAN versus anaerobic FAN media are signi@cantly different ($P < 0.05$ and $P < 0.001$, respectively).
[b] Values for aerobic resin versus aerobic FAN media, anaerobic resin versus anaerobic FAN media, aerobic resin versus anaerobic resin media, and aerobic FAN versus anaerobic FAN media are signi@cantly different ($P < 0.001$).

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bacteriaceae and *Pseudomonas* by use of the BacT/Alert system with fewer false-positive results. In comparison with the results of other studies (4, 11, 12, 17), the positivity rate of blood cultures in our study was high (21.5% positive sets), with 13.4% sets recovering clinically signi@cant organisms. With the exception of members of the *Enterobacteriaceae* group, which were recovered signi@cantly ($P < 0.01$) more often by the BacT/Alert system alone, there were no signi@cant differences in terms of microbial recovery between the two systems. The *Enterobacteriaceae* that were detected signi@cantly more frequently by the BacT/Alert system resulted from blood cultures from patients without antimicrobial therapy. There was also a tendency towards a similar result for the fungi group: BacT/Alert detected slightly more *Candida* sp. isolates from patients without antibiotics than from patients with antimicrobial therapy. However, these are results of an explorative analysis in which, due to the small numbers of cases, a high beta error and the problems of multiple testing must be taken into account.

Reports of high false-negative rates, up to 6% (12, 13), suggest that terminal subculturing of negative BACTEC cultures after 5 days of incubation may be necessary, whereas others have suggested that this is not needed in the BacT/Alert system (3). In our trial, the false-negative rates were similarly low for both systems (0.20% for BACTEC and 0.32% for BacT/Alert) and the sensitivities for the BACTEC and BacT/Alert instruments with reference to the related terminal subcultures were 98.3 and 97.4%, respectively; therefore, we have concluded that a blind terminal subculture may not be necessary for either of the two systems.

The introduction of automated blood culture systems also serves the purpose of reducing the routine workload for laboratory personnel. A low false-positive rate is one important factor here. Our results showed a signi@cantly ($P < 0.0001$) higher false-positive rate for the aerobic and anaerobic resin media (6.2%) than for the FAN media (1.4%). During the study period, both instruments were used in accordance with the recommendations and speci@cations of each manufacturer. Laboratory facilities were equal for both systems. All false-positive blood cultures were replaced into the instrument, incubated for the rest of the 5-day incubation period, and terminally subcultured. A small percentage of the false-positive signals by the BACTEC instrument occurred after an electricity breakdown, which did not affect the BacT/Alert instrument.

Due to the need to reduce laboratory costs, many microbiology laboratories do not have 24-h coverage by technical personnel. Especially in smaller hospitals, there is no microbiology laboratory available, so that blood cultures must be sent to external laboratories. Therefore, a delay may occur from the time blood is drawn until the bottle is placed into a blood culture instrument. Our hospital consists of an original building complex with 1,500 beds and a new building with 1,000 beds which is situated 10 km away. All blood specimens from the new building must be transferred to the laboratory in the original building, so that a delay of >12 h may occur.

Those blood cultures that were obtained after the microbiology laboratory was closed for the day were collected in a central laboratory that is open 24 h per day and were incubated at 35°C, so that almost all blood cultures with delayed entry were preincubated at 35°C. Delayed entry did affect the sensitivity of the BACTEC instrument in that the detection rate was signi@cantly lower for blood cultures with delayed entry than for those with no delay ($P = 0.0097$).

The numbers of false-negative sets with delayed entry and of false negative sets with a transport time of <12 h were too small for valid comparison. For the BACTEC system, 6 of 9 false-negative sets were sets with delayed entry; for BacT/Alert, 8 of 14 false negatives were sets with delayed entry. In spite of the small number, there seems to be no need for blind terminal subculture either for sets with overnight preincubation at 35°C or for sets processed within the @rst 12 h after collection. Both systems detected organisms faster from culture sets with delayed entry since these sets were preincubated. With regards to the handling of preincubated blood culture bottles, the BacT/Alert system offers the advantage of a visible change on the bottom of a positive bottle so that the bottle can be processed onto subcultures before incubation into the instrument. The interpretation of Gram stain results for positive bottles was more dif@cult for FAN media than for resin media due to the charcoal particles in the media.

Staphylococcus epidermidis, which is considered a contaminant, was recovered more frequently from the FAN aerobic bottle ($n = 424$) than from the resin aerobic bottle ($n = 349$); this more frequent recovery may be due to the fact that the FAN aerobic bottle must be vented before incubation in the instrument. The use of needles to manually vent the aerobic FAN bottles may increase the probability of contaminating the bottle.

The question whether there is any advantage to using both aerobic and anaerobic blood culture media routinely (5) or whether anaerobic media should be used for the detection of bacteremia only in patients at risk of having an anaerobic infection is often raised. Only 13 positive blood cultures out of 589 sets with clinically signi@cant organisms recovered anaerobic bacteria, 11 being isolated from the anaerobic medium only and 2 being isolated from both the aerobic and anaerobic media. Four of the 11 blood culture sets with obligate anaerobic bacteria represented polymicrobial septicemia; in addition to the anaerobic bacteria, *Enterobacteriaceae*, *Staphylococcus aureus*, and *Candida* spp. were isolated from the corresponding aerobic bottle as well. De@nitively, seven (1.2%) blood cultures with monomicrobic obligate anaerobic pathogens would not have been detected by using only an aerobic bottle. By using the anaerobic resin bottle in addition to the aerobic one, the detection rate increased by 10.2%, with facultative anaerobic bacteria contributing 8.7% and obligate anaerobic bacteria contributing 1.6%. Analogously, the anaerobic FAN bottle increased the positivity by 9%, of which 8% was due to facultative anaerobic bacteria and 1% was due to strict anaerobic ones. Diagnoses of patients with septicemia due to obligate anaerobic bacteria included colitis ulcerosa, pancreatitis, diabetes mellitus with erysipelas, cholangitis, leukemia, and pneumonia, so that anaerobic infections could have been expected. According to Weinstein et al. (17), an increase in the volume of blood inoculated into BacT/Alert aerobic bottles (from 5 to 10 ml) increased the overall yield (7.2%) of clinically important organisms. From our results and those reported by Weinstein et al. (15, 17), we conclude that the higher recovery rate achieved when the anaerobic bottle is included is due to the inoculation of a larger blood volume rather than to the use of an additional anaerobic medium.

In summary, both systems are comparable for recovering clinically signi@cant microorganisms from adult patients with bacteremia and fungemia receiving antibiotic therapy at the time of blood culture collection. With blood from patients without antibiotic therapy, the BacT/Alert system detected signi@cantly more *Enterobacteriaceae*. The high false-positive rate of the BACTEC system caused additional work and material costs in our laboratory. With the BacT/Alert instrument, the software capabilities were more convenient for the user, and failure rarely occurred.

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ACKNOWLEDGMENTS

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פ.ק 26

תאריך : י״ג שבט תשפ״ד
23/01/2024
מספרכם : 1000-018-02

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה על ליקויים בבקשת פטנט מספר 302893</u>**
סימוכין : מכתבכם מיום 08/09/2023, 10/09/2023

לתשומת לבכם : מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 226.00 ש״ח בעד כל חודש או חלק ממנו. **לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים** בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

<u>הודעה זו מבוססת על המסמכים הבאים :</u>
שרטוטים מתאריך : 13/05/2023
פרטי הבקשה מתאריך : 20/08/2023
תביעות מתאריך : 20/08/2023

<u>ההפניות בהודעה זו מתייחסות לפרסומים הבאים :</u>

D1: US 3848581 A [CINQUALBRE L] - 19/11/1974
D2: US 4207870 A [BECTON DICKINSON CO] - 17/06/1980

<u>בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדתי לעניין כשירות התביעות לפטנט :</u>

תביעה/ות מס׳ 2-9,12-14 הינן כשירות לפטנט בהתאם לסעיף 17(א) לחוק.
בתביעה/ות מס׳ 1,10-11,15-18 נמצאו ליקויים.
ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות **תקנה 41** הנני להודיעכם כי נמצאו בבקשה הנ״ל הליקויים המפורטים להלן :

1. <u>בחינת הבקשה מבוססת על ההודעות הבאות :</u>

1.1 הריני להודיעכם כי :

תאריך הבקשה הנוכחית, שהינה בקשת חלוקה מן הבקשה מס׳ 267684, הוקדם לתאריך 27/12/2017, שהוא תאריך הבקשה ההורה, וזאת בהתאם ל**סעיף 24(ג) לחוק**.

2. <u>חידוש והתקדמות המצאתית</u>

2.1 תביעות 1,10-11,15-18 אינן מגדירות אמצאה שיש בה התקדמות המצאתית כהגדרתה ב**סעיף 5 לחוק**, לאור פרסומים : D1 ,D2.

תביעות 1,10-11,15-18 בבקשה שבפניי תואמות לתביעות 1,3-4,6-7,23,34 בבקשה 17/893,079 שנבחנה על ידי ה- USPTO והופק עבורה דוח בחינה בתאריך 22/08/2023. לאחר עיון בדוח הבחינה האמור ולאור תאימות התביעות, מצאתי כי הליקוי שפורט בנוגע לחוסר התקדמות המצאתית חל גם על התביעות שבפניי לפי חוק הפטנטים הישראלי.

2.2 תביעות 2-9,12-14 עונות על דרישות **סעיפים 4 ו-5 לחוק**, מאחר שהאמצאה המוגדרת בתביעות אלה לא נתפרסמה בפומבי לפני תאריך הבקשה ויש בה התקדמות המצאתית.

<u>חובת המבקש לעדכן את הרשות</u>

תשומת לבכם ל**סעיף 18א לחוק** לעניין חובת המבקשת לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור ב**סעיף 18(א) לחוק** ול**סעיף 18ג לחוק** בדבר אמצעי האכיפה.

<u>הגשת תיקונים לפירוט במהלך בחינת הבקשה</u>

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית **לתקנה 22(א)**. יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך : <u>דוגמה</u>) והשמטות בקו חוצה (כך :~~דוגמה~~). **אין להגיש מחדש קבצים שלא תוקנו**.

לתשומת לבכם:

א) בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהודעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלקם, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון בתביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק .

ב) בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת הודעה לפני סירוב.

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור :

https://israelpatents.justice.gov.il/#/en/patent-file/details/302893

<u>ראיון עם בוחן</u>

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחן באמצעות פגישה במשרדי הרשות, בשיחה טלפונית או בהיוועדות חזותית.

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחן למבקש או בא-כוחו באמצעות שירות זה.

קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט.

במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה.

תיאום הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם.

לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

<u>השגה בפני הרשם</u>

על פי **סעיף 161 לחוק**, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בתקווה לימים שקטים ובטוחים יותר.

בכבוד רב

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בוחן פטנטים בכיר
טלפון : 073-3927233
דואר אלקטרוני : albertak@justice.gov.il
ראש צוות : מוריה שלמה לוי

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Carroll, Christopher P.
Burns & Levinson London LLP
4-12 Regent Street, 4th Floor
London SW1Y 4PE
ROYAUME UNI

Date
26.07.2023

Reference	Application No./Patent No.
KUR-002EP3	23155927.9 - 1122 / 4215114
Applicant/Proprietor	
Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the European search report (R. 61 EPC) or the partial European search report/ declaration of no search (R. 63 EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

The following have been approved:

☐ Abstract ☐ Title

☒ The Abstract was modified and the definitive text is attached to this communication.

The following figure(s) will be published together with the abstract: 23B

Refund of search fee
If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued once the date of publication of the European search report has been mentioned in the European Patent Bulletin (R. 69(1), R. 70(2) EPC).

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The examination is being carried out on the **following application documents**

Description, Pages

1-35 as originally filed

Claims, Numbers

1-16 filed in electronic form on 20-02-2023

Drawings, Sheets

1/50-50/50 as originally filed

Reference is made to the following document; the numbering will be adhered to in the rest of the procedure.

D1 WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29)

1. The amendments filed with the letter dated 20-02-2023 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 123(2) EPC. The amendments concerned are the following: claims 1-16 relate to a device while the application as filed as well as in particular paragraphs [0051],[0125],[0126] relate to a blood sequestration device.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claim 1 is not new within the meaning of Article 54(1) and (2) EPC.

D1 discloses a device (10) comprising:
an inlet port (14);
an outlet port (42);
a chamber (22) connected with the inlet port (14) and configured to receive a first portion of blood the chamber (22) including an air permeable material (30) that seals at least partially upon contact with a portion of the first portion of blood (see p.7 l.172-174); and
a sampling channel (36) having a proximal end connected with the inlet port (14, see fig. 1) and a distal end connected with the outlet port (42, see fig.1).

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

3. Dependent claims 2-16 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to novelty and/or inventive step.

3.1 The features of claims 2,9,10,13,15 are merely some straightforward possibilities which the skilled person would select, depending on the circumstances, without exercising inventive skill, in order to solve the problem posed.

3.2 The subject matter of claim 3 is already known from D1 (p.7 l.172-174).

3.3 The subject matter of claim 4 is already known from D1 (p.7 l.188,189).

3.4 The subject matter of claim 5 is already known from D1 (fig. 1).

3.5 The subject matter of claims 6,7 is already known from D1 (p.5 l.2).

3.6 The subject matter of claim 8 is already known from D1 (p.4 l.25: adsorbing material 24).

3.7 The subject matter of claims 11,12,14 is already known from D1 (fig.1).

3.8 The subject matter of claim 16 is already known from D1 (fig.2).

4. The applicant **should bring the description into conformity** with the claims on file (Article 84 EPC). In particular should features that are present in the independent claim(s) not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment" and so forth, but be clearly identified as forming part of the invention. **This applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. recitation of superseded claims be removed or adapted to the wording of the new claims. Please also note that no method is claimed.

5. To meet the requirements of Rule 42(1)(b) EPC, the document D1 should be identified in the description and the relevant background art disclosed therein should be briefly discussed, observing that references to the prior art introduced after filing must be purely factual.

6. In order to meet the requirements of Rule 43(1) EPC, the independent claim should be properly cast in the two-part form, with those features which in combination are part of the prior art being placed in the preamble (see Guidelines F-IV, 2.2).Arguments in support of inventive step should be presented in an accompanying letter.

If the applicant is of the opinion that a two-part form of claim would be inappropriate he is invited to provide reasons in his reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of the independent claim are known from the prior art (see Guidelines F-IV, 2.3.2).

7. The vague and imprecise statements used in the description at paragraph [0128] imply that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 84 EPC) when used to interpret them (see the Guidelines, F-IV, 4.4). These statements should therefore be amended to remove this inconsistency.

8. "Incorporation by reference" is not an option in the European procedure; the description thus requires amendments in this respect at paragraph.

9. The unit inch expressed in paragraphs [0084],[0090],[0105] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex 2). The present expression should, however, be retained in parentheses after the replacement expression.

10. Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage**, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).**

11. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant should **clearly identify the amendments made**, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (**see Guidelines H-IV**).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

12. Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

13. Amendments should be made by filing replacement pages. Unnecessary recasting of the description should be avoided. An amended abstract is not required. The applicant should also take account of the requirements of Rule 50(1) EPC. According to Rule 50(1) in conjunction with Rule 49(8) EPC, amendments shall be typed or printed. Handwritten amendments may only be made in documents other than those replacing application documents (Rule 50(2) EPC); they may, for example, be used to fulfil the requirements of Rule 137(4) EPC (identifying amendments and indicating basis for them).

14. In order to expedite the procedure, the applicant is requested to deal with all of the raised objections and to **perform all necessary amendments along with the first response to this communication**.

Europäisches Patentamt
European Patent Office
Office européen des brevets

EUROPEAN SEARCH REPORT

Application Number
EP 23 15 5927

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29) * the whole document *	1-16	INV. A61B5/15 A61B5/153 A61B5/154
A	WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHEL LLOYD [US]; BR) 29 December 2011 (2011-12-29) * paragraph [0070] * * figure 15 * * abstract *	1-16	
A	US 2009/227953 A1 (TAN CHEE LEONG [SG] ET AL) 10 September 2009 (2009-09-10) * the whole document *	1-16	
A	JP H08 257018 A (NISSHO KK) 8 October 1996 (1996-10-08) * abstract; figures *	1-16	
A	US 4 416 291 A (KAUFMAN JOSEPH [US]) 22 November 1983 (1983-11-22) * column 5, line 40 - line 52; figure 7 *	1-16	TECHNICAL FIELDS SEARCHED (IPC) A61B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	18 July 2023	Coja, Michael

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

1

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 23 15 5927

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

18-07-2023

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9605875 A1	29-02-1996	AT 208640 T	15-11-2001
		AU 686450 B2	05-02-1998
		CA 2173331 A1	29-02-1996
		DE 69523887 T2	29-08-2002
		EP 0725658 A1	14-08-1996
		JP H09504726 A	13-05-1997
		US 5947932 A	07-09-1999
		WO 9605875 A1	29-02-1996
WO 2011162772 A1	29-12-2011	NONE	
US 2009227953 A1	10-09-2009	US 2009227953 A1	10-09-2009
		US 2010262038 A1	14-10-2010
		US 2012330187 A1	27-12-2012
JP H08257018 A	08-10-1996	NONE	
US 4416291 A	22-11-1983	AU 549400 B2	23-01-1986
		BR 8202753 A	19-04-1983
		EP 0070356 A2	26-01-1983
		ES 8307509 A1	01-07-1983
		JP S649011 B2	16-02-1989
		JP S5825146 A	15-02-1983
		MX 151907 A	02-05-1985
		NZ 200914 A	31-05-1984
		US 4416291 A	22-11-1983
		ZA 822891 B	30-03-1983
		ZA 822892 B	30-03-1983

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

Information on Search Strategy

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

EP 23 15 5927

TITLE: BLOOD SAMPLE CONTAMINANT SEQUESTRATION DEVICE

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: A61B5/15, A61B5/153, A61B5/154

EXAMINER: Coja, Michael

CONSULTED DATABASES: EPODOC, WPI, COMBI, TXT+

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150389, A61B5/150473, A61B5/150572, A61B5/153, A61B5/154, A61B5/150251

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

EPO FORM P04A42

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 07/19/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
07/19/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/893,079	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 05/22/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-7 and 32-41 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-7 and 32-41 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 8/22/02022 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the amendment filed 5/22/2023. Claims 1-4, 6-7, and 32-41 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "junction" in **Claims 3-4 and 40-41** must be shown *with element numbers* or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the

filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as

otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 40-41 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims recite a junction connecting the inlet port, sampling channel, and the chamber. However, as the instant invention appears to be drawn to the embodiment in Figure 24 and said junction has not been identified in Figure 24 per the drawing objection above, it is unclear that applicant has proper support for the embodiment of Figure 24 with the moving part having a first and second position along with said junction as claimed. If support exists for said junction, applicant is requested to point out portions of the disclosure showing said support.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 1-4, 6-7, 32, 34-38, and 40-41 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al (US Pat No. 3848581) in view of Eldridge (US Pat No. 4207870).

In regard to Claim 1, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood, thus bypassing the first test tube/chamber as defined; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

2. Eldridge discloses the material is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

3. Cinqualbre et al disclose a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

4. Cinqualbre et al disclose wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

6. Cinqualbre et al disclose wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

7. Cinqualbre et al disclose the moving part 11 as defined further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled, the user can close the valve 11 to move it into the closed position so that the next test tube in the series can be

filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

32. Cinqualbre et al disclose wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

In regard to Claim 34, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

35. Eldridge discloses the device in accordance with claim 34, wherein the air permeable blood barrier is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

36. Cinqualbre et al disclose the device in accordance with claim 34, wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling

channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

37. Cinqualbre et al disclose the device in accordance with claim 36, the moving part further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled with blood, the user can close the valve 11 to move it into closed position so that the next test tube in the series can be filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

38. Cinqualbre et al disclose the device in accordance with claim 36, wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

40. Cinqualbre et al disclose the device in accordance with claim 34, further comprising a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

41. Cinqualbre et al disclose the device in accordance with claim 40, wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

Claim(s) 33 and 39 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al in view of Eldridge, further in view of Vaillancouert (US Pat No. 6126643).

Cinqualbre et al in view of Eldridge disclose the inventio above but do not expressly disclose a locking mechanism configured to maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Vaillancouert teach that it is well-known in the art to provide an analogous blood sampling device comprising a locking mechanism 24 that enables plunger 21 to be releasably locked relative to barrel 11 so that blood is selectively introduced into the syringe, best see n in Figure 4-5 (Col.4: 63-Col.5: 53). Vaillancouert also teaches that other suitable releasable locking means may also be used to secure the plunger 21 relative to the barrel 11 (Col.5: 8-9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the invention of Cinqualbre et al in view of Eldridge such that there is a locking mechanism configured to selectively maintain the moving part in the first position until the chamber is filled, as taught by Vaillancouert, to effectively prevent the moving part (valve 11 of Cinqualbre et al) from prematurely closing the window 12 before blood sufficiently fills chamber 5 (defined as first test tube on left), which when combined with the user, would thus provide force to overcome the locking mechanism to enable movement of the moving part to the second position as desired. It is noted that the disclosure does not provide any detail into how force would overcome the locking mechanism other than as broadly as has been claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 3, and 20-21 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a

housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 and 8-9 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Response to Arguments

Applicant's arguments with respect to claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

The previous Drawing objections and 112 rejections are moot in light of applicant's amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner
Art Unit 3791

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791

China National Intellectual Property Administration

1110-11, A, Floor 11, Chengjian Plaza, 18 Beitaipingzhuang Road, Haidian District, Beijing 100088, PR China Beijing Pat SF Intellectual Property Agency Co Ltd	Issue Date: August 3, 2023

Application No. or patent No.: 202010300942.7 Issue serial No.: 2023080301552950

Applicant（s）: KURIN, INC.

Title of invention-creation: BLOOD OPTIMIZATION DEVICE

First Office Action

1 ☒ Upon the request of the applicant for substantive examination, the China National Intellectual Property Administration has performed the examination for the above-identified application for a patent for invention according to the provisions of Article 35.1 of the Patent Law.

☐ The China National Intellectual Property Administration itself has decided to perform the substantive examination for the above-identified application for a patent for invention according to the provisions of Article 35.2 of the Patent Law.

2 ☒ The applicant requested to designate the filing date of

March 13, 2020 in the Patent Office of US as the priority date;

March 19, 2020 in the Patent Office of US as the priority date.

3 ☐ After examination, the amendment submitted on_____is not in conformity with the provisions of Rule 51.1 of the Implementing Regulations of the Patent Law, so it has not been accepted.

4 ☐ Examination is made based on the Chinese text or translation of the international application as originally filed.

☒ Examination is made based on the following documents:

Drawings and abstract as filed on the filing date;

items 1-23 of claims and paragraphs 1-251 of description as filed on June 29, 2023.

5 ☒ This notification cited reference documents as follows:（its code will continue to be used in the future when examined.）

code	File No. or title	Publication date (or filing date of conflicting application)
1	US2018177445A1	20180628
2	US4349035A	19820914
3	US5401262A	19950328

6 The conclusion of the examination:

In regard to the Description:

☐ The subject matter of the application belongs to the objects mentioned in Article 5 of the Patent Law, for which no patent right shall be granted.

☐ The description is not in conformity with the provisions of Article 26.3 of the Patent Law.

☐ The description is not in conformity with the provisions of Article 33 of the Patent Law.

☐ The description is not in conformity with the provisions of Rule 17 of Implementing Regulations of the Patent Law.

☐

In regard to the Claims:

☐ Claims_____are not in conformity with the provisions of Article 2.2 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 9.1 of the Patent Law.
☒ Claims__1-4, 12, 18_____do not possess the novelty under Article 22.2 of the Patent Law.
☒ Claims__5-11, 13-17, 19-23_____do not possess the inventiveness under Article 22.3 of the Patent Law.
☐ Claims_____do not possess the practical applicability under Article 22.4 of the Patent Law
☐ Claims_____belong to the objects mentioned in Article 25 of the Patent Law, for which no patent right shall be granted.
☒ Claims__1, 12_____are not in conformity with the provisions of Article 26.4 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 31.1 of the Patent Law.
☒ Claim____19___is not in conformity with the provisions of Article 33 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 19 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 20 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 21 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Rule 22 of Implementing Regulations of the Patent Law.
☐ _____
☐ The application is not in conformity with the provisions of Article 26.5 of the Patent Law or with the provisions of Rule 26 of Implementing Regulations of the Patent Law.
☐ The application is not in conformity with the provisions of Article 20.1 of the Patent Law.
☐ The division application is not in conformity with the provisions of Rule 43.1 of Implementing Regulations of the Patent Law.

7. According to the above conclusion, the examiner deems that:
☐ The applicant shall amend the application documents as required by the text of Office Action.
☐ The applicant shall state the reason why the application can be accepted and amend the part that is indicated not to be in conformity with the provisions, otherwise the application will be rejected.
☒ No subject matter in the application is patentable, the application will be rejected if the applicant does not make a statement or the statement is not convincing.
☐ ___

8. The applicant shall pay attention to the following items:
(1) In accordance with the provisions of Article 37 of the Patent Law, the applicant shall submit the observations within __**4**___months from the date of receiving this notification. If the applicant, without any justified reason, fails to reply within the time limit, the application shall be deemed to have been withdrawn.
(2) The amendments to the application made by the applicant shall be in conformity with the provisions of Article 33 of the Patent Law. The amended text shall not go beyond the disclosure scope of the initial description and claims. The amendment should be in conformity with the provisions of Rule 51.3 of the Implementing Regulations of the Patent Law. The applicant shall make the amendment according to the request of this notification.
(3) Any observation and/or amended text shall be mailed or sent by hand to the Receiving Division of the Patent Office. Any document that is not mailed or sent by hand to the Receiving Division does not have legal effect.
(4) The applicant and/or his agent shall not go to the Patent Office to hold an interview with the examiner if no interview is arranged in advance.
(5) For an invention patent application that entered the substantive examination stage, if the applicant withdraws the application on his own initiative before the due date for responding to the first Office Action (except for the case that a response has already been filed), the applicant can request a refund of 50% of the substantive examination fee.

9. The text of the notification embraces __4__ pages, along with the enclosures herein:
☐ _____Copy(ies) of the cited references is enclosed in pages of _____.
☐ _____

Examiner: Examining Department:
Tel:

Text of the First Office Action

Application number: 202010300942.7

The present application relates to blood optimization device. The following examination opinions are now set forth.

Claim 19 does not comply with the provision under Article 33[1] of the Patent Law.

Claim 19 defines "the vent further comprises a cover that inhibits air from reentering the chamber after air has been displaced". It can be known from the disclosure contained in the original description that: "an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid" (see paragraph [0070] of the description <*Translator's note: corresponding to paragraph [0067] of the English description provided by the former Chinese agency*>), "the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes" (see the description, paragraph [0105] <*Translator's note:*

[1] Article 33 An applicant may amend his or its patent application documents, however, the amendment to the patent application documents for an invention or utility model may not go beyond the scope of disclosure contained in the original description and claims, and the amendment to the patent application documents for a design may not go beyond the scope of the disclosure as shown in the original drawings or photographs.

corresponding to paragraph [00102] of the English description provided by the former Chinese agency>). Accordingly, it is the air permeable blood barrier rather than the structure e.g., protective cover or cover, etc., that inhibits air from reentering the chamber after the air is displaced, and the protective cover or cover is to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes (see paragraphs [0105], [0115], [0136] of the description <*Translator's note: corresponding to paragraphs [00102], [00112], [00133] of the English description provided by the former Chinese agency*>). The limitation in claim 19 is not disclosed in the original application documents, nor can be directly and unambiguously determined from the original application documents. Therefore, claim 19 goes beyond the scope of disclosure contained in the original description and claims, and does not comply with the provision under Article 33 of the Patent Law.

Claims 1-4, 12, and 18 do not possess novelty prescribed under Article 22.2[2] of the Patent Law, and claims 5-11, 13-17, and 19-23 do not possess inventiveness prescribed under Article 22.3[3] of the Patent Law.

1. Claims 1 and 12 seek to protect a device. Reference 1 (US2018177445A1) discloses (see the description, paragraphs [0058]-[0170], and Figs. 1-30G): a blood sequestration device comprises an inlet port (see the description, paragraphs [0156], [0161]) and an outlet port (see the description, paragraphs [0159], [0161]), and a housing 3001 (see the description, paragraph [0161]), the housing 3001 comprising:

an inlet path 3002 (see the description, paragraph [0156], Fig. 30A)

[2] Article 22.2 Novelty means that, the invention or utility model does not form part of the prior art; nor has any entity or individual filed a patent application for the identical invention or utility model with the patent administrative department under the State Council before the filing date, and the content of the application is disclosed in patent application documents published or patent documents announced after the filing date.

[3] Article 22.3 Inventiveness means that, as compared with the prior art, the invention possesses prominent substantive features and represents a notable progress and that the utility model possesses substantive features and represents a progress.

(namely comprising an inlet port, an inlet path connected with the inlet port);

an outlet path 3004 (see the description, paragraph [0158], Fig. 30A) (namely comprising an outlet port, an outlet path connected with the outlet port);

a chamber 3008 (see the description, paragraph [0160], Fig. 30A) connected with the inlet path 3002 by a junction 3007 and being configured to receive a first portion of blood through the inlet path 3002 (see the description, paragraphs [0160], [0163]-[0164]), the junction 3007 being configured to inhibit a return to the inlet path 3002 of any of the first portion of blood received by the chamber 3008 (see the description, paragraphs [0061], [0067], [0156], [0160]-[0161]); and

a sampling channel 3006 connected between the inlet path 3002 and the outlet path 3004 (see the description, paragraphs [0159]-[0160]), the sampling channel 3006 being configured to convey subsequent amounts of blood between the inlet path 3002 and the outlet path 3004 after the first amount of blood is received by the chamber 3008 (see the description, paragraphs [0160]-[0170]).

As can be seen, Reference 1 has disclosed all the technical features of claim 1. Moreover, the technical solution disclosed by Reference 1 and the technical solution sought for protection in claim 1 belong to the same technical field, are used for solving the same technical problem, and can produce the same technical effect. Therefore, the technical solution sought for protection in claim 1 does not possess novelty.

2. Claim 20 seeks to protect a blood sample optimization system. Reference 1 (US2018177445A1) discloses (see the description, paragraphs [0058]-[0170], and Figs. 1-30G): a blood sample optimization system (see the description, paragraph [0156]) comprises a blood sampling system comprising:

the blood sequestration device 3000 includes an inlet path 3002 that can

be connected with a patient needle (namely the venipuncture apparatus) that is inserted into a patient's vascular system for access to and withdrawing of a blood sample (namely configuring the same for venipuncture of a patient to access a sample of blood of the patient);

the blood sequestration device 3000 includes a sampling channel 3006 (namely the blood sampling pathway connected with the venipuncture apparatus for conveying the sample of blood) between the inlet port 3002 and the outlet port 3004;

an outlet path 3004 (comprising a reservoir) for collecting a subsequent portion of the sample of blood; and

a device connected along the blood sampling pathway 3006 between the patient needle and the outlet path 3004 (comprising a reservoir), the device comprising:

an inlet path 3002 connected with the patient needle (see the description, paragraph [0156], Fig. 30A) (namely comprising an inlet port, an inlet path connected with the inlet port);

an outlet path 3004 (see the description, paragraph [0158], Fig. 30A) (namely comprising an outlet port, an outlet path connected with the outlet port);

a chamber 3008 (see the description, paragraph [0160], Fig. 30A) connected with the inlet path 3002 by a junction 3007 and being configured to receive a first portion of blood through the inlet path 3002 (see the description, paragraphs [0160], [0163]-[0164]), the junction 3007 being configured to inhibit a return to the inlet path 3002 of any of the first portion of blood received by the chamber 3008 (see the description, paragraphs [0061], [0067], [0156], [0160]-[0161]); and

a sampling channel 3006 connected between the inlet path 3002 and the outlet path 3004 (see the description, paragraphs [0159]-[0160]), the sampling channel 3006 being configured to convey subsequent amounts of blood between the inlet path 3002 and the outlet path 3004 after the first

amount of blood is received by the chamber 3008 (see the description, paragraphs [0160]-[0170]).

The differences of the technical solution sought for protection in claim 20 as compare with the contents disclosed by Reference 1 lie in: a reservoir configured for receiving an evacuated blood collection tube to collect a subsequent portion of the sample of blood; an outlet path connected with the sample needle. Based on the differences, it is determined that the technical problem to be practically solved by the present application is how to collect a sample. However, Reference 1 discloses in another embodiment: a reservoir configured for receiving an evacuated blood collection tube to collect a subsequent portion of the sample of blood; an outlet path connected with the sample needle 5 (see the description, paragraph [0065], Figs. 1, 7). The above differences are disclosed by another embodiment of Reference 1.

Thus, it is obvious for a person skilled in the art to obtain the technical solution sought for protection in claim 20 on the basis of Reference 1 in combination with routine technical means in the art. Therefore, the technical solution sought for protection in claim 20 does not possess prominent substantive features or represent notable progress, and does not possess inventiveness prescribed under Article 22.3 of the Patent Law.

3. Claims 2-4 refer to claim 1, claim 10 refers to claim 1, and claim 11 refers to claim 10. It is disclosed: the junction is angled from the inlet path toward the chamber (see the description, paragraph [0160], Figs. 17A, 30A); the junction has a cross-sectional area that is smaller than a cross-sectional area of the inlet path (see the description, paragraph [0160], Figs. 17A, 30A); the junction has a cross-sectional area that is larger than a cross-sectional area of the inlet path (see the description, paragraphs [0160], [0163], Figs. 17A, 30A); the chamber 3008 has a vent 3010 that allows air to be displaced by the first

portion of blood (see the description, paragraphs [0161], [0163]-[0165], Figs. 30A-D); the vent 3010 includes two or more vent apertures 3012 (see the description, paragraphs [0160]-[0161]). Therefore, where the claims referred to do not possess novelty, claims 2-4 and 10-11 do not possess novelty prescribed under Article 22.2 of the Patent Law, either.

4. Claim 5 refers to claim 1, claim 13 refers to claim 12, and claim 21 refers to claim 20. Reference 2 (US4349035A) discloses (see the description, line 20 in column 4 to line 7 in column 8, and Figs. 1-10): a blood collection assembly comprises a cannular 19 (comprising an inlet path) (see the description, lines 23-28 in column 4, Fig. 5), a valve 22 connected to a receptacle 21 (comprising a chamber) (see the description, lines 23-28 in column 4, Figs. 4-5); the purpose of valve 22 (namely one or more passive structures) is to operably open to allow blood to only flow into receptacle 21, but to operably close to prevent blood from backflowing out of the receptacle 21 toward the patient (namely passive structures configured to inhibit the return to the inlet path of any of the first portion of blood received by the chamber); valve 22 is an elastomeric material, such as rubber, which is substantially tubular in cross-section and which projects from stopper 25 a short distance into receptacle 21; at the far or distal end of valve 22, it tapers to a point; at the point of the tubular valve is a slit 28 which communicates with space 26; this slit serves as an operable passageway to open up to allow blood to flow into receptacle 21; when slit 28 is closed, it forms a liquid tight seal so as to prevent blood from flowing therethrough in that closed position; other configurations in this type valve may be employed, for example, a dome-shaped valve with an operable hole therein. Accordingly, partial of the additional technical features of claim 5 is disclosed by Reference 2. Moreover, the disclosed feature performs the same function in Reference 2 as in the present application, namely inhibiting backflow of the blood. Reference 2 provides a technical inspiration, based on which the person skilled in the art would easily envisage disposing

the junction of Reference 1 to have said structure, thereby inhibiting backflow of the blood. Therefore, where the claims referred to do not possess novelty, claims 5, 13, and 21 do not possess inventiveness prescribed under Article 22.3 of the Patent Law, either.

5. Claim 6 refers to claim 5, and claim 14 refers to claim 13. The additional features of claims 6 and 14 are disclosed by Reference 1: the valve 22 exhibits a conical shape (namely the feature “one or more passive structures include a conical baffle having a tapered end directed toward the chamber”) (see the description, lines 13-17 in column 5, and Figs. 4-5). Therefore, where the claims referred to do not possess inventiveness, claims 6 and 14 do not possess inventiveness prescribed under Article 22.3 of the Patent Law, either.

6. Claim 7 refers to claim 5, and claim 15 refers to claim 13. Reference 3 (US5401262A) discloses (see the description, line 9 in column 8 to line 53 in column 26, Figs. 1-15): a blood drainage device; the plurality of curved baffles 112a-112c (namely two or more staggered baffles) in the upper portion of the manometer chamber return spray and condensate to the water column, resulting in further effectiveness of fluid retention in the column. The disclosed feature performs the same function in Reference 3 as in the present application, namely retaining fluid. Reference 3 provides with a technical inspiration. In view of this, the remaining additional features belong to routine technical means easily envisaged by the person skilled in the art. Therefore, where the claims referred to do not possess inventiveness, claims 7 and 15 do not possess inventiveness prescribed under Article 22.3 of the Patent Law, either.

7. Claims 8 and 9 refer to claim 5, claims 16 and 17 refer to claim 13, and claim 22 refers to claim 21. The additional features of claims 8-9, 16-17, and 22 belong to routine technical means easily envisaged by the person skilled in the

art on the basis of valve 22 disclosed by Reference 2. Therefore, where the claims referred to do not possess inventiveness, claims 8-9, 16-17, and 22 do not possess inventiveness prescribed under Article 22.3 of the Patent Law, either.

8. Claim 18 refers to claim 12. The additional feature of claim 18 is disclosed by Reference 1 (*ibid*): the chamber 3008 has a vent 3010 that allows air to be displace by the first portion of blood, and the vent 3010 is further configured to close upon the chamber 3008 being filled with the first portion of blood. Therefore, where the claim referred to does not possess novelty, claim 18 does not possess novelty prescribed under Article 22.2 of the Patent Law, either.

9. Claim 23 refers to claim 20. The additional feature of claim 23 is disclosed by Reference 1 (*ibid*): the chamber 3008 has a vent 3010 that allows air to be displaced by the first portion of blood (see the description, paragraphs [0161], [0163]-[0165], Figs. 30A-D). Therefore, where the claim referred to does not possess inventiveness, claim 23 does not possess inventiveness prescribed under Article 22.3 of the Patent Law, either.

Claims 1 and 12 do not comply with the provision under Article 26.4[4] of the Patent Law.

The subject matter of claims 1 and 12 cannot clearly reflect the technical field to which the technical solutions sought for protection relate, with the result that the protection scope of claims 1 and 12 is unclear. Therefore, claims 1 and 12 do not comply with the provision under Article 26.4 of the Patent Law.

[4] Article 26.4 The claims shall be supported by the description and shall define the scope of the patent protection sought for in a clear and concise manner.

For the above reasons, no patent right can be granted for the present application. Moreover, the description of the present application does not disclose any other patentable substantive content. Therefore, the present application does not possess a prospect of grant even if the amendments would be made to the application documents. If the Applicant cannot present convincing causes within the time limit specified in the present office action, the present application will be rejected.

Moreover, pursuant to *Announcement on Suspending the Collection and Adjustment of Some Patent Charges* (No. 272) issued by China National Intellectual Property Administration, where an invention patent application that entered into the substantive examination phase is withdrawn on the Applicant's own initiative prior to expiration of the time limit for responding to the First Office Action (except the case where a response has been filed) from 1 August 2018, it is allowed to request a refund 50% of the substantive examination fee.

Should you have any questions on the examination opinions, you may feed back your opinions via the following ways: phone of the Examiner: 010-53962499, or phone on-duty: 010-53962356, or email address: sxbjzx_yijian@cnipa.gov.cn. Please note that the contents fed back through the email address should not have legal force and formal observation and/or amendment texts should be submitted to the Receiving Department of the Patent Office within the time limit specified.

Examiner: Peijie JIANG

Code: 30082386

国 家 知 识 产 权 局

100088

北京市海淀区北太平庄路 18 号 11 层 A1110-11 北京世峰知识产权代理有限公司
卓霖(010-82800919) 许向彤(010-82800919)

发文日：

2023 年 08 月 03 日

申请号：202010300942.7 **发文序号：2023080301552950**

申请人：酷睿有限公司

发明创造名称：具有被动流体控制接合部的血液污染物分离装置

第 一 次 审 查 意 见 通 知 书

1.☒应申请人提出的实质审查请求，根据专利法第 35 条第 1 款的规定，国家知识产权局对上述发明专利申请进行实质审查。

☐根据专利法第 35 条第 2 款的规定，国家知识产权局决定自行对上述发明专利申请进行审查。

2.☒申请人要求以其在：

US 专利局的申请日 2020 年 03 月 13 日为优先权日， US 专利局的申请日 2020 年 03 月 19 日为优先权日。

☒申请人已经提交了经原受理机构证明的第一次提出的在先申请文件的副本。

☐申请人尚未提交经原受理机构证明的第一次提出的在先申请文件的副本，根据专利法第 30 条的规定视为未要求优先权要求。

3.☐经审查，申请人于_____提交的修改文件，不符合专利法实施细则第 51 条第 1 款的规定，不予接受。

4.审查针对的申请文件：

☐原始申请文件。☐分案申请递交日提交的文件。☒下列申请文件：

申请日提交的说明书摘要、说明书附图； 2023 年 6 月 29 日提交的权利要求第 1-23 项、说明书第 1-251 段。

5.☐本通知书是在未进行检索的情况下作出的。

☒本通知书是在进行了检索的情况下作出的。

☒本通知书引用下列对比文件(其编号在今后的审查过程中继续沿用)：

编号	文 件 号 或 名 称	公开日期（或抵触申请的申请日）
1	US2018177445A1	2018-06-28
2	US4349035A	1982-09-14
3	US5401262A	1995-03-28

6.审查的结论性意见：

关于说明书：

☐申请的内容属于专利法第 5 条规定的不授予专利权的范围。
☐说明书不符合专利法第 26 条第 3 款的规定。
☐说明书不符合专利法第 33 条的规定。
☐说明书的撰写不符合专利法实施细则第 17 条的规定。
☐_____

关于权利要求书：

☐权利要求_____不符合专利法第 2 条第 2 款的规定。
☐权利要求_____不符合专利法第 9 条第 1 款的规定。
☒权利要求 1-4、12、18 不具备专利法第 22 条第 2 款规定的新颖性。
☒权利要求 5-11、13-17、19-23 不具备专利法第 22 条第 3 款规定的创造性。
☐权利要求_____不具备专利法第 22 条第 4 款规定的实用性。
☐权利要求_____属于专利法第 25 条规定的不授予专利权的范围。
☒权利要求 1、12 不符合专利法第 26 条第 4 款的规定。
☐权利要求_____不符合专利法第 31 条第 1 款的规定。
☒权利要求 19 不符合专利法第 33 条的规定。
☐权利要求_____不符合专利法实施细则第 19 条的规定。
☐权利要求_____不符合专利法实施细则第 20 条的规定。
☐权利要求_____不符合专利法实施细则第 21 条的规定。
☐权利要求_____不符合专利法实施细则第 22 条的规定。
☐_____

☐申请不符合专利法第 26 条第 5 款或者实施细则第 26 条的规定。
☐申请不符合专利法第 19 条第 1 款的规定。
☐分案申请不符合专利法实施细则第 43 条第 1 款的规定。

上述结论性意见的具体分析见本通知书的正文部分。

7.基于上述结论性意见，审查员认为：

☐申请人应当按照通知书正文部分提出的要求，对申请文件进行修改。
☐申请人应当在意见陈述书中论述其专利申请可以被授予专利权的理由，并对通知书正文部分中指出的不符合规定之处进行修改，否则将不能授予专利权。
☒专利申请中没有可以被授予专利权的实质性内容，如果申请人没有陈述理由或者陈述理由不充分，其申请将被驳回。
☐_____

8.申请人应注意下列事项：

(1) 根据专利法第 37 条的规定，申请人应在收到本通知书之日起的 4 个月内陈述意见，如果申请人无正当理由逾期不答复，其申请被视为撤回。

(2) 申请人对其申请的修改应当符合专利法第 33 条的规定，不得超出原说明书和权利要求书记载的范围，同时申请人对专利申请文件进行的修改应当符合专利法实施细则第 51 条第 3 款的规定，按照本通知书的要求进行修改。

(3) 申请人的意见陈述书和/或修改文本应邮寄或递交国家知识产权局专利局受理处，凡未邮寄或递交给受理处的文件不具备法律效力。

(4) 未经预约，申请人和/或代理师不得前来国家知识产权局专利局与审查员举行会晤。

(5) 对进入实质审查阶段的发明专利申请，在第一次审查意见通知书答复期限届满前（已提交答复意见的除外），主动申请撤回的，可以请求退还 50%的专利申请实质审查费。

9.本通知书正文部分共有 4 页，并附有下述附件：

☐引用的对比文件的复印件共_____份_____页。
☐_____

审查员：姜佩杰　　联系电话：010-53962499　　审查部门：专利审查协作北京中心

210401
2022.10
纸件申请，回函请寄：100088 北京市海淀区蓟门桥西土城路 6 号 国家知识产权局专利局受理处收。
电子申请，应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外，以纸件等其他形式提交的文件视为未提交。

第 一 次 审 查 意 见 通 知 书

申请号:202010300942 7

本申请涉及血液优化装置，现提出如下的审查意见：

权利要求 19 不符合专利法第 33 条的规定

权利要求 19 中限定“通气口还包括盖，在空气被置换后，所述盖抑制空气重新进入所述腔室”，而通过原说明书中记载可知，“透气性血液屏障可以由一种或多种材料形成，该材料允许空气通过直到与液体接触，然后这种材料被完全或部分密封以防止或抑制空气和/或液体的通过”（参见说明书第 0070 段）；“透气性血液屏障 1412 可以覆盖有保护罩 1416。保护罩 1416 的尺寸和构造可以设定成禁止使用者通过其手指或其他外部器具触摸透气性血液屏障 1412，同时当由于血液借助患者自身的血压而被迫进入隔离室 1408 中而使空气从隔离室 1408 中排出时，仍允许空气离开透气性血液屏障 1412。另外，保护罩 1416 可被构造成抑制或防止透气性血液屏障对环境流体或飞溅物的意外暴露。”（参见说明书第 0105 段）；由此可知，空气被置换后，抑制空气重新进入腔室的是透气性血液屏障，而非保护罩或盖等结构，保护罩或盖是用于抑制或防止透气性血液屏障对环境流体或飞溅物的意外暴露（可参见说明书第 0105、0115、0136 段）。权利要求 9 的上述限定并未记载在原申请文件中，且不能由原申请文件直接的、毫无疑义确定得到，权利要求 9 超出了原说明书和权利要求书记载范围，不符合专利法第 33 条的规定。

权利要求 1-4、12、18 不符合专利法第 22 条第 2 款规定的新颖性；权利要求 5-11、13-17、19-23 不符合专利法第 22 条第 3 款规定的创造性

1.权利要求 1、12 请求保护一种装置，对比文件 1（US2018177445A1）公开了（说明书第 0058-0170 段，附图 1-30G）：一种血液隔离装置，包括具有入口端口（说明书第 0156、0161 段）和出口端口（说明书第 0159、0161 段）的壳体 3001（说明书第 0161 段），该壳体 3001 包含：

入口路径 3002（说明书第 0156 段，图 30A）（即包含入口端口，与入口端口连接的入口路径）；

出口路径 3004（说明书第 0158 段，图 30A）（即包含出口端口，与出口端口连接的出口路径）；

腔室 3008（说明书第 0160 段，图 30A），通过接合部 3007 与所述入口路径 3002 连接，并被构造成通过所述入口路径 3002 接收第一部分血液（说明书第 0160、0163-0164 段），所述接合部 3007 被构造为抑制由腔室 3008 接收的任何所述第一部分血液返回所述入口路径 3002（说明书第 0061、0067、0156、0160-0161 段）；以及

在入口路径 3002 和出口路径 3004 之间连接的采样通道 3006（说明书第 0159-0160 段），所述采样通道 3006 被构造为在第一量的血液被腔室 3008 接收之后在入口路径 3002 和出口路径 3004 之间输送后续量的血液（说明书第 0160-0170 段）。

由此可见，对比文件 1 已经公开了上述权利要求的全部技术特征，且对比文件 1 所公开的技术方案与该

权利要求所要求保护的技术方案属于同一技术领域，用于解决相同的技术问题，并能产生相同的技术效果，因此上述权利要求所要求保护的技术方案不具备新颖性。

2. 权利要求 20 请求保护一种血液样本优化系统，对比文件 1（US2018177445A1）公开了（说明书第 0058-0170 段，附图 1-30G）：一种血液样本优化系统（说明书第 0156 段），包括血液采样系统，包括：血液隔离装置 3000 包括入口路径 3002，该入口路径 3002 可以与患者针（即静脉穿刺设备）连接，该患者针插入患者的血管系统中以用于进入和抽出血液样品（即其构造成对患者进行静脉穿刺以获取患者的血液样本）。血液隔离装置 3000 包括从入口路径 3002 到出口路径 3004 的采样通道 3006（即与所述静脉穿刺设备连接的血液采样通路，用于输送所述血液样本）；出口路径 3004（包含储存器），以收集血液样本的后续部分；以及沿患者针和出口路径 3004（包含储存器）之间的血液采样通路 3006 连接的装置，该装置包括：

与患者针连接的入口路径 3002（说明书第 0156 段，图 30A）（即包含入口端口，与入口端口连接的入口路径）；

出口路径 3004（说明书第 0158 段，图 30A）（即包含出口端口，与出口端口连接的出口路径）；

腔室 3008（说明书第 0160 段，图 30A），通过接合部 3007 与所述入口路径 3002 连接，并被构造成通过所述入口路径 3002 接收第一部分血液（说明书第 0160、0163-0164 段），所述接合部 3007 被构造为抑制由腔室 3008 接收的任何所述第一部分血液返回所述入口路径 3002（说明书第 0061、0067、0156、0160-0161 段）；以及

在入口路径 3002 和出口路径 3004 之间连接的采样通道 3006（说明书第 0159-0160 段），所述采样通道 3006 被构造为在第一量的血液被腔室 3008 接收之后在入口路径 3002 和出口路径 3004 之间输送后续量的血液（说明书第 0160-0170 段）。

权利要求 20 所要求保护的技术方案与对比文件 1 公开的内容相比，其区别在于：储存器，其构造成用于接收抽空的采血管，以收集血液样本的后续部分；与样本针连接的出口路径，基于上述区别，本申请实际要解决的技术问题是：如何采集样本。但是对比文件 1 的另一实施例公开：储存器，其构造成用于接收抽空的采血管，以收集血液样本的后续部分；与样本针 5 连接的出口路径（说明书第 0065 段，图 1、7），上述区别被对比文件 1 的另一实施例公开。

由此可知，在对比文件 1 的基础上结合常规技术手段以获得该权利要求请求保护的技术方案对本领域技术人员来说是显而易见的，因此，该权利要求的技术方案不具备突出的实质性特点和显著的进步，不具备专利法第 22 条第 3 款规定的创造性。

3.权利要求 2-4 引用权利要求 1、权利要求 10 引用权利要求 1、权利要求 11 引用权利要求 10，接合部从入口路径朝向腔室成角度（说明书第 0160 段，图 17A、30A）；接合部的截面积小于入口路径的截面积（说明书第 0160 段，图 17A、30A）；接合部的截面积大于入口路径的截面积（说明书第 0160、0163 段，图

17A、30A）；腔室 3008 具有通气口 3010，所述通气口 3010 允许空气被所述第一部分血液置换（说明书第 0161、0163-0165 段，图 30A-D）；通气口 3010 包括两个或更多个通气孔 3012(说明书第 0160-0161 段）；因此，在其引用的权利要求不具备新颖性时，上述权利要求也不具备专利法第 22 条第 2 款规定的新颖性。

4.权利要求 5 引用权利要求 1，权利要求 13 引用权利要求 12，权利要求 21 引用权利要求 20，对比文件 2（US4349035A）公开（说明书第 4 栏第 20 行至第 8 栏第 7 行，图 1-10）：一种血液采集组件，包括管 19（包含入口路径）（参见说明书第 4 栏第 23-28 行，图 5），连接到容器 21（具有腔室）的阀 22（参见说明书第 4 栏第 23-28 行，图 4-5），阀 22（即一个或多个被动结构）的目的是可操作地打开以允许血液仅流入容器 21，但是可操作地关闭以防止血液从容器 21 向患者回流（即被动结构构造成抑制由腔室接收的任何第一部分血液返回到入口路径）。阀 22 是弹性体材料，例如橡胶，其横截面基本上是管状的并且从止动件 25 突出短距离到容器 21 中。在阀 22 的远端或远端处，它逐渐变细到一点。在管状阀的点处是与空间 26 连通的狭缝 28。该狭缝用作可操作通道以打开以允许血液流入容器 21；当狭缝 28 闭合时，其形成液密密封，以便防止血液在该闭合位置流过其中。在这种类型的阀中可以采用其他构造，例如，其中具有可操作孔的圆顶形阀。故部分附加特征 5 被对比文件 2 公开，且其在对比文件 2 中的所起的作用与其在本申请中所起的作用相同，都是用于抑制血液回流。对比文件 2 给出技术启示，在此基础上，本领域技术人员容易想到将对比文件 1 的接合部设置成具有上述结构，进而抑制血液回流。因此，在其引用的权利要求不具备新颖性时，上述权利要求也不具备专利法第 22 条第 3 款规定的创造性。

5.权利要求 6 引用权利要求 5，权利要求 14 引用权利要求 13，其附加特征被对比文件 1 公开：阀 22 程锥形（即一个或多个被动结构包括锥形挡板，所述锥形挡板具有指向所述腔室的锥形端）（参见说明书第 5 栏第 13-17 行，图 4-5），因此，在其引用的权利要求不具备创造性时，上述权利要求也不具备专利法第 22 条第 3 款规定的创造性。

6.权利要求 7 引用权利要求 5，权利要求 15 引用权利要求 13，对比文件 3（US5401262A）公开（说明书第 8 栏第 9 行至第 26 栏第 53 行，图 1-15）：一种血液引流装置，压力计腔室的上部中的多个弯曲挡板 112a-112c（即两个或更多个交错的挡板）将喷雾和冷凝物返回到水柱，从而进一步有效地保持柱中的流体。其在对比文件 3 中的作用与其在本申请中作用相同，都是用于流体潴留，对比文件 3 给出了技术启示，在此基础上，其余附加特征属于本领域技术人员容易想到的常规技术手段，因此，在其引用的权利要求不具备创造性时，上述权利要求也不具备专利法第 22 条第 3 款规定的创造性。

7.权利要求 8、9 引用权利要求 5，权利要求 16、17 引用权利要求 13，权利要求 22 引用权利要求 21，其附加特征属于本领域技术人员在对比文件 2 公开的阀 22 的基础上容易想到的常规技术手段，因此，在其引用的权利要求不具备创造性时，上述权利要求也不具备专利法第 22 条第 3 款规定的创造性。

8.权利要求 18 引用权利要求 12，其附加特征被对比文件 1 公开（参见同上）：腔室 3008 具有通气口

3010，所述通气口 3019 允许空气被所述第一部分血液置换，所述通气口 3010 进一步构造成在所述腔室 3008 中充满所述第一部分血液时关闭。因此，在其引用的权利要求不具备新颖性时，上述权利要求也不具备专利法第 22 条第 2 款规定的新颖性。

9.权利要求 23 引用权利要求 20，其附加特征被对本比文件 1 公开（参见同上）：腔室 3008 具有通气口 3010，所述通气口 3010 允许空气被所述第一部分血液置换（说明书第 0161、0163-0165 段，图 30A-D）；因此，在其引用的权利要求不具备创造性时，上述权利要求也不具备专利法第 22 条第 3 款规定的创造性。

权利要求 1,12 不符合专利法第 26 条第 4 款的规定

权利要求 1、12 主题名称未能清楚反映出请求保护的技术方案所涉及的技术领域，导致该权利要求的保护范围不清楚，不符合专利法第 26 条第 4 款的规定。

基于上述理由，本申请不能被授予专利权，而且本申请的说明书中也没有记载其它任何可获得专利权的实质性内容，因而即使对申请文件进行修改，本申请也不具备被授予专利权的前景。如果申请人不能在本通知书规定的答复期限内提出具有说服力的理由，本申请将被驳回。

另根据国家知识产权局《关于停征和调整部分专利收费的公告》（第 272 号）规定，对进入实质审查的发明专利申请，在第一次审查意见通知书答复期限前（已提交答复意见的除外）主动申请撤回的，可以请求退还 50%的专利申请实质审查费。

如您对审查意见存在疑问，可拨打审查员电话 010-53962499，或值班电话 010-53962356 ，也可通过邮箱 sxbjzx_yijian@cnipa.gov.cn 反馈意见。请注意：邮箱反馈的内容不具备法律效力，请将正式的意见陈述书和/或修改文本在规定期限内提交给专利局受理部门。

审查员姓名:姜佩杰
审查员代码:30082386

国 家 知 识 产 权 局

检 索 报 告

申请号：2020103009427	申请日：2020 年 04 月 16 日	首次检索
申请人：酷睿有限公司	最早的优先权日：2020 年 03 月 13 日	
权利要求项数：23	说明书段数：251+117	

审查员确定的 IPC 分类号：A61B 5/15,A61B 5/153

检索记录信息：US2004073171A1: 美局检索报告

US2018177445A1: 欧局检索报告

US2018271425A1: 欧局检索报告

US2018353117A1: 欧局检索报告

US4349035A: 欧局检索报告

US5401262A: 欧局检索报告

US2018177445A1: 3 VCN, /PN US2018177445 or us4349035 OR US5401246

相 关 专 利 文 献

类型	国别以及代码[11] 给出的文献号	代码[43]或[45] 给出的日期	IPC 分类号	相关的段落 和/或图号	涉及的权 利要求
X	US2018177445A1	2018-06-28	A61B5/15	说明书第 0058-0170 段，附图 1-30G	1-4、6、8-12、14、16-18、20、23
Y	US2018177445A1	2018-06-28	A61B5/15	说明书第 0058-0170 段，附图 1-30G	5、7、13、15、21、22
Y	US4349035A	1982-09-14	A61M1/00	说明书第 4 栏第 20 行至第 8 栏第 7 行，图 1-10	5、13、21、22
Y	US5401262A	1995-03-28	A61M1/00	说明书第 8 栏第 9 行至第 26 栏第 53 行，图 1-15	7、15

A	US2004073171A1	2004-04-15	A61M5/178	全文	1-18、20-23
A	US2018271425A1	2018-09-27	A61B5/15	全文	1-18、20-23
A	US2018353117A1	2018-12-13	A61B5/15	全文	1-18、20-23

相 关 非 专 利 文 献					
类型	书名（包括版本号和卷号）	出版日期	作者姓名和出版者名称	相关页数	涉及的权利要求
类型	期刊或文摘名称 （包括卷号和期号）	发行日期	作者姓名和文章标题	相关页数	涉及的权利要求
类型	网址	网络发布日 或公开日	作者姓名和网页标题	相关部分	涉及的权利要求

表格填写说明事项：

1. 审查员实际检索领域的 IPC 分类号应当填写到大组和／或小组所在的分类位置。
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3. 相关文件的类型说明：

   X：单独影响权利要求的新颖性或创造性的文件；

   Y：与本检索报告中其他 Y 类文件组合后影响权利要求的创造性的文件；

   A：背景技术文件，即反映权利要求的部分技术特征或者有关的现有技术的文件；

   R：任何单位或个人在申请日向专利局提交的、属于同样的发明创造的专利或专利申请文件。

   P：中间文件，其公开日在申请的申请日与所要求的优先权日之间的文件，或者会导致需要核实该申请优先权的文件；

E：单独影响权利要求新颖性的抵触申请文件；

T：申请日或优先权日当天或之后公布的，可以对所要求保护发明的理论或原理提供清楚解释的文件，或者可显示出所要求保护发明的推理或事实不成立的文件；

L：除 X、Y、A、R、P、E 和 T 类文件之外的文件。

审 查 员：姜佩杰　　审查部门：专利审查协作北京中心
2023 年 08 月 01 日

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18 March 2022

Examination report No. 1 for standard patent application

Griffith Hack
GPO Box 4164
Sydney NSW 2001
Australia

Your reference:	P108089.AU.1
Application number:	2021202622
Applicant name:	KURIN, INC.
Earliest priority date:	24 July 2015

Final date for acceptance:	**18 March 2023**
Date of this report:	18 March 2022
Examination request date:	6 July 2021

Dear Griffith Hack,

Your application has been examined under *section 45 of the Patents Act 1990*.

You have **12 months** from the date of this report to overcome all my objection(s) otherwise this application will lapse.

You will also need to pay any annual continuation fees that apply. Your next continuation fee is due on **22 July 2022**.

While the application is otherwise in order for acceptance, it cannot be accepted because there is a current postponement of acceptance in place.

You must respond to this report in order to gain acceptance. The Commissioner will only proceed to accept the application if you file a clear and unambiguous statement requesting the postponement be withdrawn with sufficient time for the request to be processed. If the application is not accepted by **18 March 2023**, your application will lapse.

Details of this patent application can be viewed on Auspat, our Australian patent search database.

Yours sincerely,

Kevin Sivieng
Section: MECH 4 - MEDICAL DEVICES
Phone: +61 2 6283 2609

Alternate contact: Vijay Singh
Phone: +61 2 6283 2665

Report details

Basis of the report

In examining this application I have considered:

- the specification as filed.
- allowed and/or proposed amendment/s under S104 including amendment item number 1, filed on 4 May 2021.

Summary of novelty, inventive step and patentable subject matter

	Satisfy requirements?	*Claim numbers*
Novelty/inventive step	**Yes**	1-16
	No	NONE
Patentable subject matter	**Yes**	1-16
	No	NONE

Detailed objections on issues that have been identified

Documents cited or considered relevant

D1: WO 2011162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US], et al) 29 December 2011 [1]
Category: A

D2: WO 1996005875 A1 (BAXTER INT [US]) 29 February 1996 [2]
Category: A

D3: US 20130317391 A1 (BULLINGTON GREGORY J [US], et al) 28 November 2013 [3]
Category: A

D4: US 4207870 A (ELDRIDGE WILLIAM N [US]) 17 June 1980 [3]
Category: A

D5: US 4416291 A (KAUFMAN) 22 November 1983 [4]
& JP S 5825146 A
Category: A

D6: US 20080145933 A1 (PATTON RICHARD G [US]) 19 June 2008 [5]
Category: A

D7: JP 2001000424 A (NISSHO KK) 9 January 2001, English translation retrieved from Espacenet [5]
Category: A

[1] Cited in the search/examination report of WO 2017/019552 A1

[2] Cited in the search/examination report of EP 3622890

[3] Cited in the search/examination report of US 2017/0020427 A1

[4] Cited in the search/examination report of JP 2018525191

[5] Cited in the search/examination report of JP 2020192333

Special categories of cited documents:

A: Document defining the general state of the art which is not considered to be of particular relevance.
&: Document member of the same patent family.

END OF REPORT

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 02/21/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
02/21/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/893,079	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 8/22/2022.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-30 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-30 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 8/22/02022 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

It noted that there are two claims numbered 15. The second of which has been renumbered as Claim 16, and all others following have been renumbered accordingly. Thus, there are 31 claims in total and the claims are referred to by the new numbering.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

It is noted that no IDS has been submitted. Applicant is reminded of the duty to disclose all known prior art resulting from all prior art searches.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the structural components to enable the fluid controller to move from a first to a second position as described in the specification and in **Claims 6, 9, 24, and 27**. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended

drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element

(also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under

35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word "means," but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

First flow controller (Claim 9, 12, 26, 27 – defined in specification by air permeable blood barrier 0060)

Second flow controller that is movable between first and second position (Claim 6, 9, 13, 23, 26, 28 – Figure 24, element 2419).

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 8, 9, 13, 24, and 26-31 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or

for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regard to Claims 6, 9, 24, 27, per the drawing objections and 112(b) rejection below, it is unclear that applicant has proper support for the entire structural mechanism of the flow controller that is movable from a first position to a second position through a pressure differential.

While Figure 24B shows inner chamber housing 2419 that is movable from a first position to second position (0141), it is unclear both from the drawings and the limited disclosure how this occurs structurally. For example, there are no details provided or explanation of the structural connection between the inner chamber housing 2419, the apertures 2424, and the housing 2416 that enable movement of said inner chamber housing 2419 *from the first position*. Further, though paragraph 0142 states that as the blood contacts blood barrier 2420, this forces the inner chamber housing 2419 to the second position, it is again unclear how the inner chamber housing 2419 structurally moves to the second position from the first. Again, while paragraph 0143 describes tangs 2421 to stop the inner chamber housing 2419 in the second position, this does not provide any information about how the chamber moved from the first position.

Claims 8, 13, 26, and 29 recite that a pressure differential moves the inner chamber housing. However, as elaborated above, the details of this have not been provided to sufficiently describe the mechanics of said movement from the first position to the second position. As this mechanism is the crux of the embodiment in Figure 24 which are recited in the claims, the claims are therefore not properly supported by the disclosure.

> The following is a quotation of 35 U.S.C. 112(b):
> (b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.
>
> The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

In regard to Claims 1 and 18, the recitation of "an air permeable bodily fluid resistor" is indefinite. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

The term "resistor" in claims 1 and 18 is used by the claim to mean "an air permeable blood barrier" (see paragraph 0060 of publication – listed as known in the art to include membranes, coatings, mesh, filter, valve, etc.) while the accepted meaning is "a specific electrical circuit component" The term is indefinite because the specification does not clearly redefine the term. In fact, the specification does not use the term "resistor" at all. Therefore, the use of the term above is unclear because a skilled artisan would not reasonably be able to ascertain its desired meaning from the limitation.

In the rejection that follows, it is assumed that the term "an air permeable bodily fluid resistor" refers to the air permeable blood barrier as disclosed in the specification. However, clarification and correction are required.

In regard to Claims 6, 9, 23, 26, per the drawing objections and 112(a) rejection above, it is unclear how the flow controller that is movable from a first position to a second position through a pressure differential is structured to enable such functioning.

While Figure 24B shows inner chamber housing 2419 that movable from a first position to second position (0141), it is unclear both from the drawings and the limited disclosure how this occurs structurally. For example, there are no details provided or explanation of the structural connection between the inner chamber housing 2419, the apertures 2424, and the housing 2416 that enable movement of said inner chamber housing 2419 *from the first position*. Further, though paragraph 0142 states that as the blood contacts blood barrier 2420, this forces the inner chamber housing 2419 to the second position, it is again unclear how the inner chamber 2419 structurally moves to the second position from the first. Again, while paragraph 0143 describes tangs 2421 to stop the inner chamber housing 2419 in the second position, this does not provide any information about how the chamber moved from the first position.

Claims 8, 13, 25, and 28 recite that a pressure differential moves the inner chamber housing. However, as elaborated above, the details of this have not been provided to sufficiently describe the mechanics of said movement from the first position to the second position. As this mechanism is the crux of the embodiment in Figure 24 which are recited in the

claims, the claims are therefore indefinite because a skilled artisan cannot ascertain how the invention operates as claimed.

In regard to Claims 4, 6, 21, and 23, the recitation of "the connection" between the sample path and the inlet lacks proper antecedent basis. Correction is requested.

In regard to Claims 18 and 26, the recitation of "a bodily fluid source comprising a venipuncture device" is indefinite because it is unclear how a venipuncture device may provide a body fluid source as claimed. As known to a skilled artisan in the art, venipuncture devices are used to collect blood from human veins but the devices themselves are not sources of fluid. The specification also does not appear to provide support for a structure within the venipuncture device that provides a source of body fluid other than from the human body itself. Furthermore, applicant is reminded that it is human body parts are not eligible subject matter. Clarification is requested.

It is also noted that there are two claims numbered 15. The second of which has been renumbered as Claim 16, and all others following have been renumbered accordingly. Thus, there are 31 claims in total. Correction of the misnumbering including claim dependencies is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-5 and 19-23 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Haynes et al (US Pat No. 4980297).

In regard to Claim 1, Haynes et al disclose a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device 63 from a bodily fluid source (vein Figure 16-17), a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising:

an inlet 61 configured to connect with the bodily fluid source, best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 configured to connect with the bodily fluid collection device 63, best seen in Figure 9 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sample path 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46); and

a contaminant containment reservoir 55/55a between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor 112 (Figure 24) proximate the outlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (vacuum force – Col.9: 3-46), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the

contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17),

such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet 62 and to the bodily fluid collection device 63, best seen in Figure 15-18 (Col.9: 3-46).

2, 20. The bodily fluid sample optimization device in accordance with claim 1, further including a housing 48, 49 that defines the inlet 61 and the outlet 62, and contains the sample path 54 and the contaminant containment reservoir 55, and wherein the housing does not vent to atmosphere when the outlet is connected with the bodily fluid collection device, best seen in Figure 9 and 15-18 (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17).

3, 21. The bodily fluid sample optimization device in accordance with claim 1, wherein the pressure differential applied between the inlet 61 and the outlet 62 is applied by a vacuum of the bodily fluid collection device relative to a pressure of the bodily fluid source (Col.9: 3-46).

4, 22. The bodily fluid sample optimization device in accordance with claim 1, wherein the connection between the sample path 54 and the inlet 61 is made when the contaminant containment reservoir 55 receives the first portion of the bodily fluid sample (Col.9: 3-46).

5, 23. The bodily fluid sample optimization device in accordance with claim 1, wherein once the first portion is received in the contaminant containment reservoir 55, a resistance to a flow of the subsequent portions of the bodily fluid sample in the contaminant containment reservoir is higher than a resistance in the sample path due to the pressure (Col.9: 3-46).

In regard to Claim 19, Haynes et al disclose a patient bodily fluid sample optimization system comprising:

a bodily fluid source comprising a venipuncture device 58 configured for venipuncture of the patient, best seen in Figure 15-18;

a bodily fluid collection device 63 comprising a sealed collection needle 69 (Figures 21-22 show sleeve 105 – Col.11: 18-50) on which an evacuated tube 63, 80 can be placed to draw the patient bodily fluid with a pressure differential between the evacuated tube and the patient (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17); and

a bodily fluid sample optimization device comprising:

an inlet 61 configured to connect with the bodily fluid source, best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 configured to connect with the bodily fluid collection device, best seen in Figure 9 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sample path 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46); and

a contaminant containment reservoir 55/55a between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor 112 (Figure 24) proximate the outlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

the contaminant containment reservoir being arranged to receive, when the pressure differential is formed between the inlet and the outlet (vacuum force – Col.9: 3-46), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the

contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17),

such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet 62and to the bodily fluid collection device 63, best seen in Figure 15-18 (Col.9: 3-46).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 6-8 and 24-26 is/are rejected under 35 U.S.C. 103 as being unpatentable over Haynes et al as applied to claims 1 and 18 above, further in view of Eldridge (US Pat No. 4207870).

Haynes et al disclose the invention above but do not expressly disclose a flow controller that is movable from a first position to a second position.

Eldridge teach an analogous fluid sampling device comprising a flow controller 22 that is movable from a first position to a second position to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

6, 24. The bodily fluid sample optimization device in accordance with claim 4, wherein the contaminant containment reservoir includes a flow controller 22 that is movable from a first position to enable the contaminant containment reservoir to receive, when the pressure differential is applied between the inlet and the outlet, the first portion of the bodily fluid

sample from the bodily fluid source via the inlet, to a second position to open the connection between the sample path and the inlet to allow the subsequent portions of the bodily fluid sample to be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

7, 25. The bodily fluid sample optimization device in accordance with claim 6, wherein movement of the flow controller exposes at least one aperture between the inlet and the sample path (after valve skirt 22 opens), best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

8, 26. The bodily fluid sample optimization device in accordance with claim 6, wherein the flow controller is movable by the pressure differential, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al such that there is included a flow controller that is movable from a first position to a second position as taught by Eldridge above to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded.

Claim(s) 9-12, 14-18, 27-28, and 30-31 is/are rejected under 35 U.S.C. 103 as being unpatentable over Haynes et al in view of Bullington et al (US Pub No. 20140155781).

In regard to Claim 9, Haynes et al disclose a bodily fluid control device comprising:

an inlet 61 fluidically coupleable to a bodily fluid source (vein, Figure 16-17), best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 fluidically coupleable to a bodily fluid sample collection device 63, and to allow a negative pressure differential between the outlet and the inlet when the outlet is fluidically coupled to the bodily fluid sample collection device, best seen in Figure 9 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sampling channel 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a containment chamber 55/55a between the inlet and the outlet, the containment chamber having a first flow controller 112 (Figure 24) that allows air to flow from the containment chamber to the outlet by the negative pressure differential between the outlet and the inlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

such that a first volume of bodily fluid is drawn from the inlet into the containment chamber, and to prevent the first volume of bodily fluid from flowing to the outlet (plasma in receiving portion 55/55a is collected by tube 80, not 63), best seen in Figure 15-18 (Col.9: 3-46).

However, Haynes et al do not expressly disclose a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device.

Bullington et al teach that it is well-known in the art to provide an analogous body sampling device comprising a flow controller 120, 130, 140 that is movable from a first position

as the first volume of bodily fluid is drawn from the inlet into a containment chamber 170, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device 180 (0006, 0054). Bullington et al teach that in the second position, fluid is directed into a second reservoir 180 and bypassing a first reservoir 170, which must be used first. This enables controlled sampling to reduce contamination of the sample by requiring isolation of the first volume of the collected body fluid in the first reservoir initially. (0002-0004).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al such that there is included a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device, as taught by Bullington et al to effectively reduce contamination of the sample by requiring isolation of the first volume of the collected body fluid in the first reservoir initially.

10. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the bodily fluid source includes a patient needle 58, best seen in Figure 15-19.

11. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the bodily fluid sample collection device includes a sealed collection needle 69 (Figures

21-22 show sleeve 105 – Col.11: 18-50) on which an evacuated tube 63, 80 can be placed (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17).

12. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the first flow controller 112 includes an air permeable blood barrier that seals upon contact with bodily fluid, best seen in Figure 24 (Col.12: 38-Col.13: 17).

14. Haynes et al disclose the bodily fluid control device in accordance with claim 9, further including a housing 48, 49 that defines the inlet 61 and the outlet 62, and wherein the housing contains the containment chamber 55 and the sampling channel 54, best seen in Figure 9 and 17 (Col.7: 15-Col.8: 68; Col.9: 3-46).

15. Haynes et al disclose the bodily fluid control device in accordance with claim 14, wherein the housing 48, 49 does not vent to atmosphere when the inlet 61 is fluidically coupleable to the bodily fluid source and the outlet 62 is fluidically coupled to the bodily fluid sample collection device 63 (Col.7: 15-Col.8: 68; Col.9: 3-46).

16. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein the negative pressure differential applied between the inlet 61 and the outlet 62 is applied by a vacuum of the bodily fluid sample collection device relative to a pressure of the bodily fluid source (Col.9: 3-46).

17. Haynes et al disclose the bodily fluid control device in accordance with claim 9, wherein a fluidic coupling between the sample path 54 and the inlet 61 is made only after the containment chamber 55 receives the first volume of the bodily fluid (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17).

18. Haynes et al disclose the bodily fluid control device in accordance with claim 1, wherein once the first portion is received in the containment chamber 55, a resistance to a flow of the subsequent volumes of the bodily fluid in the containment chamber is higher than a resistance in the sampling channel due to the pressure (Col.9: 3-46).

In regard to Claim 27, Haynes et al disclose a patient bodily fluid control system comprising:

a bodily fluid source comprising venipuncture device 58 for venipuncture to the patient, best seen in Figure 9;

a bodily fluid sample collection device 63, 80 comprising a sealed collection needle 69 (Figures 21-22 show sleeve 105 – Col.11: 18-50) on which an evacuated tube 63, 80 can be placed to draw the patient bodily fluid with a pressure differential between the evacuated tube and the patient (Col.7: 15-Col.8: 68; Col.9: 3-46; Col.11: 18-50; Col.12: 38-Col.13: 17); and

a bodily fluid control device comprising:

an inlet 61 fluidically coupleable to the bodily fluid source, best seen in Figure 9 (Col.7: 15-Col.8: 68);

an outlet 62 fluidically coupleable to a bodily fluid sample collection device, and to allow a negative pressure differential between the outlet and the inlet when the outlet is fluidically coupled to the bodily fluid sample collection device, best seen in Figure 9 and 15-18 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a sampling channel 54 between the inlet and the outlet, best seen in Figure 17 (Col.7: 15-Col.8: 68; Col.9: 3-46);

a containment chamber 55/55a between the inlet and the outlet, the containment chamber having a first flow controller 112 (Figure 24) that allows air to flow from the containment chamber to the outlet by the negative pressure differential between the outlet and the inlet, best seen in Figure 15-18 and 24 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17),

such that a first volume of bodily fluid is drawn from the inlet into the containment chamber, and to prevent the first volume of bodily fluid from flowing to the outlet (plasma in receiving portion 55/55a is collected by tube 80, not 63), best seen in Figure 15-18 (Col.9: 3-46).

However, Haynes et al do not expressly disclose a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device.

Bullington et al teach that it is well-known in the art to provide an analogous body sampling device comprising a flow controller 120, 130, 140 that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber 170, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device 180 (0006, 0054). Bullington et al teach that in the second position, fluid is directed into a second reservoir 180 and bypassing a first reservoir 170, which must be used first. This enables controlled sampling to reduce contamination of the sample by requiring

isolation of the first volume of the collected body fluid in the first reservoir initially. (0002-0004).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al such that there is included a second flow controller that is movable from a first position as the first volume of bodily fluid is drawn from the inlet into the containment chamber, to a second position to allow subsequent volumes of bodily fluid from the inlet to bypass the containment chamber via the sampling channel and to the outlet and the bodily fluid sample collection device, as taught by Bullington et al to effectively reduce contamination of the sample by requiring isolation of the first volume of the collected body fluid in the first reservoir initially.

28. Haynes et al disclose the bodily fluid control system in accordance with claim 26, wherein the first flow controller includes an air permeable blood barrier 112 that seals upon contact with bodily fluid, best seen in Figure 24.

30. Haynes et al disclose the bodily fluid control system in accordance with claim 26, further including a housing 48, 49 that defines the inlet 61 and the outlet 62, and wherein the housing contains the containment chamber 55 and the sampling channel 54, best seen in Figure 9 and 15-18 (Col.7: 15-Col.8: 68).

31. Haynes et al disclose the bodily fluid control system in accordance with claim 29, wherein the housing 48, 49 does not vent to atmosphere when the inlet 61 is fluidically coupleable to the bodily fluid source and the outlet 62 is fluidically coupled to the bodily fluid sample collection device 63 (Col.7: 15-Col.8: 68; Col.12: 38-Col.13: 17).

Claim(s) 13 and 29 is/are rejected under 35 U.S.C. 103 as being unpatentable over Haynes et al in view of Bullington et al as applied to Claim 9 above, further in view of Eldridge.

Haynes et al in combination with Bullington et al disclose the invention above but do not expressly disclose the second flow controller that is movable from a first position to a second position by the pressure differential.

Eldridge teach an analogous fluid sampling device comprising a flow controller 22 that is movable from a first position to a second position by a pressure differential to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Haynes et al as modified by Bullington et al such that the second flow controller is movable from a first position to a second position by the pressure differential as taught by Eldridge above to effectively enable flow of the body fluid only once the evacuated tube has been attached as well as preventing backflow of the body fluid once the sampling has concluded.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely

online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample opti mization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Claims 1 and 18 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a patient bodily fluid sample optimization system comprising: a bodily fluid source comprising a venipuncture device configured for venipuncture of the patient; a bodily fluid collection device comprising a sealed collection needle on which an evacuated tube can be placed to draw the patient bodily fluid with a pressure differential between the evacuated tube and the patient; and a bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when the pressure differential is formed between the inlet and the outlet, a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet, such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device, wherein air is necessarily displaced in such configuration.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample opti mization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet, such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 20 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid

sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device (functional use); a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device when the bodily fluid collection device is connected.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claim 8 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a bodily fluid sample optimization device for optimizing a bodily fluid sample collected by a bodily fluid collection device from a bodily fluid source, a first portion of the bodily fluid sample potentially having contaminants, the bodily fluid sample optimization

device comprising: an inlet configured to connect with the bodily fluid source; an outlet configured to connect with the bodily fluid collection device; a sample path between the inlet and the outlet; and a contaminant containment reservoir between the inlet and the outlet, the contaminant containment reservoir having an air permeable bodily fluid resistor proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet (functional use), a first portion of the bodily fluid sample from the bodily fluid source via the inlet to displace air in the contaminant containment reservoir through the air permeable bodily fluid resistor and the outlet (displacement of air necessarily occurs), such that upon receipt of the first portion of the bodily fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the bodily fluid sample can be conveyed by the sample path from the inlet to the outlet and to the bodily fluid collection device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner
Art Unit 3791

/TSE W CHEN/
Supervisory Patent Examiner, Art Unit 3791

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: JAMES SCOTT NOLAN
P.O. BOX 371710
SAN DIEGO, CA 92110

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference KURIN4PCT	Date of mailing *(day month year)* 19JUN 2020 **FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US 20/23617	International filing date *(day month year)* 19 March 2020 (19.03.2020)
Applicant KURIN, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   How? Directly to the International Bureau preferably through ePCT, or on paper to:
   The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

   For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2020)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
KURIN4PCT		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 20/23617	19 March 2020 (19.03.2020)	13 March 2020 (13.03.2020)
Applicant KURIN, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 9 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 35

☐ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☒ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

Pending processing

Form PCT/ISA/210 (first sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/23617

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 5/15, A61B 5/153, A61B 5/154, A61B 5/157 (2020.01)

CPC - A61B 5/15003, A61B 5/150213, A61B 5/150251, A61B 5/150992, A61B 5/150206, A61B 5/150221, A61B 5/150946

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
See Search History document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2018/0177445 A1 (Kurin, Inc.) 28 June 2018 (28.06.2018), entire document	1-4, 10-12, 18 --- 5-9, 13-17, 19-20
Y	US 4,349,035 A (Thomas et al.) 14 September 1982 (14.09.1982), entire document	5-6, 8-9, 13-14, 16-17, 19-20
Y	US 5,401,262 A (Karwoski et al.) 28 March 1995 (28.03.1995), entire document	5, 7, 13, 15
A	US 2018/0271425 A1 (Kurin, Inc.) 27 September 2018 (27.09.2018), entire document	1-20
A	US 2018/0353117 A1 (Magnolia Medical Technologies, Inc.) 13 December 2018 (13.12.2018), entire document	1-20

Automated processing

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
07 JUNE 2020	19 JUN 2020
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: JAMES SCOTT NOLAN
P.O. BOX 371710
SAN DIEGO, CA 92110

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	19 JUN 2020

Applicant's or agent's file reference	FOR FURTHER ACTION
KURIN4PCT	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 20/23617	19 March 2020 (19.03.2020)	13 March 2020 (13.03.2020)

International Patent Classification (IPC) or both national classification and IPC

IPC - A61B 5/15, A61B 5/153, A61B 5/154, A61B 5/157 (2020.01)

CPC - A61B 5/15003, A61B 5/150213, A61B 5/150251, A61B 5/150992, A61B 5/150206, A61B 5/150221, A61B 5/150946

Applicant KURIN, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

International Processing

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	07 JUNE 2020	Lee Young PCT Help Desk Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(b)).

3. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing:

   a. ☐ forming part of the international application as filed:

      ☐ in the form of an Annex C/ST.25 text file.

      ☐ on paper or in the form of an image file.

   b. ☐ furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. ☐ furnished subsequent to the international filing date for the purposes of international search only:

      ☐ in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      ☐ on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Pending processing

Form PCT/ISA/237 (Box No. I) (revised January 2019)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	5-9, 13-20	YES
	Claims	1-4, 10-12	NO
Inventive step (IS)	Claims	none	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	none	NO

2. Citations and explanations:

Claims 1-4 and 10-12 lack novelty under PCT Article 33(2) as being anticipated by US 2018/0177445 A1 to Kurin, Inc. (hereinafter Kurin).

Regarding claim 1, Kurin teaches a blood sequestration device (see fig. 30A-G; para [0156]) comprising; an inlet path (fig. 30A see inlet path 3002; para [0156]); an outlet path (fig. 30A see outlet path 3004; para [0158]); a sequestration chamber (fig. 30A see sequestration chamber 3008; para [0160]) connected with the inlet path by a junction (fig. 30A see junction 3007; para [0160]; see fig. 17A-B) and being configured to receive a first portion of blood through the inlet path (para [0160]; para [0163]-[0164]), the sequestration chamber having a vent that allows air to be displaced by the first portion of blood (fig. 30A-D see vent 3010; para [0161]; para [0163]-[0165]), the junction being configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber (intended use - see para [0160] "the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008" - since the junction is configured to direct flow away from the inlet port, it is thereby considered capable of inhibiting a return to the inlet path of any of the first portion of blood received by the sequestration chamber; see para[0156], [0160]-[0161], [0061],[0067]); and a sampling channel connected between the inlet path and the outlet path (fig. 30A see sampling channel 3006; para [0159]-[0160]), the sampling channel being configured to convey subsequent amounts of blood between the inlet path and the outlet path after the first amount of blood is received by the sequestration chamber (para [0160]-[0170]).

Regarding claim 2, Kurin teaches the blood sequestration device in accordance with claim 1, wherein the junction is angled from the inlet path toward the sequestration chamber (fig. 30A; fig. 17A see junction 3007 is angled from the inlet path to the sequestration chamber; para [0160]) .

Regarding claim 3, Kurin teaches the blood sequestration device in accordance with claim 1, wherein the junction has a cross-sectional area that is smaller than a cross-sectional area of the inlet path (fig. 30A; fig. 17A see junction 3007 has a cross-sectional area closest to the inlet path that is smaller than a cross-sectional area of the inlet path below where it meets the junction; para [0160]).

Regarding claim 4, Kurin teaches the blood sequestration device in accordance with claim 1, wherein the junction has a cross-sectional area that is larger than a cross-sectional area of the inlet path (fig. 30A; fig. 17A see junction 3007 has a cross-sectional area near the sequestration chamber 3008 that is larger than a cross-sectional area of the inlet path where the inlet path opens to the junction; para [0160]; para [0163] junction cross-sectional area widens towards the sequestration chamber to direct blood).

Regarding claim 10, Kurin teaches the blood sequestration device in accordance with claim 1, wherein the vent includes two or more vent apertures (para [0161] vent 3010 comprises air permeable blood barrier 3012 as previously described; para [0060] air permeable blood barrier may comprise a mesh, a mesh inherently comprises two or more vent apertures).

Regarding claim 11, Kurin teaches a blood sequestration device (see fig. 30A-G; para [0156]) comprising; a housing (fig. 30A see housing 3001; para [0161]) having in inlet port (fig. 30A see inlet path 3002 has port opening in housing 3001; para [0156; para [0161]) and an outlet port (fig. 30A see outlet path 3004 has outlet opening in housing 3001; para [0159]; para [0161]), the housing containing: an inlet path connected to the inlet port (fig. 30A see inlet path 3002; para [0156]); an outlet path connected with the outlet port (fig. 30A see outlet path 3004; para [0158]); a sequestration chamber (fig. 30A see sequestration chamber 3008; para [0160]) connected with the inlet path by a junction (fig. 30A see junction 3007; para [0160]; see fig. 17A-B) and being configured to receive a first amount of blood through the inlet path (para [0160]; para [0163]-[0164]), the sequestration chamber having a vent that allows air to be displaced by the first portion of blood (fig. 30A see vent 3010; para [0161]; para [0163]-[0165]), the vent further being further configured to close upon the sequestration chamber being filled with the first portion of blood (para [0161] vent 3010 comprises air permeable blood barrier 3012 as previously described; para [0060]; para [0160]-[0170]), the junction being configured to inhibit a return of the first portion of blood out of the sequestration chamber (intended use - see para [0160] "the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008" - since the junction is configured to direct flow away from the inlet port, is is thereby considered capable of inhibiting a return to the inlet path of any of the first portion of blood received by the sequestration chamber; see also para[0156],[0160]-[0161],[0061],[0067]); and a sampling channel connected between the inlet path and the outlet path (fig. 30A see sampling channel 3006; para [0159]-[0160]), the sampling channel being configured to convey subsequent amounts of blood between the inlet path and the outlet path after the first portion of blood is received by the sequestration chamber (para [0160]-[0170]).

-*-Continued in Supplemental Box-*-

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Regarding claim 18, the claim language is confusing and lacks clarity. Specifically, the recitation "the patient needle and the sample needle", lack proper antecedent basis. In order to give meaning to this claim and to give proper antecedent basis, based on the specification (para [0063]), this recitation has been interpreted as the following: "and a blood sequestration device connected along the blood sampling pathway between a patient needle and a sample needle, wherein the venipunture apparatus includes the patient needle and the reservoir includes the sample needle".

Pending processing

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Box V.2 - Citations and Explanations-*-

Regarding claim 12, Kurin teaches the blood sequestration device in accordance with claim 11, wherein the vent further comprises a closure mechanism that inhibits air from reentering the sequestration chamber after it has been displaced (para [0161] vent 3010 comprises air permeable blood barrier 3012 as previously described; para [0060]).

Claim 18 lacks an inventive step under PCT Article 33(3) as being obvious over Kurin.

Regarding claim 18, Kurin teaches a blood sample optimization system (fig. 30A-G; para [0156]) comprising: a blood sampling system (para [0156]) comprising: a venipuncture apparatus configured for venipuncture of a patient to access a sample of blood of a patient (para [0156] inlet port 3002 with opening connects to patient needle, needle is a suitable venipuncture apparatus); a blood sampling pathway connected with the venipuncture apparatus for conveying the sample of blood (fig. 30A see system 3000 comprises blood sampling pathway from inlet 3002 to outlet 3004 through sampling channel 3006; para [0156]); and a reservoir (fig. 30A see reservoir 3004; para [0158]); and a blood sequestration device connected along the blood sampling pathway between a patient needle and the reservoir (see fig. 30A-G; para [0156]), wherein the venipunture apparatus includes the patient needle (para [0156] inlet port 3002 with opening connects to patient needle), the blood sequestration device comprising: an inlet path connected with the patient needle (fig. 30A see inlet path 3002; para [0156]); an outlet path connected with the reservoir (fig. 30A see outlet path through outlet reservoir 3004; para [0158]); a sequestration chamber (fig. 30A see sequestration chamber 3008; para [0160]) connected with the inlet path by a junction (fig. 30A see junction 3007; para [0160]; see fig. 17A-B) and being configured to receive a first portion of blood through the inlet path (para [0160]; para [0163]-[0164]), the sequestration chamber having a vent that allows air to be displaced by the first portion of blood (fig. 30A see vent 3010; para [0161]; para [0163]-[0165]), the junction being configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber (intended use - see para [0160] "the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008" - since the junction is configured to direct flow away from the inlet port, is is thereby considered capable of inhibiting a return to the inlet path of any of the first portion of blood received by the sequestration chamber; see para[0156], [0160]-[0161], [0061],[0067]); and a sampling channel connected between the inlet path and the outlet path (fig. 30A see sampling channel 3006; para [0159]-[0160]), the sampling channel being configured to convey subsequent amounts of blood between the inlet path and the outlet path after the first amount of blood is received by the sequestration chamber (para [0160]-[0170]); but Kurin does not explicitly teach wherein the reservoir is configured for receiving an evacuated blood collection tube to collect and contain at subsequent portion of the sample of blood, nor wherein reservoir and connected outlet path comprise a sample needle. However, in another embodiment, Kurin teaches a sample needle at an outlet path of a blood sample collection device facilitates connection to an evacuated blood collection tube to collect and contain at subsequent portion of the sample of blood (fig. 1 see sample needle 5; para [0065]; see fig. 7). Combining embodiments is within the ordinary skill of a person within the art. Accordingly, it would have been obvious to a person having ordinary skill in the art to have provided a sample needle such that the reservoir is configured for receiving an evacuated blood collection tube to collect and contain at subsequent portion of the sample of blood in order to provide blood collection means with the blood sampling device.

Claims 5-6, 8-9, 13-14, 16-17 and 19-20 lack an inventive step under PCT Article 33(3) as being obvious over Kurin in view of US 4,349,035 A to Thomas et al. (hereinafter Thomas).

Regarding claim 5, Kurin teaches the blood sequestration device in accordance with claim 1, but does not explicitly teach wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber. However, in similar art, Thomas teaches a blood collection device (see fig. 1; column 4, ln 20-24) comprising an inlet path (fig. 5 see cannula 19; column 4, ln 23-38) and a chamber connected by a junction (fig. 4-5 see junction 22 leads to chamber 21; column 4, ln 23-38). Kurin further teaches wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber (fig. 4-5 see junction 22 comprises one-way valve to prevent backflow; column 4, ln 32-38). Passive structures for preventing backflow are well known in the art for improved blood collection by preventing contaminated blood from returning to a patient. Accordingly, it would have been obvious to a person having ordinary skill in the art to have included a passive structure as taught by Thomas in the device taught by Kurin in order to prevent return flow to the patient for improved blood sampling.

Regarding claim 6, Kurin in view of Thomas teaches the blood sequestration device in accordance with claim 5, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a conical baffle having a tapered end directed toward the sequestration chamber (see Thomas fig. 4-5 passive structure tapers to a point towards chamber, thus restricting flow; see column 5, ln 13 -17).

Regarding claim 8, Kurin in view of Thomas teach the blood sequestration device in accordance with claim 5, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a divider wall extending across a cross-section of the junction (see Thomas fig. 4-5 divider wall 25; column 6, ln 7-13).

-*-Continued in next Supplemental Box-*-

Examiner Copy

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

Regarding claim 9, Kurin in view of Thomas teach the blood sequestration device in accordance with claim 5, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a flow director extending from an inner surface of the junction (see Thomas fig. 4-5 valve 22 is a flow director; column 4, ln 23-38; column 5, ln 13-17), the flow director being configured to control a flow of blood (see Thomas column 4, ln 23-28 flow director valve 22 controls flow by directing into chamber 21 and preventing backflow).

Regarding claim 13, Kurin teaches the blood sequestration device in accordance with claim 11, but does not explicitly teach wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber. However, in similar art, Thomas teaches a blood collection device (see fig. 1; column 4, ln 20-24) comprising an inlet path (fig. 5 see cannula 19; column 4, ln 23-38) and a chamber connected by a junction (fig. 4-5 see junction 22 leads to chamber 21; column 4, ln 23-38). Kurin further teaches wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber (fig. 4-5 see junction 22 comprises one-way valve to prevent backflow; column 4, ln 32-38). Passive structures for preventing backflow are well known in the art for improved blood collection by preventing contaminated blood from returning to a patient. Accordingly, it would have been obvious to a person having ordinary skill in the art to have included a passive structure as taught by Thomas in the device taught by Kurin in order to prevent return flow to the patient for improved blood sampling.

Regarding claim 14, Kurin in view of Thomas teach the blood sequestration device in accordance with claim 13, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a conical baffle having a tapered end directed toward the sequestration chamber (see Thomas fig. 4-5 passive structure tapers to a point towards chamber, thus restricting flow; see column 5, ln 13 -17).

Regarding claim 16 Kurin in view of Thomas teach the blood sequestration device in accordance with claim 13, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a divider wall extending across a cross-section of the junction. (see Thomas fig. 4-5 divider wall 25; column 6, ln 7-13).

Regarding claim 17 Kurin in view of Thomas teach the blood sequestration device in accordance with claim 13, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a flow director extending from an inner surface of the junction (see Thomas fig. 4-5 valve 22 is a flow director; column 4, ln 23-38; column 5, ln 13-17), the flow director being configured to control a flow of blood (see Thomas column 4, ln 23-28 flow director valve 22 controls flow by directing into chamber 21 and preventing backflow).

Regarding claim 19, Kurin teaches the blood sample optimization system in accordance with claim 18, but does not explicitly teach wherein the junction of the blood sequestration device includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber. However, in similar art, Thomas teaches a blood collection device (see fig. 1; column 4, ln 20-24) comprising an inlet path (fig. 5 see cannula 19; column 4, ln 23-38) and a chamber connected by a junction (fig. 4-5 see junction 22 leads to chamber 21; column 4, ln 23-38). Kurin further teaches wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber (fig. 4-5 see junction 22 comprises one-way valve to prevent backflow; column 4, ln 32-38). Passive structures for preventing backflow are well known in the art for improved blood collection by preventing contaminated blood from returning to a patient. Accordingly, it would have been obvious to a person having ordinary skill in the art to have included a passive structure as taught by Thomas in the device taught by Kurin in order to prevent return flow to the patient for improved blood sampling.

Regarding claim 20, Kurin in view of Thomas teach the blood sample optimization system in accordance with claim 19, and Kurin modified by Thomas further teaches wherein the one or more passive structures includes a wall extending from an inner surface of the junction to control a flow of the first portion of blood (see Thomas fig. 4-5 divider wall 25; column 6, ln 7-13).

-*-Continued in next Supplemental Box-*-

Pending Publication

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

Claim 5, 7 and 13, 15 lack an inventive step under PCT Article 33(3) as being obvious over Kurin in view of US 5,401,262 A to Karwoski et al. (hereinafter Karwoski).

Regarding claim 5, Kurin teaches the blood sequestration device in accordance with claim 1, but does not explicitly teach wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber. However, in similar art, Karwoski teaches a blood collection device (see fig. 1; column 4, ln 20-40). Karwoski further teaches wherein a pathway of the blood collection devices includes one or more passive structures configured to inhibit a return to an inlet path of any of a sample of blood (fig. 1 see baffles 112a-f direct flow through pathway and assist in fluid retention; column 18, ln 1-24; column 21, ln 55-65). Passive structures for preventing backflow are well known in the art for improved blood collection by preventing contaminated blood from returning to a patient. Accordingly, it would have been obvious to a person having ordinary skill in the art to have included a passive structures as taught by Karwoski in the device taught by Kurin in order to prevent return flow to the patient for improved blood sampling.

Regarding claim 7, Kurin in view of Karwoski teach the blood sequestration device in accordance with claim 5, and Kurin modified by Karwoski further teaches wherein the one or more passive structures include two or more staggered baffles extending from an inner surface of the junction (Karwoski fig. 1 see baffles 112a-f direct flow through pathway and assist in fluid retention; column 18, ln 1-24; column 21, ln 55-65).

Regarding claim 13, Kurin teaches the blood sequestration device in accordance with claim 11, wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber. However, in similar art, Karwoski teaches a blood collection device (see fig. 1; column 4, ln 20-40). Karwoski further teaches wherein a pathway of the blood collection devices includes one or more passive structures configured to inhibit a return to an inlet path of any of a sample of blood (fig. 1 see baffles 112a-f direct flow through pathway and assist in fluid retention; column 18, ln 1-24; column 21, ln 55-65). Passive structures for preventing backflow are well known in the art for improved blood collection by preventing contaminated blood from returning to a patient. Accordingly, it would have been obvious to a person having ordinary skill in the art to have included a passive structures as taught by Karwoski in the device taught by Kurin in order to prevent return flow to the patient for improved blood sampling.

Regarding claim 15, Kurin in view of Karwoski teach the blood sequestration device in accordance with claim 13, and Kurin modified by Karwoski further teaches wherein the one or more passive structures include two or more staggered baffles extending from an inner surface of the junction (Karwoski fig. 1 see baffles 112a-f direct flow through pathway and assist in fluid retention; column 18, ln 1-24; column 21, ln 55-65).

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

Pending processing

Form PCT/ISA/237 (Supplemental Box) (revised January 2019)

SEARCH HISTORY

Application Number	PCT/US 20/23617
Search Conducted By	EAW
Search Approved By	SCL

CPC/IPC Classifications Searched	IPC(8): A61B 5/15, A61B 5/153, A61B 5/154, A61B5/157 (2020.01) CPC: A61B 5/15003, A61B 5/150213, A61B 5/150251, A61B 5/150992, A61B 5/150206, A61B 5/150221, A61B 5/150946
Date Conducted	7 June 2020 (07.06.2020)

Documentation Searched	IPC(8): A61B 5/15, A61B 5/153, A61B 5/154, A61B5/157 (2020.01) CPC: (keyword limited; see below)
Search Terms Used	baffle*, prevent*, inhibit*, back*, return*, sequestration*, flow*, blood*, sample*, restrict*
Date Conducted	7 June 2020 (07.06.2020)

Electronic Database Searched	PatBase
Files Searched	Full-text: AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO Bibliographic: (European) AT BA BE BG CH CS CY CZ DD DK EE ES FI GE GR HR HU IE IS IT LT LU LV MC MD MT NL NO PL PT RO RS SE SI SK SM TR UA YU (Asia) EA GC HK ID IL IN KZ MN MY PH RU SG SU TH TJ TW UZ VN (North America) CA CR CU DO GT HN MX NI PA SV TT (South America) AR BR CL CO EC PE UY (Australasia) AU NZ (Africa) AP DZ EG KE MA MW OA ZA ZM ZW
Date Conducted	7 June 2020 (07.06.2020)
Search Logic:	

Search 1: PA=(Kurin inc) (Results 5)

Search 2: PN=(US2018/0177445) (Results 1)

Search 3: ctb 2 or ctf 2 (Results 5)

Search 4: CPC=(A61B5/15003) (Results 2650)

Search 5: 4 and ft=(baffle%) (Results 36)

Search 6: 4 and ft=((prevent* or inhibit*) near (back* or return*)) (Results 226)

Search 7: 6 and ft=(sequestration) (Results 3)

Search 8: 6 and ft=(flow*) (Results 182)

Search 9: IPC=(A61B5/15 or A61B5/153 or A61B5/154 or A61B5/157) (Results 13750)

Search 10: CPC=(A61B5/15003 or A61B5/150213 or A61B5/150251 or A61B5/150992 or A61B5/150206 or A61B5/150221 or A61B5/150946) (Results 3410)

Search 11: 9 or 10 (Results 14204)

Search 12: 11 and ft=(sequestration) (Results 32)

Search 13: 11 and ft=((prevent* or inhibit*) near (back* or return*)) (Results 535)

Search 14: 13 and ft=(blood* near sample*) (Results 335)

Search 15: 14 not 8 (Results 198)

Search 16: ft=(sequestration* and baffle* and blood*) (Results 170)

Search 17: 16 not (14 or 8) (Results 170)

Search 18: ft=(blood* and sequestration* and (restrict* near flow*)) (Results 176)

Electronic Database Searched	Google
Files Searched	Patents
Date Conducted	7 June 2020 (07.06.2020)

Search Logic:

blood sampling sequestration device prevent backflow

blood sampling sequestration device baffle directs flow

blood sampling collection device prevent backflow

blood sampling device valve restricts backflow controls flow

blood sequestration junction prevents backflow blood sequestration junction flow restriction

Electronic Database Searched	Google
Files Searched	Web
Date Conducted	7 June 2020 (07.06.2020)
Search Logic:	
blood sampling sequestration device prevent backflow blood sampling sequestration device baffle directs flow blood sampling collection device prevent backflow blood sampling device valve restricts backflow controls flow blood sequestration junction prevents backflow blood sequestration junction flow restriction	

拒絶理由通知書

特許出願の番号	特願２０２１－２１４１７７
起案日	令和　４年１１月２９日
特許庁審査官	▲高▼木　尚哉　３６１１　２Ｑ００
特許出願人代理人	三好　秀和（ほか　３名）　様
適用条文	第３６条第６項第１号（サポート要件） 第３６条第６項第２号（明確性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（サポート要件）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第１号に規定する要件を満たしていない。

２．（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第２号に規定する要件を満たしていない。

記

●理由１（サポート要件）について

・請求項　１－２０
・備考
本願の発明の詳細な説明には、本願発明の課題として、段落[0004]には、「血液培養を行うための血液サンプルの採取は、現代の患者ケアの重要な要素であり、正確な診断を提供することによって患者の結果に良い影響を与えることも、不必要な抗菌療法を長引かせ、入院期間を長くし、コストを増加させることによって結果に悪影響を与えることもある。」と記載され、段落[0007]には、「偽陽性の血液培養は、一般的に、不十分なサンプリング技術の結果である。それらは、必要でないときに抗生物質を使用させ、病院費及び患者の不安を増大させる。血液培養は、皮膚内への針刺しから採取され、その後で血液のサンプルを取り込むためにバキュテナー（登録商標）が取り付けられる。汚染は、穿刺部位及びその周辺の皮膚領域の不適切又は不完全な消毒によって生じ得る。それはまた、挿入

中の針による皮膚のくりぬきから、くりぬかれた皮膚細胞と関連する汚染物質とがサンプル中に引き込まれることで生じることもある。」と記載されており、血液培養のための血液サンプルの採取において、血液が汚染されることが記載されている。

そして、当該課題を解決するための手段として、段落[0014]には、「採血経路と接続される血液隔離デバイス」を備えることが記載されている。

そうすると、本願の発明の詳細な説明には、一貫して、汚染を避ける対象が「血液」であることが記載されていると言える。

しかしながら、本願の請求項１には、「流体分流デバイス」と記載されているのみであって、「流体」として「血液」を用いることが特定されていない。

よって、請求項１には、発明の詳細な説明に記載された、発明の課題を解決するための手段が反映されておらず、請求項１に係る発明は、発明の詳細な説明に記載した範囲を超えることとなる。

上記と同様の理由により、請求項８、請求項１５は、発明の詳細な説明に記載した範囲を超えることとなる。

よって、請求項１－２０に係る発明は、発明の詳細な説明に記載したものでない。

●理由２（明確性）について

・請求項　１５－２０
・備考

請求項１５には、「前記チャンバ、前記サンプリング流路及び前記分岐点は、流体の第１の部分が前記チャンバに流れ込んで前記チャンバを満たし、前記空気透過孔を通して前記チャンバ内の空気を追い出すように、及び、流体の第２の部分が前記チャンバ及び前記チャンバ内に隔離された流体の第１の部分を迂回し、前記出口ポートに向かって前記サンプリング流路に導かれるように寸法設定されかつ構成される」ことが記載されているが、「前記空気透過孔を通して前記チャンバ内の空気を追い出すように、」との記載が、「流体の第１の部分」についての記載であるのか、あるいは、「流体の第２の部分」についての記載であるのか明らかでない。（上記記載の「流体の第１の部分が前記チャンバに流れ込んで前記チャンバを満たし、前記空気透過孔を通して前記チャンバ内の空気を追い出すように、」が「流体の第１の部分が前記チャンバに流れ込んで、前記空気透過孔を通して前記チャンバ内の空気を追い出すように、前記チャンバを満たし、」を意味するのであれば、そのように記載されたい。）

したがって、請求項１５－２０に係る発明は明確でない。

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

＜先行技術文献調査結果の記録＞

・調査した分野　ＩＰＣ　Ａ６１Ｂ１／００－１／３２
Ｇ０２Ｂ２３／２４－２３／２６

・先行技術文献　特開２０１３－２４０６２８号公報
特表２０１６－５０４０７５号公報
国際公開第２０１４／０５８９４５号
米国特許出願公開第２００５／０２４５８８５号明細書

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません。

この拒絶理由通知の内容に関するお問合せ又は面接のご希望がありましたら次の連絡先までご連絡ください。電子メール等で補正案等の送付を希望される場合は、その旨を電話でお知らせください。

審査第一部分析診断　医学診断(PA2J)　高木尚哉
ＴＥＬ．０３－３５８１－１１０１　内線３２９２

פ.ק 26

תאריך : י״ח שבט תשפ״ב
20/01/2022
מספרכם : 1000-018-01

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14, ת.ד.
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה על ליקויים בבקשת פטנט מספר 267684</u>**
סימוכין : מכתבכם מיום

לתשומת לבכם : מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 208.00 ש״ח בעד כל חודש או חלק ממנו. **לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים** בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

<u>הודעה זו מבוססת על המסמכים הבאים:</u>
שרטוטים מתאריך : 26/06/2019
פרטי הבקשה מתאריך : 26/06/2019
תביעות מתאריך : 26/06/2019

<u>בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדתי לעניין כשירות התביעות לפטנט :</u>

בתביעה/ות מס׳ 1-20 נמצאו ליקויים.
ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות **תקנה 41** הנני להודיעכם כי נמצאו בבקשה הנ״ל הליקויים המפורטים להלן :

1. <u>חידוש והתקדמות המצאתית</u>

1.1 תביעה/ות 1-20 עונה/ות על דרישות **סעיפים 4 ו-5 לחוק**, מאחר והאמצאה המוגדרת בתביעה/ות זו/אלה לא נתפרסמה בפומבי לפני תאריך הבקשה ויש בה התקדמות המצאתית.

2. <u>התביעות</u>

2.1 תביעות מס׳ 1-20 אינן עומדות בהוראות **סעיף 13(א) לחוק** היות שהן אינן כוללות את כל יסודות האמצאה הדרושים לביצועה כפי שנלמד מהתיאור.

לגבי התביעות הבלתי תביעות 1,8,15, בלשון תביעות אלו מופיע הביטוי :

״the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier **and includes one or more air vents**״

שיוצר אי בהירות האם ה- vents הנוספים הם חלק מה- vent השייך ל- sequestration chamber או

שהם חלק מה- outer wall.

כמו כן, בלשון תביעות 1,8,15 מופיע הביטוי:

"the vent further including a cap that at least partially covers the wall **and a one-way seal**"

שיוצר אי בהירות האם ה- cap מכסה גם את ה- one-way seal או שאותו one-way seal הוא חלק מה- vent עצמו.

התביעות התלויות 2-7,9-14,16-20 אינן עומדות בהוראות **סעיף 13(א)** לחוק עקב תלותן בתביעות 1,8,15 בהתאמה.

2.2 בניגוד ל**תקנה 20(א)(3)**, תביעות 4,11,18 אינן ברורות מאחר שהביטוי/המונח "the inner wall" המופיע בתביעות אלו זו מחוסר התייחסות קודמת (antecedence) בתביעה/ות קודמת/ות מתאימה/ות.

<u>חובת המבקש לעדכן את הרשות</u>

תשומת לבכם ל**סעיף 18א לחוק** לעניין חובת המבקשת לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור ב**סעיף 18(א) לחוק** ול**סעיף 18ג לחוק** בדבר אמצעי האכיפה.

<u>הגשת תיקונים לפירוט במהלך בחינת הבקשה</u>

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית **לתקנה 22(א)**. יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך: <u>דוגמה</u>) והשמטות בקו חוצה (כך: ~~דוגמה~~). **אין להגיש מחדש קבצים שלא תוקנו**.

לתשומת לבכם:

א) בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהודעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלקם, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון בתביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק.

ב) בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת הודעה לפני סירוב.

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

https://israelpatents.justice.gov.il/#/en/patent-file/details/267684

<u>ראיון עם בוחן</u>

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחן באמצעות פגישה במשרדי הרשות או בשיחה טלפונית.

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחן למבקש או בא-כוחו באמצעות שירות זה.

קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט.

במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה.

תיאום הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם.

לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

<u>השגה בפני הרשם</u>

על פי **סעיף 161 לחוק**, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
טלפון: 073-3927233
דואר אלקטרוני: albertak@justice.gov.il
ראש צוות: מוריה שלמה לוי

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/838,017	04/01/2020	Bobby E. ROGERS	069366-0572158_KUR7001US	1044

27500 7590 04/16/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
PORTILLO, JAIRO H	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
04/16/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 16/838,017	Applicant(s) ROGERS et al.	
	Examiner JAIRO H PORTILLO	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 4/05/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-9,14 and 16-18 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-9,14 and 16-18 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/05/2024 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 1-3, 6-8, 14, and 16-17 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Bullington et al (US 2019/0365303) ("Bullington").**

Regarding Claim 1, while Bullington teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet configured to connect with the fluid source ([0135] Figs. 9 and 10, inlet 512);

an outlet configured to connect with the fluid collection device ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), the sample path further having a resistive plug ([0141] Figs, 9 and 10, barrier 574); and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574, pierceable by the piercing member); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 2, Bullington teaches the device in accordance with claim 1, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 1 Rejection,* housing of fluid control device 500).

Regarding Claim 3, Bullington teaches the device in accordance with claim 1, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Regarding Claim 6, Bullington teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet configured to connect with the fluid source ([0135] Figs. 9 and 10, inlet 512);

an outlet configured to connect with the fluid collection device ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), the sample path further having a resistive plug that is configured to inhibit at least a part of a first portion of the fluid sample from entering the sample path ([0141] Figs, 9 and 10, barrier 574 acts as resistive plug); and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber further having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet, after piercing, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 7, Bullington teaches the device in accordance with claim 6, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 6 Rejection,* housing of fluid control device 500).

Regarding Claim 8, Bullington teaches the device in accordance with claim 6, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Regarding Claim 14, Bullington teaches a device for optimizing a fluid sample (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet ([0135] Figs. 9 and 10, inlet 512);

an outlet ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet),

wherein the sample path further includes a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample from entering the sample path during receipt of the first portion of the fluid sample in the chamber ([0141] Figs. 9 and 10, barrier 574 acts as resistive plug),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 16, Bullington teaches the device in accordance with claim 14, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 14 Rejection,* housing of fluid control device 500).

Regarding Claim 17, Bullington teaches the device in accordance with claim 14, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Claim(s) 4, 9, and 18 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Bullington** in view of **Rogers et al (US 2017/0020428) ("Rogers").**

Regarding Claim 4, while Bullington teaches the device in accordance with claim 1, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Regarding Claim 9, while Bullington teaches the device in accordance with claim 6, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Regarding Claim 18, while Bullington teaches the device in accordance with claim 14, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Response to Arguments

Applicant's amendments filed 4/05/2024 with respect to the 35 USC 103 rejection have been fully considered, and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bullington.

Applicant's arguments filed 4/05/2024 with respect to the 35 USC 103 rejection have been fully considered, but are not persuasive.

Applicant argues that Bullington teaches the opposite of the amended claim by having the needle move to puncture the membrane, rather than the membrane moving to be punctured by the piercing member. Redesigning Bullington to meet the claim language is not obvious as it would require a substantial redesign and change in the operation of Bullington's device. Examiner respectfully disagrees. Changing Bullington to meet the claim limitations merely requires a reversal of which membrane flexes upon receipt of the fluid sample. This does not require a change in operation as the system would still guide a first portion of the sample to a sequestration chamber, leading to a membrane flexing to enable a piercing action, the piercing action allowing the subsequent portion of the fluid sample to flow to the outlet. Further, a

substantial redesign is not needed as the only change required would be which membrane has the flexing property (barrier 574 instead of diaphragm 576).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAIRO H PORTILLO whose telephone number is (571)272-1073. The examiner can normally be reached M-F 9:00 am - 5:15 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAIRO H. PORTILLO/
Examiner
Art Unit 3791

/PUYA AGAHI/
Primary Examiner, Art Unit 3791

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16838017
Filing Date	2020-04-01
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	PORTILLO, JAIRO H
Attorney Docket Number	069366-0572158_KUR7001US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4416291		1983-11-22	KAUFMAN JOSEPH	
	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
	7	11660030		2023-05-30	BULLINGTON GREGORY J	
	8	11259727		2022-03-01	BULLINGTON GREGORY J	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

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	Art Unit	3791
	Examiner Name	PORTILLO, JAIRO H
	Attorney Docket Number	069366-0572158_KUR7001US

	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
	12	11612340		2023-03-28	BULLINGTON GREGORY J	
	13	11234626		2022-02-01	BULLINGTON GREGORY J	
	14	10624977		2020-04-21	BULLINGTON GREGORY J	
	15	11653863		2023-05-23	BULLINGTON GREGORY J	
	16	11419531		2022-08-23	BULLINGTON GREGORY J	
	17	11786155		2023-10-17	BULLINGTON GREGORY J	
	18	11789017		2023-10-17	BULLINGTON GREGORY J	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
	2	20220151527		2022-05-19	BULLINGTON GREGORY J	
	3	20200289039		2020-09-17	BULLINGTON GREGORY J	
	4	20210275068		2021-09-09	MIAZGA JAY M	
	5	20220304664		2022-09-29	HAMMER JEREMY	
	6	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	

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	1	S5825146	JP		1983-02-15	BECTON DICKINSON CO		☒

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	Attorney Docket Number	069366-0572158_KUR7001US

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	2	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	3	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐
	4	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
	5	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16838017
	Filing Date	2020-04-01
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	PORTILLO, JAIRO H
	Attorney Docket Number	069366-0572158_KUR7001US

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Bacterial Contamination of Platelets for Transfusion: Recent Advances and Issues

Chelsea A. Sheppard, MD, Cassandra D. Josephson, MD, Christopher D. Hillyer, MD

(Transfusion Medicine Program, Department of Pathology and Laboratory Medicine, Emory University School of Medicine, Atlanta, GA)

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- Bacterial contamination of blood products has emerged as a serious problem in transfusion medicine in the past 20 years and is second only to ABO-mismatch in causing transfusion-associated death.
- Data from 1985 - 1999 showed that 11% (77/694) of transfusion-associated fatalities reported to the FDA were caused by bacterially contaminated products leading to sepsis.
- As platelets are stored at room temperature, and in a large volume of plasma and a bag that allows oxygen diffusion, it is platelet products that are the most frequently implicated in transfusion-associated fatalities due to bacterial contamination.

The transfusion medicine community has attempted to reduce the amount of bacterial contamination in the blood supply by several methods including improved skin disinfection prior to donation, removal of the skin plug with diversion of the first 10 cc of the collection, ongoing donor screening, and analysis/culture of the donated product. Even with these measures in place, several fatalities due to septic reactions associated with transfusion have occurred and been reported. At the time of this writing, the exact "residual risk" of bacterial contamination is not known.

While packed red blood cell units can be contaminated by bacteria, the fact that they are *not* stored at room temperature and are not in a medium containing a large amount of plasma, leads the incidence of sepsis following transfusion of these units to be much less frequent. For a discussion of pRBC bacterial contamination, the first 3 references are recommended to the reader.[1-3] Below, the authors focus on the risks, strategies, and regulations regarding bacterial contamination of platelet products and its mitigation.

Estimates of Prevalence and Incidence

Prior to routine culturing of platelet units, which became universal following implementation AABB Standard 5.1.5.1 (discussed in more detail below), the estimated numbers of bacterially contaminated units, transfusion-associated septic reactions and deaths were usually made retrospectively based on reported or published reactions and sequelae.

By 2000, it was generally held that between 1:1,000 and 1:4,000 units[3-8] were contaminated with bacteria; the estimate of 1:2,000 to 3,000 became commonly accepted. Sepsis due to bacterial contamination was less common and estimated to occur in 1:20,000 to 1:85,000 units.[8] Estimates at the number of deaths due to this transfusion related complication were more difficult to elucidate.

In 2001, Yomtovian and colleagues estimated that 500 to 750 "severe and possibly fatal" events occurred annually.[4] Other estimates of this figure are more on the order of 100 to 150 deaths per year.[9,10] (The estimated risk of bacterially contaminated red cell units was significantly lower (approximately 1:500,000)[11] and approximately 10 to 1,000 times greater than the combined risk of transfusing HIV, HBV, HCV, and HTLV.[11]

Sources of Bacterial Contamination

Occult donor bacteremia and contamination of the product during collection have been the main avenues for entry of bacteria and have been the focus of prevention efforts. Gram-positive skin flora, introduced to the unit during collection, are the most common contaminates identified in retrospective analysis of platelet units.[12] Three reporting systems have suggested that 70% of contaminates isolated were gram-positive bacteria, while 80% of fatalities due to transfusion-related sepsis were caused by gram-negative organisms.[13-15] This finding was also observed in a recent review of the American Red Cross (ARC) experience with pretransfusion culturing of apheresis-derived platelets (ADP) between March and December 2004 (discussed in detail below).[16] This data showed that gram-positive organisms are implicated in approximately 4/5 of the cases. Gram-negative bacteria comprise the other 20%; however, they account for 40% of deaths due to septic transfusion reactions. Burns and colleagues recently published an extensive list of primary reports of clinically significant sepsis attributed to platelet transfusion from a PubMed literature search of all published cases.[17]

Due to the clinical significance of bacterial contamination, much effort has been made over the years to improve disinfection of skin at the phlebotomy site including the discontinuation of "green soap." Additionally, diversion of the skin plug produced by the needle as it passes through the skin, away from the bag into a pouch used for other viral testing, has been instituted nationwide in the United States. Despite these efforts, bacterial contamination of products continued(s) to be observed and skin flora continued(s) to be the most frequently cultured organisms.

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Asymptomatic donor bacteremia is the reason seemingly healthy volunteers may be allowed to donate while infectious, leading to bacterial contamination of blood products. In this case, even stringent donor screening will not catch this potential source of bacterial contamination. There are many examples of donors who unknowingly donate blood while bacteremic. For example, a case of transfusion associated *Staphylococcus aureus* platelet contamination has been reported in a blood donor who had undergone a tooth extraction 3 hours prior to donation, and was likely the result of transient bacteremia.[12] Haimowitz and colleagues discovered *Streptococcus bovis* at 11.4 hours after incubation of a platelet product donated by an asymptomatic female. After being informed of the result and despite negative follow up blood cultures, she underwent colonoscopy and a 3 cm mass was noted and removed.[18] Jafari and colleagues reported a case of *Salmonella* sepsis transmitted via platelet transfusion to 2 recipients from an asymptomatic donor who upon retrospective questioning reported that he had fever, abdominal pain, diarrhea, and hematochezia 13 days *prior* to donation. The donor owned a pet boa constrictor. The snake was thought to have been colonized with *Salmonella* and the original source of the infection.[19] Finally, there have been several cases of pRBC transfusion-associated *Yersinia enterolitica* septicemia in which many of the donors retrospectively reported diarrhea in the days preceding donation.[20]

An Open Letter to the Blood Community and AABB Standard 5.1.5.1

Physicians concerned that the risk from infected units was too high and that there were technologies that could address the issue at least in part wrote an "open letter" to the transfusion medicine community urging implementation of a method to stem this complication.[21] In 2003, AABB Standard 5.1.5.1 was released after considerable discussion, debate, and a public comment period. To be implemented within 1 year, the Standard read, "The blood bank or transfusion service shall have methods to limit and detect bacterial contamination in all platelet components."

At that time and presently, there were no FDA-approved tests for unit-by-unit bacteria screening at the time and point of transfusion. In addition, it was known that more than 15 tests *could* be used but none met "optimal" criteria including sensitivity and specificity, cost:efficacy, and logistical considerations affecting product supply and outdating. Thus, AABB was in an unenviable position of introducing a standard without guidance (at that time) as to *how* to implement it. **Table 1** below (adapted from reference 22) lists the tests capable of detecting bacteria and some comments regarding each.

Clinical Relevance

Typically at the time of collection, the level of contamination is relatively low (between 1 to 10 colony forming units (CFU)/mL.[23] However, once the product is inoculated, the bacteria can proliferate to levels of 10^6/mL or greater.[3] This amount of bacteria transfused during a short period of time can cause bacteremia, fever, chills, hypotension, nausea, vomiting, diarrhea, and oliguria, which may progress to sepsis and ultimately multi-system organ failure and death. Alternatively, the transfusion of contaminated cellular blood products may produce no symptoms or long-term clinical consequences. The severity of the reaction depends on: 1) the species of bacteria present, 2) the inoculum, 3) the rate of bacterial propagation, and 4) underlying disease, leukocyte count, the status of the immune system, and receipt of concomitant antibiotics in the recipient.[3] Gram-negative bacteria tend to cause more severe reactions due to the presence of endotoxin produced by these organisms. While causing only one-fifth of the cases, gram-negative bacteria have been reported to account for 40% of deaths due to septic transfusion reactions.[12,16]

Table 1_Description of Tests Capable of Detecting Bacteria

Methodology	Comments
Culture-based methodology: BacT/ALERT 3D Automated Microbial Detection System (bioMérieux, Durham, NC)	Detects CO_2 production by bacteria; FDA approved for quality control; Semi-closed system; Detects 5-10 CFU/mL (12-26 hr incubation);4 mL required
Culture-based methodology: (Pall eBDS, Pall Corporation, East Hills, NY)	Measures O_2 consumption by bacteria; FDA approved for quality control; Completely closed system; Requires 5-6 mL (concentrated to 2-3 mL)
DNA/RNA-based amplification and non-amplification, Chemiluminescence systems	Highly sensitive and specific; Requires highly conserved target by all bacteria or multiple primers and large inoculum; In experimental use only
Tests detecting changes in metabolic parameters or physical elements (glucose concentration, pH, platelet swirling)	Low sensitivity and specificity; Platelet concentration of the sample can affect results; Can be used at point of issue; Validation and QC difficult
Flow or static cytometry: (Scansystem, Hemosystem, Marseilles, France [laser-based, solid-phase cytometry])	Recently approved in Europe; Rapid (30 hr incubation and 90 min test time); Acceptable sensitivity and specificity; Requires reagent antibody to highly conserved common antigen or multiple reagent antibodies; 3 mL required
Bacterial cell wall component detection systems: (Platelet PGD test, Verax Biomedical, Worcester, MA)	Rapid (20 minutes); Lateral flow format; Sensitivity (10^3 to 10^4) in preliminary trial; 0.5 mL required; In experimental use only
Dielectrophoretic method: (Cell Analysis, Slough, United Kingdom)	Recently approved in Europe; Rapid (30 min); Sensitivity (10^3 to 10^5) in preliminary trial; 1 mL required
Gram stain	Requires a high level of contamination; Low sensitivity at lower concentrations; Can be used at point of issue; Validation and QC difficult
Endotoxin detection	Requires a high level of contamination; Low sensitivity at lower concentrations

Adapted from Reference 22.

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Strategies for the Mitigation of Contaminated Blood Products

As previously stated, detection strategies show variable sensitivity and specificity. Measuring abnormal glucose concentrations, low pH, microscopic examination of gram-stained specimens, and platelet swirling characteristics have been less useful due to low sensitivity and specificity. However, these methods have the advantage of being able to be used at the time and point of transfusion, are less expensive and use equipment commonly available.

Automated culture-based systems used for years in the hospital setting for detection of bacteremia in blood cultures obtained from patients were implemented by many of the nation's blood collection systems. Principally, they detect CO_2 generation or O_2 consumption by bacteria. Some of the limitations of culture-based systems are relatively insensitive at low levels of bacterial contamination causing false negative results, long incubation times for slow-growing bacteria, false positive results, high cost and the need for capital investment.[24-26] Holme and colleagues have recently shown that modifications to the Pall eBDS system have attempted to minimize these limitations.[29] While feasible for apheresis-derived platelets (ADP), culture based methods are not considered feasible for each whole blood-derived platelet (WBP) unit at the time of collection because of the high cost. Thus, those centers and services that used ADP could comply more easily and effectively with the new standard than those who used WBP, and converting entire systems from ADP to WBP was in-and-of-itself costly and met with resistance due to standard of care, cost, and availability concerns.

Apheresis Derived (ADP) Versus Whole Blood Derived Platelets (WBP)

Even before the implementation of Standard 5.1.5.1, the use of ADP had increased (52% to 99% of total transfused products per Ness and colleagues from 1987-1998) likely in part due to concern by some authorities about bacterial contamination.[8] Indeed, Ness and colleagues concluded that the rate of septic transfusion reactions due to WBP was 5.39 times higher than ADP (95% CI, 1.89, 12.9). Dykstra and colleagues found that the rate of bacterial contamination in ADP and WBP was identical (P=1.0); however, when platelet concentrates were pooled, the risk increased by 5 fold.[7]

Despite the apparent advantages of using ADP, maintaining adequate inventories and simultaneously providing adequate bacterial contamination testing is still a challenge due to the time it takes for the culture. Many experts have considered the effect and possibility of extending the expiration date to 7 days. In order to have a licensed 7 day ADP, clinical tests of the platelets, storage and medium will be required as will demonstration of bacteria detection and an acceptable rate of "residual risk." In order to allow the use of WBP with cost effective and optimal bacterial detection performance, 2 alternatives can be considered, but both are in clinical development and thus are not available. These include: 1) a 5 or 7 day "pooled and stored" WBP where a culture-based system could be used as a single test on a pre-storage pooled product, and 2) the approval of a effective test that could be used at the point and time of transfusion and which would be rapid enough for most clinical situations.

Residual Risk in "Tested" Components

Despite the strategies described above, bacterial contamination continues to be observed, although markedly reduced, and fatal consequences have been reported. As there was no standardized or required system in place to determine the true incidence of the morbidity and mortality caused by septic platelet units prior to the implementation of AABB Standard 5.1.5.1, it is impossible to determine with accuracy the effect of the standard in terms of percent improvement or reduction in adverse events. Some relevant data are available however.

From March 1, 2004 through December 31, 2004, approximately 350,000 units from 87,000 voluntary donors at 36 regional centers were cultured by the American Red Cross. Two hundred nineteen were initially positive, 67 were confirmed on re-sampling for an overall confirmed positive rate of 0.019% or 1:5,234 as compared to published reports of 1:2,000 to 3,000. Initially, 4 to 5 mL from each unit was transferred through a sterile docking device at least 24 hours after collection and used to inoculate BacT/ALERT BPA aerobic culture bottles. Confirmation of a positive blood culture bottle was performed by taking a new sample from product, inoculating a new BacT/ALERT aerobic culture bottle and if positive, performing bacterial isolation and identification. Eighty percent of the confirmed positive cases were gram-positive bacteria, mainly *Staphylococcus* (46.3%) and *Streptococcus* (26.9%) species. Serratia was the most commonly isolated gram-negative bacteria (n=4). Seventy-two percent of gram-negative organisms were identified within the first 12 hours of inoculation (personal communication; ARC). No patient transfused with an unconfirmed positive product had a septic transfusion reaction.

Three fatal cases and 2 non-fatal cases of transfusion-associated sepsis in platelet recipients have occurred since the standard was adopted. The first 2 cases were reported in MMWR.[27] The first case was that of a 74-year-old man who received 1 pool of 5 platelet concentrates. The pooled unit was tested by a pH method and found to be acceptable. After a hypotensive reaction, *S. aureus* was cultured from both the patient's blood and the platelet bag and by pulsed-field gel electrophoresis (PFGE) were identical. The second case was a 79-year-old man who was transfused a single platelet pheresis unit. The unit was tested by an automated culture system using a standard method. One hour after transfusion the patient had shortness of breath, chills, and fever. *S. lugdenensis* was cultured from both the patient's blood and the platelet bag and by PFGE were identical. The final case of fatality [presented to the Advisory Committee on Blood Safety (1/25/2005)] was a premature infant who received 2 doses of a single platelet pheresis. The unit was tested by a manual culture. The patient had symptoms consistent with sepsis. The platelet unit was then recultured and found to be growing *Serratia marcescens*. The patient's cultures were negative, but the cultures were taken after antibiotic therapy was initiated. One of the non-fatal cases was a BacT/ALERT failure of an apheresis platelet unit.[16]

Using numbers that are estimates only, and recognizing the limitations therein, a residual risk figure may be on the order of 3 to 6 fatal cases per year following the administration of approximately 2 million platelet doses per year (*The reader is asked to note that the true number of transfused platelet doses per year in the United States has not been established with certainty. While as many as 9 million units are given, the proportion of ADP vs. WBP is not known, nor is the number of WBP pooled into a dose*). Therefore, an incidence figure of approximately 1 fatality per approximately 500,000 tested doses may be posited. This is

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likely to be grossly inaccurate due to the lack of validated data, suboptimal test methods for WBP, and reporting and assumptions used. If one uses the figures given earlier in this report of 100 to 150 deaths annually (pre-standard implementation) and a residual as high as 6, then the improvement has been about 95%. Again, this number is a gross estimate, which will likely be revised with the collection of additional data. Though the "improvement rate" seems excellent, a residual risk of fatality incidence of 1:500,000 may be judged unacceptable by some, and thus other means of improving upon this complication may be warranted.

Pathogen Reduction (Inactivation)

Pathogen reduction is the term given to a number of technologies that prevent pathogens from replicating and thus prevent them from causing disease following transfusion. Methods under investigation (some are in use in Europe) use a variety of compounds including methylene blue, riboflavin and solvent-detergent treatment. In addition, a number of photodynamic processes use psoralen-based chemicals followed by ultraviolet light to inactivate bacteria and viruses by preventing replication and transcription of nucleic acids. This latter method has been extensively tested for bacterial reduction in platelet products. Gram-positive and gram-negative bacteria have been shown in three preclinical trials to be sensitive to pathogen inactivation (reviewed in reference 28). The main disadvantage of pathogen inactivation is that no method is equally effective for all organisms and these methods may be especially ineffective for spore-forming organisms.[28] The advantage is that this is a proactive method for bacterial reduction and has the potential to be as effective for known pathogens as it is for emerging pathogens.

Ongoing Issues

Bacterial contamination of blood products was, and may continue to be, a serious health risk to transfusion recipients. While we believe substantial improvement has been made, though difficult to accurately quantify, some level of residual risk appears to exist. Systems to help quantify this residual risk need to be implemented and/or strengthened. In addition, there is some evidence to suggest that the implementation of Standard 5.1.5.1 has caused a significant reduction in platelet availability, delay in their release to hospital transfusion services, and/or a declination in WBP use which may have added to the overall cost of platelet provision and transfusion. In order to address these issues, rapid and cost-effective tests need to be developed and approved for use at the time and point of transfusion. Alternatively, and with the use of a validated bacterial detection test, prestorage pooling may be "allowed" and thus lead to a state of equipoise between ADP and WBP safety and therefore use. An effective method or methods for bacterial detection and limitation will likely allow the extension of either ADP or pooled and stored WBP to 7 or perhaps even 8 days, thus likely improving the logistical and availability issues currently surrounding this valuable human resource. Finally, the adoption of pathogen reduction technologies in Europe and their approval in the United States may abrogate any residual or evolving risk.

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לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה לפני קיבול בקשת פטנט מספר 286030</u>**

סימוכין : מכתבכם מיום 25/08/2022

לתשומת לבכם: מקום בו הנכם מופנים ל״חוק״, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים ל״תקנות״, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. בהתאם לחוזר רשם 035/2017 – פטנטים **לא ניתן להשהות פרסום בקשות פטנט לפי סעיף 26 לחוק.**

<u>הודעה זו מבוססת על המסמכים הבאים:</u>

שרטוטים מתאריך : 01/09/2021
פרטי הבקשה מתאריך : 01/09/2021
תביעות מתאריך : 25/08/2022

<u>מענה לטיעוני המבקש</u>

מערכת התביעות המוצעת מתקבלת.

<u>הריני להודיעכם כי בחינת הבקשה הנ״ל הושלמה לפי הוראות סעיף 48ו(ג)(1) ו- (2) לחוק.</u>

<u>תשלום אגרת קיבול</u>

1. הבקשה תתקבל בהתאם לסעיף 26 לחוק לאחר תשלום אגרת הקיבול.
2. יש לשלם את האגרה תוך 3 חודשים מתאריך הודעה זו.
3. סכום האגרה נכון למועד הודעה זו הינו 764.00 ש״ח. הסכום כפוף לעדכונו על פי המדד בהתאם לתקנה 6א.

<u>הפניה בפירוט למסמך הבכורה</u>

לפי הוראות **סעיף 20 לחוזר הרשם 034/2017-פטנטים** במידה ופירוט הבקשה מכיל הפניה למסמך בכורה באמצעות הביטוי ״incorporated by reference״ ובמידה וחלפו 14 חודשים ממועד דין הקדימה (אם נדרש) לא ניתן עוד להוסיף דבר מתוך מסמך הבכורה והמבקש לא יכול להסתמך על האמור במסמך הבכורה, לצורך סעיפים 12 ו-13 לחוק.

<u>עדכון רשימות האסמכתאות והפרסומים לפי סעיף 18א לחוק</u>

לתשומת לבכם, בהתאם להוראות פרק ג' בחוזר רשם 035/2017-פטנטים חובת המבקש לעדכן את הרשות בכל שינוי שחל ברשימת הפרסומים בהתאם לסעיף 18 לחוק נמשכת עד קיבול הבקשה.

באם ברצונכם להחזיר את הבקשה לבחינה בעקבות שינוי ברשימת הפרסומים שהתרחש לאחר תשובתכם להודעת הליקויים האחרונה, עליכם להגיש בקשה לבחינה חוזרת בה עליכם לציין מהו השינוי ברשימת הפרסומים ומתי נודע על שינוי זה.

בקשה לבחינה חוזרת יש להגיש באמצעות פניה ל-"בקשה לתיקונים לאחר פ.ק. 13".

<u>הגשת בקשות חלוקה</u>

בהתאם להוראות סעיף 24(א) לחוק זכאי המבקש כל עוד לא קובלה הבקשה לדרוש את חלוקת הבקשה לבקשות אחדות. לפיכך, באם ברצונכם להגיש בקשות חלוקה מבקשה זו עליכם לעשות זאת בטרם מועד הקיבול. לא נוכל להכיר בבקשות שיוגשו לאחר מועד הקיבול של הבקשה הנוכחית כבקשות חלוקה לעניין סעיף 24(ג) לחוק.

<u>בדיקה פורמלית</u>

להודעה הנוכחית מצורף העתק פירוט הבקשה המעודכן - אם נפלו טעויות נא להודיע עליהן לרשות לפני מועד תשלום אגרת הקיבול.

לצורך אימות פרטי הפרסום בהתאם לסעיף 26 לחוק ניתן לעיין בנסח הבקשה באתר הרשות בקישור הבא:

https://israelpatents.justice.gov.il/#/en/patent-extract/286030

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

https://israelpatents.justice.gov.il/#/en/patent-file/details/286030

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
טלפון: 073-3927233
דואר אלקטרוני: albertak@justice.gov.il
ראש צוות: מוריה שלמה לוי

claims

1. A blood device connected with a blood sampling system comprising:

a patient needle for accessing a blood sample from a patient and a sample needle that is sealed,

an inlet port connected with the patient needle to receive the blood sample from the patient;

a chamber connected with the inlet port and having a vent

comprising an air permeable blood barrier, wherein the chamber for receiving a first portion of the blood sample prior to the sample needle is unsealed;

a sampling channel having a proximal end connected with the inlet port, wherein the sampling channel for conveying a second portion of the blood sample once the sample needle is unsealed;

an outlet port connected with a distal end of the sampling channel for conveying the second portion of the blood sample to the sample needle; and

a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

2. The blood device in accordance with claim 1, wherein the chamber is at ambient air pressure, and wherein the chamber receives the first portion of the blood sample by blood pressure of the patient overcoming the ambient air pressure in the chamber.

3. The blood device in accordance with claim 1, wherein the sampling channel causes the second portion of the blood sample to bypass the first portion of blood in the chamber and exit the outlet port for conveyance to a blood collection device.

4. The blood device in accordance with claim 1, wherein the air permeable blood barrier includes an air permeable material that seals upon contact with blood.

BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

ABSTRACT

Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING"; and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT

SEQUESTRATION DEVICE AND METHOD," the disclosures of which are incorporated by reference in their entirety.

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin

antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback

with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0013] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration

device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0016] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0017] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0018] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the

patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0019] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0020] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0021] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0031] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0032] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0033] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0034] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0035] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0036] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0037] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0038] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0039] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0040] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0041] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and methods for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by

the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that

allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a

predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of

the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better

affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with

one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or

amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401

further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the

sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C

is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In

some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer

capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member

1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The

air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00126] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel before the initial aliquot of blood is sequestered in the sequestration chamber 2306.

[00127] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

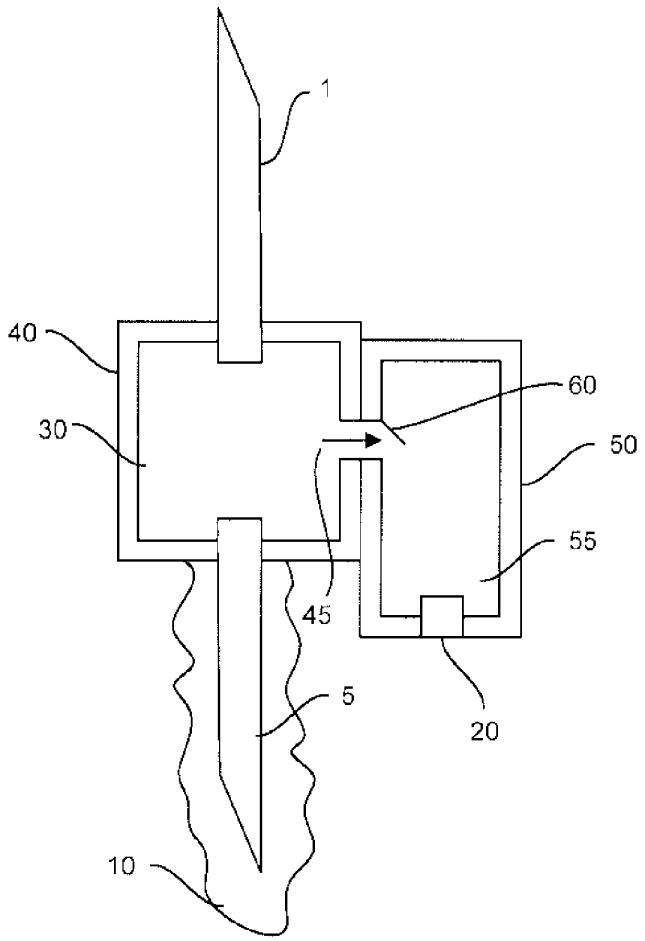


FIG. 1

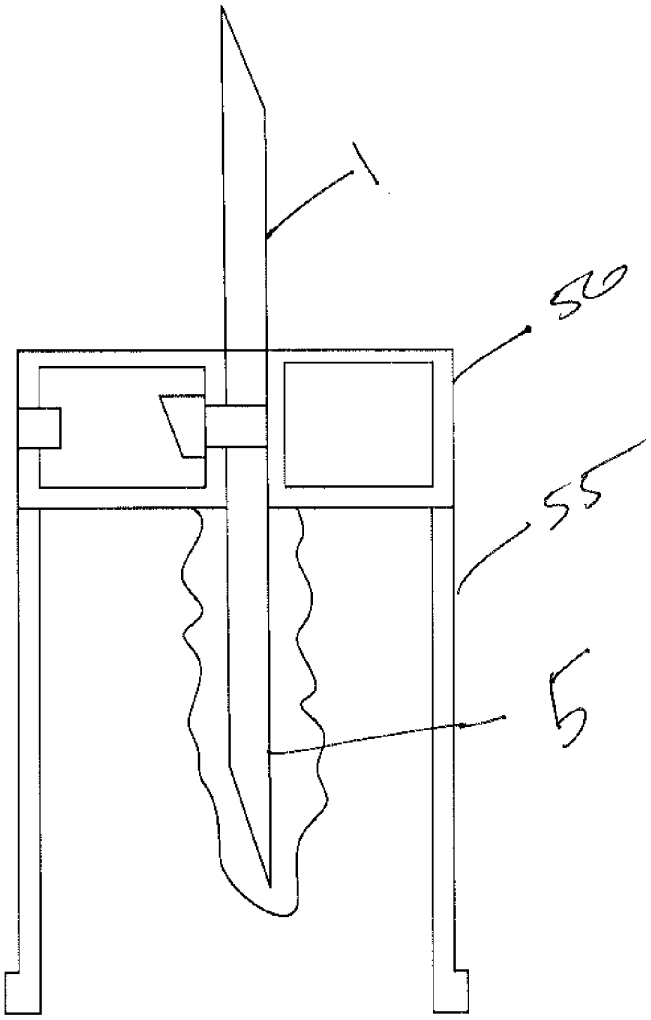


FIG. 2

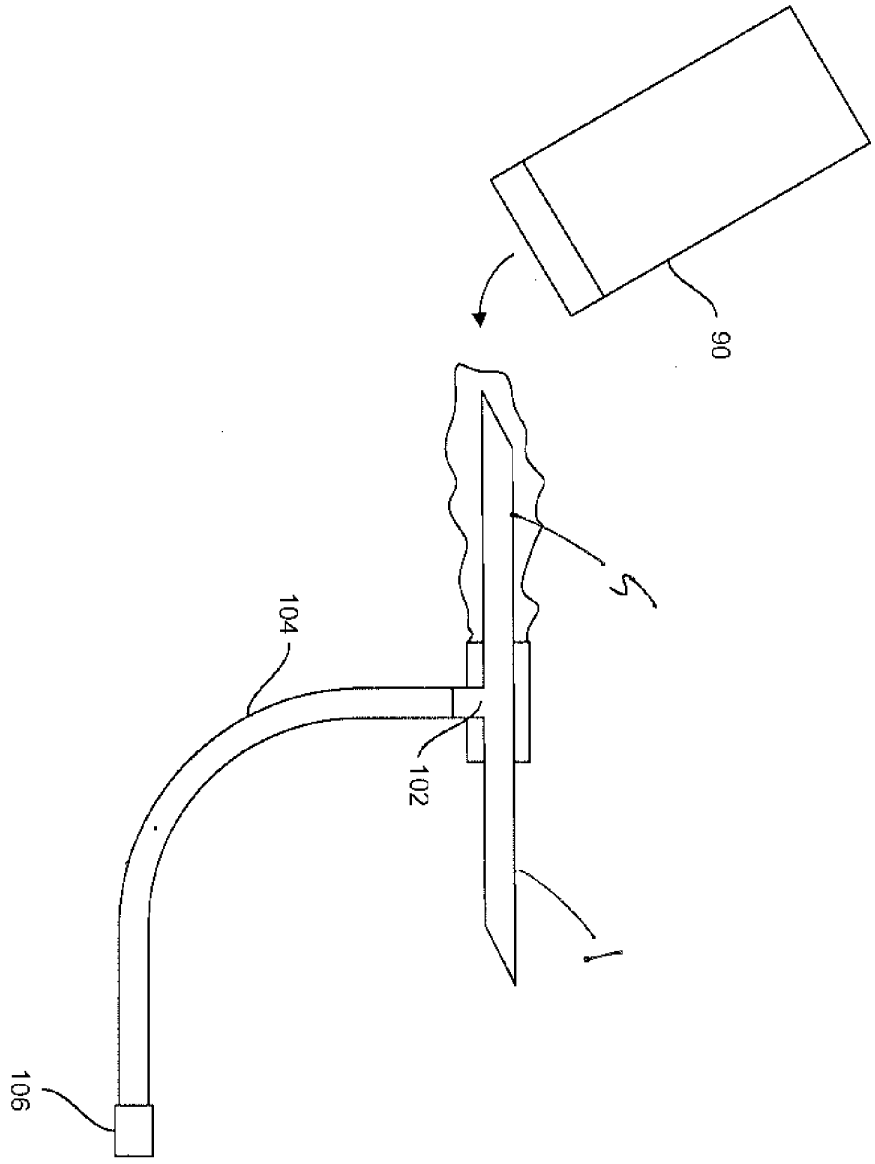


FIG. 3

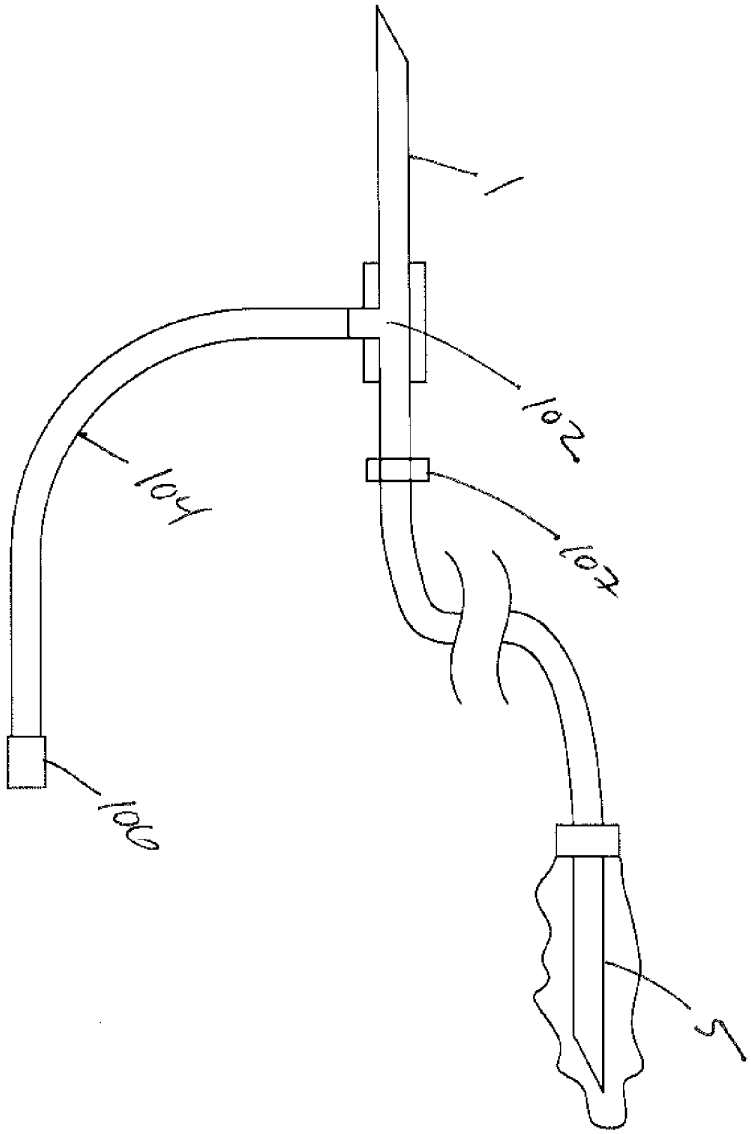


FIG. 4

FIG. 5

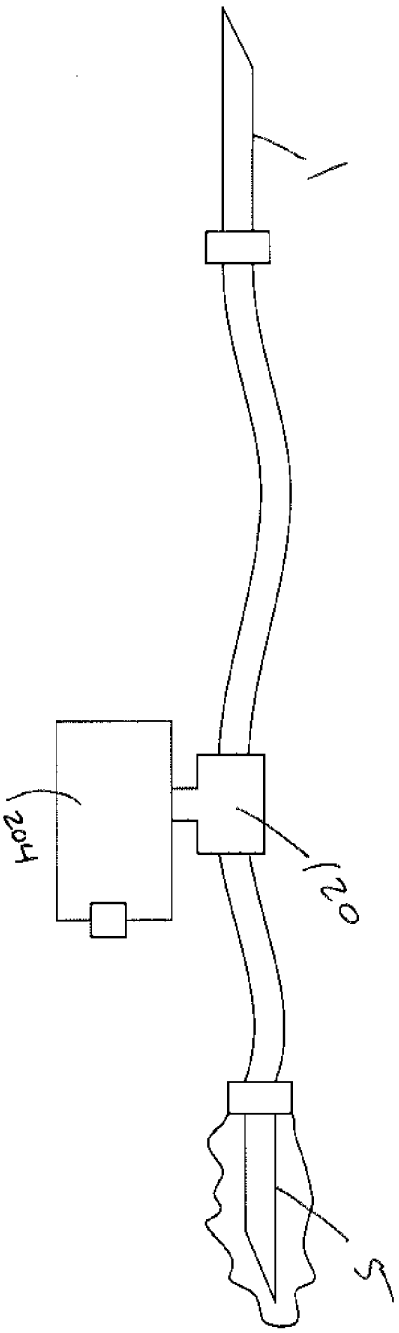
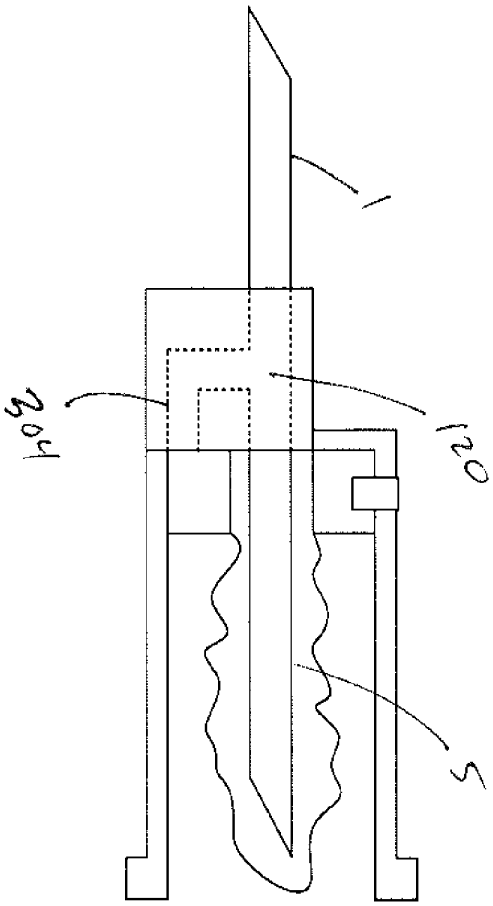


FIG. 6



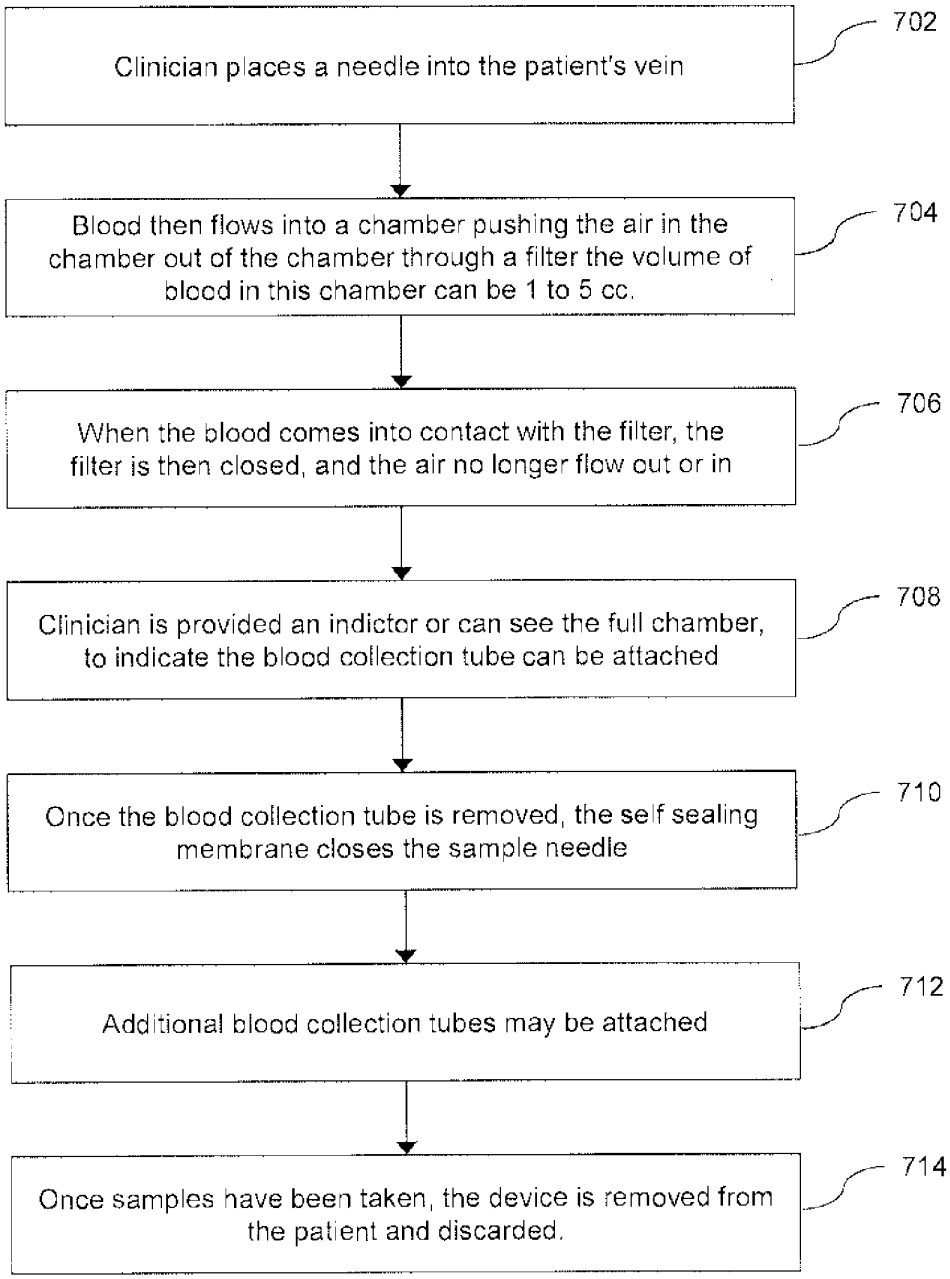

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

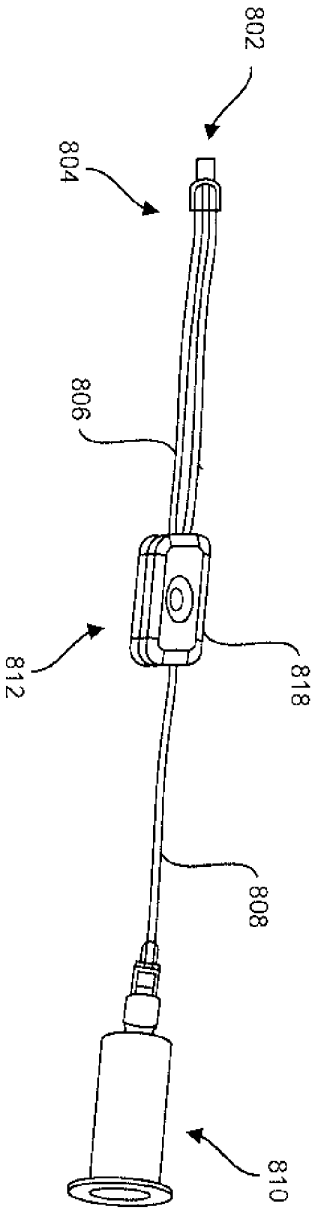


FIG. 8A

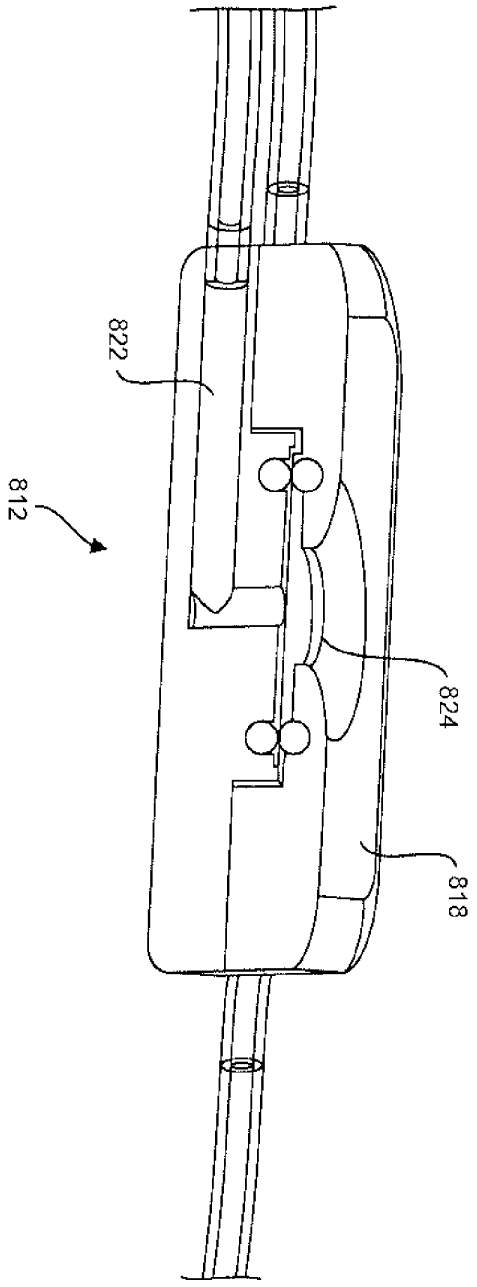


FIG. 8B

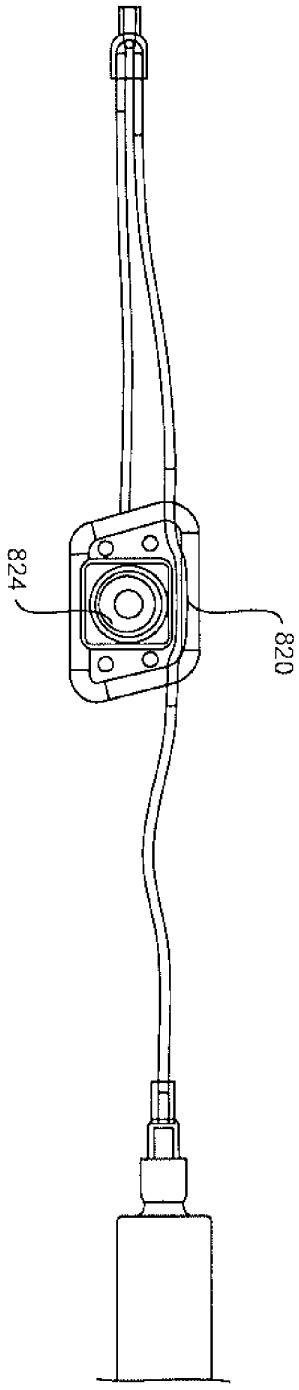


FIG. 8C

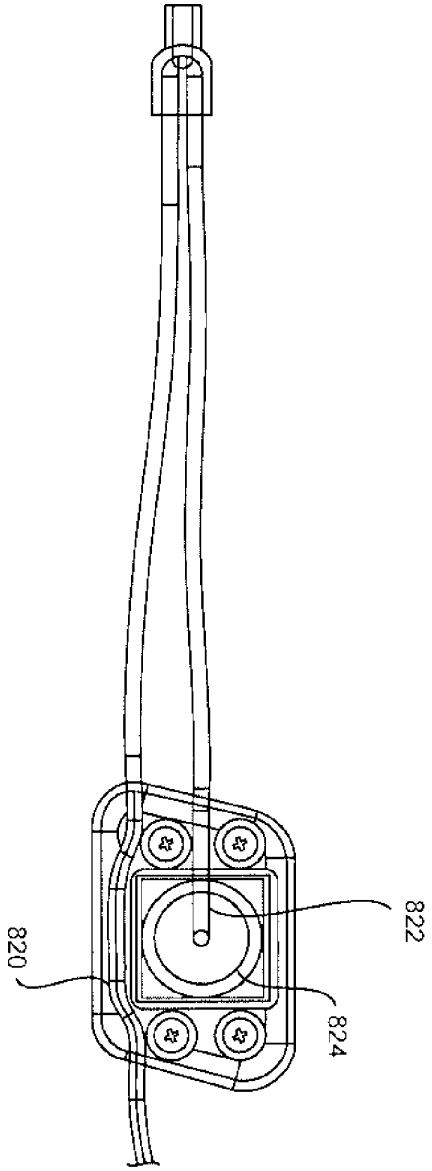


FIG. 8D

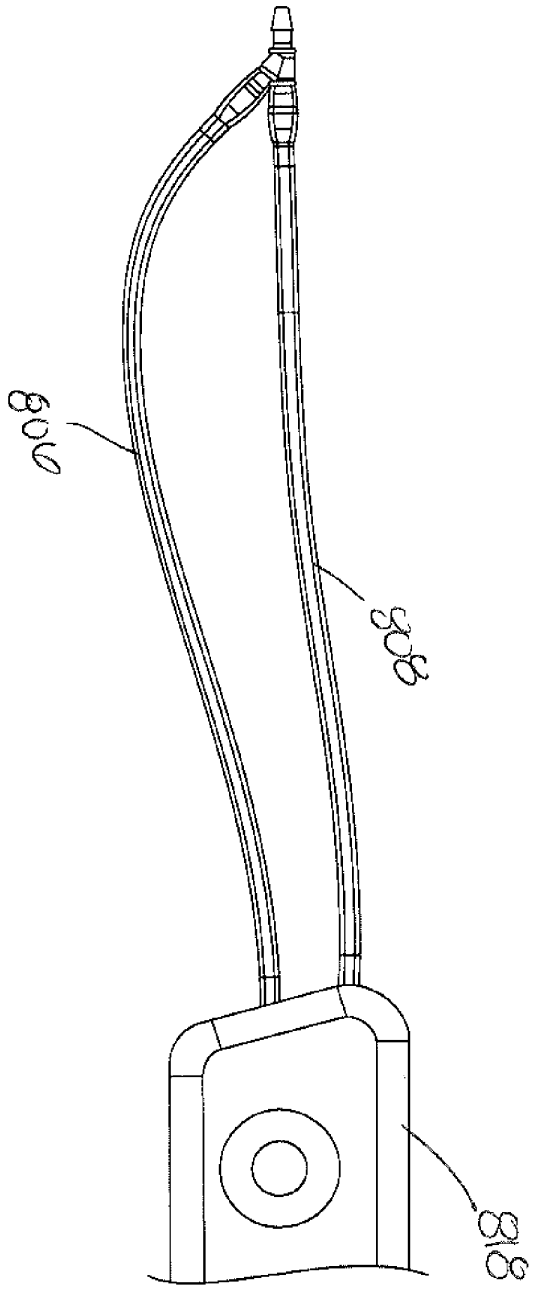


FIG. 8E

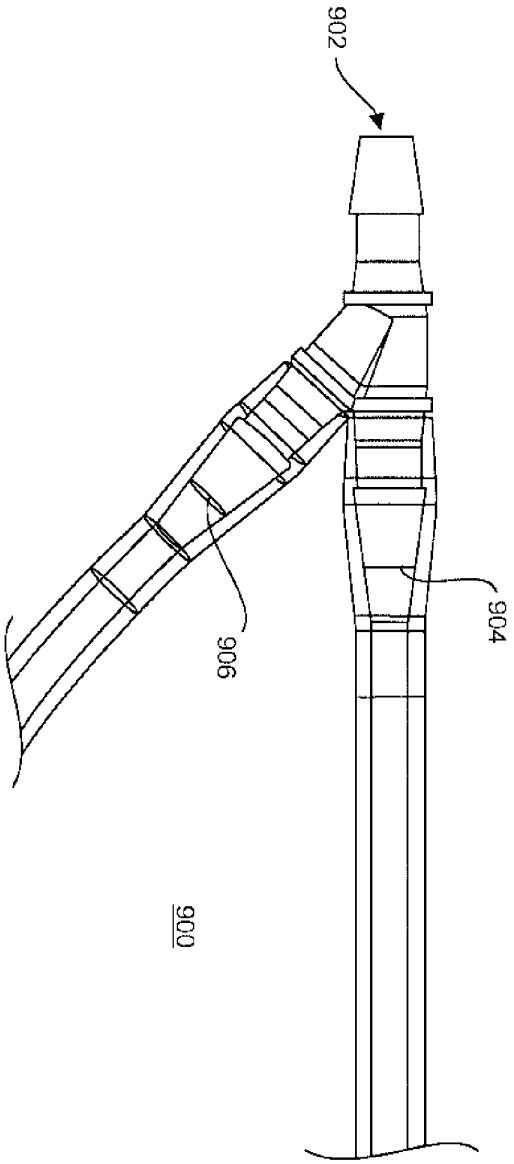


FIG. 9

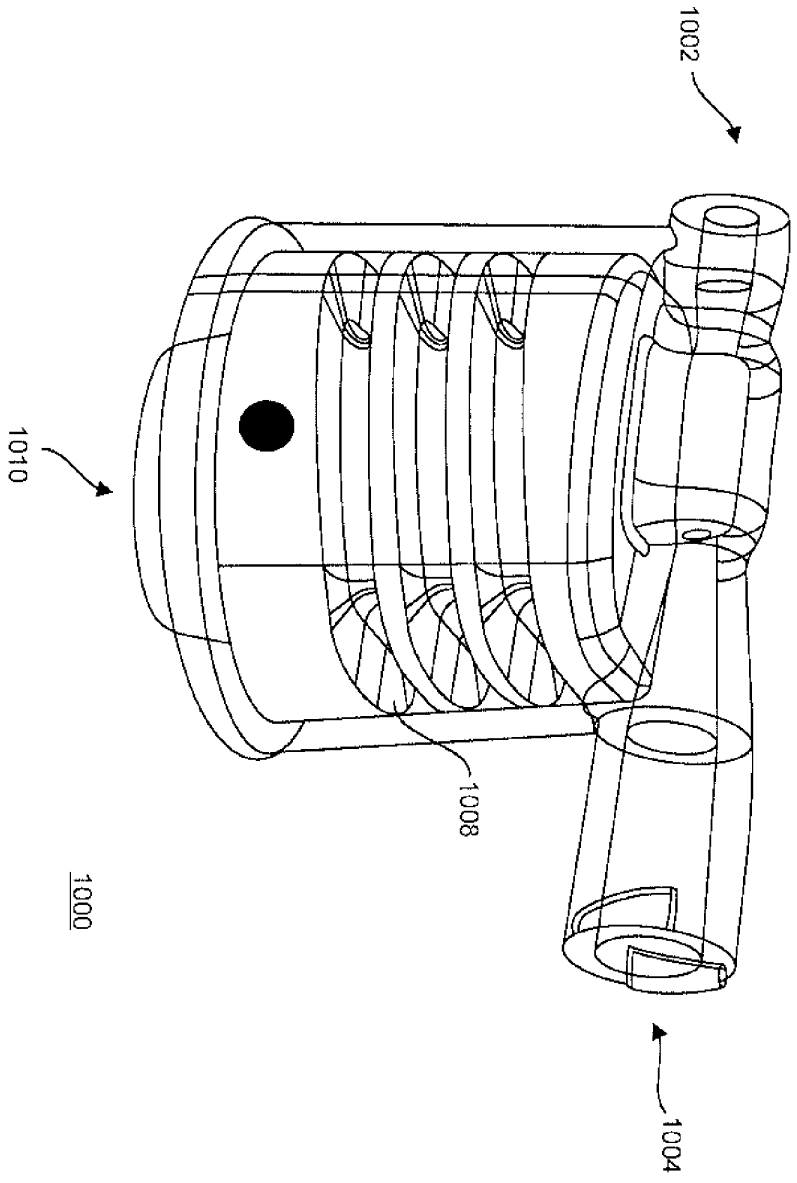


FIG. 10A

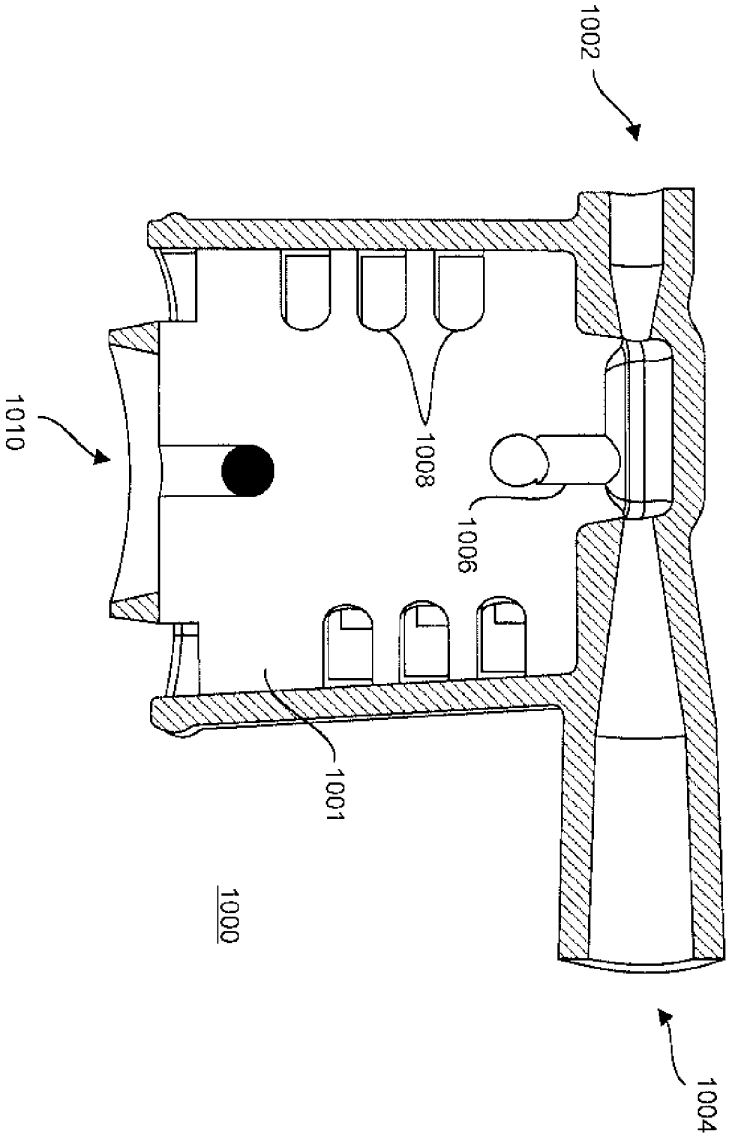


FIG. 10B

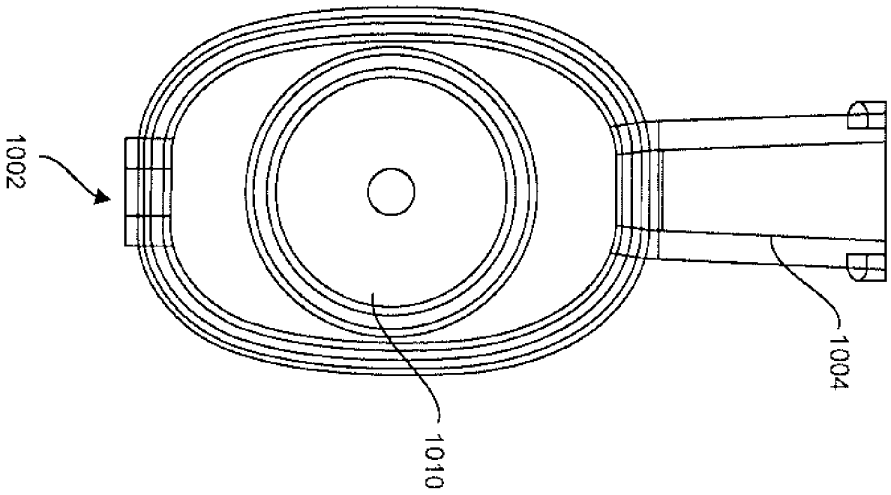


FIG. 10C

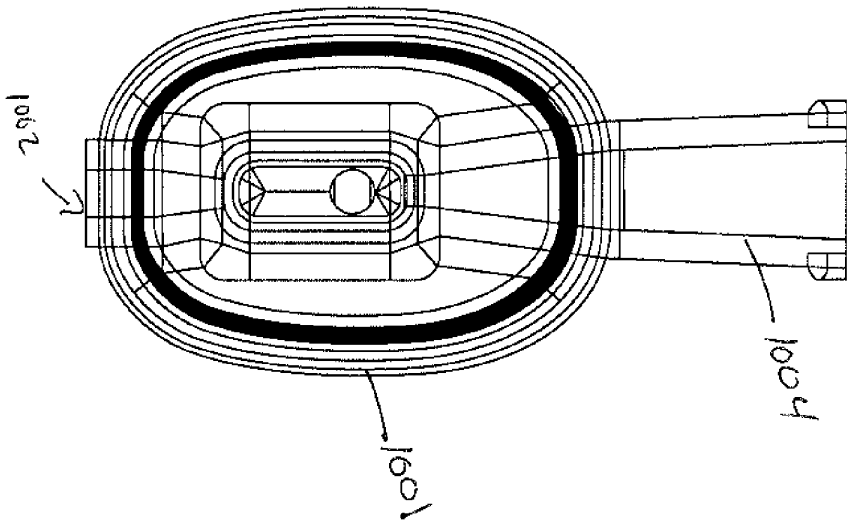


FIG. 10D

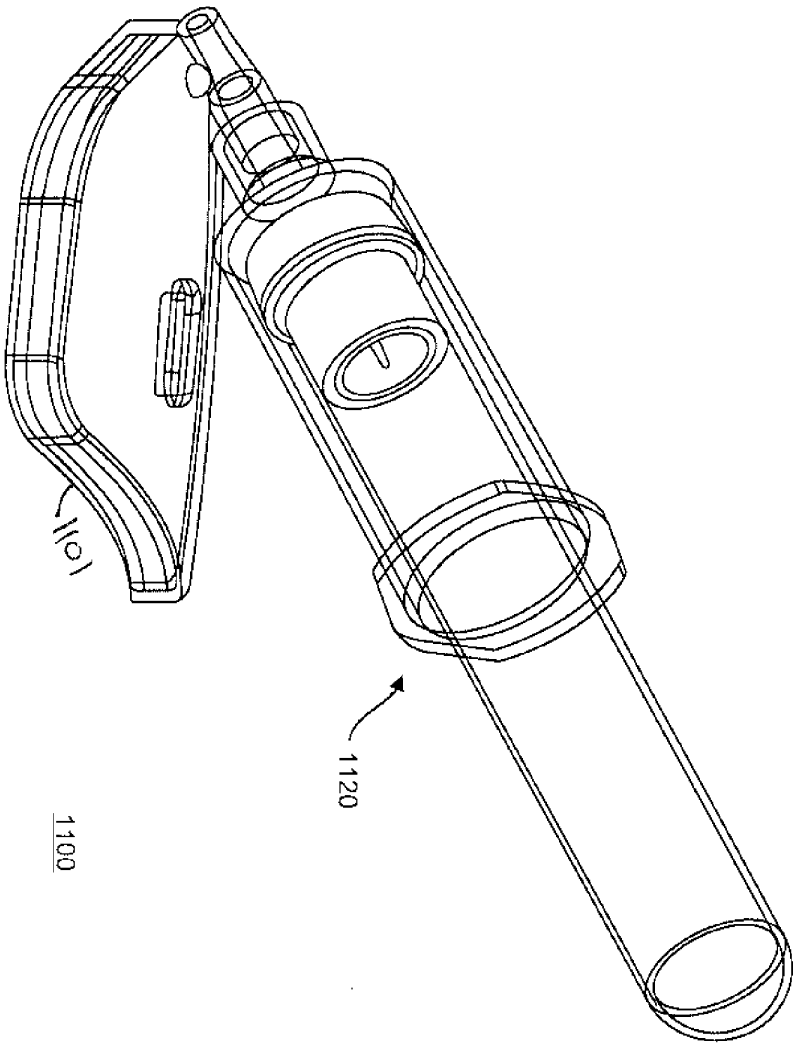


FIG. 11A

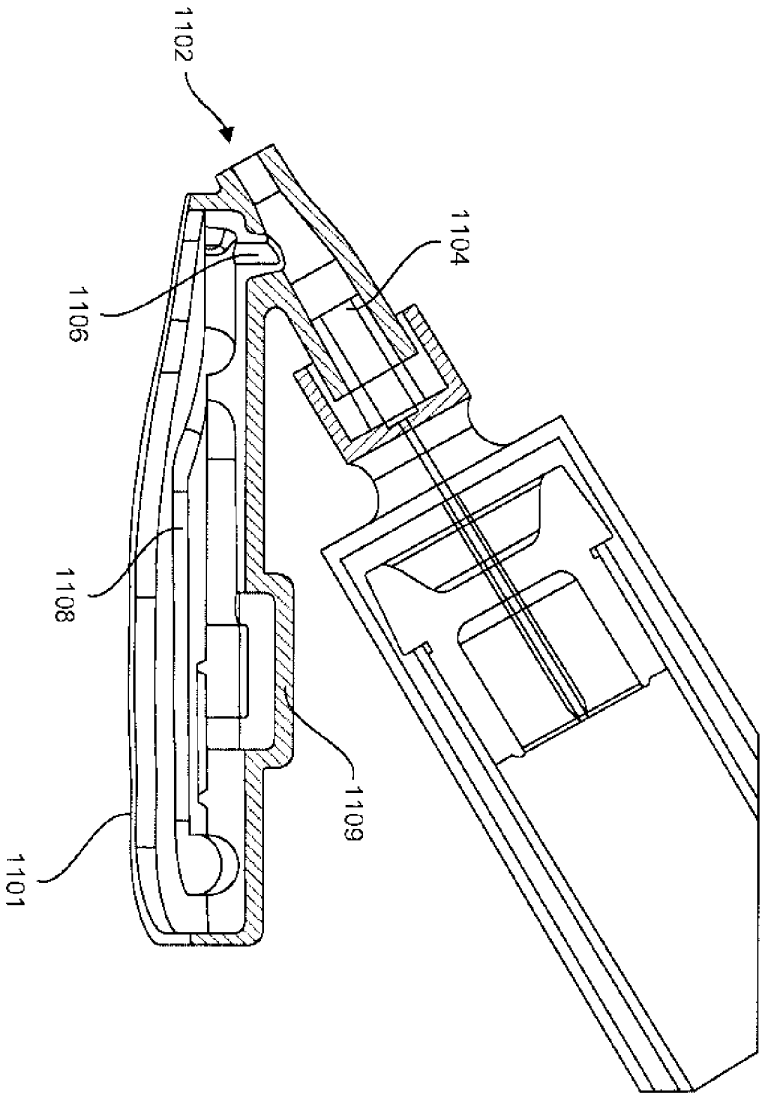


FIG. 11B

FIG. 11C

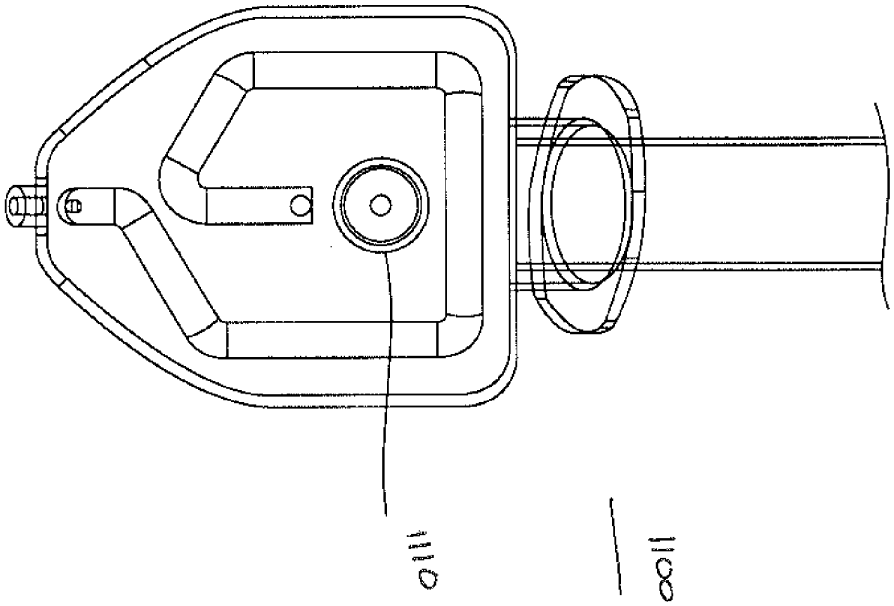
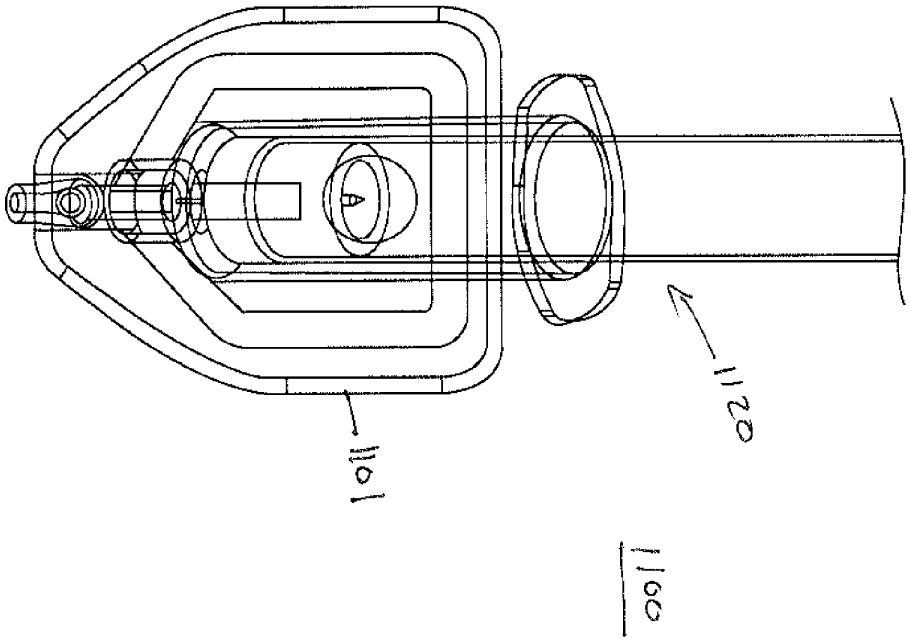


FIG. 11D



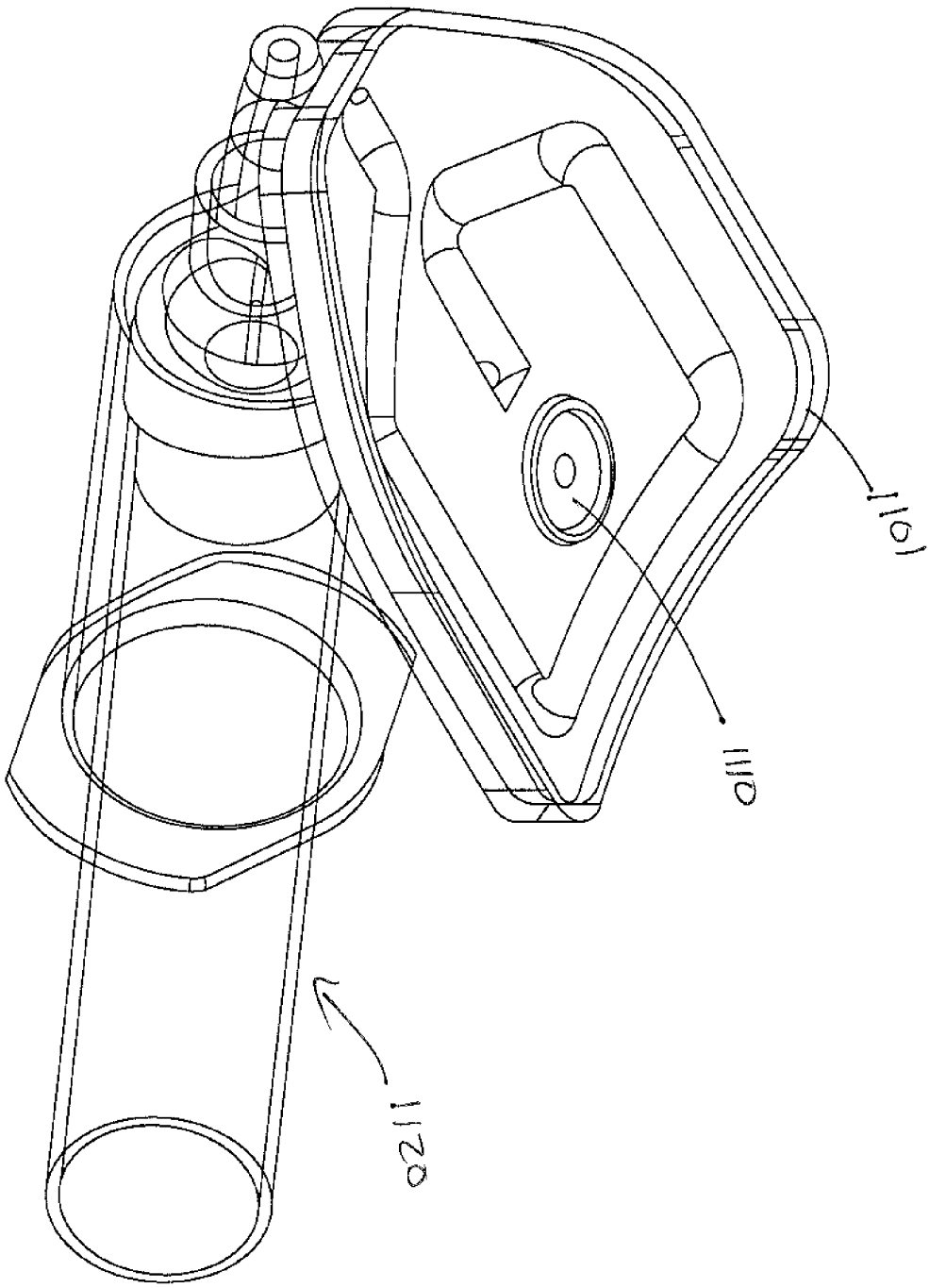


FIG. 11E

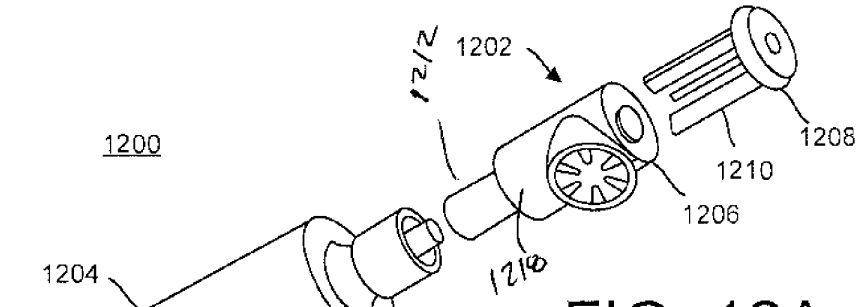


FIG. 12A

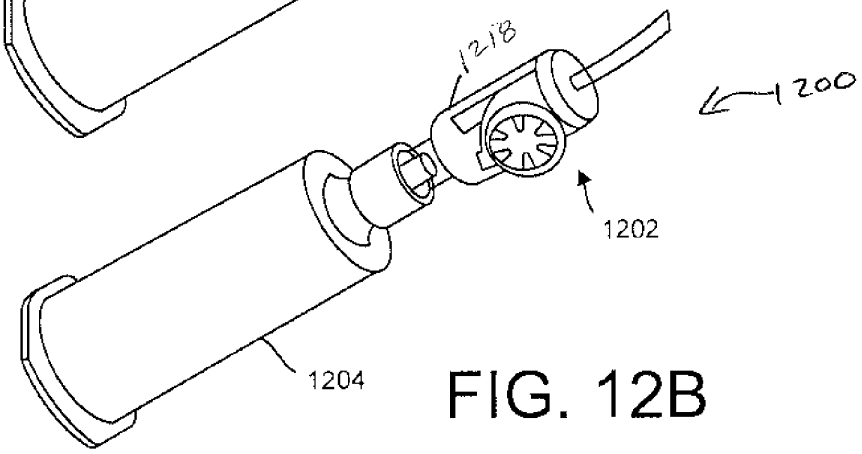


FIG. 12B

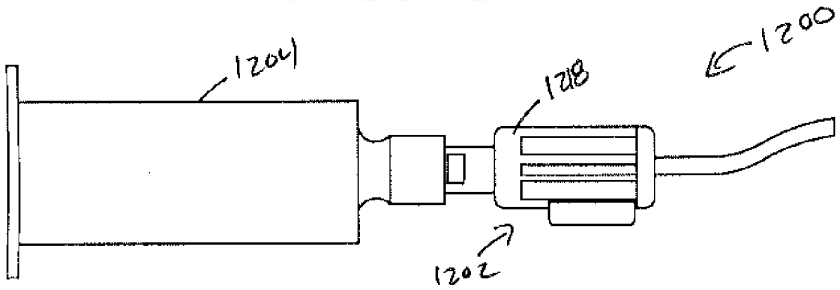


FIG. 12C

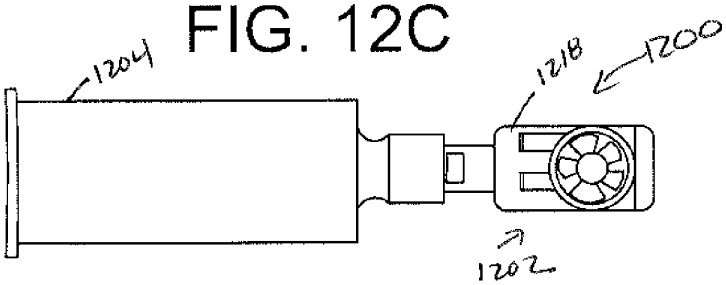


FIG. 12D

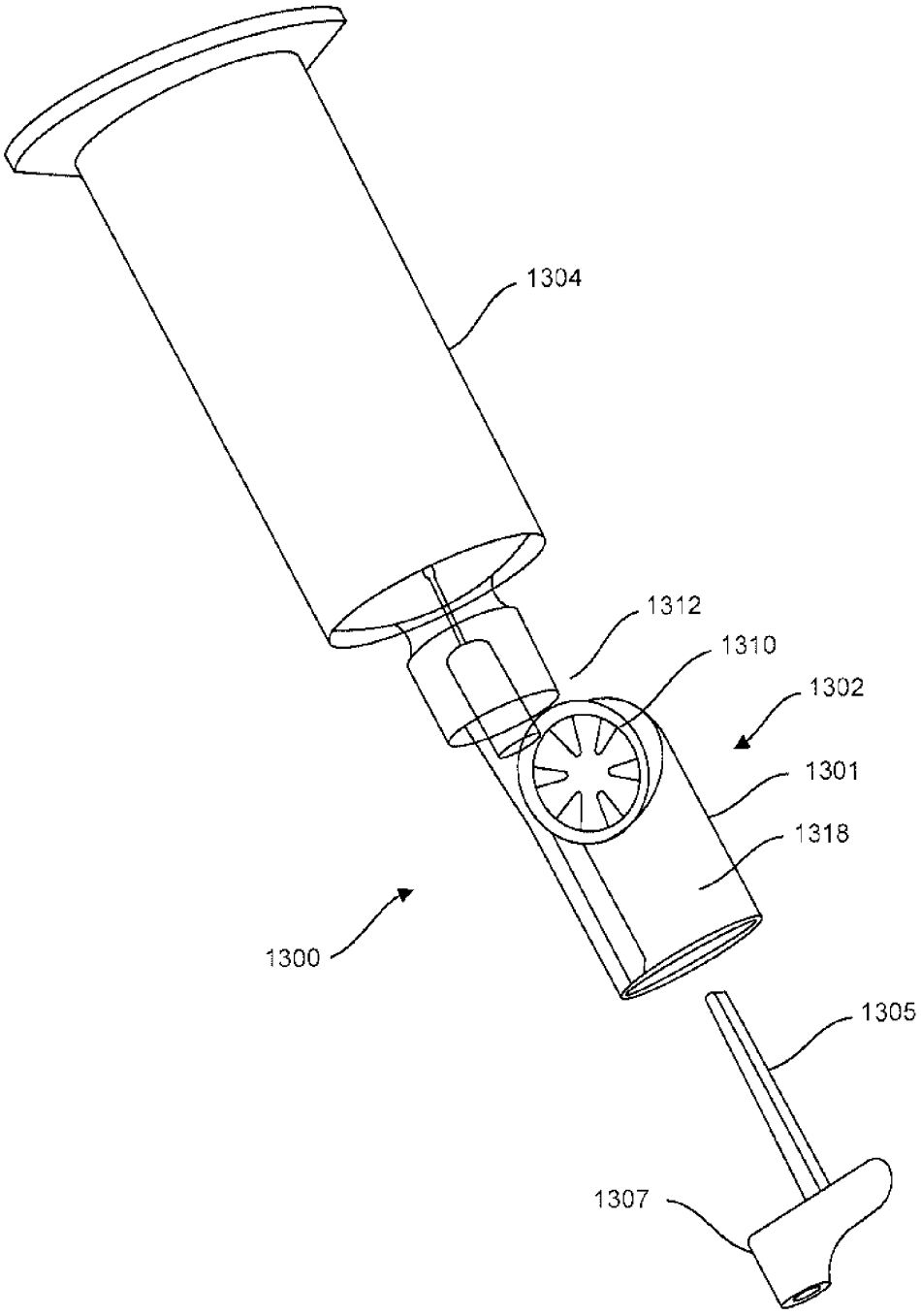


FIG. 13A

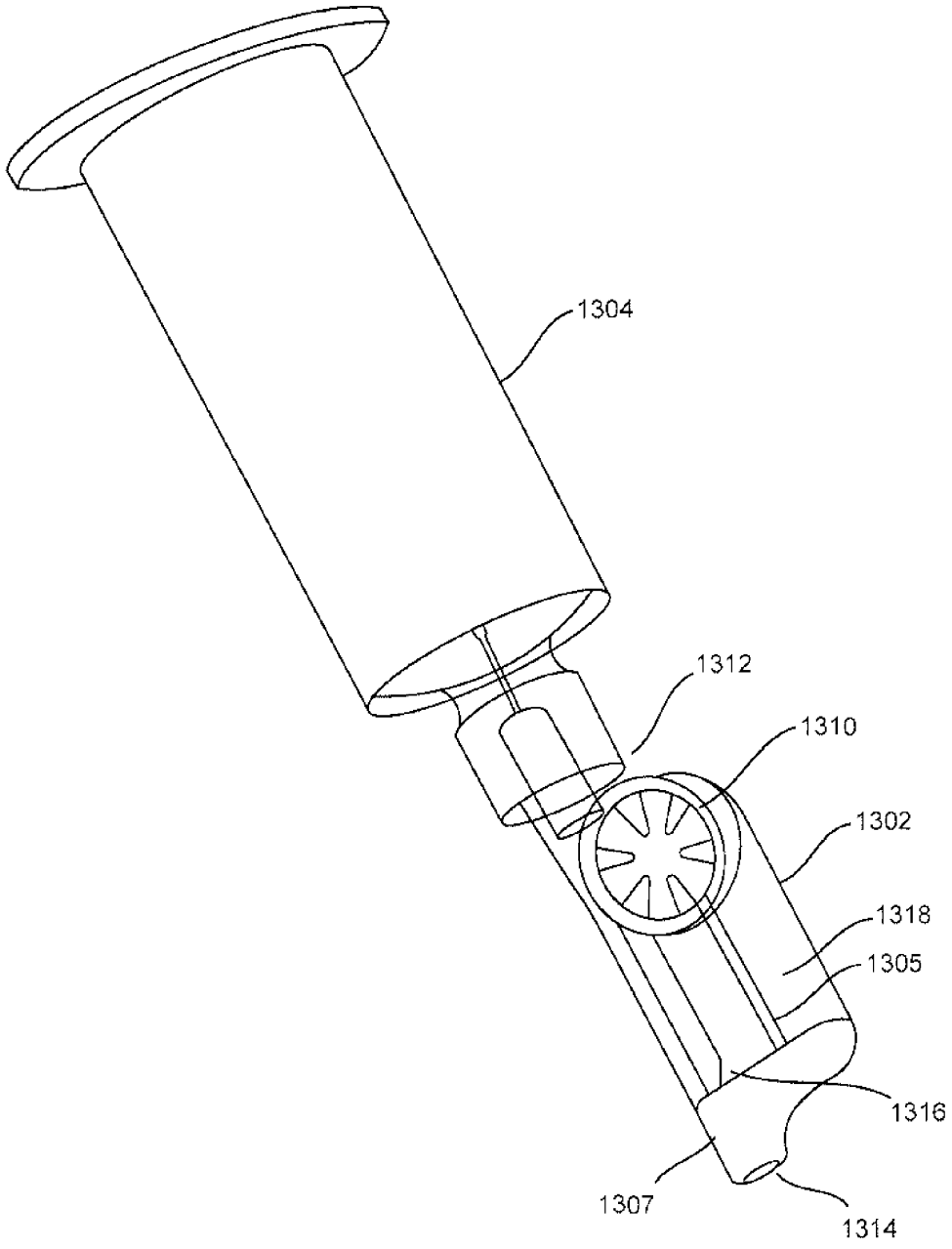


FIG. 13B

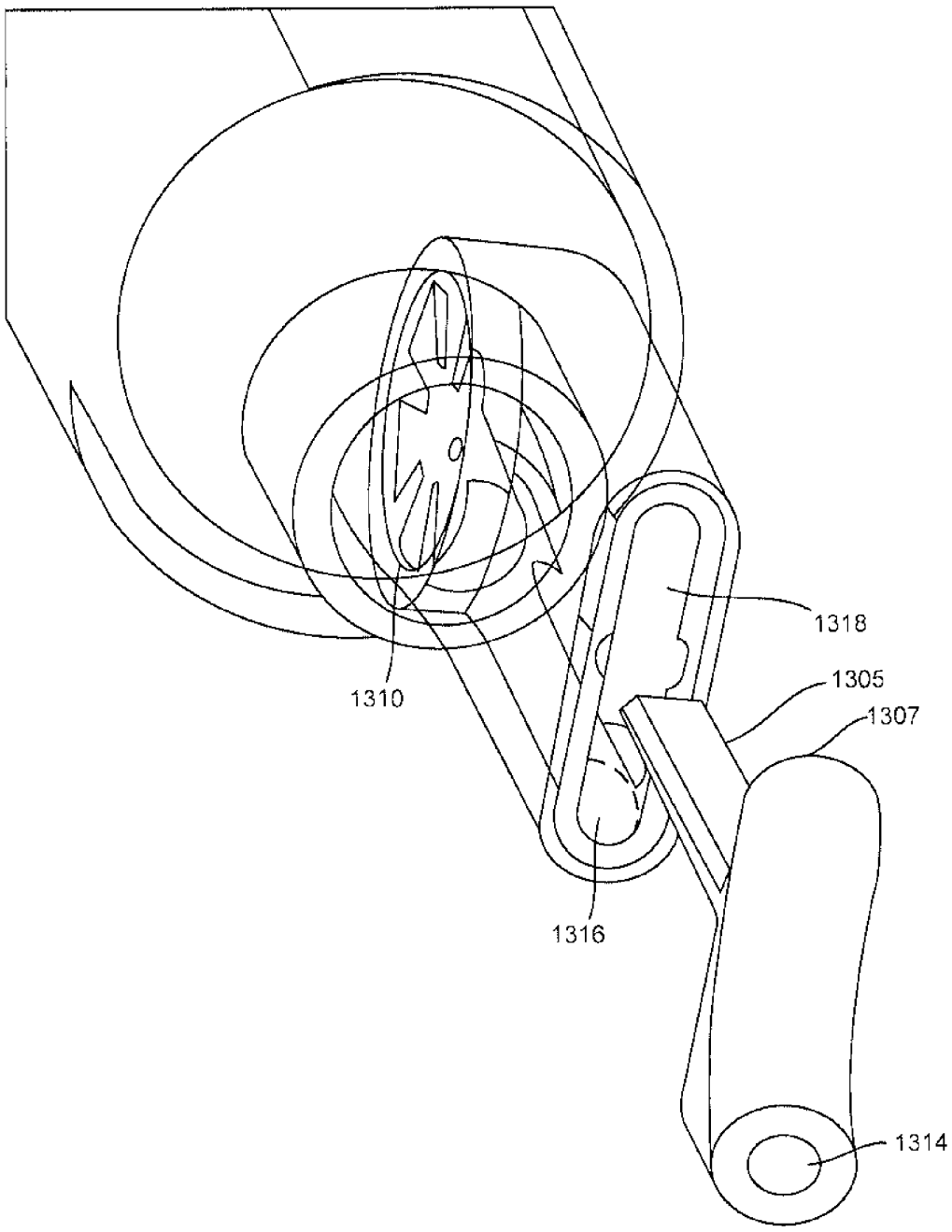


FIG. 13C

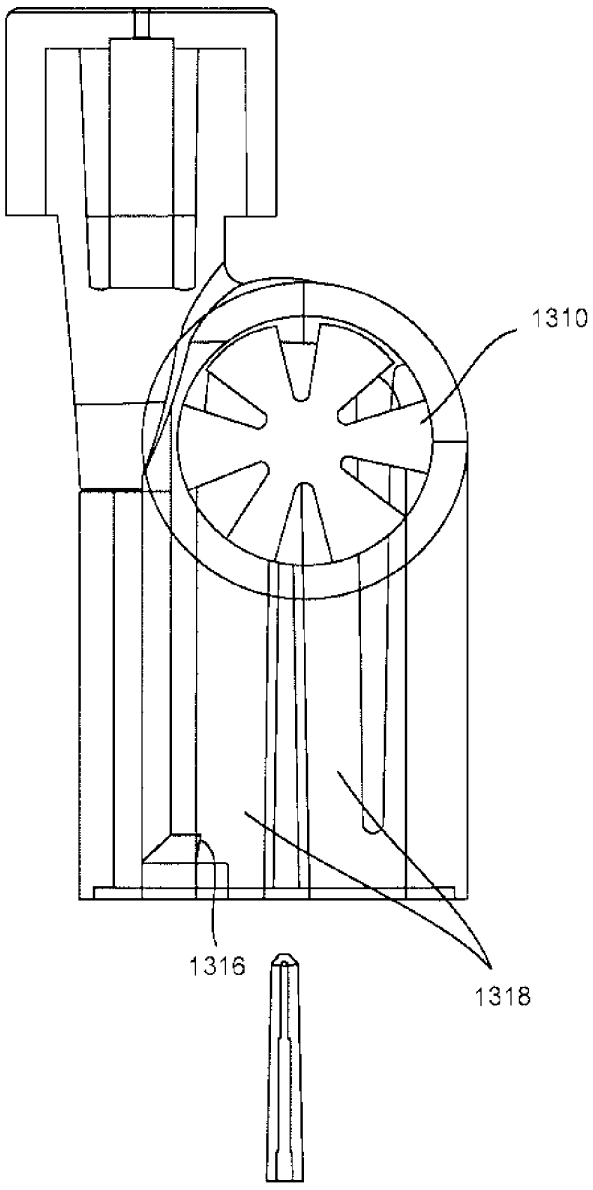


FIG. 13D

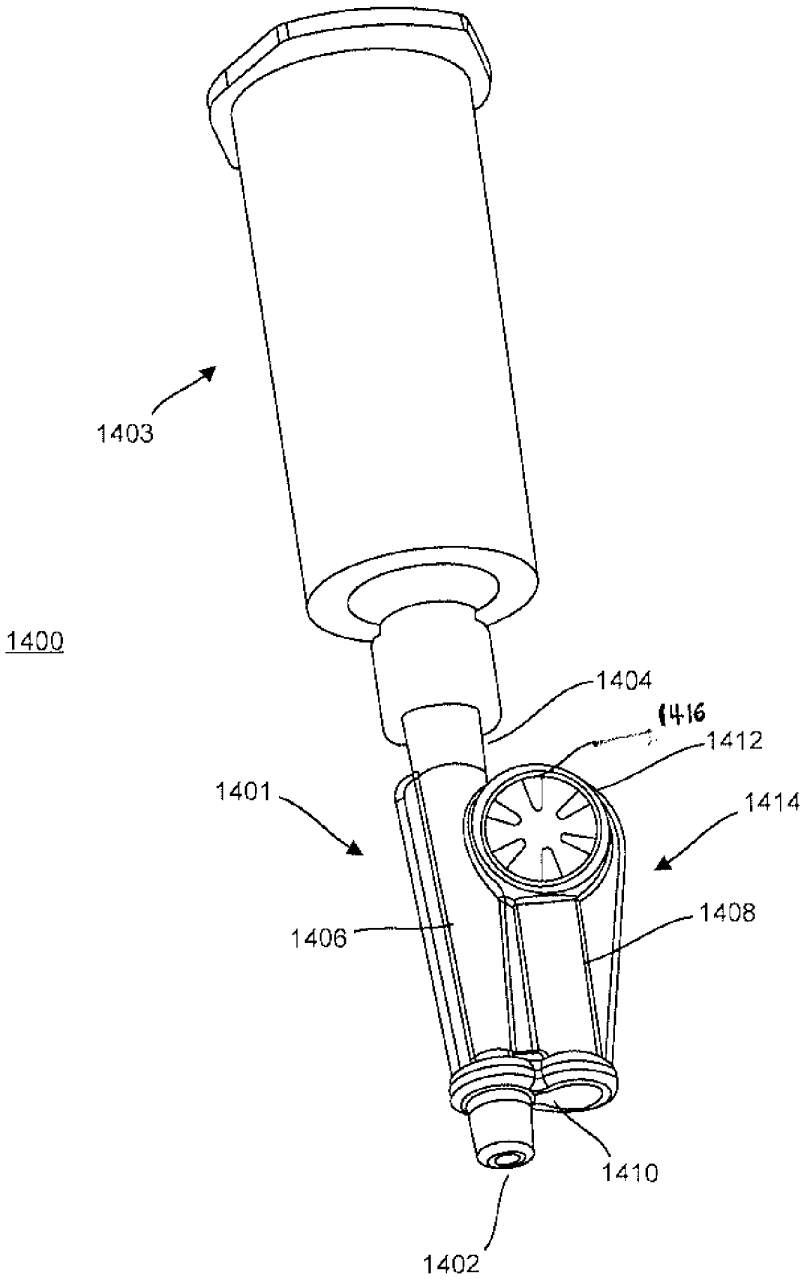


FIG. 14A

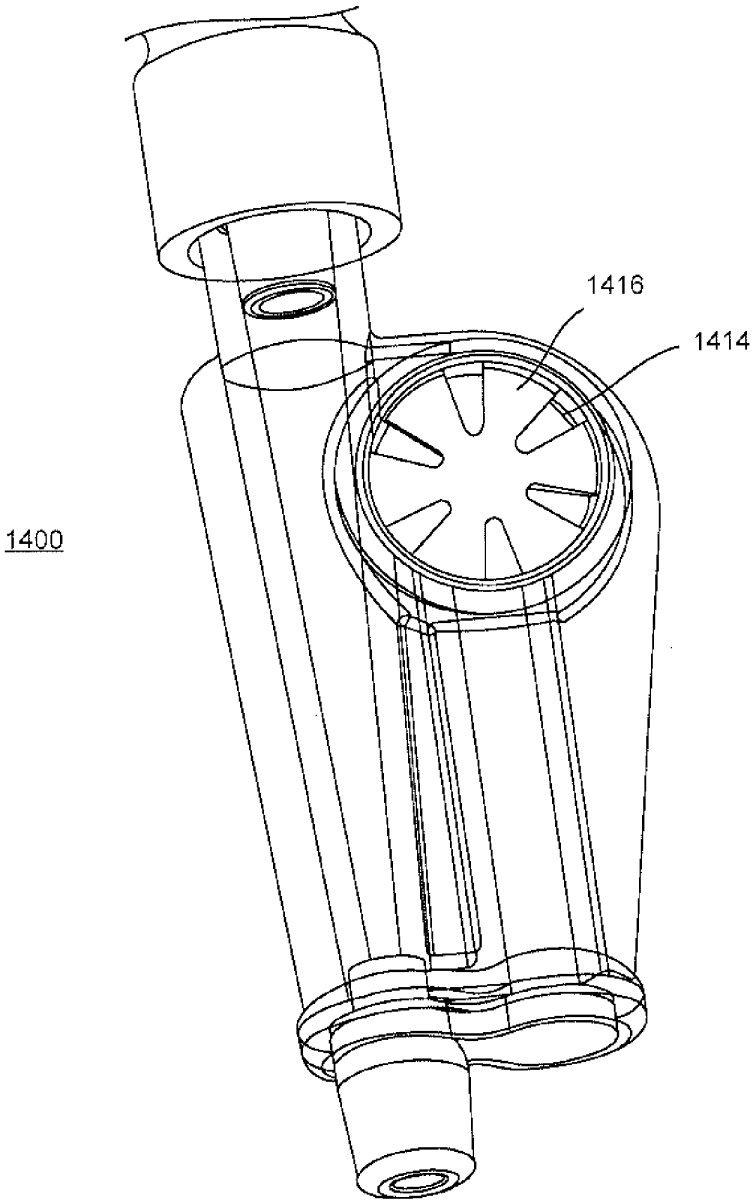


FIG. 14B

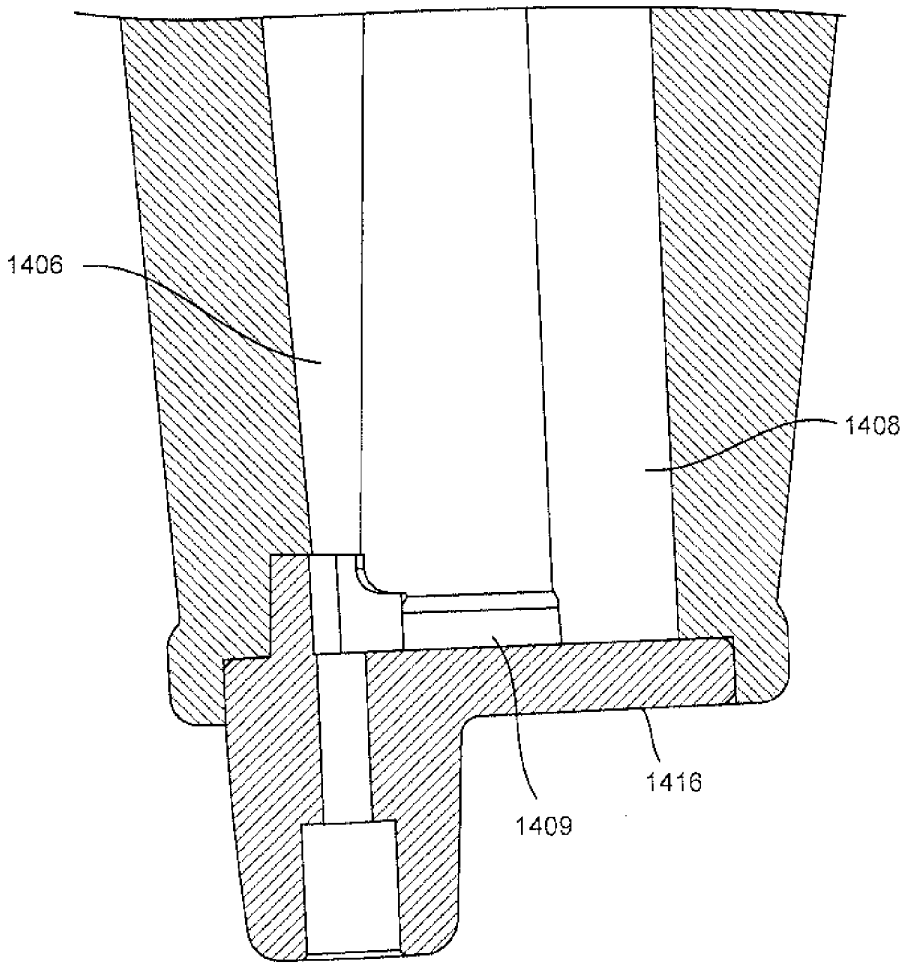


FIG. 14C

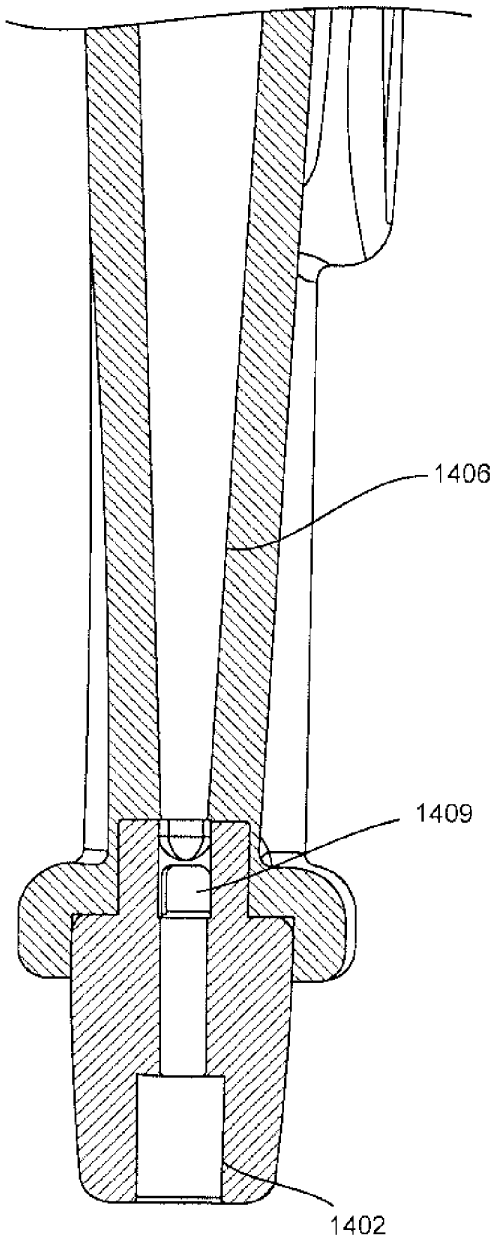


FIG. 14D

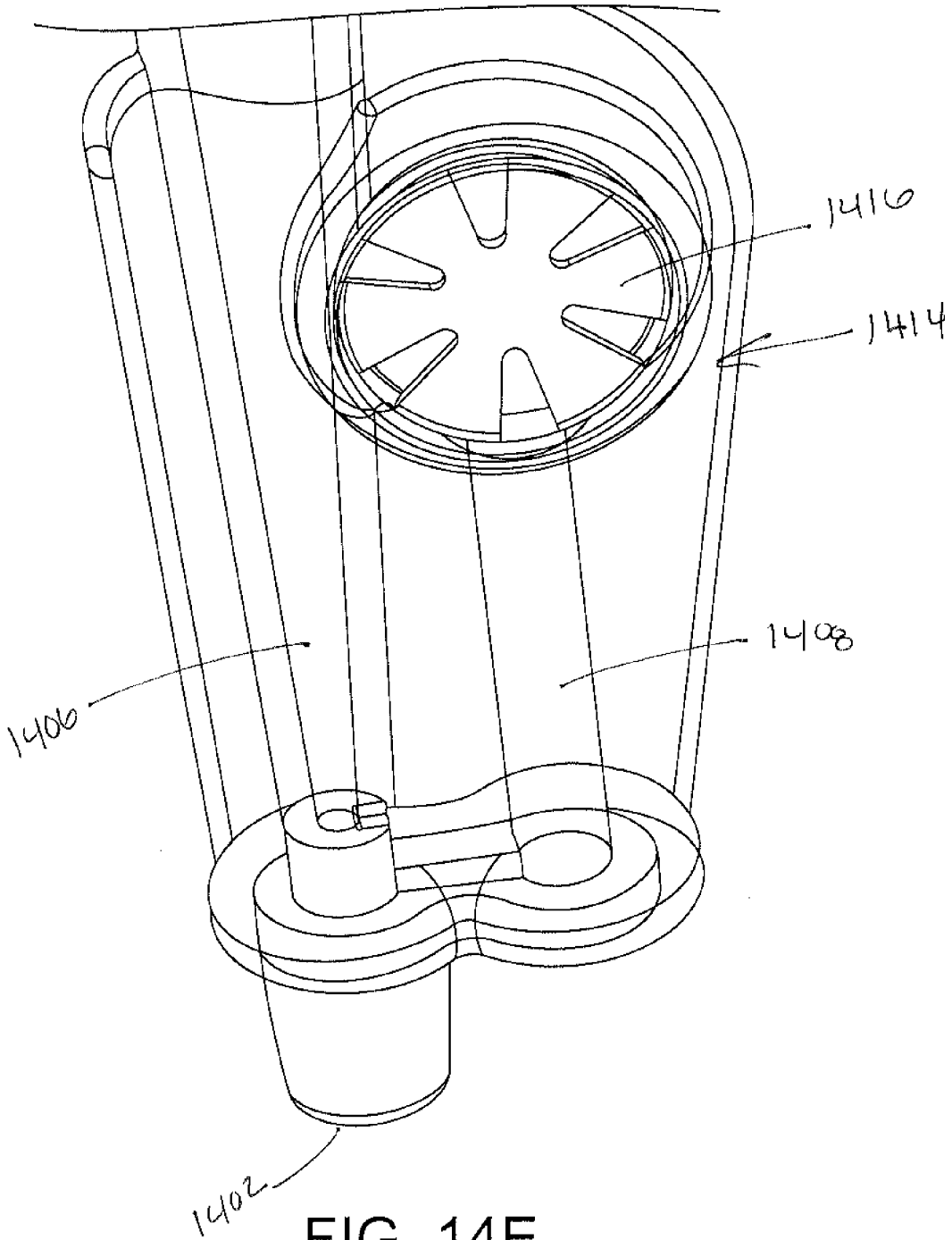


FIG. 14E

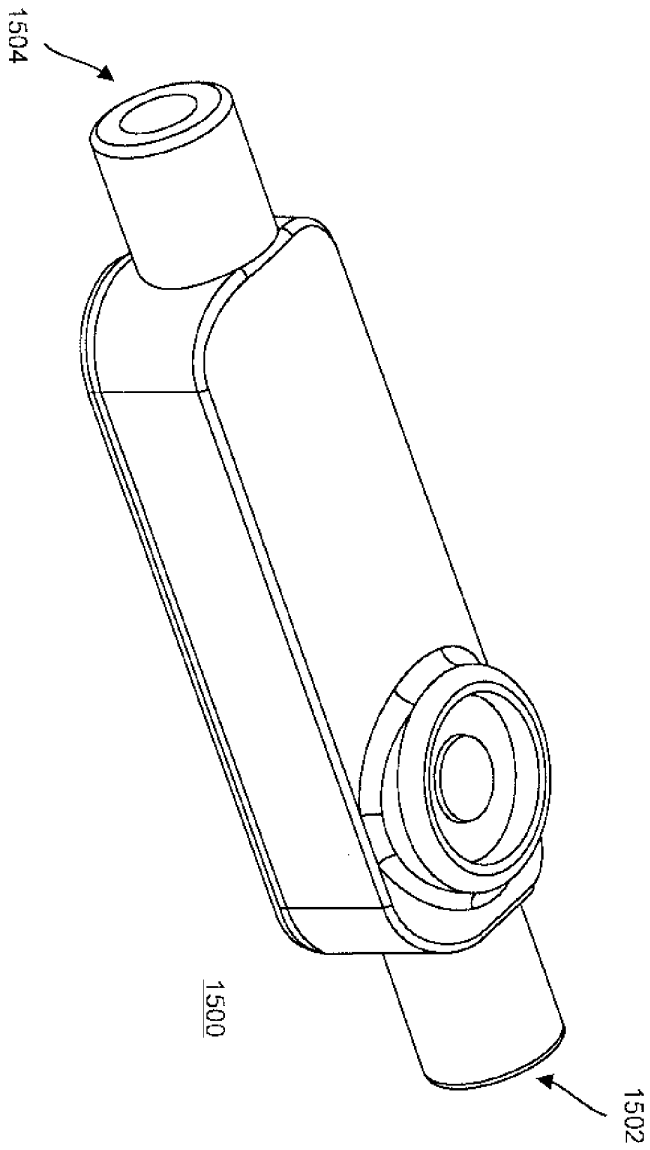


FIG. 15A

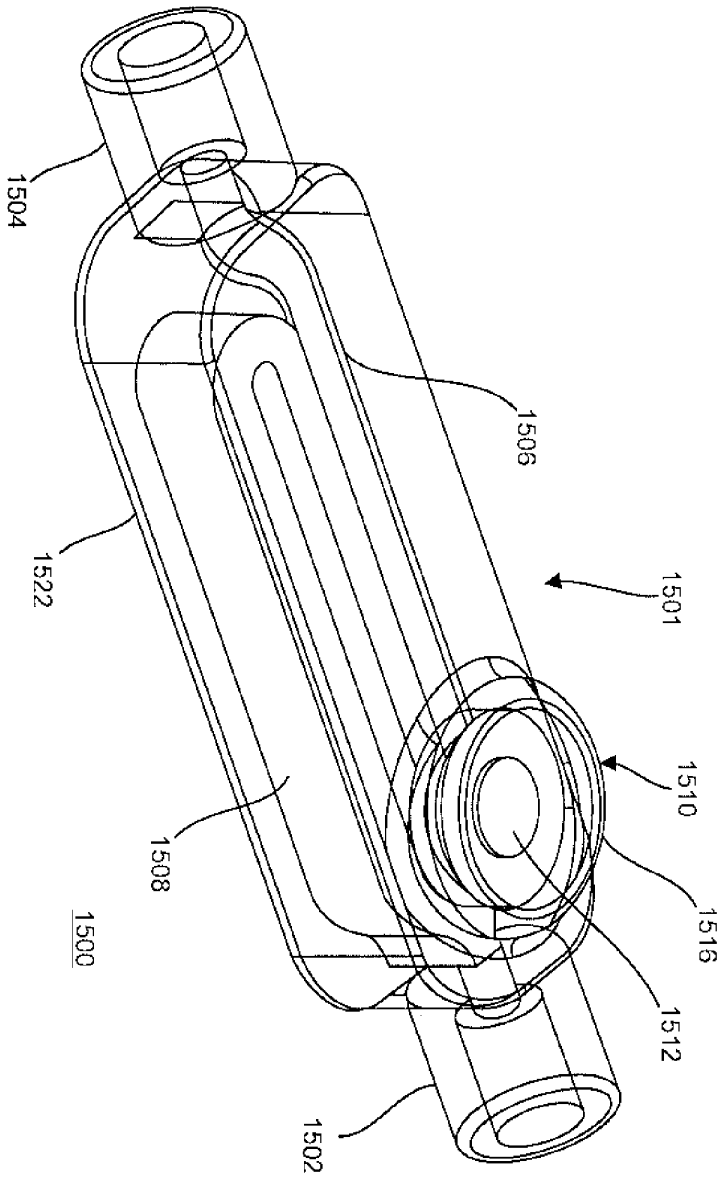


FIG. 15B

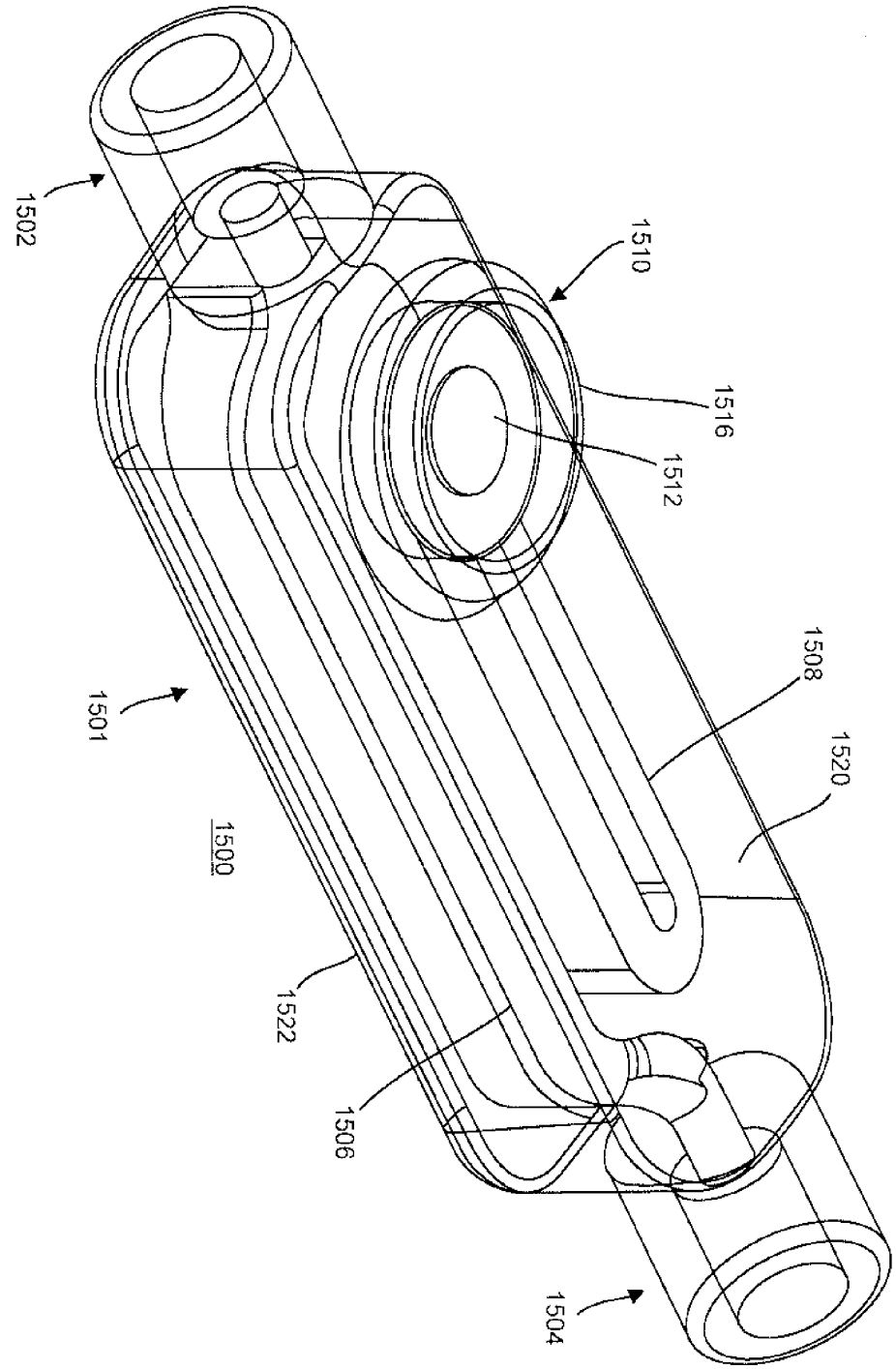


FIG. 15C

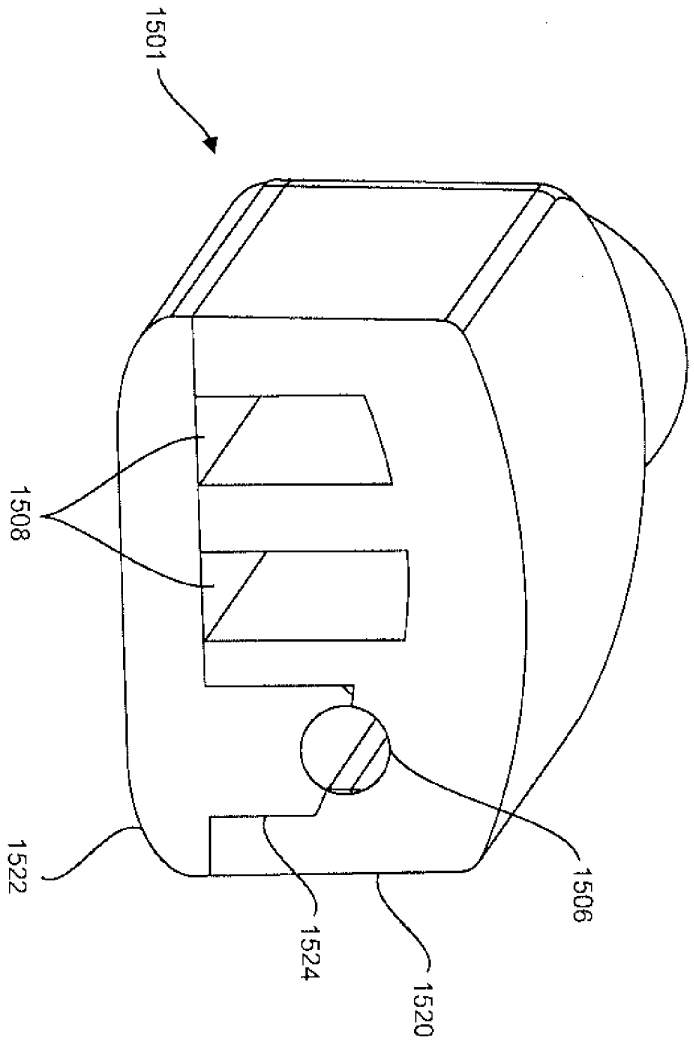


FIG. 15D

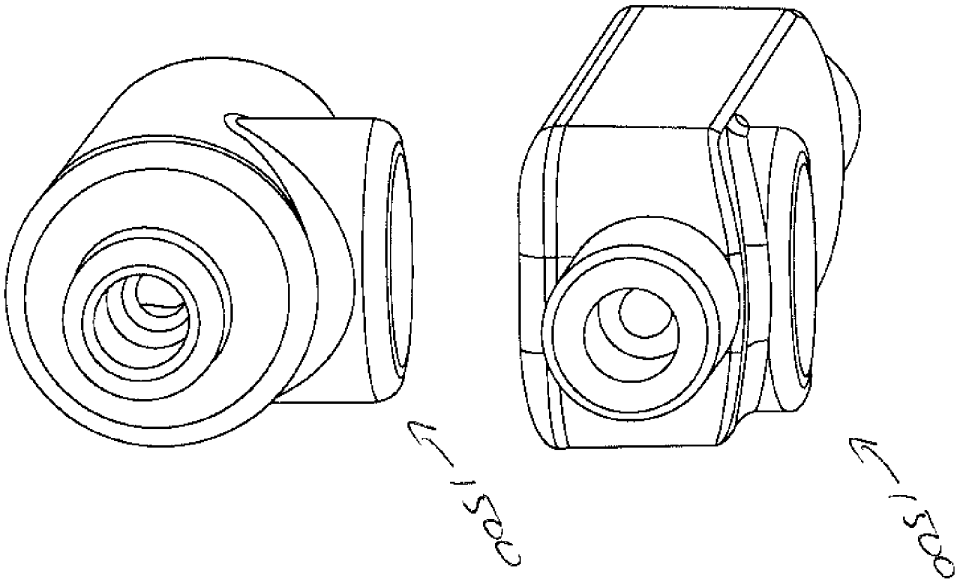


FIG. 15E

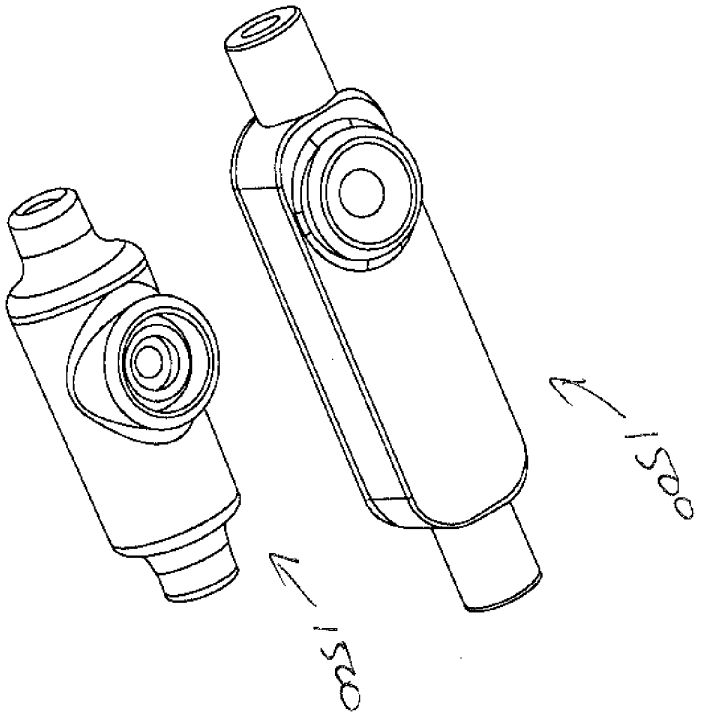


FIG. 15F

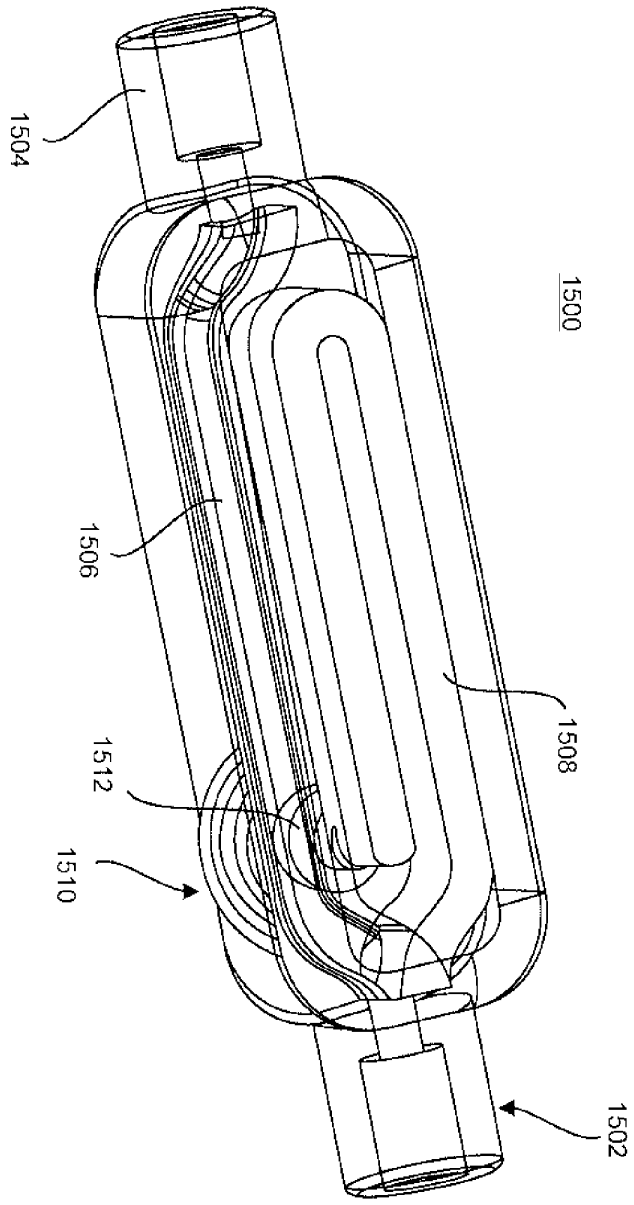


FIG. 15G

FIG. 16B

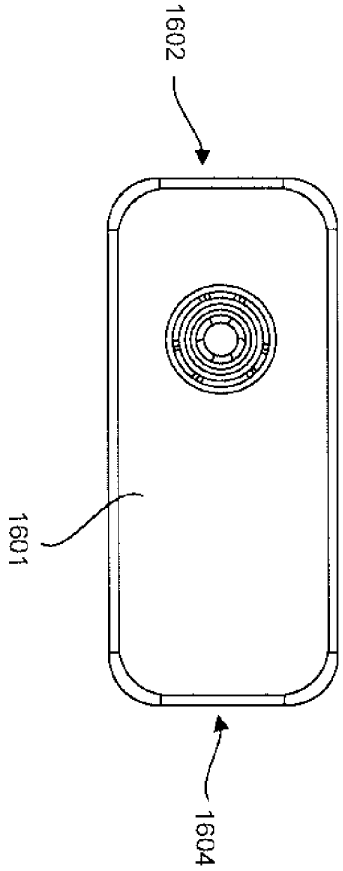


FIG. 16A

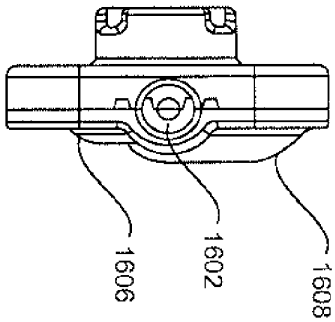


FIG. 16C

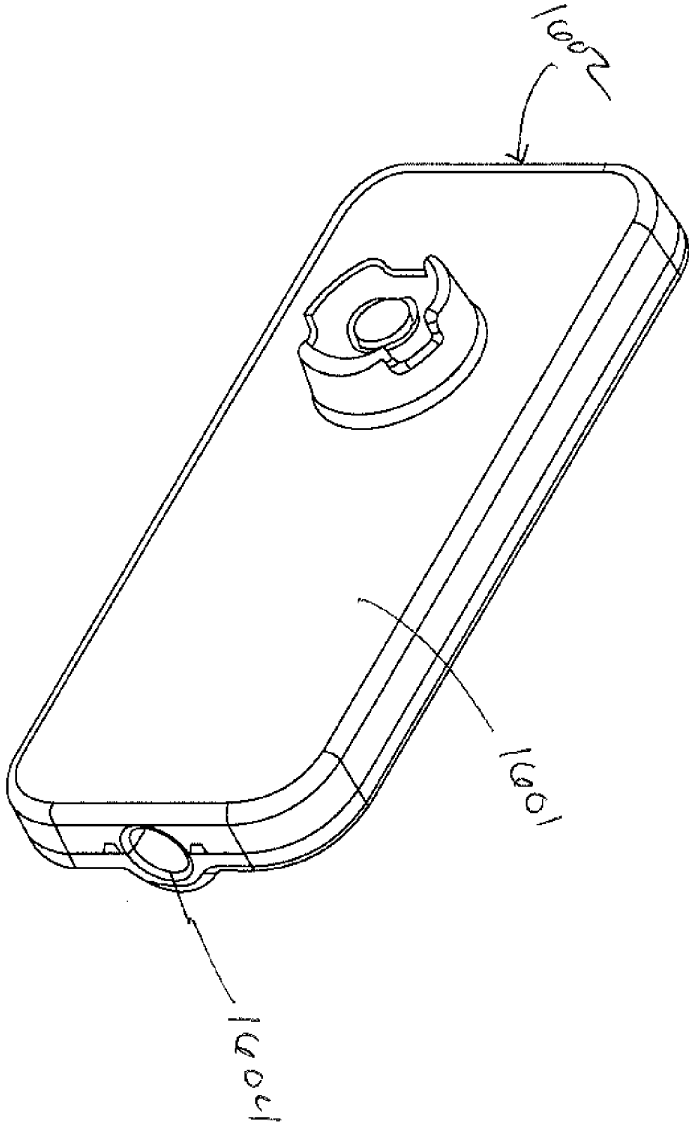


FIG. 16D

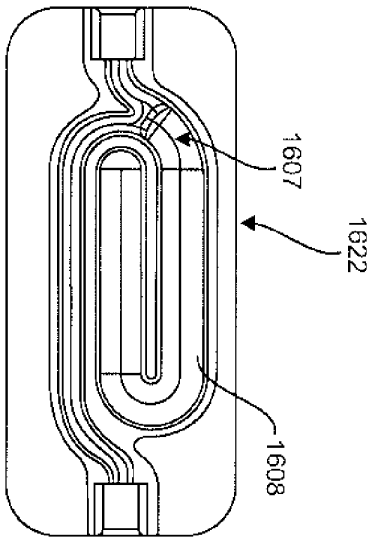


FIG. 17A

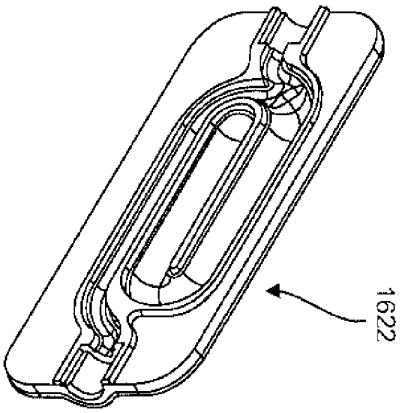


FIG. 17B

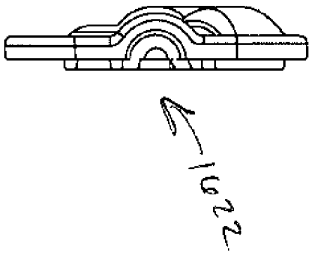


FIG. 17C

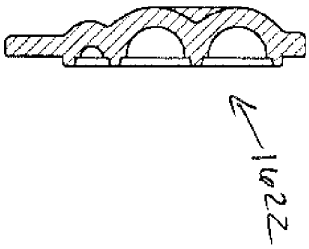


FIG. 17D

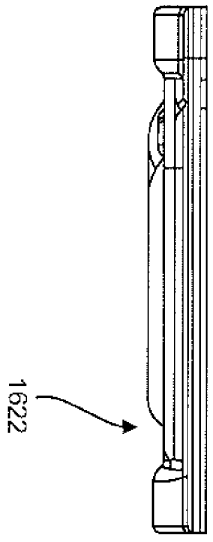


FIG. 17E

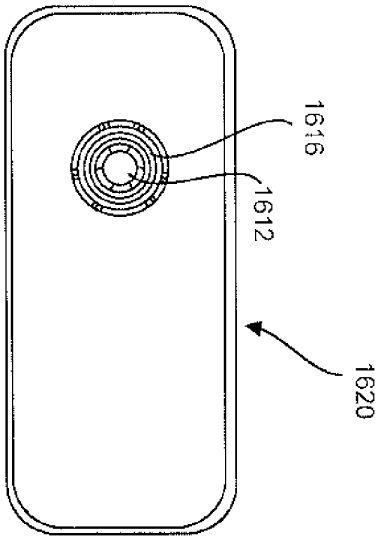


FIG. 18A

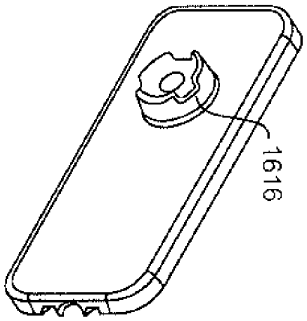


FIG. 18B

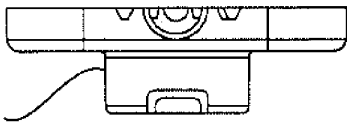


FIG. 18C

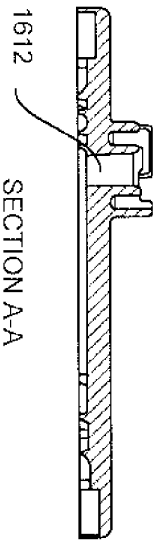


FIG. 18D

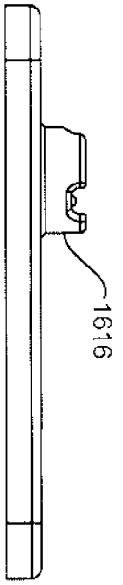


FIG. 18E

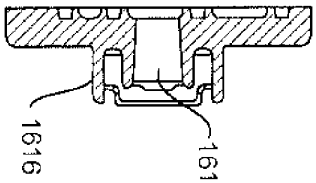


FIG. 18F

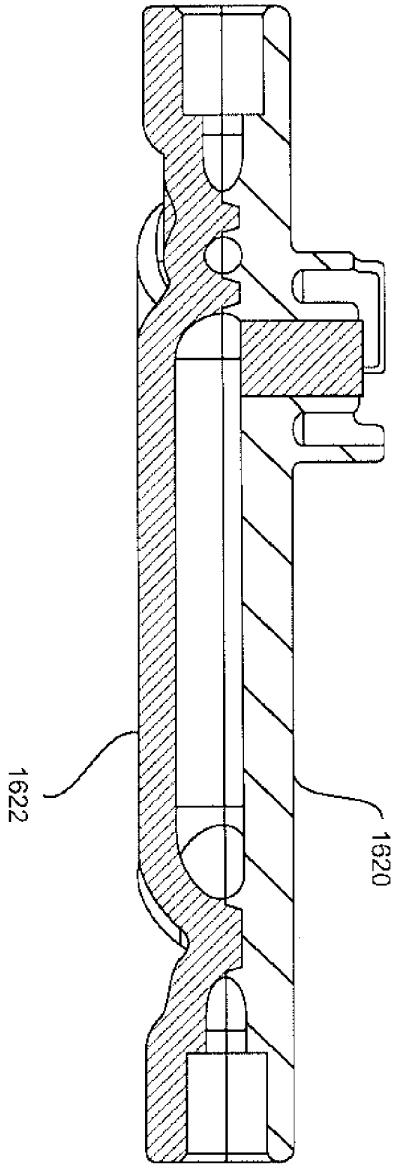


FIG. 19A

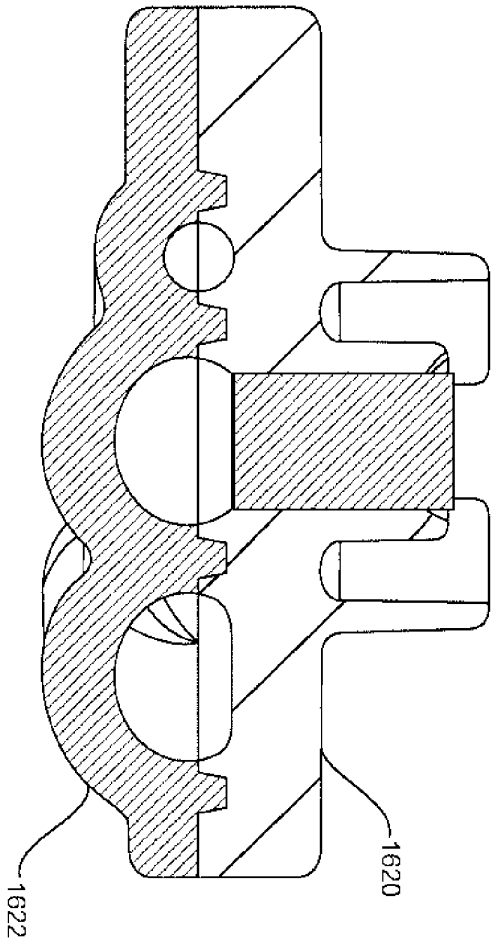


FIG. 19B

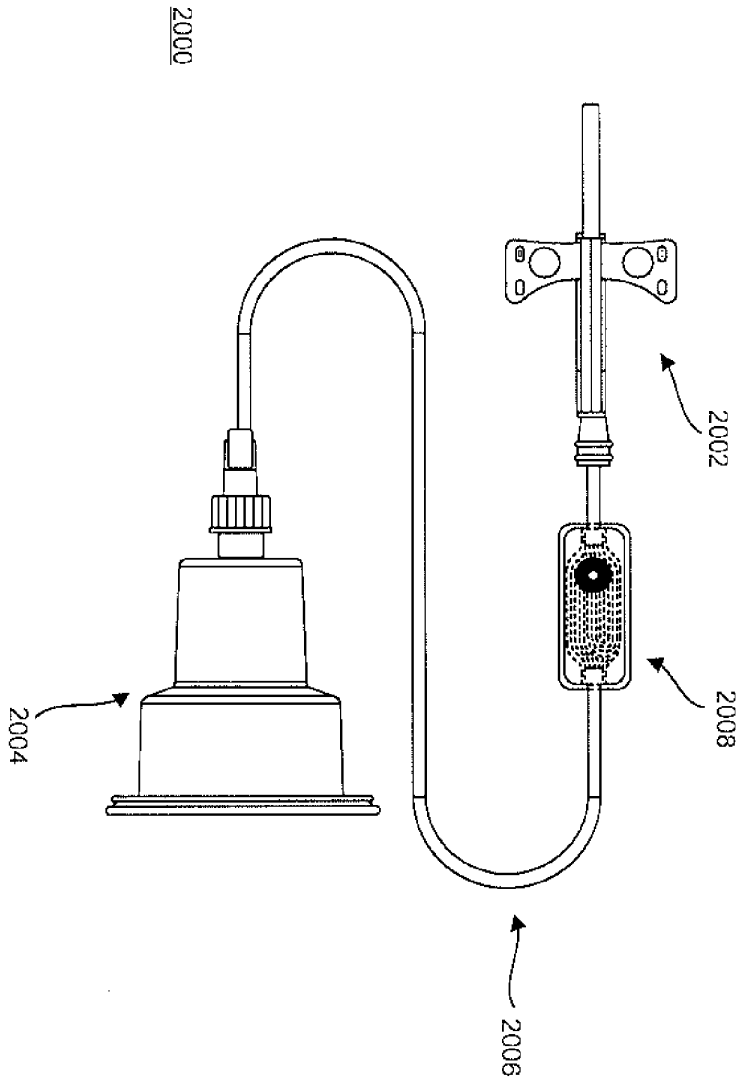


FIG. 20

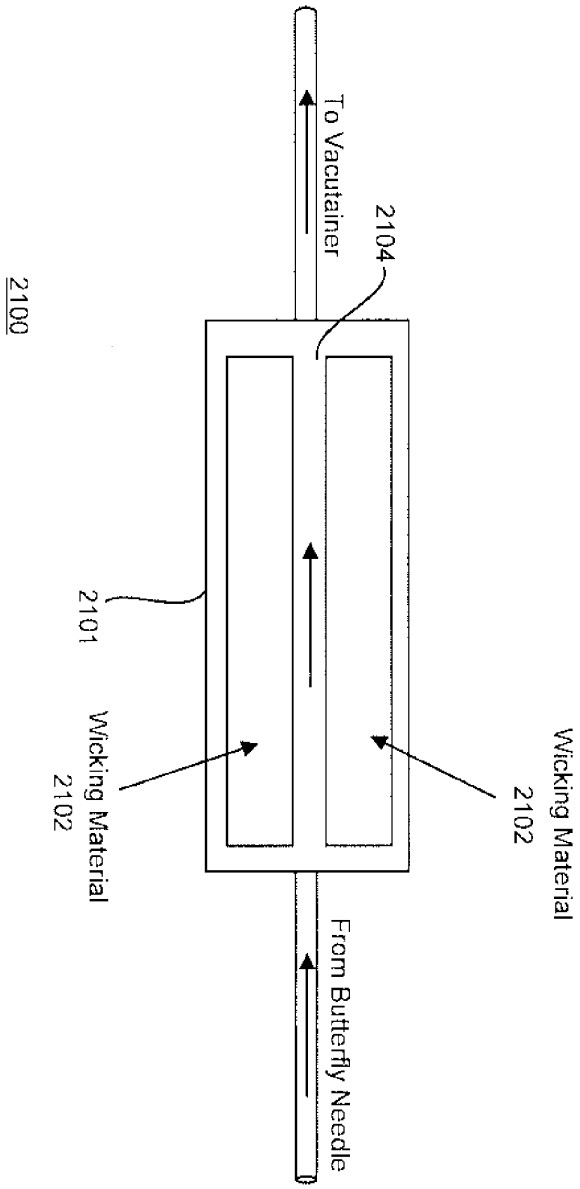

2100
To Vacutainer
2104
2101
Wicking Material
2102
Wicking Material
2102
From Butterfly Needle

FIG. 21

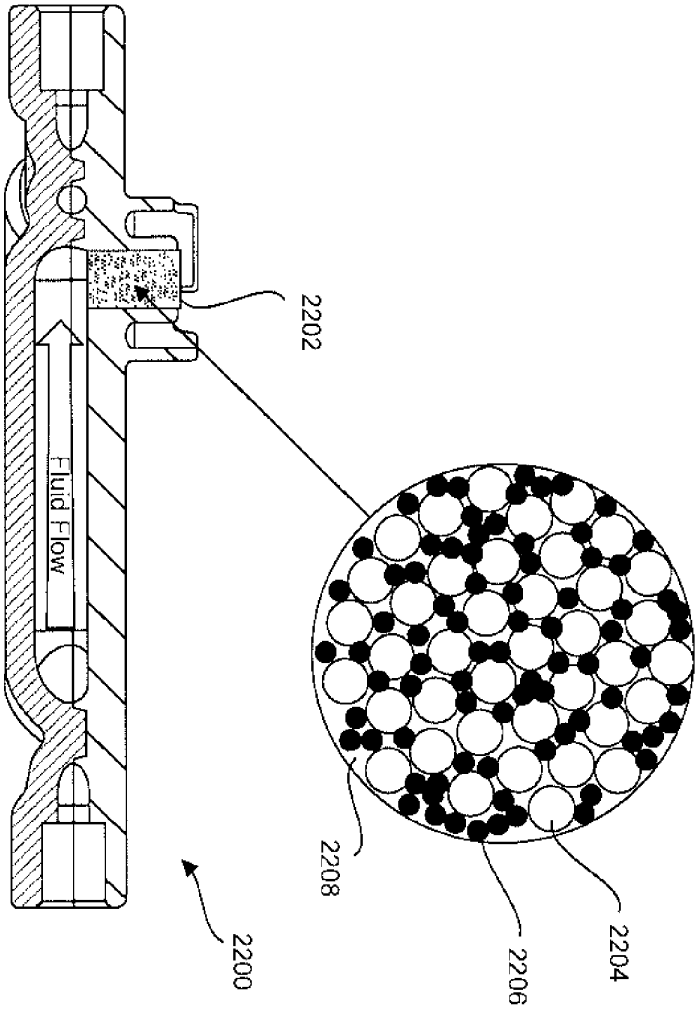


FIG. 22A

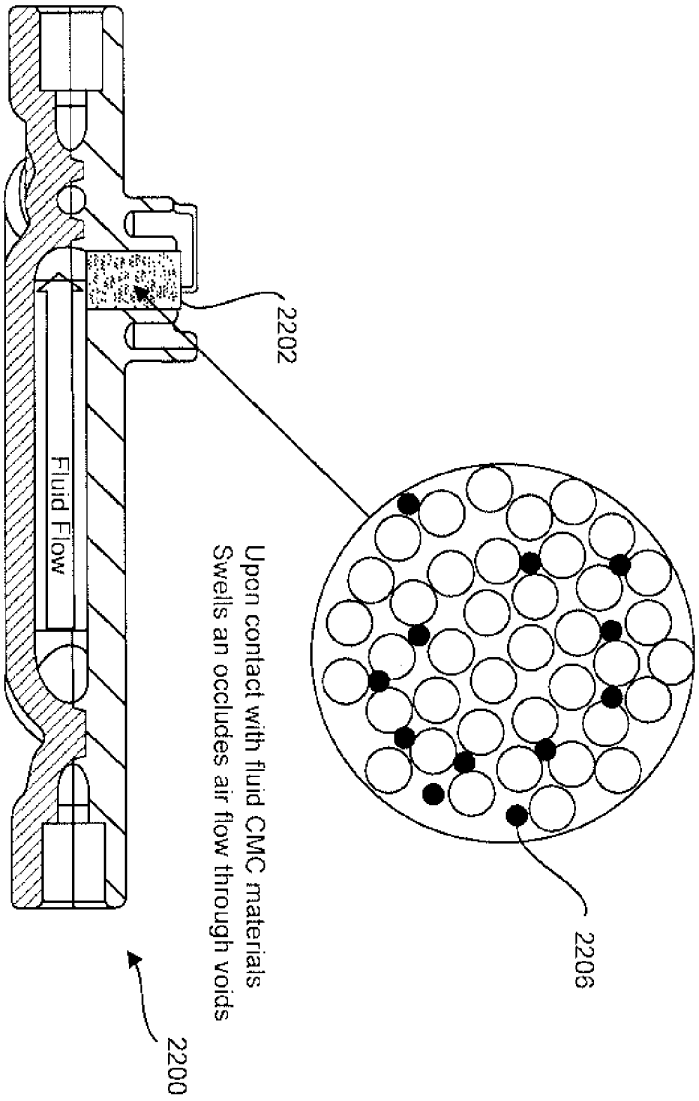

2202
Fluid Flow
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
2206
2200

FIG. 22B

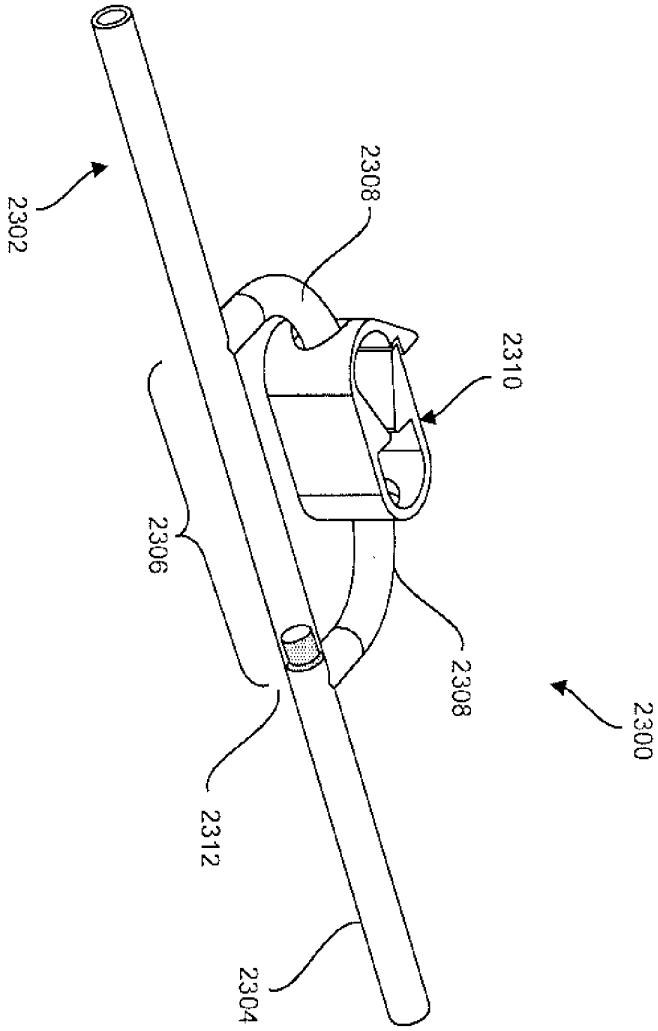


FIG. 23A

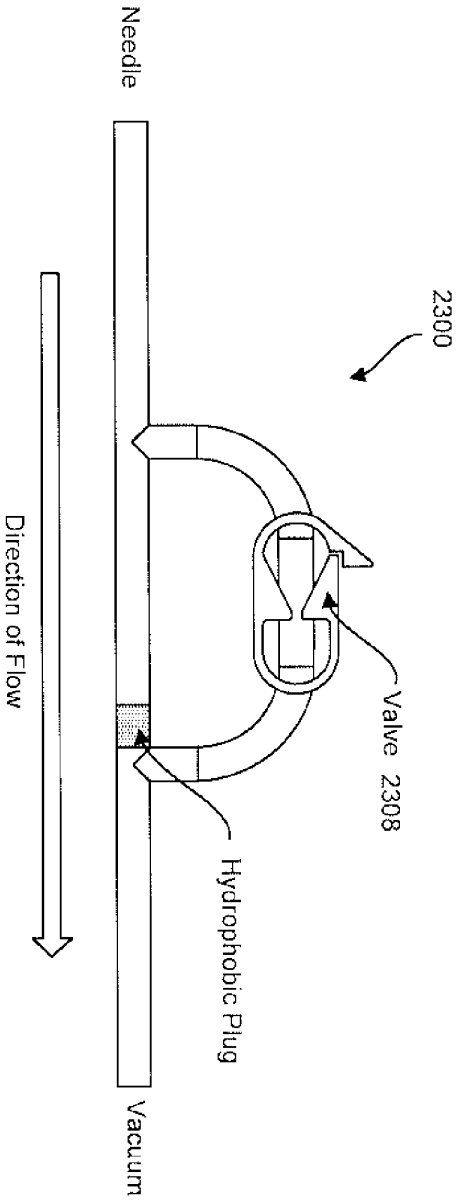

Needle
2300
Valve 2308
Hydrophobic Plug
Vacuum
Direction of Flow

FIG. 23B

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715

27500 7590 08/25/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
08/25/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/113,710	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 08/09/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-13 and 16-31 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☑ Claim(s) 17-31 is/are allowed.

7) ☑ Claim(s) 1-13 and 16 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/09/2023, and 05/10/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1, 5, 8-13 and 16 is/are rejected under 35 U.S.C. 102(1)(a) as being anticipated by Christensen et al (US 20100057004).

As to claim 1, Christensen discloses a device comprising:

an inlet port (catheter 14 and the frontal inlet port of device 10 where catheter 14 is connected/inserted therein, par.41-43 and par.47, fig.1-4);

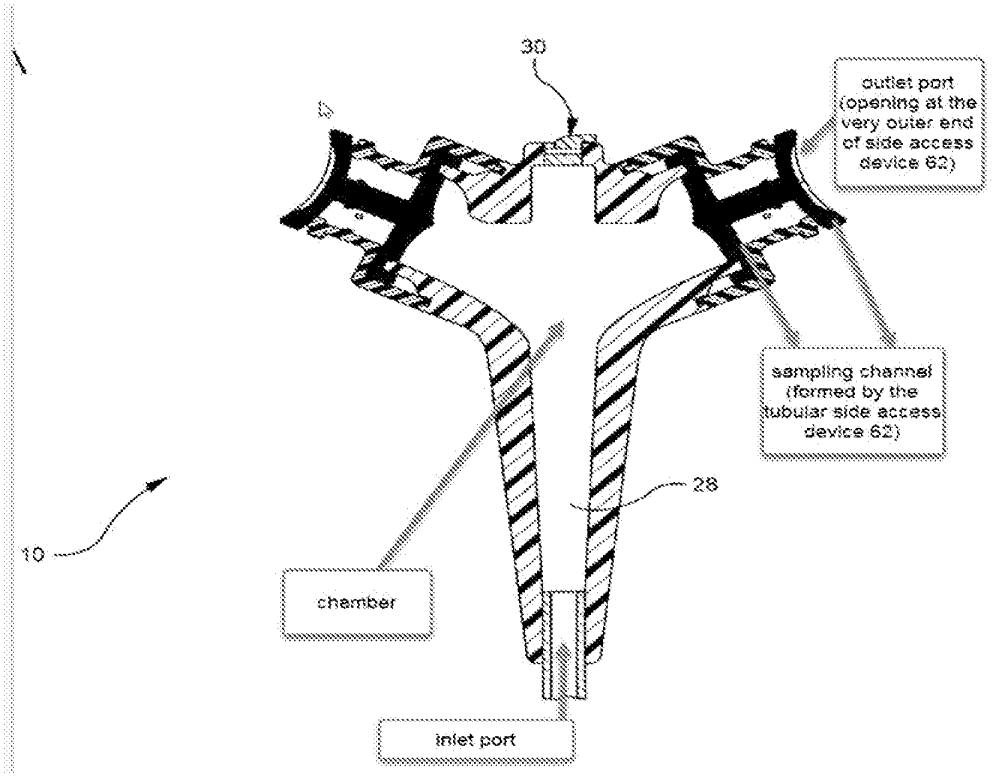
an outlet port (outlet opening at the very outer end of side access device 62 of device 10 where tube 16 is connected to and/or outlet port at the end of tube 16 connected to Y-adapter 18, par.41-43, par.53, fig.1-5);

a chamber (a fluid path 28 filling the interior of the extravascular system 10, par.47, fig.1-4) connected with the inlet port (fluid path 28 within the interior of device 10 is connected to catheter 14 and the frontal inlet port of device 10, fig.1-5) and configured to receive a first portion of blood (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into the system 10 to confirm that the needle 12 is properly located within the vasculature of the patient, par.7, par.42, and blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43)(The Examiner respectfully notes that flashback of blood, is considered the initial portion of blood),

the chamber including an air permeable material (venting material in vent 30, par.48-50, a removable filter plug 50 and a re-seal elastomer 52 in vent 30, par.51-53, or 114 that expands when exposed to liquid from bath 28, and thus seals the vent, par.71-72, fig.1-16, and/or curing material 108 of the vent 30 described with reference to FIGS. 13 and 14 provides a vent capable of venting gas from the system 10 without permitting the escape of liquid after the liquid has come into contact with the material 108, par.69, a porous membrane 110, par.70) that seals at least partially upon contact with a portion of the first portion of blood (par.48-53); and

a sampling channel (tubular channel formed by side access device 62 of device 10 and integrated extension tube 16, par.41-42, fig.1-6) having a proximal end connected with

the inlet port and a distal end connected with the outlet port (tubular channel formed by side access device 62 of device 10 having proximal end connected to frontal inlet port of device 10 at catheter 14, and having a distal end connected to the outlet opening at the very outer end of side access device 62 of device 10, as best seen in fig.1-6)(Examiner respectfully notes that since blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43, so tubular channel formed by side access device 62 is configured to sample and convey blood to tubing 16).



As to claim 5, Christensen discloses the device, wherein the air permeable material is located at a distal end of the chamber (a vent may be placed at or near the start of the fluid path, or the vent may be placed at any point in between the start or end of the fluid path of the extravascular system, par.45, as best seen in fig.1-3).

As to claim 8, Christensen discloses the device, wherein the air permeable material is a hydrophilic membrane (vent 30 includes an expandable vent material 114 that is hydrophilic, par.71, fig.16).

As to claim 9, Christensen discloses the device, wherein the sampling channel further comprises a valve configured to close off the sampling channel (side clamp 20, par.41, slide clamp 20 on the integrated extension tubing 16 is provided to eliminate blood exposure when the vent plug 22 is replaced with another vascular access device, par.42, fig.1).

As to claim 10, Christensen discloses the device, wherein the valve is a clip (clamp 20, par.41, fig.1)

As to claim 11, Christensen discloses the device, further comprising a junction configured to direct an initial blood flow into the chamber (the longitudinal shape at the beginning of fluid path 28 formed in the interior of device 10 forces the flashback blood to enter the interior of device 10, par.43-48, and/or vent 30, vent 30 may be placed at or near the terminus of the system 10 in order to allow fluid, including gas, blood, saline,

and water, to fill the internal chamber of the fluid path directly adjacent any vascular access devices of the system 10, par.51-52, fig.1-6).

As to claim 12, Christensen discloses the device, further comprising a junction configured such that flow out of the inlet port is preferentially directed toward the chamber (the longitudinal shape at the beginning of fluid path 28 formed in the interior of device 10 forces the flashback blood to enter the interior of device 10, par.43-48, and/or vent 30, vent 30 may be placed at or near the terminus of the system 10 in order to allow fluid, including gas, blood, saline, and water, to fill the internal chamber of the fluid path directly adjacent any vascular access devices of the system 10, par.51-52, fig.1-6).

As to claim 13, Christensen discloses the device, wherein the chamber has a larger cross-sectional area than the sampling channel (the cross-sectional area of fluid path 28 of the interior of device 10 is larger than the side tubular channel and tube 16, as best seen in fig.1-3).

As to claim 16, Christensen discloses the device, further comprising a patient needle (needle 12, par.41-43, fig.1) and a sample collection device (Luer access device or port 24, par.41)(Examiner respectfully notes that the luer access device is a device that is connected to obtain blood sample in a sampling container, see link: https://www.medline.com/product/Blood-Transfer-and-Luer-Lock-Access-Device/Z05-PF253812#:~:text=Luer%20lock%20access%20devices%20%28LLAD%20and%20AC

SD%29%20are,reduce%20the%20risk%20of%20transfer-

related%20injuries%20and%20infections).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-4, 6 and 7 is/are rejected under 35 U.S.C. 103 as being obvious over Christensen et al (US 20100057004), in view of Weilbacher et al (US 2008/0167577).

As to claims 2-4, 6 and 7, Christensen discloses the device, wherein the device is further configured such that an initial aliquot of blood will contact the air permeable material and back up into the chamber (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into the system 10 to confirm that the needle 12 is properly located within the vasculature of the patient. The blood travels into and along the catheter 14 and extension tubing The fluid path 28 is in communication with a vent 30, and the vent 30 is capable of venting gas from the fluid path 28 of the system 10, par.47 and par.53), wherein the device is further configured such that follow-on amounts of blood will flow through the sampling channel towards the outlet port (blood travels into and along the catheter 14 and extension tubing 16

because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43).

Christensen discloses the invention substantially as above, but failed to explicitly teach wherein the device is configured such that, when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber, and wherein the air permeable material is a hydrophobic plug/membrane.

However Weilbacher discloses an analogous vascular access needle assembly (abstract, fig.1-3), when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber (collection tube 17 is maintained at a vacuum such that when distal needle portion 20 is properly positioned in a vein 38 of a patient and collection tube 17 is positioned within cavity 34 OF BODY 30, blood will flow through needle 10 into blood collection tube 17, par.33, fig.1)(the Examiner respectfully notes the vacuum applies blood drawing force), and wherein the air permeable material is a hydrophobic plug/membrane (filter material 116 disposed in chamber 112, wherein material includes a hydrophobic material. In an alternate embodiment, the material includes a hydrophilic wicking material. In yet another embodiment, the material includes a hydrophobic plug, par.11 and par.35, fig.2).

As these types of blood drawing force are well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to maintain blood collection devices and/or luer accesses devices connected to port 24 taught by Christensen's invention under vacuum, as tube 17 taught by

Weilbacher's invention, to facilitated blood sampling and prevent unwanted blood exposure/spilling, as taught by Weilbacher's invention (par.33).

Still, as the hydrophobic air permeable filter/material are well known in the art to vent air, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to substitute the hydrophilic material taught by Christensen's invention, with the hydrophobic material taught by Weilbacher's invention, for the same reason of venting air from sampling chamber, as taught by Weilbacher's invention (par.11 and par.35-36).

Allowable Subject Matter

5. Claims 17-31 are allowed.

6. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Christensen et al (US 2010/0057004) teaches a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable.

The prior art does not teach, disclose and/or fairly suggest a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

7. Applicant's arguments claim objections/rejections and double patenting have been fully considered and are persuasive. The claim objections/rejections and double patenting have been withdrawn.

8. Applicant's arguments regarding Christensen's invention does not teach the claimed subject matter "an air permeable material that seals at least partially upon contact with a portion of the first portion of blood" in claim 1 have been fully considered but they are not persuasive, because Christensen's invention explicitly teaches hydrophilic air permeable material 114 that allows air to pass through vent 30, and then expands when exposed to liquid from fluid path 28, and thus seals the vent (par.71-72), similarly materials 108 and 110, par.69-70.

So, Christensen's invention explicitly teaches the claimed subject matter "an air permeable material that seals at least partially upon contact with a portion of the first portion of blood" in claim 1.

9. Still, regarding the Applicant's arguments that Christensen's invention does not teach "a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port" in claim 1 because Christensen's invention is not taking samples. Instead Christensen's invention is used for infusion therapy (see arguments page 5) have been fully considered but are not persuasive, because claim 1 broadly claims "A device comprising" in the preamble, and does not claim a blood sampling/collecting device. Under the broadest reasonable interpretation the claimed

subject matter "sampling channel" may be interpreted as sampling any type of tissue, fluid and/or infusion agents, and does not necessarily means sampling blood.

Device 10 taught by Christensen's invention comprises a fluid path 28 filling the interior of the extravascular system 10 (par.47) configured to receive a portion of blood (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into fluid path 28 to confirm that the needle 12 is properly located within the vasculature of the patient (par.7, par.42), and blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10 (par.43).

Examiner respectfully notes that since blood travels into and along the catheter 14 and extension tubing 16, so tubular channel formed by side access device 62 is configured to sample and convey blood to tubing 16.

So, it can be fairly interpreted that the tubular channel is a sampling channel that samples blood to and from tubing 16, as claimed in claim 1.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure Burkholz et al (US 20120/016266).

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/113,710	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
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*	B	US-20160262677-A1	09-2016	EBETSBERGER; Franz	A61B5/150251	1/1
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4416291		1983-11-22	KAUFMAN JOSEPH	

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-08-09
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

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	2	Pall Medical, "Leukotrap Filtration Systems for Whole Blood Derived Platelets, Leukotrap RC PL and Leukotrap PL Systems" literature, (2005) 8 pages.	
	3	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, Vol. 39, No. 3., pp. 321-323, March 1963.	
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	5	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	
	6	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	
	7	European Patent Office; Communication pursuant to Article 94(3) EPC; dated Oct. 31, 2018; 11 pages.	
	8	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	
	9	International Search Report and Written Opinion dated Jun. 19, 2020, for PCT application No. PCTUS2020/023617. 12 pages.	
	10	European Patent Office, International Search Report and Written Opinion for PCT/US16/43709, dated Oct. 19, 2016, 14 pages.	
	11	International Search Report/Written Opinion for PCT/US17/68569 dated Apr. 25, 2018. 9 pages.	
	12	European Patent Office, International Search Report/Written Opinion for PCT/US17/068569 dated Apr. 25, 2018, 9 pages.	
	13	International Search Report and Written Opinion for PCT/US16/43709, Dated October 19,2016. 13 pages.	
	14	Retractable Techs., Inc. v. Becton Dickinson & Co., CA No. 2:07-CV-250, Claim Construction Order (E.D. Tex., Jan. 20, 2009). 20 pages.	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18113710
	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

	16	De Korte, Dirk, et al. "Diversion of first blood volume results in a reduction of bacterial contamination for whole-blood collections." Vox sanguinis 83.1 (2002): 13-16.	
	17	Brecher, Mark E., et al. "Bacterial contamination of blood components." Clinical microbiology reviews 18.1 (2005): 195-204.	
	18	Van Zundert, Adrien. "New closed IV catheter system." Acta Anæsthesiologica Belgica 56.3 (2005): 283-285.	
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	22	Abbott Point of Care, Cartridge and Test Information, Art: 714258-01O; Rev. Date: 15-Aug-16, 1-6 pages.	
	23	Zimmon, David S. et al. "Effect of portal venous blood flow diversion on portal pressure." The Journal of Clinical Investigation 65.6 (1980): 1388-1397.	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18113710
	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

	27	Gottlieb, T. "Hazards of bacterial contamination of blood products." Anaesthesia and intensive care 21.1 (1993): 20-23.	
	28	Norberg, Alonna, et al. "Contamination rates of blood cultures obtained by dedicated phlebotomy vs intravenous catheter." Jama 289.6 (2003): 726-729.	
	29	Quilici, Nathalie, et al. "Differential quantitative blood cultures in the diagnosis of catheter-related sepsis in intensive care units." Clinical infectious diseases 25.5 (1997): 1066-1070.	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18113710
	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18113710
	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	08/22/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Application Number	18113710
	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18/783,088
	Filing Date	07/24/2024
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Client Number	069366
Page 1 of 1	**Matter Number**	0580418_KUR2C06US

GENERAL

Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention, nor is it intended to constitute an admission that such information is "analogous prior art".

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING

In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

FEE

No fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

ADDITIONAL COMMENTS

SIGNATURE

Signature	/Benjamin F. Hudson/	**Date**	2024-08-26
Name	Benjamin F. Hudson	**Registration Number**	71,474

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membrane

Entries 1 to 10 of 15. Next 5

On Off

membrane
basement membrane
basilar membrane
cell membrane

Main Entry: **mem·brane**
Pronunciation: \'mem-ˌbrān\
Function: *noun*
Etymology: Middle English, from Latin *membrana* skin, parchment, from *membrum*
Date: 15th century

1 : a thin soft pliable sheet or layer especially of animal or plant origin
2 : a piece of parchment forming part of a roll
— mem·braned \'mem-ˌbrānd\ *adjective*

Learn more about "membrane" and related topics at Britannica.com

See a map of "membrane" in the Visual Thesaurus

Pronunciation Symbols

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/838,017	04/01/2020	Bobby E. ROGERS	069366-0572158_KUR7001US	1044

27500 7590 02/09/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
PORTILLO, JAIRO H	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
02/09/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 16/838,017	**Applicant(s)** ROGERS et al.	
	Examiner JAIRO H PORTILLO	**Art Unit** 3791	**AIA (FITF) Status** Yes

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 February 2024 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☑ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires ____ months from the mailing date of the final rejection.
   b) ☑ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection.The current period for reply expires ____ months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☑ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☑ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☑ For purposes of appeal, the proposed amendment(s):(a) ☑ will not be entered, or (b) ☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☑ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☑ Other: PTO2323, PTO892.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed:_____.
    Claim(s) objected to:_____.
    Claim(s) rejected:1-4,6-9,14 and 16-18.
    Claim(s) withdrawn from consideration:_____.

/J.H.P/ Examiner, Art Unit 3791	/KAYLEE R WILSON/ Primary Examiner, Art Unit 3791

Continuation of 3, 7, and 12. NOTE: Applicant's amendments and arguments, filed 2/1/2024 have been fully considered and are persuasive over the currently cited art. However further search and consideration are required to make a determination on allowability. Examiner will note a newly found reference of Bullington et al (US 2019/0365303) has relevant subject matter in Figs. 9-14 specific to the new claim amendment and Bullington invention is also a device for optimizing a fluid sample with highly relevant subject matter.

Notice of References Cited	Application/Control No. 16/838,017	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner JAIRO H PORTILLO	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20190365303-A1	2019-12-05	BULLINGTON; Gregory J.	A61B5/150213	1/1
	B					
	C					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
	N					
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	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in YYYY-MM-DD format are publication dates. Classifications may be US or foreign.

AFCP 2.0 Decision	Application No.	Applicant(s)	
	16/838,017	ROGERS et al.	
	Examiner	Art Unit	AIA (FITF) Status
	JAIRO H PORTILLO	3791	Yes

This is in response to the After Final Consideration Pilot request filed 01 February 2024.

1. **Improper Request** – The AFCP 2.0 request is improper for the following reason(s) and the after final amendment submitted with the request will be treated under pre-pilot procedure.

   ☐ An AFCP 2.0 request form PTO/SB/434 (or equivalent document) was not submitted.

   ☐ A non-broadening amendment to at least one independent claim was not submitted.

   ☐ The request is not the first proper AFCP 2.0 request submitted in response to the most recent final rejection.

   ☐ Other: _____

2. **Proper Request**

   A. After final amendment submitted with the request will not be treated under AFCP 2.0.
   The after final amendment cannot be reviewed and a search conducted within the guidelines of the pilot program.

   ☑ The after final amendment will be treated under pre-pilot procedure.

   B. Updated search and/or completed additional consideration.
   The examiner performed an updated search and/or completed additional consideration of the after final amendment within the time authorized for the pilot program. The result(s) of the updated search and/or completed additional consideration are:

   ☐ 1. All of the rejections in the most recent final Office action are overcome and a Notice of Allowance is issued herewith.

   ☐ 2. The after final amendment would not overcome all of the rejections in the most recent final Office action . See attached interview summary for further details.

   ☐ 3. The after final amendment was reviewed, and it raises a new issue(s). See attached interview summary for further details.

   ☐ 4. The after final amendment raises new issues, but would overcome all of the rejections in the most recent final Office action. A decision on determining allowability could not be made within the guidelines of the pilot. See attached interview summary for further details, including any newly discovered prior art.

   ☐ 5. Other: _____

   Examiner Note: Please attach an interview summary when necessary as described above.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al. **Confirmation No:** 1044

Application No.: 16/838,017 **Art Unit:** 3791

Filed: April 1, 2020 **Examiner:** Jairo H. Portillo

For: Non-Venting Bodily Fluid Sample Optimization Device And System

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO FINAL OFFICE ACTION

Dear Examiner Portillo:

This reply is responsive to the Final Office Action mailed January 29, 2024, in the above-referenced matter (hereinafter "the Office Action"). Reconsideration and allowance of the application is requested in view of the following:

Listing of Claims beginning on page 2.

Remarks beginning on page 8.

DO NOT ENTER: /J.H.P/

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Carroll, Christopher P.
Burns & Levinson London LLP
4-12 Regent Street, 4th Floor
London SW1Y 4PE
ROYAUME UNI

Date
22.04.2024

Reference	Application No./Patent No.
KUR-008EP1	21818838.1 - 1122 / 4158303 PCT/US2021035294
Applicant/Proprietor	
Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the supplementary European search report (Art. 153(7) EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

Refund of the search fee
If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued shortly (R. 70(2) EPC).

Europäisches Patentamt • European Patent Office • Office européen des brevets

The examination is being carried out on the **following application documents**

Description, Pages

1-49 as published

Claims, Numbers

1-15 filed in electronic form on 01-09-2023

Drawings, Sheets

1/81-81/81 as published

Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

D1 WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05)

D2 WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21)

1. The amendments filed with the letter dated 01-09-2023 introduce subject-matter which extend beyond the content of the application as filed, contrary to Article 123(2) EPC. The amendments concerned are the following:

- removal of the features "**a displaceable plug between the inlet and the sample path that is displaced by the subsequent pressure differentials to allow the subsequent portions of the fluid to be conveyed through the sample path**" in claim 1.

Indeed these features appear to be described as essential throughout the original description and figures (see also claim 6 of the original application and Guidelines H-V. 3.1). Furthermore no alternatives for theses features are presented in the application as originally filed.

The applicant is invited to indicate where the basis for claim 1 can be found in the original application as filed.

Further amendments appear to be contrary to Article 123(2) EPC:

- features "**wherein the displaceable plug (3119) is hollowed out towards the sample path (3118) or hollowed out away from the sample path (3118)**" in claim 10

- features "**wherein the device (3100) is configured to allow a free flow of fluid from the inlet (3112) to the sample path (3118) when the displaceable plug (3119) moves into a receptacle**" in claim 15

No basis for these amendments could be found in the original application.

The applicant is invited to indicate where the basis for the dependent claims 10 and 15 as well as for the dependent claims 2-9 and 11-14 can be found in the original application as filed.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claim 1 is not new within the meaning of Article 54(1) and (2) EPC.

2.1 D1 discloses **a device** (see fig.11-14: 600;700) **comprising:**
an inlet (612);
an outlet (616);
a sample path (654;754) **connected between the inlet and the outlet;**
a chamber (614) **connected between the inlet and the outlet, the chamber having an air permeable fluid resistor** (615) **proximate the outlet** (see par.[0148]:"The flow controller 615 can be any suitable shape, size, and/or configuration and can be configured to selectively control, permit, allow, and/or transfer a flow of fluid therethrough. For example, as described above, the flow controller 615 can be a selectively permeable member configured to be selectively permeable to a gas (e.g., air) and substantially impermeable to a liquid (e.g., bodily fluid)."), **the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of a fluid sample to displace air therein through the air permeable fluid resistor and the outlet** (see par.[0158]:"Thus, when a negative pressure is generated within a portion of the device 700 (e.g., in response to coupling a fluid collection device to an outlet of the device 700), an initial volume of bodily fluid can flow into a sequestration chamber of the device 700 (e.g., a sequestration portion of the device 700, a sequestration flow path, a sequestration reservoir or container, etc.), as

described in detail above with reference to the device 600."), **with subsequent portions of the fluid sample conveyed by the sample path from the inlet to the outlet** (see par.[0160]:" Thus, a subsequent volume of bodily fluid that is substantially free of contaminants can flow through the device 700 and into the fluid collection device coupled thereto."); **and**
a displaceable plug (676;775) **which, when displaced, allows the subsequent portions of the fluid sample to be conveyed through the sample path.**

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

2.2 Furthermore, the document D2 also disclose all the features of claim 1. For further details, see the relevant parts thereof as cited in the Search Report.

3. The dependent claims 2 to 15 seem not to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC in respect of novelty and/or inventive step, defining either features already known from any of D1-D2 or straightforward possibilities from which the person skilled in the art would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

4. The applicant **should bring the description into conformity** with the claims on file (Article 84 EPC). In particular should features that are present in the independent claim(s) not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment" and so forth, but be clearly identified as forming part of the invention. **This applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. recitation of superseded claims be removed or adapted to the wording of the new claims. Please also note that no method is claimed.

5. To meet the requirements of Rule 42(1)(b) EPC, the documents D1 and D2 should be identified in the description and the relevant background art disclosed therein should be briefly discussed, observing that references to the prior art introduced after filing must be purely factual.

6. In order to meet the requirements of Rule 43(1) EPC, the independent claim should be properly cast in the two-part form, with those features which in combination are part of the prior art being placed in the preamble (see Guidelines F-IV, 2.2). Arguments in support of inventive step should be presented in an accompanying letter.

If the applicant is of the opinion that a two-part form of claim would be inappropriate he is invited to provide reasons in his reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of the independent claim are known from the prior art (see Guidelines F-IV, 2.3.2).

7. The features of the claims should be provided with **reference signs placed in parentheses** to increase the intelligibility of the claims (Rule 43(7) EPC). This applies to both the preamble and characterising portion (see Guidelines F-IV, 4.19).

8. The vague and imprecise statements (e.g. "any modifications", "spirit of the invention") used in the description at paragraphs [0065],[0194],[0212] imply that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity of the claims (Article 84 EPC) when used to interpret them (see the Guidelines, F-IV, 4.4). These statements should therefore be amended to remove this inconsistency.

9. "Incorporation by reference" is not an option in the European procedure; the description thus requires amendments in this respect at paragraph [0001].

10. The unit inch expressed in paragraphs [0095],[0101],[0117],[0158] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex 2). The present expression should, however, be retained in parentheses after the replacement expression.

11. Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage**, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).**

12. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 123(2) EPC, the applicant should **clearly identify the amendments made**, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (**see Guidelines H-IV**).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

13. Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Article 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

14. Amendments should be made by filing replacement pages. Unnecessary recasting of the description should be avoided. An amended abstract is not required. The applicant should also take account of the requirements of Rule 50(1) EPC. According to Rule 50(1) in conjunction with Rule 49(8) EPC, amendments shall be typed or printed. Handwritten amendments may only be made in documents other than those replacing application documents (Rule 50(2) EPC); they may, for example, be used to fulfil the requirements of Rule 137(4) EPC (identifying amendments and indicating basis for them).

15. In order to expedite the procedure, the applicant is requested to deal with all of the raised objections and to **perform all necessary amendments along with the first response to this communication**.

Information on Search Strategy

The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number

EP 21 81 8838

TITLE: FLUID OPTIMIZATION AND CONTAMINANT CONTAINMENT DEVICE AND METHOD USING DISPLACEABLE PLUG

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: G01N1/10, G01N1/02, A61B5/15, A61B5/00, A61M39/00, A61M39/06, B01L3/00, G01N1/18, A61B5/154

EXAMINER: Coja, Michael

CONSULTED DATABASES: EPODOC, WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150221, A61B5/150251

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

EPO FORM P04A42

Europäisches Patentamt
European Patent Office
Office européen des brevets

SUPPLEMENTARY EUROPEAN SEARCH REPORT

Application Number
EP 21 81 8838

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05) * the whole document *	1-15	INV. G01N1/10 G01N1/02 A61B5/15 A61B5/00 A61M39/00 A61M39/06 B01L3/00 G01N1/18 A61B5/154
X	WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21) * paragraph [1070] - paragraph [1092]; figures 2-5 *	1-15	
A	US 2017/020427 A1 (ROGERS BOBBY E [US] ET AL) 26 January 2017 (2017-01-26) * the whole document *	1-15	
A	US 2018/353117 A1 (BULLINGTON GREGORY J [US] ET AL) 13 December 2018 (2018-12-13) * the whole document *	1-15	
A	US 2019/175087 A1 (BULLINGTON GREGORY J [US] ET AL) 13 June 2019 (2019-06-13) * the whole document *	1-15	TECHNICAL FIELDS SEARCHED (IPC) A61B
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The supplementary search report has been based on the last set of claims valid and available at the start of the search.

Place of search	Date of completion of the search	Examiner
The Hague	10 April 2024	Coja, Michael

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C04)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 21 81 8838

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The members are as contained in the European Patent Office EDP file on
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10-04-2024

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 21 81 8838

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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EP 21 81 8838

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10-04-2024

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EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

Japanese Patent Application No. 2020-118498
Your Ref: KURIN2JP-DIV2
Our Ref: TS/KRN-C0137JP03
October 13, 2022

Translation of "Notice of Reasons for Rejection"

Patent Application Number:	JP 2020-118498	
Date of Delivery:	September 6, 2022	
Applied Provision:	Patent Law Article(s)	36(6)(ii) (Clarity)
		36(6)(i) (Support requirement)

The present application should be rejected for the following reasons. The applicant may present an argument against the reasons within three months from the date of delivery of this notice.

Reasons

1. (Clarity) The following claims do not comply with the requirements under Patent Law Article 36(6)(ii) as being unclear.

2. (Support requirement) The following claims do not comply with the requirements under Patent Law Article 36(6)(i) as lacking the support of the detailed description.

Remarks

- Reason 1 (Clarity)
- Claims 1 to 8

Claim 1 recites "an air permeable material that seals upon contact with blood from the first portion of the sample of blood". However, it is not clear from the above recitation whether the "air permeable material" after contact with blood seals from air.

From the recitation of "seals … from the first portion of the sample of blood", it can be understood that it is sufficient if the "air permeable material" seals from the sample of blood that is liquid. Further, the recitation of "air permeable material" can be interpreted by itself as always permeable to air. Therefore, the "air permeable material" after contact with blood can be understood as not sealing from air. On the other hand, from the recitation of "seals upon contact with blood", since the "air permeable material", which is originally permeable to air, changes in its sealing, the "air permeable material" after contact with blood can be understood as sealing from air. In addition, the applicant's argument in the Argument (especially, comparison with the invention disclosed in D2) is found to presuppose that the "air permeable material" after contact with blood seals from air.

Therefore, the property of the "air permeable material" after contact with blood, referred to by the recitation of "an air permeable material that seals upon contact with blood from the first portion of the sample of blood" in claim 1, is unclear.

Further, regarding the recitation of "an air permeable material that seals upon contact with blood" in claim 6, the recitation does not include "from the first portion of the sample of blood".

However, from the recitation of "air permeable material" the "air permeable material" after contact with blood can be understood as not sealing from air. On the other hand, from the recitation of "seals upon contact with blood", the "air permeable material" after contact with blood can be understood as sealing from air. Therefore, as in claim 1, the property of the "air permeable material" after contact with blood is unclear.

The same applies to claims 2-5 and 7-8 that refer to claims 1 and 6.

Therefore, the inventions of claims 1-8 are unclear.

- Reason 2 (Support requirement)
- Claims 1 to 8

As pointed out in Reason 1, in the inventions of claims 1 and 6, as a result of it being unclear whether the "air permeable material" after contact with blood seals from the air, a configuration may be included in which the "air permeable material" after contact with blood does not seal from air.

On the other hand, the Detailed Description of the Invention (see, in particular, paragraphs [0041], [0100], etc.) exclusively describes that the "air permeable material" after contact with blood seals from air. And it is not allowed that the invention can be extended or generalized from the Detailed Description of the Invention to a configuration in which the "air permeable material" after contact with blood does not seal from air.

The same applies to claims 2-5 and 7-8 that refer to claims 1 and 6.

Therefore, the inventions of claims 1-8 are not described in the Detailed Description of the Invention.

拒絶理由通知書

特許出願の番号	特願２０２０－１１８４９８
起案日	令和　４年　９月　１日
特許庁審査官	磯野　光司　３４１１　２Ｑ００
特許出願人代理人	三好　秀和（ほか　３名）　様
適用条文	第３６条第６項第２号（明確性） 第３６条第６項第１号（サポート要件）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第２号に規定する要件を満たしていない。

２．（サポート要件）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第１号に規定する要件を満たしていない。

記

●理由１（明確性）について

・請求項　１－８

請求項１において「血液と接触すると前記血液サンプルの第１の部分から密封する空気透過性材料」と記載されているが、血液と接触した後の「空気透過性材料」が空気から密封するものであるのか否かが、上記記載からは明確でない。

すなわち、「血液サンプルの第１の部分から密封する」という記載からすると、「空気透過性材料」は液体である血液サンプルから密封すれば足りるようにも解せ、また、「空気透過性材料」という記載のみからは、常に空気を透過するようにも解せるため、血液と接触した後の「空気透過性材料」は空気からは密封しないようにも解せる。その一方、「血液と接触すると・・・密封する」という記載からは、元々空気を透過する「空気透過性材料」に密封に関する変化が生じる訳であるから、血液と接触した後の「空気透過性材料」は空気から密封するようにも解せる。また、意見書における出願人の主張（特に、引用文献２に記載され

た発明との対比）は、血液と接触した後の「空気透過性材料」は空気から密封するものであることを前提としていると認められる。

そのため、請求項１における「血液と接触すると前記血液サンプルの第１の部分から密封する空気透過性材料」という記載が指す、血液と接触した後の「空気透過性材料」の性質は明確でない。

また、請求項６における「血液と接触すると密封する空気透過性材料」という記載について、当該記載には「血液サンプルの第１の部分から」という記載はないものの、「空気透過性材料」という記載のみからは、血液と接触した後の「空気透過性材料」は空気からは密封しないようにも解せ、その一方、「血液と接触すると・・・密封する」という記載からは、血液と接触した後の「空気透過性材料」は空気から密封するようにも解せるため、請求項１の記載と同様に、血液と接触した後の「空気透過性材料」の性質は明確でない。

請求項１，６を引用する、請求項２－５，７－８についても同様である。

よって、請求項１－８に係る発明は明確でない。

●理由２（サポート要件）について

・請求項　１－８

理由１において指摘したように、請求項１，６に係る発明において、血液と接触した後の「空気透過性材料」が空気から密封するものであるのか否かが明確でない結果、血液と接触した後の「空気透過性材料」が空気からは密封しない構成をも含みうるものとなっている。

一方、発明の詳細な説明（特に、段落［００４１］，［０１００］等参照）には、血液と接触した後の「空気透過性材料」が空気から密封するものであることが専ら記載されている。そして、発明の詳細な説明の記載から、血液と接触した後の「空気透過性材料」が空気からは密封しない構成にまで拡張ないし一般化することができるとは認められない。

請求項１，６を引用する、請求項２－５，７－８についても同様である。

よって、請求項１－８に係る発明は、発明の詳細な説明に記載したものでない。

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

この拒絶理由通知の内容に関するお問合せ又は面接のご希望がありましたら次の連絡先までご連絡ください。電子メール等で補正案等の送付を希望される場合は、その旨を電話でお知らせください。

審査第一部分析診断（医学診断）（PA2J）　磯野光司（いその　こうじ）
ＴＥＬ．０３－３５８１－１１０１　内線３２９１

国 家 知 识 产 权 局

100088

北京市朝阳区安定路 5 号院 8 号楼 1 至 21 层 101 五层 503 室 北京世峰知识产权代理有限公司

卓霖(010-82800919) 许向彤(010-82800919)

发文日：

2024 年 04 月 28 日

申请号：202080000666.0 **发文序号：** 2024042801618990

申请人：酷睿有限公司

发明创造名称：非排气机体流体样品优化装置和系统

第 二 次 审 查 意 见 通 知 书

1.☒审查员已经收到申请人于 2024 年 02 月 05 日提交的意见陈述书，在此基础上审查员对上述专利申请继续进行实质审查。

☐根据国家知识产权局于_____年_____月_____日作出的复审决定，审查员对上述专利申请继续进行实质审查。

☐_____

2.☐经审查，申请人于_____提交的修改文件，不符合专利法实施细则第 57 条第 3 款的规定，不予接受。

3.继续审查是针对下列申请文件进行的：

☐上述意见陈述书中所附的经修改的申请文件。

☒前次审查意见通知书所针对的申请文件以及上述意见陈述书中所附的经修改的申请文件替换文件。

☐前次审查意见通知书所针对的申请文件。

☐上述复审决定所确定的申请文件。

☐_____

4.☐本通知书未引用新的对比文件。

☒本通知书引用下列对比文件(其编号续前，并在今后的审查过程中继续沿用)：

编号	文 件 号 或 名 称	公开日期（或抵触申请的申请日）
2	US 2018297303A1	20181018

5.审查的结论性意见：

关于说明书：

☐申请的内容属于专利法第 5 条规定的不授予专利权的范围。

☐说明书不符合专利法第 26 条第 3 款的规定。

☐说明书的修改不符合专利法第 33 条的规定。

☐说明书的撰写不符合专利法实施细则第 20 条的规定。

☐_____

关于权利要求书：

☐权利要求_____不符合专利法第 2 条第 2 款的规定。
☐权利要求_____不符合专利法第 9 条第 1 款的规定。
☐权利要求_____不具备专利法第 22 条第 2 款规定的新颖性。
☒权利要求 1-13 不具备专利法第 22 条第 3 款规定的创造性。
☐权利要求_____不具备专利法第 22 条第 4 款规定的实用性。
☐权利要求_____属于专利法第 25 条规定的不授予专利权的范围。
☐权利要求_____不符合专利法第 26 条第 4 款的规定。
☐权利要求_____不符合专利法第 31 条第 1 款的规定。
☐权利要求_____的修改不符合专利法第 33 条的规定。
☐权利要求_____不符合专利法实施细则第 22 条的规定。
☐权利要求_____不符合专利法实施细则第 23 条的规定。
☐权利要求_____不符合专利法实施细则第 24 条的规定。
☐权利要求_____不符合专利法实施细则第 25 条的规定。
☐_____

☐申请不符合专利法第 26 条第 5 款或者实施细则第 29 条的规定。
☐申请不符合专利法第 19 条第 1 款的规定。
☐申请不符合专利法实施细则第 11 条的规定。
☐分案申请不符合专利法实施细则第 49 条第 1 款的规定。
上述结论性意见的具体分析见本通知书的正文部分。

6.基于上述结论性意见，审查员认为：
☐申请人应当按照通知书正文部分提出的要求，对申请文件进行修改。
☐申请人应当在意见陈述书中论述其专利申请可以被授予专利权的理由，并对通知书正文部分中指出的不符合规定之处进行修改，否则将不能授予专利权。
☒专利申请中没有可以被授予专利权的实质性内容，如果申请人没有陈述理由或者陈述理由不充分，其申请将被驳回。
☐_____

7.申请人应注意下列事项：

（1）根据专利法第 37 条的规定，申请人应在收到本通知书之日起的 2 个月内陈述意见，如果申请人无正当理由逾期不答复，其申请被视为撤回。

（2）申请人对其申请的修改应当符合专利法第 33 条的规定，不得超出原说明书和权利要求书记载的范围，同时申请人对专利申请文件进行的修改应当符合专利法实施细则第 57 条第 3 款的规定，按照本通知书的要求进行修改。

（3）申请人的意见陈述书和/或修改文本应当邮寄或递交国家知识产权局专利局受理处，凡未邮寄或递交给受理处的文件不具备法律效力。

（4）未经预约，申请人和/或代理师不得前来国家知识产权局与审查员举行会晤。

8. 本通知书正文部分共有 7 页，并附有下列附件：
☐引用的对比文件的复印件共_____份_____页。
☐_____

审查员：李媛媛　　联系电话：0371-87791927　　审查部门：专利审查协作河南中心

第二次审查意见通知书

申请号:2020800006660

申请人于2024年2月5日提交了意见陈述书和经过修改的申请文件，审查员在阅读了上述文件后，对本案继续进行审查，再次提出如下审查意见。

一、针对修改后的权利要求书

1. 权利要求1 不符合专利法第22 条第3 款的规定

权利要求1 请求一种用于优化由流体收集装置从流体源收集的流体样品的装置，对比文件1(US2018/0271425A1)公开了一种流体样品优化装置，具体的用于优化由流体收集装置从流体源收集流体样品(相当于一种用于优化由流体收集装置从流体源收集的流体样品的装置)，并具体公开了(参见说明书第0141-0149 段，说明书附图23A-23B)：

血液隔离装置2300 的又一实施方式，其具有与患者针连接的入口端口 2302(相当于被配置为与所述流体源连接的入口)、与血液样本收集装置连接的出口端口 2304(相当于被配置为与流体收集装置接触的出口)、隔离室2306 和旁路的采样通道2308(相当于样品路径)。一旦隔离室2306(相当于腔室)被填充至待隔离的潜在污染血液的初始等分部分，则隔离室2306 被填充。

隔离室2306 包括在隔离室2306 的距入口 2302 最远的远端处的疏水塞2312(相当于腔室在所述出口附近具有流阻器)。

从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室2306，其中血液的初始等分试样将接触疏水塞2312 并导致血液的初始等分部分返回到隔离室2306 中并被隔离在那里(相当于当入口和出口之间施加压差时，所述腔室被布置为从所述流体源接收所述流体样品的第一部分)。可以明确对比文件1 中血液的第一部分潜在地具有污染物。

少量血液可以进入采样通道2308，采样通道2308 最初被阀2308 关闭。

当释放阀2308 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液(相当于流体样品)将流入入口端口 2302，绕过隔离室2306，并且流入并穿过采样通道2308(相当于连接在所述入口和所述出口之间的样品路径)朝向出口端口 2304 并至收集装置(相当于使得当腔室接收到流体样品的第一部分时，所述流体样品的后续部分能够由所述样品路径从所述入口传送到所述出口)。

少量血液可以进入采样通道2308(相当于样品路径)，采样通道2308 最初被阀2310(相当于阻力塞)关闭(相当于样品路径还具有阻力塞)。

权利要求1 请求保护的技术方案与对比文件1 相比，其区别技术特征为：(1)流阻器为透气的，通过所述透气的流阻器和所述出口置换其中的空气；(2)所述阻力塞包括可刺穿的膜和刺穿构件，该刺穿构件被配置为刺穿所述膜，其中，所述装置被配置为使得一旦所述腔室填充有所述流体样品的所20 述第一部分，则在所

述膜上施加压力使得所述膜拉伸并接触所述刺穿构件。

针对上述区别技术特征(1)：对比文件 1 中已经记载了从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离空 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离空 2306 中并被隔离在那里流阻隔器；因此为了使得血液能在真空的作用下使得被吸入隔离空 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

针对上述区别技术特征(2)：对比文件 2（US2018297303A1，20181018）公开了一种刺破修补液盛装容器，并具体记载了(参见权利要求书，说明书第 0024-0041 段，说明书附图 1-5)管设置有阻挡所述穿孔修复液流入所述第二流动通道的密封膜(相当于膜)， 并且其中密封膜阻塞(相当于阻力塞包括可刺穿的膜)第二流动通道的闭合状态可以切换到其中密封膜被容器内部压力破坏使得第二流动通道打开的打开状态。包括刺穿机构，所述刺穿机构用于破坏所述管的内部部分上的所述密封膜。刺穿机构 63a(相当于刺穿构件)在储存期间也不接触密封膜 61，但是当在刺穿修复工作期间容器内部压力增加并且密封膜 61 朝向管 60 的内部凸出时，刺穿部分 63b 接触密封膜 61(相当于在膜上施加压力使得所述膜拉伸并接触所述刺穿构件)，使得密封膜 61 破裂(相当于该刺穿构件被配置为刺穿所述膜，阻力塞包括可刺穿的膜和刺穿构件)。因此，对比文件 2 给出了在压力增加时，可以使得密封膜拉伸或凸出，进而使得穿刺机构接触密封膜，进而使得密封膜破裂，第二流动通道打开。这与本申请的作用相同，在面对相同的技术问题时，本领域技术人员能够想到将其应用于对比文件 1 中。具体的应将该手段应用于对比文件 1 中时，装置被配置为使得一旦腔室填充有流体样品的第一部分，则在膜上施加压力使得膜拉伸并接触刺穿构件对于本领域技术人员来说是有能力做到的。

因此，在对比文件 1 的基础上结合对比文件 2 及本领域常规的技术手段，得出该权利要求的技术方案对本技术领域的技术人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具有突出的实质性特点和显著的进步，该权利要求不具备专利法第二十二条第三款规定的创造性。

2. 权利要求 2-4 不符合专利法第 22 条第 3 款的规定

权利要求 2-4 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述腔室中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离空 2306 包括在隔离空 2306 的距入口 2302 最远的远端处的疏水塞 2312，从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离空 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离空 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料)；

在对比文件 1 的基础上，根据需要可以选择腔室包括曲折路径；

因此，当其引用的权利要求不具备创造性时，权利要求 2-4 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

3. 权利要求 5 不符合专利法第 22 条第 3 款的规定

权利要求 5 请求一种用于优化由流体收集装置从流体源收集的流体样品的装置，对比文件 1 公开了一种流体样品优化装置，具体的用于优化由流体收集装置从流体源收集流体样品(相当于一种用于优化由流体收集装置从流体源收集的流体样品的装置)，并具体公开了(参见说明书第 0141-0149 段，说明书附图 23A-23B)：

血液隔离装置 2300 的又一实施方式，其具有与患者针连接的入口端口 2302(相当于被配置为与所述流体源连接的入口)、与血液样本收集装置连接的出口端口 2304(相当于被配置为与流体收集装置接触的出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于腔室)被填充至待隔离的潜在污染血液的初始等分部分，则隔离室 2306 被填充，结合说明书附图 23A 可以明确隔离室 2306 设置在入口和出口之间(相当于连接在所述入口和所述出口之间的腔室)。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于流阻器，相当于腔室在所述出口附近还具有流阻器)。

从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样(相当于流体样品的第一部分)将接触疏水塞 2312（相当于流阻器）并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于腔室被布置为从所述流体源接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物。可以确定对比文件 1 中接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库中。

少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310(相当于阻力塞)关闭(相当于样品路径还具有阻力塞，该阻力塞被配置为抑制所述流体样品的第一部分的至少一部分和污染物进入所述样品路径中)。

当释放阀 2310 时，并且在进一步的真空力或其他力的作用下，后续量的血液(相当于流体样品)将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于连接在所述入口和所述出口之间的样品路径)朝向出口端口 2304 并至收集装置(相当于使得当在所述腔室中接收到所述流体样品的所述第一部分时，流体样品的后续部分能够被迫通过所述阻力塞，并由所述样品路径从所述入口传送到所述出口)。

权利要求 5 请求保护的技术方案与对比文件 1 相比，其区别技术特征为：(1)流阻器为透气的，以通过所述透气的流阻器和所述出口置换其中的空气；(2)所述阻力塞包括可刺穿的膜和刺穿构件，该刺穿构件被配置为刺穿所述膜，其中，所述装置被配置为使得一旦所述腔室填充有所述流体样品的所述第一部分，则在所述膜上施加压力使得所述膜拉伸并接触所述刺穿构。

针对上述区别技术特征(1)：对比文件 1 中已经记载了从出口端口 2304(例如从真空采血管等)施加的真空

或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻隔器；因此为了使得血液能在真空的作用下使得被吸入隔离室 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

针对上述区别技术特征(2)：对比文件 2（US2018297303A1，20181018）公开了一种刺破修补液盛装容器，并具体记载了(参见权利要求书，说明书第 0024-0041 段，说明书附图 1-5)管设置有阻挡所述穿孔修复液流入所述第二流动通道的密封膜(相当于膜)， 并且其中密封膜阻塞(相当于阻力塞包括可刺穿的膜)第二流动通道的闭合状态可以切换到其中密封膜被容器内部压力破坏使得第二流动通道打开的打开状态。包括刺穿机构，所述刺穿机构用于破坏所述管的内部部分上的所述密封膜。刺穿机构 63a(相当于刺穿构件)在储存期间也不接触密封膜 61，但是当在刺穿修复工作期间容器内部压力增加并且密封膜 61 朝向管 60 的内部凸出时，刺穿部分 63b 接触密封膜 61(相当于在膜上施加压力使得所述膜拉伸并接触所述刺穿构件)，使得密封膜 61 破裂(相当于该刺穿构件被配置为刺穿所述膜，阻力塞包括可刺穿的膜和刺穿构件)。因此，对比文件 2 给出了在压力增加时，可以使得密封膜拉伸或凸出，进而使得穿刺机构接触密封膜，进而使得密封膜破裂，第二流动通道打开。这与本申请的作用相同，在面对相同的技术问题时，本领域技术人员能够想到将其应用于对比文件 1 中。具体的应将该手段应用于对比文件 1 中时，装置被配置为使得一旦腔室填充有流体样品的第一部分，则在膜上施加压力使得膜拉伸并接触刺穿构件对于本领域技术人员来说是有能力做到的。

在对比文件1 的基础上结合对比文件2和本领域常规技术手段以获得该权利要求所要求保护的技术方案，对所属技术领域的技术人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步，因而不具第 22 条第 3 款规定的创造性。

4. 权利要求 6-9 不符合专利法第 22 条第 3 款的规定

权利要求 6-9 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述腔室中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312，从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料)；

在对比文件 1 的基础上，根据需要可以选择污染物容纳储库包括曲折路径；

对比文件 1 中记载了当释放阀 2308 时，并且在进一步的真空力或其他力的作用下，后续量的血液将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308；

对比文件 1 中已经公开了采样通道 2308 最初被阀 2310(相当于阻力塞)关闭；在对比文件 1 的基础上，关于阻力塞的设置方式是根据需要可以选择的，具体的阻力塞包括具有可溶解材料的网，该可溶解材料在与流体样品的后续第一部分接触时溶解也是不难确定出的一种方式。

因此，当其引用的权利要求不具备创造性时，权利要求 6-9 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

5. 权利要求 10 不符合专利法第 22 条第 3 款的规定

权利要求 10 请求保护一种用于优化流体样品的流体样品优化装置，对比文件 1 公开了一种流体样品优化装置，具体的为一种优化流体样品的优化装置(相当于一种用于优化流体样品的优化装置)，并具体公开了(参见说明书第 0141-0149 段，说明书附图 23A-23B)：

血液隔离装置 2300 的又一实施方式，其具有与患者针连接的入口端口 2302(相当于入口)、与血液样本收集装置连接的出口端口 2304(相当于出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于腔室)被填充至待隔离的潜在污染血液的初始等分部分，则隔离室 2306 被填充，结合说明书附图 23A 可以明确隔离室 2306 设置在入口和出口之间(相当于连接在所述入口和所述出口之间的腔室)；样品路径设置在入口和出口之间(相当于连接在所述入口和所述出口之间的样品路径)。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于流阻器，腔室在所述出口附近具有透气的流阻器)。

从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样(相当于流体样品的第一部分)将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于腔室被布置为接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物。可以确定对比文件 1 中腔室中接收到流体样品的第一部分。

少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310 关闭。

当释放阀 2310 （相当于阻力塞，样品路径还包括阻力塞）时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液(相当于流体样品)将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308 朝向出口端口 2304 并至收集装置(相当于当在所述腔室中接收到所述流体样品的所述第一部分时，所述流体样品的后续部分能够由所述样品路径从所述入口传送到所述出口)。本领域技术人员可以确定对比文件 1 中公开了所述阻力塞被配置为，当在所述腔室中接收了所述流体样品的第一部分时，抑制所述流体样品的所述第一部分的至少一部分进入所述样品路径。

权利要求 10 请求保护的技术方案与对比文件 1 相比，其区别技术特征为：(1)流阻器为透气的，以通过所述透气的流阻器和所述出口置换其中的空气；(2)所述阻力塞包括可刺破的膜；和刺穿构件，该刺穿构件被配置为刺穿所述膜，其中，所述装置被配置为使得一旦所述腔室填充有所述流体样品的所述第一部分，则在

所述膜上施加压力使得所述膜拉伸并接触所述刺穿构件。

针对上述区别技术特征(1)：对比文件 1 中已经记载了从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离空 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离空 2306 中并被隔离在那里流阻隔器；因此为了使得血液能在真空的作用下使得被吸入隔离空 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

针对上述区别技术特征(2)：对比文件 2（US2018297303A1，20181018）公开了一种刺破修补液盛装容器，并具体记载了(参见权利要求书，说明书第 0024-0041 段，说明书附图 1-5)管设置有阻挡所述穿孔修复液流入所述第二流动通道的密封膜(相当于膜)， 并且其中密封膜阻塞(相当于阻力塞包括可刺穿的膜)第二流动通道的闭合状态可以切换到其中密封膜被容器内部压力破坏使得第二流动通道打开的打开状态。包括刺穿机构，所述刺穿机构用于破坏所述管的内部部分上的所述密封膜。刺穿机构 63a(相当于刺穿构件)在储存期间也不接触密封膜 61，但是当在刺穿修复工作期间容器内部压力增加并且密封膜 61 朝向管 60 的内部凸出时，刺穿部分 63b 接触密封膜 61(相当于在膜上施加压力使得所述膜拉伸并接触所述刺穿构件)，使得密封膜 61 破裂(相当于该刺穿构件被配置为刺穿所述膜，阻力塞包括可刺穿的膜和刺穿构件)。因此，对比文件 2 给出了在压力增加时，可以使得密封膜拉伸或凸出，进而使得穿刺机构接触密封膜，进而使得密封膜破裂，第二流动通道打开。这与本申请的作用相同，在面对相同的技术问题时，本领域技术人员能够想到将其应用于对比文件 1 中。具体的应将该手段应用于对比文件 1 中时，装置被配置为使得一旦腔室填充有流体样品的第一部分，则在膜上施加压力使得膜拉伸并接触刺穿构件对于本领域技术人员来说是有能力做到的。

在对比文件1 的基础上结合对比文件2和本领域常规技术手段以获得该权利要求所要求保护的技术方案，对所属技术领域的技术人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步，因而不具第 22 条第 3 款规定的创造性。

6. 权利要求 11-13 不符合专利法第 22 条第 3 款的规定

权利要求 11-13 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述腔室中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离空 2306 包括在隔离空 2306 的距入口 2302 最远的远端处的疏水塞 2312，从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离空 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离空 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料)；

在对比文件 1 的基础上，根据需要可以选择腔室包括曲折路径；

因此，当其引用的权利要求不具备创造性时，权利要求 11-13 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

二、针对申请人的意见陈述书

申请人主要认为：

对比文件 1 没有公开刺穿构件，该刺穿构件被配置为刺穿所述膜。

本发明参照图 9A-9C 详细描述了上述技术特征及其运作原理。可刺穿的膜 702 与刺穿构件 704 间隔开，膜 702 可以是弹性材料片，例如橡胶或其他弹性材料。如图 9C 所示，一旦污染物容纳容器中充满了流体，便在膜片 702 上施加一定的压力以使其进一步拉伸，从而与刺穿构件 704 接触。一旦在膜片 702 与刺穿构件 704 之间形成接触，膜 702 被刺穿构件 704 刺穿或以其他方式破裂，以打开较大的区域，以便随后的一定量或部分的流体流入样品路径（[0086]段）。由此，权利要求 1 所述的装置避免了收集的血液样品中污染物的积累，从而避免了由血液样品中的污染物导致的假阳性的检查结果

审查员充分考虑了其意见陈述，答复如下：

虽然对比文件 1 没有公开穿刺构件，穿刺构件被配置为刺穿膜；然而，对比文件 2（US2018297303A1，20181018）公开了一种刺破修补液盛装容器，并具体记载了(参见权利要求书，说明书第 0024-0041 段，说明书附图 1-5)管设置有阻挡所述穿孔修复液流入所述第二流动通道的密封膜， 并且其中密封膜阻塞第二流动通道的闭合状态可以切换到其中密封膜被容器内部压力破坏使得第二流动通道打开的打开状态。包括刺穿机构，所述刺穿机构用于破坏所述管的内部部分上的所述密封膜。刺穿机构 63a 在储存期间也不接触密封膜 61，但是当在刺穿修复工作期间容器内部压力增加并且密封膜 61 朝向管 60 的内部凸出时，刺穿部分 63b 接触密封膜 61，使得密封膜 61 破裂。因此，对比文件 2 给出了在压力增加时，可以使得密封膜拉伸或凸出，进而使得穿刺机构接触密封膜，进而使得密封膜破裂，第二流动通道打开。这与本申请的作用相同，在面对相同的技术问题时，本领域技术人员能够想到将其应用于对比文件 1 中。

基于上述理由，本申请的独立权利要求以及从属权利要求都不具备创造性，同时说明书中也没有记载其他任何可以授予专利权的实质性内容，因而即使申请人对权利要求进行重新组合和/或根据说明书记载的内容作进一步的限定，本申请也不具备被授予专利权的前景。如果申请人不能在本通知书规定的答复期限内提出表明本申请具有创造性的充分理由，本申请将被驳回。

审查员姓名:李媛媛　　审查员代码:30110854

国 家 知 识 产 权 局

检 索 报 告

申请号：2020800006660	申请日：2020 年 04 月 01 日	补充检索
申请人：酷睿有限公司	最早的优先权日：2019 年 04 月 01 日	
权利要求项数：13	说明书段数：95	

审查员确定的 IPC 分类号：G01N1/10,G01N1/02,A61B5/15

检索记录信息：US2018271425A1: 参见他局检索报告

US2018297303A1: ENTXTC 语义检索,语义基准:流体或血液或液体充满后，对膜上施加一定的压力以使其进一步拉伸，从而与刺穿构件接触。膜被刺穿构件刺穿或...

WO2015150742A1: ENTXTC 语义检索,语义基准:污染物容纳容器中充满了流体，便在膜片 702 上施加一定的压力以使其进一步拉伸，从而与刺穿构件 704 接触...

US9764891B1: ENTXTC 语义检索,语义基准:流体或血液或液体充满后，对膜施加压力，从而使得膜与刺穿构件接触。膜被刺穿构件刺穿或刺破，流体或液体或...

相 关 专 利 文 献

类型	国别以及代码[11] 给出的文献号	代码[43]或[45] 给出的日期	IPC 分类号	相关的段落 和/或图号	涉及的权 利要求
Y	US2018271425A1	2018-09-27	A61B5/15	说明书第 0141-0149 段，说明书附图 23A-23B	1-13
Y	US2018297303A1	2018-10-18	B29C73/16	权利要求书，说明书第 0024-0041 段，说明书附图 1-5	1-13
A	WO2015150742A1	2015-10-08	B01L3/00	全文	1-13
A	US9764891B1	2017-09-19	B65D85/804	全文	1-13

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相 关 非 专 利 文 献					
类型	书名（包括版本号和卷号）	出版日期	作者姓名和出版者名称	相关页数	涉及的权利要求
类型	期刊或文摘名称 （包括卷号和期号）	发行日期	作者姓名和文章标题	相关页数	涉及的权利要求
类型	网址	网络发布日 或公开日	作者姓名和网页标题	相关部分	涉及的权利要求

表格填写说明事项：

1. 审查员实际检索领域的 IPC 分类号应当填写到大组和／或小组所在的分类位置。
2. 期刊或其它定期出版物的名称可以使用符合一般公认的国际惯例的缩写名称。
3. 相关文件的类型说明：

   X：单独影响权利要求的新颖性或创造性的文件；

   Y：与本检索报告中其他 Y 类文件组合后影响权利要求的创造性的文件；

   A：背景技术文件，即反映权利要求的部分技术特征或者有关的现有技术的文件；

   R：任何单位或个人在申请日向专利局提交的、属于同样的发明创造的专利或专利申请文件。

   P：中间文件，其公开日在申请的申请日与所要求的优先权日之间的文件，或者会导致需要核实该申请优先权的文件；

   E：单独影响权利要求新颖性的抵触申请文件；

   T：申请日或优先权日当天或之后公布的，可以对所要求保护发明的理论或原理提供清楚解释的文件，或者可显示出所要求保护发明的推理或事实不成立的文件；

   L：除 X、Y、A、R、P、E 和 T 类文件之外的文件。

审 查 员：李媛媛　　审查部门：专利审查协作河南中心
2024 年 04 月 26 日

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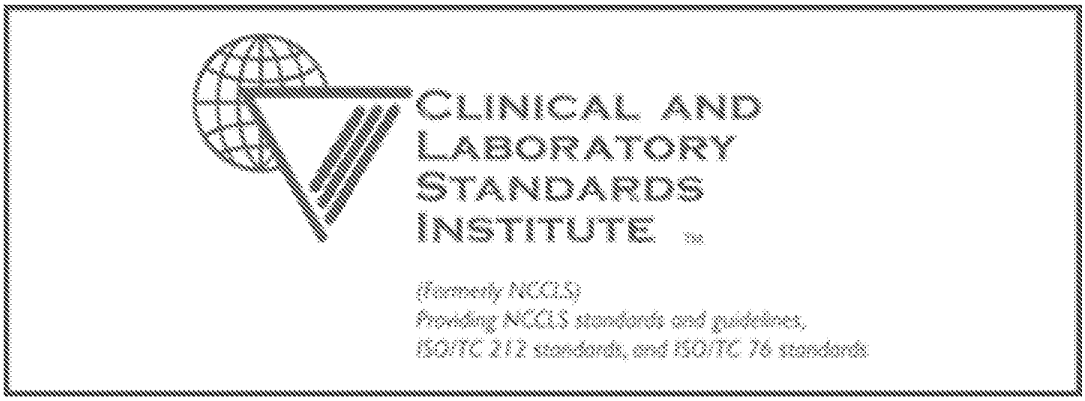
Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition



This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.

A standard for global application developed through the NCCLS consensus process.

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Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition

Charles F. Arkin, M.D.
J. David Bessman, M.D.
Roger R. Calam, Ph.D., DABCC
Dennis J Ernst, M.T.(ASCP)
Gary T. Parish
Diane I. Szamosi, M.A., M.T.(ASCP), SH
David J. Warunek, Ph.D.
Joan D. Wiseman, M.T.(ASCP)CT

Abstract

H3-A5—*Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition* provides a descriptive, stepwise procedure for the collection of diagnostic blood specimens by venipuncture. Special considerations for venipuncture in children, line draws, blood culture collection, and venipuncture in isolation situations are included.

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Committee Membership

Area Committee on Hematology

Charles F. Arkin, M.D.
Chairholder
Lahey Clinic
Burlington, Massachusetts

Bruce H. Davis, M.D.
Vice-Chairholder
Maine Medical Center Research Institute
Scarborough, Maine

J. David Bessman, M.D.
University of Texas Medical Branch
Galveston, Texas

Berend Houwen, M.D., Ph.D.
Beckman Coulter, Inc.
Brea, California

Frank M. LaDuca, Ph.D.
International Technidyne Corporation
Edison, New Jersey

Ginette Y. Michaud, M.D.
FDA Center for Devices/Rad. Health
Rockville, Maryland

Onno W. van Assendelft, M.D., Ph.D.
Centers for Disease Control and Prevention
Atlanta, Georgia

Advisors

Dorothy M. Adcock, M.D.
Esoterix Coagulation
Aurora, Colorado

Sheila Clover, CPT (ASCP) (NCA)
Phlebotomy West
Brentwood, California

Dennis J. Ernst, M.T.(ASCP)
Center for Phlebotomy Education
Ramsey, Indiana

J. Heinrich Joist, M.D., Ph.D.
St. Louis University Health Science Center
St. Louis, Missouri

John A. Koepke, M.D.
Durham, North Carolina

Francis Lacombe, M.D., Ph.D.
Laboratoire d'Hematologie
Pessac, France

Samuel J. Machin, MB, Ch.B, FRCPath
The University College London Hospital
London, United Kingdom

Richard A. Marlar, Ph.D.
Denver VA Medical Center
Denver, Colorado

Diane L. Szamosi, M.A.,M.T.(ASCP)SH
Greiner Bio-One, VACUETTE North America, Inc.
Monroe, North Carolina

Luc Van Hove, M.D., Ph.D.
Abbott Laboratories
Abbott Park, Illinois

Staff

Tracy A. Dooley, M.L.T.(ASCP)
Staff Liaison
NCCLS
Wayne, Pennsylvania

David E. Sterry, M.T.(ASCP)
Project Manager
NCCLS
Wayne, Pennsylvania

Donna M. Wilhelm
Editor
NCCLS
Wayne, Pennsylvania

Melissa A. Lewis
Assistant Editor
NCCLS
Wayne, Pennsylvania

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Charles F. Arkin, M.D.
Lahey Clinic

J. David Bessman, M.D.
University of Texas Medical Branch

Roger R. Calam, Ph.D., DABCC
St. John Hospital

Dennis J. Ernst, M.T.(ASCP)
Center for Phlebotomy Education

Gary T. Parish
Sarstedt, Inc.

Diane I. Szamosi, M.A., M.T.(ASCP), SH
Greiner Bio-One, VACUETTE North America, Inc.

David J. Warunek, Ph.D., M.B.A.
BD VACUTAINER Systems

Joan D. Wiseman, M.T.(ASCP), CT
Consultant
Bernardsville, New Jersey

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Foreword

The errors that can occur during the collection and handling of blood specimens are potentially numerous (e.g., inaccurate identification of specimens, specimen hemolysis, the improper handling of anticoagulants, the formation of hematomas, hemoconcentration). Standards for venipuncture can reduce or alleviate many of these errors in much the same way that quality control standards have reduced errors within the laboratory.

Reducing errors during blood collecting will result in biologically representative specimens that are comparable from one institution to another. A well-planned, attractive environment in which to perform venipunctures will reduce patient anxiety and increase the efficiency and accuracy of the phlebotomist. Phlebotomists need a complete assortment of equipment at their fingertips so they can judiciously select the most appropriate materials for each patient. Standards governing the processing of paperwork will reduce errors and save time. Without question, a comprehensive training program is needed to produce efficient, well-trained phlebotomists. Finally, standards for the actual venipuncture procedure are needed to help eliminate the many errors that can occur during blood collection. Biologically representative specimens for laboratory testing will be obtained if national venipuncture standards are used.

Various comments received on the previous edition of this standard have been reviewed and incorporated where appropriate. All comments and the subcommittee's responses are summarized at the end of the document.

This document replaces the fourth edition approved standard, H3-A4, which was published in 1998. Several changes have been made in this edition; chief among them is the revised order of draw (Section 8.10.2), which reflects the increased use of plastic blood collection tubes. This standard also contains revised recommendations regarding collection of blood specimens in relation to intravenous sites (Section 11.6). The recommendations regarding the collection of coagulation specimens (Section 8.10.3) have been revised for consistency with NCCLS document H21—*Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays.*

Key Words

Accession, blood specimen, phlebotomist, sample, venipuncture

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Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition

1 Scope[a]

This document establishes criteria for the correct collection of blood specimens by venipuncture. These procedures are intended to be a suitable model for adoption by all healthcare providers responsible for the collection and handling of blood specimens in both outpatient and inpatient settings.

2 Introduction

Since 1977, NCCLS has progressively recognized the quality requirement that significant attention be directed towards the preanalytical components of laboratory testing, specifically, the correct collection and handling of blood specimens. Highly sophisticated testing technology cannot produce a good result from a poor specimen. Proper specimen collection and handling are of the utmost importance because significant errors occur in the preanalytical phase of laboratory testing.[1]

Preanalytical errors have the potential to be numerous: incorrect patient ID, incorrect order-of-draw, incorrect use of additive tubes, labeling errors, incorrect timing of collection, clerical errors, etc. Standard procedures and protocols are intended to prevent these problems and protect patient results quality.

3 Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to the most current edition of NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections.*

4 Definitions

In the context of this publication, the terms listed below are defined as follows:

Accession – The steps required to ensure that a specific patient specimen and the accompanying documentation are unmistakably identified as referring to a specific person.

Angle of insertion – The angle formed by the surface of the arm and the needle entering the arm.

[a] This standard reflects recent revisions to OSHA's Blood Borne Pathogens Standard (29 CFR 1910.1030). Therefore, all references to needles/winged blood collection sets indicate sharps with engineered safety features. This also encompasses safety accessories used in combination with conventional needles.

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(Patient) sample – A sample taken from the patient specimen and used to obtain information by means of a specific laboratory test.

(Patient) specimen – The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole.

Pre-evacuation – The creation of a vacuum (in a collection tube), induced by either the manufacturer or by the user immediately before a liquid specimen is taken.

Vascular access device (VAD) – A device inserted into a vein or artery to allow access to the circulatory system for the administration of intravenous fluids and/or medications.

Venipuncture – The puncture of a vein for surgical, or therapeutic, purposes, or for collecting blood specimens for analysis.

5 Factors That Affect Laboratory Values

Interpretation of laboratory data has assumed new importance and attracted increased attention with both more frequent testing and multiple testing. The increased use of laboratories predictably yields abnormal unsolicited data that requires interpretation and may lead to costly, unproductive, and unnecessary sequential testing. Even when an analytical procedure has been performed correctly and precisely, variables can affect the test result. Knowledge of these variables and standardization of laboratory testing procedures are essential for correct interpretation and optimal use of the data.

Major causes of "laboratory error" can be related to nonanalytical factors such as specimen collection, handling, and transport. Nonbiological factors—such as patient misidentification, and biological factors—such as patient posture and the time a specimen is drawn, all contribute to the total "laboratory error."

Physiological factors that influence results include age, activity, bed rest, food ingestion, alcohol ingestion, menstrual cycle, obesity, oral contraceptives, posture, pregnancy, race, gender, smoking, and time of day. All biological phenomena exhibit rhythms, with the circadian rhythm (the change in a 24-hour period) being the most important to laboratory testing. Many factors with documented effects on laboratory values have been published.[2-6]

6 Facilities

The venipuncture should be performed in a clean, quiet, and private environment. Reasonably soundproof rooms for pediatric patients should be considered.

The room should have facilities to allow the phlebotomist to wash his/her hands between patients. Washing with soap and running water is recommended; however, any standard detergent product acceptable to personnel may be used. In settings where water is not available, alcohol-based gels or liquids, hand-wipe towelettes, and cleansing foams can be used.[b]

6.1 Venipuncture Chairs

Venipuncture chairs should be designed for the maximum comfort and safety of the patient. Consideration should be given to the ergonomic comfort plus easy accessibility to the patient for the phlebotomist. Both armrests of the chairs should be adjustable so that the best venipuncture position for

[b] In the U.S., employees must wash their hands with soap and running water as soon as feasible thereafter.

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each patient can be achieved. The chair should have a safety device to prevent patients from falling if feeling faint.

6.2 Hospital Area

A central venipuncture area should be designed to include the following features.

6.2.1 Central Desk

The central desk is a location for a telephone system used to handle emergency request calls, facilities for processing daily and future requests, and a paging system for contacting the phlebotomist who is collecting specimens outside of the central area.

6.2.2 Cart Area

The cart area is constructed to allow easy access to the supplies.

6.2.3 Storage Area

The storage area should be large enough to accommodate the necessary supplies.

6.2.4 Counter Space

Counter space should be adequate for efficient sorting and dispatching of specimens.

6.2.5 Sampling Time Recorder

The sampling time recorder (i.e., time stampers, bar codes, or information system) should be located for convenient time recording of venipuncture paperwork.

7 Supplies

The following supplies should be available at any location where venipunctures are performed routinely.

7.1 Utility Carts

Utility carts, designed to roll smoothly and silently over all types of surfaces, may be useful. The phlebotomist may also find it very useful to have a specially designed rack on the top shelf for storing supplies.

7.2 Blood Collecting Trays

Blood collecting trays or carts may be used. The trays should be lightweight and easy to handle with enough space and compartments for the various supplies that are needed.

7.3 Gloves

Latex, vinyl, or nitrile gloves provide barrier protection. Disposable latex, vinyl, or nitrile gloves are available from hospital suppliers.

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Some workers may develop dermatitis from wearing latex gloves for long periods of time. These workers should experiment with nitrile, polyethylene or other gloves of various composition or gloves without powdered lubricant or they may wear cotton gloves under latex or plastic gloves.

Severe hypersensitivity has been reported and cases of anaphylactic shock have occurred. In such hypersensitive individuals, latex gloves must be avoided.

7.4 Needles and Holders

Needles/holders should be compatible with the tubes selected for use. For more information on venous blood collection tubes and additives, refer to the most current edition of NCCLS document H1—*Evacuated Tubes and Additives for Blood Specimen Collection.*

Needles and winged blood collection sets are individually color-coded according to their respective gauge sizes. The gauge number indicates the size of the needle. A large gauge number indicates a small needle, while a small gauge number indicates a large needle. The sizes for venipuncture range from 19 through 23. Needles must always be sterile.

In order to prevent potential worker exposure, the needle safety feature should be activated immediately after specimen collection and discarded without disassembly into a sharps container.[c]

7.5 Sterile Syringes

In general, venipuncture using a needle and syringe should be avoided for safety reasons; however, it may be suitable under some circumstances to have sterile syringes of the appropriate size available.

7.6 Venous Blood Collection Tubes

Venous blood collection tubes are manufactured to withdraw a predetermined volume of blood. At present, venous blood collection tubes used in venipuncture are designated sterile. It is recommended that information regarding the venous blood collection tubes selected for general use be clearly displayed in venipuncture areas for easy reference. Similar information should also be made available to all personnel who collect blood. Instructions furnished in the package insert by the manufacturer of venous blood collection tubes and needles should be available. (See also the most current version of NCCLS document H1—*Evacuated Tubes and Additives for Blood Specimen Collection* for information on venous blood collection tubes.)

7.7 Tourniquets

Tourniquets or products for use as tourniquets should be available. Examples include:

- Single-use disposable tourniquet, preferably latex-free.
- Blood pressure cuff inflated to 40 mmHg.
- Rubber/fabric-type tourniquets with closure tape, plastic clip, buckle, or similar type of fastening.

Tourniquets must be discarded immediately when contaminated with blood or body fluids or must be discarded if contamination is suspected.

[c] In the U.S., refer to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030), the safe practice of phlebotomy and blood tube holder use (CPL2-2.9 at XIII.D.5).

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7.8 Antiseptics

Antiseptics for skin preparation are necessary. The following are some examples:

- Isopropyl or ethyl alcohol: 70%
- 1 to 10% povidone-iodine as swab sticks or chlorhexidine gluconate for blood cultures[7] (see Section 8.8.2).
- Nonalcohol-based cleanser for blood alcohol specimens (e.g., chlorhexidine).

7.9 Gauze Pads

Small prepackaged gauze pads, (i.e., 2 x 2 in or 3 x 3 in [5.0 x 5.0 cm or 7.5 x 7.5 cm]) should be available. Cotton balls are not recommended because of the possibility of dislodging the platelet plug at the venipuncture site.

7.10 Puncture-Resistant Disposal Container

An approved puncture-resistant disposal container that is compliant with OSHA regulations must be available.

7.11 Ice

Ice or refrigerant should be available.

7.12 Adhesive Bandages

Adhesive bandages and/or gauze pads should be available. Hypoallergenic adhesives should also be available.

7.13 Warming Devices

Warming devices may be used to increase blood flow.

7.14 Test Reference Manual

A test manual which explains which tube is to be used, that also indicates minimum volume requirements, special handling, and precautions to be taken should be consulted.

8 Venipuncture Procedure

The venipuncture procedure is complex and requires both knowledge and skill (refer to Sections 8.1 to 8.17 for detailed information on the procedure). When drawing a blood specimen, the trained phlebotomist must:

Step 1. Prepare accession order.
Step 2. Approach and identify the patient.
Step 3. Verify patient's diet restrictions, as appropriate, and inquire if patient has a latex sensitivity. Select appropriate gloves and tourniquet.
Step 4. Assemble necessary supplies and select appropriate tubes according to test requests.
Step 5. Position the patient.
Step 6. Apply the tourniquet, ensure the patient's hand is closed, and select the vein site.
Step 7. Put on gloves.

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Step 8. Cleanse the venipuncture site.
Step 9. Perform venipuncture; once blood flow begins, request patient to open hand.
Step 10. Use the correct order of draw.
Step 11. Release and remove the tourniquet.
Step 12. Place the gauze pad over the puncture site.
Step 13. Remove the needle, activating any safety feature according to manufacturers' instructions.
Step 14. Apply pressure to the site, making sure bleeding has stopped, and then bandage the arm.
Step 15. Label the tubes and record the time of collection.
Step 16. Chill the specimen (if required).
Step 17. Send properly labeled blood collection tubes to the appropriate laboratories.

8.1 Step 1: Prepare Accession Order

Each request for a blood specimen must be accessioned to identify all paperwork and supplies associated with each patient. An organized system will ensure prompt and accurate processing of the various forms required when performing a venipuncture and analyzing the results. Record all information on the test request form.

8.1.1 Information for Test Request Form

The following information should be included:

- The patient's name and age from identification plate
- An identification number
- The date and time the specimen is to be obtained
- An accessioning number
- The doctor's name
- The department or location for which the work is being done
- Other information as needed (e.g., special comments: intravenous site, sampling site if other than arm).

8.2 Step 2: Approach and Identify the Patient

The phlebotomist should identify himself or herself, establish a rapport, and gain the patient's confidence. Information given to the patient regarding the testing to be performed and specimen to be drawn must be in accordance with institutional policy. The phlebotomist must **NOT** perform blood collection against the patient's or guardian's consent. Instead, report the patient's objections to the physician's/nurse's station.

8.2.1 Identify Patient

Identification of the patient is crucial. The phlebotomist must ensure that the blood specimen is being drawn from the individual designated on the request form. The phlebotomist must not rely on a bed tag, or on charts or records placed on the bed, nearby tables, or equipment. The following steps are a suggested sequence for ensuring patient identification, regardless of the clinical setting.

8.2.2 Patient Who Is Conscious

The suggested sequence of steps for a patient who is conscious:

(1) Ask outpatients to give full name, address, identification number, and/or birth date.

(2) Compare this information with the information on the request form.

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(3) Ask inpatients for the same information and compare this information with the information on the request form and the patient's identification bracelet, which must be attached to the patient.

(4) Report any discrepancy, however minor, to the responsible person in the area (as determined by institutional policy) and have the patient identified by name and identification number before drawing any specimen.

8.2.3 Patient Who Is Semiconscious, Comatose, or Sleeping

The phlebotomist must take special care when drawing blood from semiconscious, comatose, or sleeping patients to anticipate any unexpected movements or jerks either while introducing the needle, or while it is in place in the arm. Sleeping patients should be awakened before drawing blood. A gauze pad should be readily available and the tourniquet quickly released in the event the needle is violently removed or repositioned. If the needle accidentally goes much deeper into the arm, the phlebotomist must inform the doctor's/nurse's station. If unable to identify the patient, then contact the nurse or physician.

8.2.4 Patient Who Is Unconscious, Too Young, Mentally Incompetent, or Does Not Speak the Language of the Phlebotomist

In any of these circumstances, the phlebotomist should follow this suggested sequence of steps:

(1) Ask the nurse, a relative, or a friend to identify the patient by name, address, identification number, and/or birth date. If unable to identify the patient, then contact the nurse or physician.

(2) Compare these data with the information on the request form and the patient's identification bracelet, which must be attached to the patient.

(3) Report any discrepancy, however minor, to the responsible person in the area (as determined by institutional policy) and have the patient identified by name and identification number before drawing any specimen.

8.2.5 Procedure for Identifying Unidentified Emergency Patients

Identification standards established by the American Association of Blood Banks (AABB) provide clear guidelines for unidentified emergency patients.[8]

The patient must be positively identified when the blood specimen is collected. The unidentified emergency patient should be given some temporary but clear designation until positive identification can be made. For a person who cannot be identified immediately, it is necessary to:

- Assign a master identification number (temporary) to the patient in accord with institutional policy.
- Select the appropriate test request forms and record with master identification number.
- Complete the necessary labels either by hand or by computer and apply the labels to the test request forms and specimens.
- When a permanent identification number is assigned to the patient, make sure the temporary identification number is cross-referenced to the permanent number to ensure correct identification and correlation of patient and test result information.

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In all cases, the name and permanent or temporary identification designation must be attached to the patient's body either by wristband or some similar device. Except in the case of isolation patients, bed labels must not be used in place of wristbands.

8.2.6 Physician Relationship

The physician has priority with the patient. The phlebotomist should not enter the room without permission while the physician or nurse is consulting with the patient. If the order is stat or the specimen is a "timed" specimen, the phlebotomist should request permission to draw the blood specimen.

8.3 Step 3: Verify Patient Diet Restrictions and Latex Sensitivity

Some tests require the patient to fast and/or eliminate certain foods from the diet before the blood is drawn. Time and diet restrictions vary according to the test. Such restrictions are necessary to ensure accurate test results.

The procedure for holding meals and notifying appropriate personnel that the patient has been drawn should be according to institutional policy.

Please refer to Section 7.3 for information regarding latex sensitivity to gloves and to Section 7.7 for tourniquets.

8.4 Step 4: Assemble Supplies

8.4.1 Supplies[d]

It is important that phlebotomy devices used reflect the most current local and regional safety regulations.[9]

Inspect all supplies for possible defects and applicable expiration dates. The following supplies should be available at any location where venipunctures are performed routinely:

- Blood collection tubes/blood culture bottles
- Needle
- Single-use tube/needle holder
- Syringe
- Syringe transfer device
- A tourniquet
- Alcohol prep pads
- 1 to 10% povidone-iodine pads, tincture iodine, or chlorhexidine compounds if blood culture is to be drawn
- Nonalcohol-based cleanser if blood alcohol is to be drawn
- Gauze pads, adhesive bandages, or tape (including hypoallergenic adhesives)
- Gloves
- Sharps container, consistent with OSHA regulations

8.4.2 Needles

The phlebotomist must select the appropriate needle gauge based on the physical characteristics of the vein, location of the vein, and the volume of blood to be drawn.

[d] In the U.S., OSHA mandates the use of engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent (e.g., safety needles, shielded needle devices, etc.).

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8.4.3 Syringes

The plunger must be moved within the barrel of the syringe to show syringe and needle patency and freedom of plunger movement.

8.4.4 System

The phlebotomist must select the appropriate blood collection system according to the patient's physical characteristics.

8.4.4.1 Venous Blood Collection Systems

When venous blood collection tubes are used, the phlebotomist must:

- Select the correct types and sizes of venous blood collection tubes. (Color-coded closures and labels make it easy to perform this step.)
- Apply a label to each of the necessary tubes and all test forms immediately after blood specimen has been drawn
- Refer to institutional policy.

All tubes should be labeled immediately *after* the blood specimen has been drawn. The completed label must be attached to the tube before leaving the side of the patient, and there must be a mechanism to identify the person who drew the blood.[8] If preprinted labels are not available, complete patient information can be handwritten on the tube label. This procedure eliminates the possibility of mixing up the blood specimens.

It is recommended that blood specimens be collected by venipuncture using a blood collection system that collects the blood directly into tubes. (For greater detail on venous blood collection tubes and additives, refer to the most current edition of NCCLS document H1—*Evacuated Tubes and Additives for Blood Specimen Collection.)* If the components are from different manufacturers, they should be checked to ensure compatibility.

8.4.4.2 Plastic Syringe

In general, the use of a syringe and needle should be avoided for safety reasons. If a syringe is used, a safety syringe shielded transfer device should be used to transfer blood to the appropriate venous blood collection tube.

8.4.4.3 Blood Collection Set

The blood collection set (i.e., winged blood collection set) is described in Section 9.2.

8.5 Step 5: Position Patient

8.5.1 Procedure for Seating Patient

(1) Ask the patient to be seated comfortably in a chair suitable for venipuncture. The chair should have arms to provide support and prevent falls if the patient loses consciousness. Chairs without arms do not provide adequate support for the arm or protect fainting patients from falls.

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(2) Have the patient position his/her arm on the slanting armrest and extend the arm to form a straight line from the shoulder to the wrist. The arm should be supported firmly by the armrest and should not be significantly bent at the elbow. A slight bend may be important in avoiding hyperextension of the arm.

8.5.2 Procedure for Having Patient Lie Down

(1) Ask the patient to lie on his/her back in a comfortable position.

(2) If additional support is needed, place a pillow under the arm from which the specimen is being drawn.

(3) Have the patient extend his/her arm to form a straight line from the shoulder to the wrist.

8.5.3 Foreign Objects in Mouth

No food or liquid, chewing gum, or thermometer should be in the patient's mouth at the time the specimen is drawn.

8.6 Step 6: Apply Tourniquet

A tourniquet is used to increase venous filling. This makes the veins more prominent and easier to enter. (See Section 7.7).

8.6.1 Precautions When Using a Tourniquet

Tourniquet application for preliminary vein selection should not exceed one minute as localized stasis with hemoconcentration and infiltration of blood into tissue can occur. This may result in erroneously high values for all protein-based analytes, packed cell volume, and other cellular elements. If the patient has a skin problem, the tourniquet should be applied over the patient's gown or a piece of gauze pad or paper tissue should be used so that the skin is not pinched.

8.6.2 Tourniquet Location

Wrap the tourniquet around the arm 3 to 4 inches (7.5 to 10.0 cm) above the venipuncture site.

8.6.3 Blood Pressure Cuff

If a blood pressure cuff is used as a tourniquet, inflate it to 40 mm Hg.

8.6.4 Ensure Patient's Hand Is Closed

The veins become more prominent and easier to enter when the patient forms a fist. There must not be vigorous hand exercise ("pumping"). Vigorous hand pumping can cause changes in the concentration of certain analytes in the blood.

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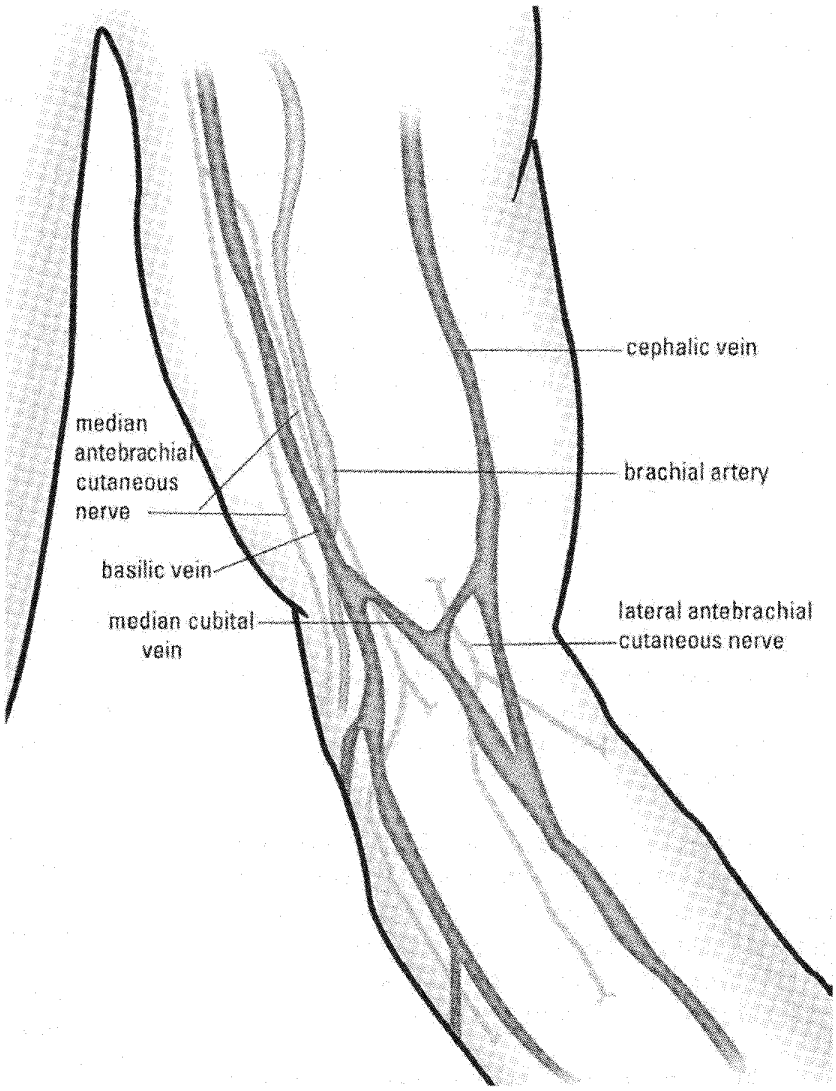

Figure 1. Superficial Veins of the Anterior Surface of the Upper Extremity (From Ernst DJ, Ernst C. Phlebotomy tools of the trade: Part 2—Surveying the antecubital area. *Home Healthcare Nurse.* 2002;20:402-403. Reprinted with permission from Lippincott Williams & Wilkins.)

8.6.5 Select Vein

Refer to Figure 1 for a description of the superficial veins of the anterior surface of the upper extremity.

8.6.5.1 Caution

It is important to select the vein carefully for blood collection because the veins also provide an avenue of entry for transfusion, infusion, and therapeutic agents. Because the brachial artery passes through the antecubital area, caution must be exercised to avoid the artery. If, during the procedure, arterial puncture is suspected, direct forceful pressure must be applied to the puncture site for a minimum of five minutes upon removal of the needle or until active bleeding has ceased. The nursing staff and physician are to be notified immediately thereafter.

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8.6.6 Preferred Veins

Arterial punctures should not be considered as an alternative to venipuncture for difficult draws. If this appears to be the only alternative, consult with the physician.

Although the larger and fuller median cubital and cephalic veins (see Figure 1) are used most frequently, veins on the back of the hand are also acceptable for venipuncture. Veins on the underside of the wrist must not be used.

Draws to the median cubital veins are preferred because they are typically closer to the surface of the skin, more stationary, less painful upon needle insertion, and less likely to injure nerves if needle placement is not accurate. Attempt to locate the median cubital vein on either arm before considering alternative veins. Due to the proximity of the basilic vein to the brachial artery and the median nerve, this vein should only be considered if no other vein is more prominent. Above all, phlebotomists should be aware of the potential for injury associated with each vein and select the vein that brings the greatest degree of confidence of being accessed successfully without risking nerve or arterial involvement. (See Figure 1.)

Alternative sites such as ankles or lower extremities must not be used without the permission of the physician because of the potential for significant medical complications (e.g., phlebitis, thrombosis, tissue necrosis, etc.)[10-12]

8.6.7 Factors in Site Selection

8.6.7.1 Extensive Scarring

Healed burn areas are to be avoided.

8.6.7.2 Mastectomy

A physician must be consulted before drawing blood from the side on which a mastectomy was performed because of the potential for complications due to lymphostasis.

8.6.7.3 Hematoma

Specimens collected through a hematoma area may cause erroneous test results. Phlebotomy must not be performed on any size hematoma. If another vein site is not available, the specimen is collected distal to the hematoma.

8.6.7.4 Intravenous Therapy

Preferably, specimens should not be collected from an arm with an intravenous site. (See Section 11.6).[13]

8.6.7.5 Cannula, Fistula, Vascular Graft

A cannulated arm is used only after consulting the attending physician.

8.6.8 Procedure for Vein Selection

8.6.8.1 Locating Veins

To locate veins, it is necessary to palpate and trace the path of veins several times with the index finger. Unlike veins, arteries pulsate, are more elastic, and have a thick wall. Thrombosed veins lack resilience,

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feel cord-like, roll easily, and should not be used. A tourniquet must be used to aid in the selection of a vein site unless specific tests require tourniquets not be used (e.g., lactate). If a tourniquet must be applied for the preliminary vein selection, it should be released and reapplied after two minutes.

8.7 Step 7: Put on Gloves

The phlebotomist must put gloves on before the venipuncture is performed, for each patient, with consideration for latex sensitivity as discussed in Section 7.3.

8.8 Step 8: Cleanse Venipuncture Site

The puncture site must be cleansed to prevent microbiological contamination of either the patient or the specimen.

8.8.1 Cleansing Method for Venipuncture

(1) Use a gauze pad with 70% isopropyl alcohol solution, or a commercially prepared alcohol pad.

(2) Cleanse the site with a circular motion from the center to the periphery.

(3) *Allow the area to air dry* to prevent hemolysis of the specimen and to prevent the patient from experiencing a burning sensation when the venipuncture is performed.

8.8.2 For Blood Culture Collection

For blood cultures, it is necessary to carefully disinfect the venipuncture site. Chlorhexidine gluconate is recommended for infants two months and older and patients with iodine sensitivity. Cleanse the site with 70% alcohol, then swab concentrically, starting at the middle of the site with a 1 to 10% povidone-iodine solution (0.1 to 1% available iodine) or chlorhexidine gluconate. Allow the site to air dry, then remove the iodine or chlorhexidine from the skin with alcohol.[8]

When specimens are obtained for blood cultures, disinfect the culture bottle stopper according to the manufacturer's instructions.

8.8.3 Touching the Site After Cleansing

If the venipuncture proves difficult and the vein must be touched again to draw blood, the site should be cleansed again.

8.9 Step 9: Perform Venipuncture

8.9.1 Venipuncture Procedure When Venous Blood Collection Tubes Are Used

There are several different blood collection systems available that collect blood samples using different principles. For example, there are evacuated tube systems and systems that have a flexible/dual collection technique that employ either a vacuum—user evacuates the tube immediately prior to use referred to as pre-evacuation—or aspiration principle of collection. For the proper venipuncture technique using the blood collection system selected refer to the manufacturers' instructions for use.

(1) If pre-evacuation is required, and the blood collection tubes are not evacuated by the manufacturer, evacuate the tubes immediately prior to use according to the manufacturer's instructions.

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(2) If not preassembled by the manufacturer, thread the appropriate needle into the holder until it is secure.

(3) When drawing blood for cultures, wipe the stopper with a suitable antiseptic solution. Make certain the stopper is dry before performing the venipuncture.

(4) Make sure the patient's arm or other venipuncture site is in a downward position to prevent reflux or "backflow."

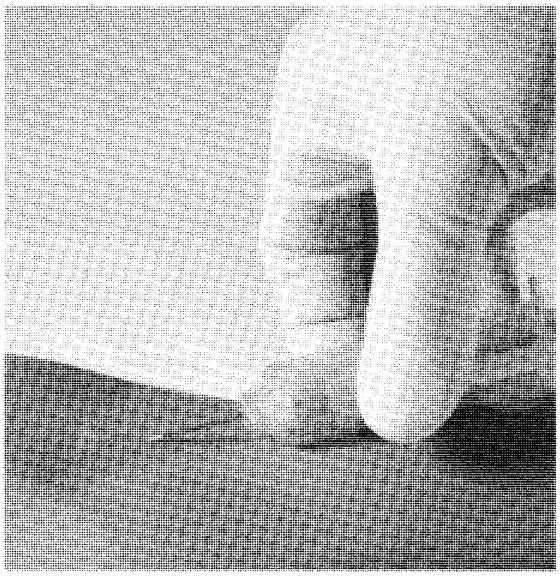

Figure 2. Proper Angle of Insertion (Figure contributed by the Center for Phlebotomy Education, Inc.)

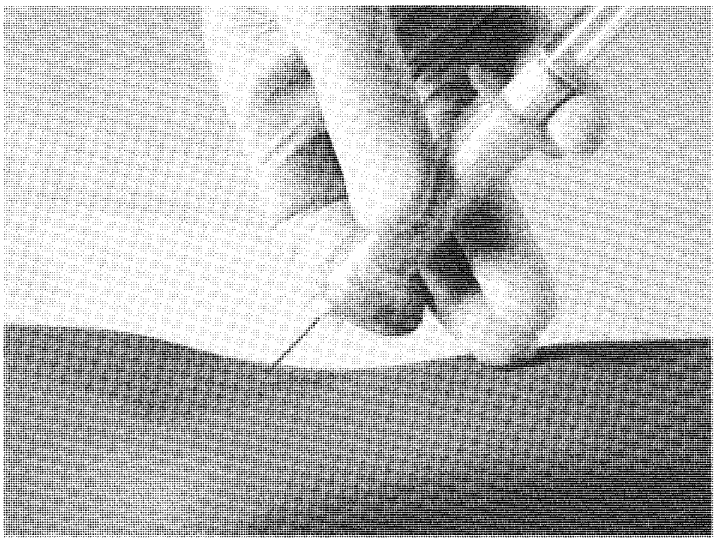

Figure 3. Improper Angle of Insertion (Figure contributed by the Center for Phlebotomy Education, Inc.)

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(5) Prior to venipuncture, if required, assemble the tube to the needle/holder according to the manufacturer's instructions.

(6) Hold the patient's arm firmly distal to the intended puncture site. The phlebotomist's thumb should be used to draw the skin taut. This anchors the vein. The thumb should be 1 to 2 inches (2.5 to 5.0 cm) below the venipuncture site.

(7) To prepare the patient, inform him or her that the venipuncture is about to occur. **NOTE:** From this point on, be prepared to react to a sudden and unexpected loss of consciousness.

(8) With the bevel up, puncture the vein with the needle at an angle of insertion of 30 degrees or less (See Figure 2). Keeping the needle as stable as possible in the vein, push/connect the first tube onto the needle. Maintain the tube below the site when the needle is in the vein.

(9) Release the tourniquet as soon as possible after the blood begins to flow. Do not change the position of the tube until it is removed from the needle. During the collection, do not allow the contents of the tube to contact the closure. Movement of the blood back and forth in the tube can cause reflux into the venous system and possible adverse patient reaction.

(10) Allow the tube to fill until the vacuum is exhausted and blood flow ceases. For tubes that contain additives, this will ensure there is a correct ratio of blood to additive.

NOTE: For systems that collect blood using an aspiration principle of collection rather than a vacuum, gently pull back on the piston rod until the piston reaches the base of the tube. This will ensure there is a correct ratio of blood to additive.

(11) When the blood ceases to flow, remove/disconnect the tube from the needle/holder. The sleeve re-covers the needlepoint that pierces the tube closure, stopping blood flow until the next tube is inserted/connected to the needle/holder. To obtain additional specimens, insert/connect the next tube to the needle/holder and repeat the collection procedure. Always remove the last tube collected from the needle/holder prior to withdrawing the needle from the vein. If only one tube is collected this must be removed prior to withdrawing the needle from the vein.

(12) Immediately after drawing each tube that contains an additive mix the blood gently and thoroughly by inverting the tube five to ten times. To avoid hemolysis, do not mix vigorously. For tubes that have been drawn using an aspiration principle, lock the piston into the base of the tube and snap off the piston rod after mixing.

8.9.2 Venipuncture Procedure Using Needle and Syringe

In general, venipuncture using a needle and syringe should be avoided for safety reasons. If conditions require a syringe draw, the following procedure is recommended:

(1) Assemble the needle and syringe.

(2) Hold the patient's arm firmly distal to the intended puncture site. The phlebotomist's thumb should be used to draw the skin taut. This anchors the vein. The phlebotomist's thumb should be 1 or 2 inches (2.5 cm or 5.0 cm) below the venipuncture site.

(3) Prepare the patient by informing him or her that the venipuncture is about to occur.

(4) With the bevel up, puncture the vein with the needle at an angle of insertion of 30 degrees or less (see Figure 2).

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(5) Keeping the needle as stable as possible in the vein, slowly withdraw the desired amount of blood.

(6) Release the tourniquet as soon as possible, after the blood begins to flow.

8.9.3 Fill the Tubes If Syringe and Needle Are Used

Syringe method of drawing venous blood is not recommended since it is much safer and easier to use a closed, venous blood collection tube system. If it is necessary to use a syringe, proceed with the following recommendations to transfer the blood from a syringe to a blood collection tube:

- Use the same "order of draw" as for a venous blood collection tube system (see Section 8.10.2).
- Rubber stoppers should not be removed from venous blood collection tubes to transfer blood to multiple tubes.
- To transfer the blood from the syringe to a venous blood collection tube, activate the safety feature of the needle or winged blood collection set used to withdraw the specimen, remove and discard the needle or winged collection set, and apply a safety transfer device.
- The stopper is pierced with the needle and the tube is allowed to fill (without applying any pressure to the plunger) until flow ceases. This technique helps to maintain the correct ratio of blood to additive if an additive tube is being used.
- Mix additive tubes by inversion.

8.9.4 Blood Specimen That Cannot Be Obtained

When a blood specimen cannot be obtained, it may be necessary to:

- Change the position of the needle. If the needle has penetrated too far into the vein, pull it back a bit. If it has not penetrated far enough, advance it farther into the vein. Rotate the needle half a turn. Lateral needle relocation should never be attempted in an effort to access the basilic vein, since nerves and the brachial artery are in close proximity.
- Try another tube to ensure the tube selected is not defective.
- Manipulation other than that recommended above is considered probing. Probing is not recommended. Probing is painful to the patient. In most cases another puncture in a site below the first site, or use of another vein on the other arm, is advisable.
- It is not advisable to attempt a venipuncture more than twice. If possible, have another person attempt to draw the specimen or notify the physician.

8.9.5 Ensure Patient's Hand Is Open

Opening the patient's hand reduces the amount of venous pressure as muscles relax. The patient must not be allowed to pump the hand.

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8.10 Step 10: Order of Draw

8.10.1 Additive Tubes

Gel separator tubes with clotting activators or anticoagulants are classified as additive tubes.[14] (For further information, refer to the most current edition of NCCLS document H18— *Procedures for the Handling and Processing of Blood Specimens*). These tubes should be drawn after the coagulation tube (blue stopper) and before other additive tubes (green, lavender, gray). All additive tubes should have a complete draw (see Section 8.9.1[10]).

8.10.2 Glass and Plastic Venous Blood Collection Tubes

The following order-of-draw is recommended when drawing multiple specimens for clinical laboratory testing during a single venipuncture. Its purpose is to avoid possible test result error due to cross contamination from tube additives.[15] This procedure should be followed for both glass and plastic venous blood collection tubes.

(1) Blood culture tube
(2) Coagulation tube (e.g., blue closure)
(3) Serum tube with or without clot activator, with or without gel (e.g., red closure)
(4) Heparin tube with or without gel plasma separator (e.g., green closure)
(5) EDTA (e.g., lavender closure)
(6) Glycolytic inhibitor (e.g., gray closure)

NOTE: The order of draw has been revised to reflect the increased use of plastic blood collection tubes. Plastic serum tubes containing a clot activator may cause interference in coagulation testing. Glass non-additive serum tubes may be drawn before the coagulation tube.

NOTE: When using a winged blood collection set for venipuncture and a coagulation tube is the first tube to be drawn, a discard tube should be drawn first. The discard tube must be used to fill the blood collection tubing dead space and to assure maintenance of the proper anticoagulant/blood ratio and need not be completely filled. The discard tube should be a nonadditive or a coagulation tube.

8.10.3 Coagulation Testing

Studies have shown that the PT (INR) and APTT results are not affected if tested on the first tube drawn.[16-18] Since it is not known whether other coagulation testing is affected, it may be advisable to draw a second tube for other coagulation assays. When a syringe system is used and a large specimen is taken, part of the blood from the second syringe should be used for the coagulation specimen. In the case of any unexplained abnormal coagulation test result, a new specimen should be obtained and the test repeated. If heparin contamination is suspected, the test should be repeated after the specimen is treated with a method that removes or neutralizes heparin. For more detailed descriptions of collection for coagulation testing, see the most current edition of NCCLS document H21—*Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays*.

8.11 Step 11: Release the Tourniquet

Release the tourniquet as soon as possible after the blood begins to flow.

8.12 Step 12: Place the Gauze Pad

A clean gauze pad should be placed lightly over the venipuncture site. Cotton balls are not recommended because of the possibility of dislodging the platelet plug at the venipuncture site.

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8.13 Step 13: Remove and Dispose of the Needle

Remove the needle and activate the safety mechanism according to the device manufacturer's instructions. Safely dispose of the unit into an easily accessible sharps container, consistent with OSHA regulations. Needles should not be resheathed, bent, broken, or cut, nor should they be removed from disposable syringes unless attaching a safety transfer device prior to disposal. Phlebotomists should anticipate a loss of consciousness and be prepared to react according to institutional policy. The use of ammonia inhalants may be associated with untoward effects and is not recommended. (See Section 11.8.1).

8.14 Step 14: Bandage the Arm

8.14.1 Normal Conditions

Under normal conditions, the phlebotomist should:

(1) Place the gauze pad over the site, continuing mild pressure.

(2) Check that bleeding has ceased, observe for hematoma, and apply an adhesive or gauze bandage over the venipuncture site. It is recommended that hypoallergenic adhesives be available.

(3) Tell patient to leave the bandage on for at least 15 minutes.

8.14.2 Continued Bleeding

The phlebotomist should watch for excessive bleeding. If a hematoma develops or bleeding persists longer than five minutes, a nurse should be alerted so that the attending physician can be notified. Pressure, applied with a gauze pad, must continue at the site as long as necessary to stop the bleeding. Wrap a gauze bandage tightly around the arm to keep the pad in place and tell the patient to leave the bandage on the site for at least 15 minutes.

8.15 Step 15: Label Blood Collection Tubes and Record Time of Collection

The patient and the patient's blood specimen must be positively identified at the time of collection. Blood specimens must be obtained in tubes identified with a firmly attached label bearing at least the following:

- The patient's first and last names
- An identification number
- The date
- The time (as required, e.g., therapeutic drug monitoring)
- The identification of the person collecting specimen.

The completed label must be attached to the tube before leaving the side of the patient, and there must be a mechanism to identify the person who drew the blood.[8] Alternatively, the manufacturer's tube label can be inscribed with the patient's complete information. Blood bank specimens must be labeled according to the standards set by the American Association of Blood Banks (AABB).

If an encoded (bar code) label is used, attach the label according to established institutional policy.

A permanent record is needed by the physician who must know exactly when each specimen was drawn to correlate the results with any change in the patient's condition. The laboratory also must document the

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time when the specimen was collected. If unable to obtain specimens, a record of the reasons and initials of the venipuncturist are necessary.

8.16 Step 16: Chill the Specimen (This is done only for certain specimens.)

Some tests require that blood specimens be cooled immediately following the venipuncture to slow down metabolic processes which may alter some test results. For more information on blood specimen handling and processing, see the most current edition of NCCLS document H18—*Procedures for the Handling and Processing of Blood Specimens*.

Examples of tests requiring chilling the specimen are:[19]

- Gastrin
- Ammonia
- Lactic acid
- Catecholamines
- pH/blood gas
- Parathyroid hormone (PTH).

8.17 Step 17: Send Blood Collection Tubes to the Proper Laboratories

Appropriately labeled blood collection tubes should be sent to appropriate laboratories designated to perform the required testing procedures. (See Section 8.15 for recommendations for labeling of tubes.)

9 Venipuncture in Children and Difficult Collections

If a venipuncture is requested on a child younger than one year of age, the phlebotomist should consult with the physician or follow institutional policy. For information on skin puncture blood collection, refer to the most current edition of NCCLS document H4—*Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture.*

9.1 Procedure

Except where indicated below, the procedure for venipuncture of adults as described in Section 8 should be followed for pediatric venipuncture.

9.2 Equipment

Venipunctures should be performed using equipment that can help to reduce the stress exerted on a vein to prevent vascular collapse. Examples include a venous blood collection system with a 22- to 23-gauge needle, or a 22- to 23-gauge (winged) blood collection set with attached tubing and venous blood collection tube holder. For pediatric patients, through the age of 16, larger gauge needles may be appropriate.

10 Additional Considerations

10.1 Monitoring Blood Volume Collected

It is recommended that a mechanism be in place to monitor the amount of blood drawn for pediatric and critically ill patients to avoid phlebotomy-induced anemia.

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10.2 Hematoma

To prevent a hematoma when performing a venipuncture, the phlebotomist should:

- Make sure the needle fully penetrates the uppermost wall of the vein (partial penetration may allow blood to leak into the soft tissue surrounding the vein by way of the needle bevel).
- Remove the tourniquet before removing the needle.
- Use the major superficial veins.
- Hold the venous blood collection assembly still while collecting the specimen.
- Before bandaging, ensure that the puncture to the vein has sealed by observing for hematoma formation after pressure is released.
- Apply a small amount of pressure to the area with the gauze pad when bandaging the arm.

10.3 Hemolysis

To prevent hemolysis when performing a venipuncture, the phlebotomist should:

- After cleansing, allow the venipuncture site to air dry.
- Never draw blood through a hematoma.
- If using a syringe, make sure the needle is fitted securely on a syringe to avoid frothing.
- When using a syringe and needle, avoid drawing the plunger back too forcibly.
- Gently invert the blood collection tube to mix additive specimens as recommended by the manufacturer.

11 Special Situations

11.1 Timed Intervals

Some specimens must be drawn at timed intervals because of medications, fasting requirements, and/or biological variations (circadian rhythm). It is important that collection of specimens for timed tests be obtained at the precisely specified interval. Directions should be given to the venipuncture team to obtain these specimens accurately.

11.1.1 Examples of Tests Requiring Timed Specimens

- Tolerance tests (e.g., two-hour postprandial glucose and three-hour glucose tolerance test), cortisol
- Therapy monitoring (e.g., prothrombin time, APTT, digoxin, and other drugs)

11.1.2 Documentation

For therapeutic drug monitoring, the dose of the medication and the time of the last dose given, as well as the time of the specimen collection, should be recorded accurately on the request slip.

11.2 Specific Collection Techniques

11.2.1 Blood Alcohol

When drawing a blood specimen for alcohol testing, a nonalcohol-based cleanser should be used to cleanse the venipuncture site (e.g., soap). (See the most current edition of NCCLS document T/DM6—*Blood Alcohol Testing in the Clinical Laboratory* for further information.)

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11.2.2 Legal Specimens

Appropriate chain-of-custody procedure should be followed. (See NCCLS document T/DM6—*Blood Alcohol Testing in the Clinical Laboratory*.)

11.2.3 Blood Culture Specimens

There are time and temperature requirements to be followed in collection, transport and storage of specimens for blood culture. In addition, there are variations in the volume of blood needed for culture. In general, adult blood cultures require 10 to 20 mL/set and infant blood cultures are done on 1 to 2 mL/set.[7] Please refer to the manufacturer's instructions for specific blood volume requirements. These requirements may vary considerably depending on the device.

11.2.4 Trace Elements

For collection of blood for trace elements testing (e.g., zinc) special, metal-free collection containers should be used. (See the most current edition of NCCLS document C38—*Control of Preanalytical Variation in Trace Element Determinations*, for more information.)

11.2.5 Immunohematology Specimens

Gel separator tubes must not be used for immunohematology specimens.[8] It is important to refer to manufacturer's package inserts for collection tubes and for test methods for other possible gel tube application limitations.

11.3 Indwelling Lines or VADs

A line is a piece of tubing inserted into a patient's vein or artery for administering fluids and medications, monitoring pressures, and obtaining blood samples for diagnostic tests. Without complete, thorough and documented training, it is not recommended that phlebotomists draw blood from indwelling cardiovascular (arterial, central venous) or umbilical lines. Institutional policy should be followed.

NOTE: Under certain circumstances, blood specimens for clinical laboratory testing may be drawn from a vascular access device (VAD) using a blood collection system or a syringe. When obtaining a blood specimen from a VAD, the components of the blood collection system (VAD, connecting device, syringe, needle, and collection device) should be checked to ensure compatibility to avoid air leaks, which may cause hemolysis and incorrect draw volumes. Collection of the blood through lines that have been previously flushed with heparin should be avoided, if possible. If the blood must be drawn through a VAD, possible heparin contamination and specimen dilution should be considered. The line should be flushed with 5 mL of saline, and the first 5 mL of blood or six dead space volumes of the VAD discarded.

11.3.1 Potential Error

Obtaining blood specimens from indwelling lines or VADs may be a problem and a potential source of test error because of incomplete flushing of collection site resulting in contamination and/or dilution of the specimen contributing to inaccurate results.[20-22]

11.3.2 Flushing Lines

Because it is normal practice to flush lines with a solution to reduce the risk of thrombosis, lines must be cleared of this fluid before blood specimens can be drawn for diagnostic testing. An adequate amount of blood must be withdrawn from the line and discarded before drawing a specimen to ensure that the actual specimen is not diluted or contaminated with the flush solution. Discard volume is dependent on the dead

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space volume of the particular line. Discarding two times the dead-space volume is recommended for noncoagulation testing, and 5 mL or six times the dead-space volume for coagulation tests.[20,23-25] (For additional information, please refer to the most current edition of NCCLS document H21—*Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays.*) See the "NOTE" in Section 11.3 for specific recommendations for coagulation testing specimens with line draws.

11.4 Heparin or Saline Locks

An indwelling winged infusion set can be successfully left in a vein from 36 to 48 hours for intravenous administration of medication or as a vein source to obtain a blood specimen. This procedure, known as a "heparin or saline lock," has become more common in hospitals to "save" veins for therapeutic use and also to cause less trauma to the patient. With this system, it is not necessary to keep the vein open with a continuous intravenous infusion, thus allowing the patient more comfort and mobility.

11.5 Fistula

A fistula is an artificial shunt connection done by a surgical procedure to fuse the vein and artery together. It is used for dialysis only.

An arm with a fistula should not be used routinely for blood drawing. When possible, specimens should be drawn from the opposite arm. Care must be taken of the fistula, as it is permanent.

11.6 Intravenous Fluids

Skin puncture is recommended when venous access is not readily available. (See the most current edition of NCCLS document H4—*Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture* for more information.)

When an intravenous fluid (including transfused blood products) is being administered in a patient's arm, blood should not be drawn from that arm if at all possible. Test results from this blood may be erroneous and thus misleading to the physician.

Satisfactory specimens may be drawn distal to the intravenous infusion site. If this is not possible, a specimen may be obtained from a proximal site.[13,26] However, it has been shown that blood drawn proximal to the intravenous site can be contaminated with the fluid being administered. Facilities should establish their own policy. The collection procedure is as follows:

(1) Ask the responsible caregiver for the intravenous infusion to be turned off for at least two minutes before venipuncture. Care should be taken to ensure that the flow has been completely discontinued.

(2) Apply the tourniquet. When drawing distal to the intravenous infusion site, apply the tourniquet between the intravenous and the intended venipuncture site.

(3) Perform the venipuncture.

It must be documented that the venipuncture was performed proximal or distal to an infusion site and from which arm.

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11.7 Isolation

Patients are isolated to prevent disease from spreading to other patients, visitors, or employees.[27] Some hospitals may also provide a different, protective isolation for patients who could be placed at increased risk from outside contamination.

11.7.1 Isolation Systems

Each hospital determines the system which best provides for their particular mix of patients, visitors, and employees. In most cases, a color-coded card placed just outside the patient's room describes the type of isolation and the precautions to be taken by those entering the room. It is important to understand and use the appropriate precautions.

11.7.1.1 Types of Isolation

Recent guidance emphasizes two tiers of infection control precautions[27]:

- standard, to be used for all patients, and
- transmission-based.

There are three types of transmission based isolation precautions[23]:

- airborne,
- droplet, and
- contact.

Hospitals have protocols for isolation procedures available through their infection control practitioner, infection control committee, or hospital epidemiologist. The example given in Sections 11.7.1.2 through 11.7.2 is an example of such a protocol. Some hospitals may provide for disinfection, dedication or disposal of equipment used in isolation rooms.

11.7.1.2 Clean Area

Gowns, gloves, masks, etc., are kept in a clean area. In some hospitals, a stand containing these supplies is kept outside the room. The new modern hospital often has an anteroom which serves as the "clean area." Here, the person entering the room can gown and apply other protective barriers as necessary before entering the patient's room. Doctors' suit coats, jackets, and other apparel are left here.

11.7.2 Isolation Room

11.7.2.1 Procedures to Follow Before Entering the Isolation Room

(1) Read the isolation sign on the door. It will explain the type of isolation, protective clothing to be worn, and the procedure to follow. Follow these instructions carefully.

(2) Check the orders and assemble an adequate amount of necessary equipment for the patient.

NOTE: Any supplies taken into the room must be left there, or discarded.

(3) Never take trays into the isolation room.

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11.7.2.2 Procedures to Follow in an Isolation Room

(1) Place paper towels on the table and place the equipment on one or two towels that have been spread open.

(2) Wash hands.

(3) Put on gloves.

(4) Obtain blood specimens in the usual manner, avoiding any unnecessary contact with the patient and bed.

(5) After mixing, place the filled tubes on a clean paper towel.

(6) Dispose of blood collection assembly into an easily accessible, approved puncture resistant disposal container, consistent with OSHA regulations, according to institutional policy.

NOTE: Recapping of needle is not recommended. (See the most current edition of NCCLS publication M29—*Protection of Laboratory Workers from Occupationally Acquired Infections*.)

(7) Dispose of the tourniquet in the proper container.

(8) Remove gown and gloves and dispose of them in the proper container.

(9) Wash hands.

(10) Turn off the faucet with a clean paper towel so that hands are not contaminated.

(11) Pick up the tubes from the paper towel and clean the outside of the tube with 1:10 dilution of bleach. Place tubes in a secondary container, which will contain the specimen if the primary container breaks or leaks in transit to the laboratory. A plastic bag with a sealable, leakproof closure can be used.

(12) If blood smears were made, place the smears on two clean paper towels. When ready to leave, wrap the smears and tubes in the top paper towel and discard the bottom paper towel and place in a secondary container.

11.7.3 Exposure

The phlebotomist must immediately report an accidental needlestick or contamination of a break in the skin by blood or excreta to a supervisor, and follow institutional guidelines. (See also NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections*.)

11.8 Emergency Situations

At least one member of available on-site healthcare personnel should have extensive first aid training, including special training in cardiopulmonary resuscitation, so that medical attention can be given to a needy patient while the physician on call is en route. This individual should be identified to phlebotomists. Emergency numbers should be posted in phlebotomy drawing areas.

11.8.1 Syncope (Fainting) or Unexpected Nonresponsiveness

The procedure for dealing with a patient who has fainted or is unexpectedly nonresponsive is to:

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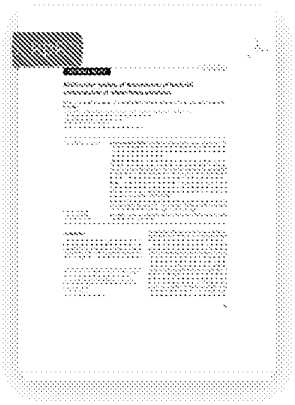

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Vox Sanguinis, 2002

Luc Noel P. Perez Paul Pérez

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ORIGINAL PAPER

Multivariate analysis of determinants of bacterial contamination of whole-blood donations

P. Perez[1], C. Bruneau[2], M. Chassaigne[2], L. R. Salmi[1], L. Noel[3], P. Allouch[3], A. Audurier[2], C. Gulian[4], G. Janus[5], G. Boulard[3] & P. de Micco[4]

[1]Institut de Santé publique, d'Epidémiologie et de Développement, Université Victor Segalen Bordeaux 2, Bordeaux, France
[2]EFS Centre-Atlantique and Faculté de Médecine, Université de Tours, Tours, France
[3]Hôpital Mignot and EFS Île-de-France, Versailles, France
[4]EFS Alpes-Méditerranée, Marseille, France
[5]Centre de Transfusion Sanguine des Armées Jean Julliard, Clamart, France

Vox Sanguinis

Background and Objectives Introduction of bacteria into blood components at the collection stage seems to be a frequent occurrence. We therefore assessed determinants of bacterial contamination of whole-blood donations to gain insight into contamination mechanisms and direct prevention.

Materials and Methods A cross-sectional study was carried out on donors accepted for whole-blood donation in four French blood banks. Each blood bank used its own two-stage procedure for phlebotomy site preparation. Contamination was identified by culturing two 15-ml samples (collected aseptically at the outset of donation) in a BacT/Alert 240® system. Determinants were assessed by logistic regression analysis.

Results Bacterial contamination, mainly by skin flora, occurred in 76 (2·2%) out of 3385 donations. Significant determinants were as follows: the blood bank (odds ratio (OR) range = 3·0–5·6, $P < 0·001$); lack of repetition of scrub (OR = 2·7, $P = 0·032$); and donor age > 35 years (OR = 1·8, $P = 0·036$).

Conclusion Systematic scrub repetition should be implemented to reduce bacterial contamination by skin flora at the collection stage. Further research is required to clarify the role of different antiseptic agents and of donor age.

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Key words: adverse effects, bacterial infections, blood donors, blood transfusion, logistic models, prevention, risk factors.

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Introduction

Transfusion-associated bacterial contamination (TABC) is a potentially serious transfusion adverse event, reported to be responsible for 10% of transfusion-related fatalities reported in the USA from 1976 to 1999 [1], and for 22% in France from 1994 to 1999 [2]. TABC was considered by the United States ing transfusion safety [3] and has been recently acknowledged as the most frequent transfusion-transmitted infection [4].

The most effective measures for preventing TABC would be systematic culture of every blood component or the application of bacterial inactivation steps during manufacture. However, bacterial inactivation methods are still under development [5], and techniques currently available for aseptic sampling and culture of cellular blood components may need further validation [6]. Other possible interventions may be aimed at avoiding or reducing the introduction of bacteria from all possible sources [7]. Contamination sources are rarely found, but that most frequently reported is the blood donor [7,8]. Bacteria may come from the bloodstream of infected but asymptomatic donors, or from the donor skin [8]. Despite well-conducted antisepsis, high concentrations of bacteria

Correspondence: Paul Perez, MD, PhD, Unité de Soutien Méthodologique à la Recherche Clinique et Epidémiologique du Centre Hospitalier Universitaire de Bordeaux, Unité INSERM 330, Case 11, Université V. Segalen Bordeaux 2, 146 Léo-Saignat, 33076 Bordeaux Cedex, France
Tel.: (33) 5 57 57 14 42
Fax: (33) 5 57 57 15 78
E-mail: Paul.Perez@isped.u-bordeaux2.fr

may remain on the skin surface [9,10]. Moreover, a core of deeper skin layers, which might not be adequately disinfected, may enter the needle during collection and introduce bacteria into the donation [7]. Pilot studies have reported that 0·3–0·6% of whole-blood donations are contaminated by bacteria, probably of skin origin [11,12].

Research on factors contributing to bacterial contamination at the collection stage may help to identify contamination mechanisms and consequently lead to the development of new interventions to improve the safety of blood transfusion. Possible factors favouring bacterial multiplication might include a high ambient temperature (leading to sweating) and poor skin hygiene. In addition, factors leading to a higher possibility of unintentional inclusion of bacteria from the phlebotomy site might be important; these factors include: skin lesions (because of their possible infectious origin); hairs (because hair follicles, rich in bacteria, may be touched by the needle); and scars (already reported to contain higher concentrations of bacteria than healthy skin) [13].

The objective of our study was to assess determinants associated with bacterial contamination of whole-blood donations.

Subjects and methods

Data collection

This cross-sectional study was nested in a study implemented to assess the efficacy of diverting the first 15 ml of blood collection to reduce bacterial contamination of whole-blood donations [14]. The study was carried out from March to December 1997 in four French volunteer blood banks: Etablissement Français du Sang (EFS) Centre-Atlantique (Tours); Centre de Transfusion Sanguine des Armées Jean Julliard (Clamart); EFS Alpes-Méditerranée (Marseille); and EFS Île-de-France (Versailles). To culture blood samples on the day of donation, collection sites were selected if they collected whole-blood donations in the morning. Donors were included if they had been accepted for donation after a medical selection complying with French regulations [15] and had given their informed consent to participate.

The phlebotomy site was prepared according to a two-stage procedure complying with the French Blood Agency recommendations [16]. This involved preparation of an area of skin of ≈ 3·5 cm in all directions around the intended phlebotomy site. The site was then scrubbed with a gauze pad soaked with an antiseptic or detergent agent (the regulations recommend that this stage is to be repeated 'if needed'). The second stage involved application of an antiseptic agent compatible with the one used in the first stage. The skin was then allowed to dry for the time recommended by the manufacturer of the antiseptic agent. Different antiseptic agents were used by each of the participating blood banks. However, all of the blood banks used the same agent for both stages of skin preparation. The scrub duration was 5–10 seconds. Application times were 5–10 seconds in all blood banks except in blood bank 4 where the second gauze pad soaked with antiseptic was left on the intended phlebotomy site for 30 seconds before being used to wipe the site. Drying times after application varied according to the antiseptic agent used: more than 15–20 seconds for iodine tincture in blood bank 1; more than 30 s for Hibisprint® (chlorhexidine) in blood bank 2; and 1 min for non-alcoholic Betadine® (povidone-iodine) in blood bank 3. Blood bank 4 used Bisseptine® (chlorhexidine, benzalkonium chloride, benzylic alcohol) and did not recommend any drying time. An additional drying time of 30 seconds between stages 1 and 2 was applied in blood bank 2.

The age and gender of the donor, the time since the last meal (as stated by the donor), and the site, date and hour of collection, were recorded by the physician. The skin at the phlebotomy site was carefully inspected by the nurse who recorded the presence of hairs, scars from previous phlebotomies, or skin lesions less than 10 cm away from the phlebotomy site. The requirement to repeat the scrub stage when the first gauze pad was dirty, and the ease of phlebotomy, were also recorded.

Blood was collected into standard Maco Pharma packs (Maco Pharma, Tourcoing, France), specially equipped with two small sample bags into which the first (S1) and second (S2) 15 ml of donation were aseptically collected, before blood was allowed to enter the unit bag. At the end of donation, the two sample bags were separated from the rest of the pack by double welding, placed into an isothermal box and brought to the bacteriology laboratory within 6 h.

Bacteriological methods

Samples were cultured in a BacT/Alert® 240 automated system (Organon Teknika, Durham, NC). Each sample bag was equipped with a needle allowing direct inoculation through the rubber cap of an anaerobic then an aerobic FAN culture bottle. Bottles were incubated in the BacT/Alert® for 7 days at 35 °C, according to the manufacturer's instructions.

A sample from each bottle detected as positive was subcultured onto trypticase–soy 5% blood agar (for aerobic culture) and onto Columbia blood agar (for anaerobic culture), both at 37 °C. When a subculture was positive, bacteria were identified according to standard microbiological methods and stored. A donation was defined as contaminated with bacteria if at least one aerobic or anaerobic bottle inoculated with S1 or S2 was culture positive.

The correct functioning of the automated culture systems was verified by inoculation and incubation of positive controls in the same conditions as study samples. One out of four strains was cultured each week in each centre, alternately: *Staphyloccocus aureus* CIP 53·156 (American Type Culture Collection [ATCC] 6538P; ATCC, Rockville, MD), *Clostridium sporogenes* CIP 79·03 (ATCC 19404), *Propionibacterium*

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acnes CIP 53·117T (ATCC 6919) and *Pseudomonas aeruginosa* CIP 76·110 (ATCC 27853). Bottles were expected to be culture positive within 10–24 h, depending on the strain of bacteria used. The rate of secondary contamination related to handling or inoculation was estimated by culturing the anticoagulant from 189 S1 and 189 S2 sample bags which were not used for donation, but which were transported, inoculated and incubated under the same experimental conditions as the study samples.

Data management and analysis

For each donation, information regarding blood collection was recorded on a report form. Culture results were recorded on a separate form at the laboratory and transferred to the corresponding donation form. Data were entered in each centre on the EPI INFO software (6·04b French version, January 1997, ENSP – Epiconcept) and files were transmitted to the Institut de Santé Publique, d'Epidémiologie et de Développement (Université Victor Segalen Bordeaux 2). Donations were excluded from analysis if clots or welding problems were reported during collection or inoculation, or if the blood volumes collected in S1 or S2 or inoculated in FAN bottles, were less than 5 ml.

The bacterial contamination rates of donations were estimated by the proportion of donations for which S1 or S2 was culture positive and its exact binomial 95% confidence intervals (95% CI). Comparisons were based upon standard tests [17]. The association between a variable and donation contamination was estimated by the odds ratio (OR) [18]. To analyse the simultaneous effect of several variables on the risk of contamination, a logistic regression model was used [19]. All variables were included in the multivariate model, regardless of their association with bacterial contamination in univariate analysis. A stepwise backward procedure was used to remove variables that were less significantly associated with donation contamination, according to Wald or the likelihood ratio test [19]. Statistical analysis was conducted using the STATA software (Stata 5·0; Stata Corporation, College Station, TX).

Results

Study population

Among 3441 whole-blood donations, collected from March through December 1997, 56 (1·6%) were excluded because of clots, welding problems or insufficient collection or culture volumes. Most donations were collected during mobile sessions (premises, 50%; vehicle, 37%), and before 14·00 h (99·4%); the time since the last meal was less than 3 h in 60·4% of the donors. A high percentage of the donors were male (73·3%) and their median age was 39 years (first quartile: 27 years; third quartile: 48 years). The presence of hairs at the phlebotomy site was reported in 29·5% of men and 2·0% of women; skin lesions close to the phlebotomy site were present in 2·3% of donors; and scars were present in 14·3% (minor signs, 10·6%; multiple scars, 2·9%; dimpled skin, 0·7%). The scrub stage of antisepsis was repeated in 8·5% of donations, and phlebotomy was reported as easy in 43·3%.

Bacteriological results

All positive controls were detected by the automated culture system. One negative control out of 378 (0·26%) was culture positive for coagulase negative staphylococci (CNS).

Seventy-nine bacteria were cultured from samples originating from 76 donations. The most common bacterial species were Gram-positive cocci, which accounted for 81% of the bacterial species and were mostly CNS (66%). Gram-positive bacilli, mostly Bacillus species and *P. acnes*, accounted for 14%, and Gram-negative bacilli for 5%, of species.

The overall prevalence rate of bacterial contamination was 2·2% (95% CI: 1·8–2·8%).

Determinants of bacterial contamination

In the univariate analysis, characteristics significantly associated with bacterial contamination were the blood bank, period of collection, time since last meal, donor age and the presence of hairs at the phlebotomy site (Table 1). As the rate of contamination was more than twofold higher when donors were > 35 years, this characteristic was used as a binary variable.

Characteristics significantly associated with bacterial contamination in the final multivariate model were the blood bank, a donor age > 35 years and the lack of repetition of the antisepsis scrub stage (Table 1).

Discussion

Our study confirmed the high frequency of bacterial contamination of whole-blood donations and revealed a strong protective role of repeating the antisepsis scrub stage. Other main determinants were the collecting blood bank and donor age. Contaminating bacteria, isolated after culture, were most likely to have a skin origin.

Our estimation of bacterial contamination rates of blood donations is higher than those previously reported in whole-blood units, but consistent with those of the first few ml collected [20] and with blood-culture contamination rates reported in clinical settings, where the same mechanisms may be implicated [21,22].

The major influence of the collecting blood bank may be related to the agent used for antisepsis. The risk of bacterial contamination was the highest in the blood bank using non-alcoholic povidone-iodine. This is consistent with studies

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Table 1 Univariate (3385 donations) and multivariate (3227 donations) analysis of associations between whole-blood donation characteristics and bacterial contamination in four French blood banks, March–December 1997

	Univariate analysis	Multivariate analysis (final model)

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1	1·59	2·71		2·05 (0·66–6·37)	
2	0·59	Ref.[d]		Ref.[d] (Ref.[d])	
3	3·92	6·87	< 0·001	5·63 (1·92–16·48)	0·0002
4	2·42	4·18		3·56 (1·16–10·91)	
Collection site					
Mobile session (premises)	2·74	1·58			
Mobile session (truck)	1·75	Ref.[d]	0·15		
Blood bank premises	1·77	1·01			
Period of collection					
March to May	1·59	Ref.[d]		Ref.[d] (Ref.[d])	
June to September	1·89	1·19	0·03	0·87 (0·41–1·86)	0·091
October to December	3·32	2·13		1·53 (0·70–3·36)	
Time since last meal (19 missing data)					
0 to 59 min	1·74	Ref.[d]		Ref.[d] (Ref.[d])	
1 h to 1 h 59 min	3·16	1·96		1·95 (0·87–4·36)	
2 h to 2 h 59 min	1·52	0·87	0·02	1·01 (0·43–2·37)	0·052
3 h to 3 h 59 min	1·57	0·90		1·01 (0·42–2·43)	
4 h or more	3·53	2·06		2·22 (0·98–5·02)	
Donor gender					
Male	2·14	Ref.[d]			
Female	2·55	1·20	0·47		
Donor age > 35 years					
No	1·43	Ref.[d]		Ref.[d] (Ref.[d])	
Yes	2·82	2.00	0·008	1·77 (1·02–3·07)	0·036
Phlebotomy site features					
Hairs (14 missing data)					
None	1·98	Ref.[d]		Ref.[d] (Ref.[d])	
Yes	3·21	1·64	0·05	1·51 (0·90–2·54)	0·125
Skin lesions (98 missing data)					
None	2·31	Ref.[d]			
Yes	2·60	1·13	0·87		
Scars					
None	2·31	Ref.[d]			
Minor signs	1·39	0·60			
Multiple scars	3·03	1·32	0·60		
Dimpled skin	4·00	1·76			
Scrub stage repeated (30 missing data)					
Yes	1·40	Ref.[d]		Ref.[d] (Ref.[d])	
No	2·35	1·68	0·32	2·72 (0·96–7·73)	0·032
Easiness of phlebotomy (29 missing data)					
Yes	1·72	Ref.[d]			
No	2·68	1·57	0·07		

[a]χ^2 or Fisher's exact test.
[b]CI: confidence interval of odds ratio (OR).
[c]Likelihood ratio test.
[d]Reference category for OR estimation.

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TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	04/17/2024

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	04/17/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-573000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via the USPTO patent electronic filing system ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

27500 7590 01/17/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 01/17/2024

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 17/538,990	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 12/20/2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-20 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. 10/08/2024.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12/20/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Terminal Disclaimer

3. The terminal disclaimer filed on 12/20/2023 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S Patent Applications No. 9820682, 10143412 and 11185266 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

4. Authorization for this examiner's amendment was given in an interview with BEN HUDSON on 01/08/2024.

Claim 5 should be amended as follow:

5. (Currently Amended) The blood sample control device in accordance with claim **3** ~~2~~, wherein the housing comprises a bottom member mated with a top member, each of the

bottom member and the top member defining a part of each of the inlet, the outlet, the chamber, and the sampling channel.

Claim 10 should be amended as follow:

10. (**Currently Amended**) The bodily fluid control device in accordance with claim 6, wherein the air permeable blood barrier includes an air permeable material that at least partially seals upon contact with **the bodily fluid** ~~blood~~.

Claim 13 should be amended as follow:

13. (Currently Amended) A bodily fluid control device comprising;

an inlet;

a junction connected with the inlet;

an outlet;

a chamber connected with the inlet via the junction, the chamber having a vent that includes an air permeable bodily fluid barrier that at least partially seals upon contact with a first portion of bodily fluid;

a housing that houses and defines the inlet, the outlet, and the chamber; and

wherein the chamber and the junction **are** ~~being~~ configured to direct the first portion of the bodily fluid from the inlet into the chamber toward the air permeable bodily fluid barrier and to displace air in the chamber, whereupon at least partially sealing of the air permeable bodily fluid barrier enables at least temporary containment of the first portion of the bodily fluid in the chamber, and enables a second portion of the bodily fluid from the inlet to bypass the chamber via the junction and be directed toward the outlet.

Allowable Subject Matter

5. Claims 1-20 are allowed.

6. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Eldridge et al (U.S 4,207,870) teaches a blood sample device for sampling blood conveyed from a patient, the blood device comprising; an inlet port configured to receive the blood conveyed from the patient; an outlet port; a chamber; and a sampling channel having a distal end connected with the outlet port; a junction connected between the inlet port, the chamber and the sampling channel, the junction being sized and configured such that a first portion of blood conveyed from the patient flows into the chamber to displace air therein through the air permeable blood barrier and to be sequestered in the chamber.

The prior art does not teach, disclose and/or fairly suggest the chamber having a vent that includes an air permeable blood barrier, and wherein the junction is configured to allow a second portion of blood to bypass the chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Examiner-Initiated Interview Summary	**Application No.** 17/538,990	**Applicant(s)** ROGERS et al.		
	Examiner MAY A ABOUELELA	**Art Unit** 3791	**AIA (First Inventor to File) Status** Yes	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
MAY A ABOUELELA	Primary Examiner	Telephonic
BEN HUDSON	Attorney of Record	

Date of Interview: 08 January 2024

Issues Discussed:

35 U.S.C. 112

Applicant and Examiner discussed the claims set mailed on 12/20/2023. Applicant and Examiner discussed the claim language with respect to the applied prior art and the disclosure. Applicant and Examiner discussed proposed claim amendments represented by the Examiner to overcome 112 rejection for claims 5, 10 and 13. The Applicant has authorized the Examiner to amend the claims.

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4416291		1983-11-22	KAUFMAN JOSEPH	
	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
	7	11660030		2023-05-30	BULLINGTON GREGORY J	
	8	11259727		2022-03-01	BULLINGTON GREGORY J	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17538990
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	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
	12	11612340		2023-03-28	BULLINGTON GREGORY J	
	13	11234626		2022-02-01	BULLINGTON GREGORY J	
	14	10624977		2020-04-21	BULLINGTON GREGORY J	
	15	11653863		2023-05-23	BULLINGTON GREGORY J	
	16	11419531		2022-08-23	BULLINGTON GREGORY J	
	17	11786155		2023-10-17	BULLINGTON GREGORY J	
	18	11789017		2023-10-17	BULLINGTON GREGORY J	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Attorney Docket Number	069366-0572201_KUR2C03US

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
	2	20220151527		2022-05-19	BULLINGTON GREGORY J	
	3	20200289039		2020-09-17	BULLINGTON GREGORY J	
	4	20210275068		2021-09-09	MIAZGA JAY M	
	5	20220304664		2022-09-29	HAMMER JEREMY	
	6	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	01/08/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17538990
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	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-12-20
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

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10958 BERLIN
GERMANY
Tel: +49 30 2590 10
Fax: +49 30 2590 1840

Annex to EPO Form 2004, Communication pursuant to Rule 71(3) EPC

Bibliographical data of European patent application No. 19 200 766.4

For the intended grant of the European patent, the bibliographical data are set out below, for information:

Title of invention:
- BLUTPROBENOPTIMIERUNGSSYSTEM SOWIE VORRICHTUNG ZUR SEQUESTRIERUNG VON BLUTKONTAMINANTEN
- BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE
- SYSTÈME D'OPTIMISATION D'ÉCHANTILLON DE SANG ET DISPOSITIF DE SÉQUESTRATION DE CONTAMINANTS DU SANG

Classification: INV. A61B5/15 A61B5/153 A61B5/154

Date of filing: 22.07.2016

Priority claimed:
US / 24.07.2015 / USP201562196797
US / 07.10.2015 / USP201562238636
US / 04.04.2016 / USP201662318194
US / 27.04.2016 / USA201615140448
US / 27.04.2016 / USA201615140443

Contracting States* for which fees have been paid:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

Extension States* for which fees have been paid:

Validation States* for which fees have been paid:

Applicant(s):**
Kurin, Inc.
10755 Scripps Poway Parkway
No. 257
San Diego, California 92131
US

Inventor(s):
Rogers, Bobby
10755 Scripps Poway Parkway No. 257
San Diego, CA 92131
US

Kang, Gino
10755 Scripps Poway Parkway No. 257
San Diego, CA 92131
US

Europäisches Patentamt
European Patent Office
Office européen des brevets

European Patent Office
10958 BERLIN
GERMANY
Tel: +49 30 2590 10
Fax: +49 30 2590 1840

Detloff, John
10755 Scripps Poway Parkway No. 257
San Diego, CA 92131
US

*)	If the time limit for the payment of designation fees according to Rule 39(1) EPC has not yet expired and the applicant has not withdrawn any designation, **all Contracting States/Extension States/Validation States** are currently still deemed to be designated. See also Rule 71a(3) EPC and, if applicable, the above Note to users of the automatic debiting procedure.
**)	If two or more applicants have designated different Contracting States, this is indicated here.

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GERMANY
Tel: +49 30 2590 10
Fax: +49 30 2590 1840

Thum, Bernhard
Thum & Partner
Thum Mötsch Weickert
Patentanwälte PartG mbB
Siebertstr. 6
81675 München
ALLEMAGNE

Formalities Officer
Name: Acquaviva, Laure
Tel: +49 89 2399 - 5656
or call
+31 (0)70 340 45 00

Application No.	Ref.	Date
19 200 766.4 - 1122	KUR-19054-P-EP	31.08.2022
Applicant: Kurin, Inc.		

Communication under Rule 71(3) EPC

1. Intention to grant

You are informed that the examining division intends to grant a European patent on the basis of the above application, with the text and drawings and the related bibliographic data as indicated below.

A copy of the relevant documents is enclosed.

1.1 In the text for the Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

Description, Pages

2, 3, 5, 7-37	as originally filed	
1, 4, 4a	filed in electronic form on	18-09-2020

Claims, Numbers

1-14	filed in electronic form on	18-09-2020

Drawings, Sheets

1/50-50/50	as originally filed

With the following amendments to the above-mentioned documents proposed by the division

Description, Pages	1, 4, 4a, 5, 7, 9, 23, 25, 29, 31, 34
	Delete Previous: 6

Registered letter
EPO Form 2004C 07.20CXP

Comments

DESCRIPTION
Page 1: Deletion of irrelevant and/or superfluous information (Rule 48(1)(c) EPC, Guidelines F-II, 7.4)
Pages 4, 5, 7, 9, 29, 34: Description adapted to the claims (Art. 84 EPC)
Pages 4(a), 5, 7: Description adapted to amended claims (Art. 84 EPC)
Page 6: (PAGE DELETED) - Description adapted to amended claims (Art. 84 EPC)
Pages 23, 25, 31: Insertion of SI/metric units (Rule 49(10) EPC)
Pages 38-43: (PAGE DELETED) -

1.2 Bibliographic data

The title of the invention in the three official languages of the European Patent Office, the international patent classification, the designated contracting states, the registered name(s) of the applicant(s) and the other bibliographic data are shown on **EPO Form 2056** (enclosed).

2. Invitation

You are invited, **within a non-extendable period of four months** of notification of this communication,

2.1 to EITHER approve the text communicated above and verify the bibliographic data (Rule 71(5) EPC)

(1) by filing a translation of the claim(s) in the other two official languages of the EPO

		Fee code	EUR
(2a)	by paying the fee for grant including the fee for publication:	**007**	990.00
	minus any amount already paid (Rule 71a(5) EPC):		0.00
		Total amount:	990.00
(3)	by paying additional claims fees under Rule 71(4) EPC; number of claims fees payable: 0	**016**	0.00
	minus any amount already paid (Rule 71a(5) EPC):		0.00
		Total amount:	0.00

Important: If the translations of the claims and fees have already been filed and paid respectively in reply to a previous communication under Rule 71(3) EPC, e.g. in the case of resumption of examination after approval (see Guidelines C-V, 6), **agreement as to the text to be granted** (Rule 71a(1) EPC) must be expressed within the same time limit (e.g. by approving the text and verifying the bibliographic data, by confirming that grant proceedings can go ahead with the documents on file and/or by stating which translations of the claims already on file are to be used).

Note 1: See "Notes concerning fee payments" below.
Note 2: Any overpaid "minus" amounts will be refunded when the decision to grant (EPO Form 2006A) has been issued.
Note 3: For the calculation of the grant fee under Article 2(2), No. 7, RFees (old fee structure), the number of pages is determined on the basis of a clean copy of the application documents, in which text deleted as a result of any amendments by the examining division is not shown.

Such clean copy is made available via on-line file inspection only.

2.2 OR, in the case of disapproval, to request reasoned amendments or corrections to the text communicated above or keep to the latest text submitted by you (Rule 71(6) EPC).

In this case the translations of the claims and fee payments mentioned under point 2.1 above are NOT due.

The terms "amendment(s)" and "correction(s)" refer only to amendments or corrections of the application documents and not of other documents (e.g. bibliographic data, the designation of the inventor, etc.).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the examining division requesting that you correct this deficiency (Rule 137(4) EPC).

2.3 Bibliographic data

Where you request a change or correction of bibliographic data in response to the Rule 71(3) communication, this will **not** cause the sending of a further communication under Rule 71(3) EPC. You will still have to pay the fees and file translations in reply to the Rule 71(3) communication in the case of 2.1 above, unless you also file a reasoned request for amendments or corrections in response to the Rule 71(3) communication (see case 2.2 above).

3. Loss of rights

If neither of the two possible actions above (see points 2.1 or 2.2) is performed in due time, the European patent application will be deemed to be withdrawn (Rule 71(7) EPC).

4. Further procedure

4.1 In the case of point 2.1 above

4.1.1 The decision to grant the European patent will be issued, and the **mention of the grant** of the patent will be published in the European Patent Bulletin, if the requirements concerning the translation of the claims and the payment of all fees are fulfilled and there is agreement as to the text to be granted (Rule 71a(1) EPC).

Note on payment of the renewal fee:
If a renewal fee becomes due before the next possible date for publication of the mention of the grant of the European patent, publication will be effected only after the renewal fee and any additional fee have been paid (Rule 71a(4) EPC).

Under Article 86(2) EPC, the obligation to pay renewal fees to the European Patent Office terminates with the payment of the renewal fee due in respect of the year in which the mention of the grant of the European patent is published.

Note on payment of the designation fee(s):
If the designation fee(s) become(s) due after the communication under Rule 71(3) EPC, the mention of the grant of the European patent will not be published until these fees have been paid (Rule 71a(3) EPC).

4.1.2 After publication, the **European patent specification** can be downloaded free of charge from the EPO publication server https://data.epo.org/publication-server.

4.1.3 Filing of translations in the contracting states

As regards translation requirements prescribed by the contracting states under Article 65(1) EPC, please consult the website of the European Patent Office
www.epo.org →Law & practice →Legal texts, National law relating to the EPC
www.epo.org →Law & practice →All Legal texts →London Agreement

In the case of a valid extension or validation

As regards translation requirements prescribed by the extension or validation states, please consult the website of the European Patent Office
www.epo.org ➞Law & practice ➞Legal texts, National law relating to the EPC

Failure to supply a prescribed translation in a contracting state, or in an extension or validation state may result in the patent being deemed to be void *ab initio* in the state concerned (Art. 65(3) EPC).

4.2 In the case of 2.2 above

If the present communication under Rule 71(3) EPC is based on an auxiliary request and, within the time limit, you maintain the main request or a higher ranking request which is not allowable, the application will be refused (Art. 97(2) EPC).

If the examining division gives its consent to the requested amendments or corrections, it will issue a new communication under Rule 71(3) EPC; otherwise, it shall resume the examination proceedings (Rule 71(6) EPC).

5. Filing of a divisional application

Any divisional application relating to this European patent application must be filed directly with the European Patent Office in Munich, The Hague or Berlin and will be in the language of the proceedings for the present application, or if the latter was not in an official language of the EPO, the divisional application may be filed in the language of the present application as filed (see Article 76(1) and Rule 36(2) EPC). Any such divisional application must be filed while the present application is still pending (Rule 36(1) EPC; Guidelines A-IV, 1.1.1).

6. Notes concerning fee payments

6.1 Making payments

For payments made via deposit account, please note that as from 1 December 2017 debit orders will only be carried out if filed in an electronically processable format (xml), using an accepted means of filing as laid down in the Arrangements for deposit accounts (ADA), published in the Supplementary publication in the Official Journal.

All relevant information related to the modes of payment of fees to the EPO can be retrieved from the EPO website at "**Making Payments**".

6.2 Information concerning fee amounts

Procedural fees are usually adjusted every two years, on even years, with effect from 1 April. Therefore, before making a payment, parties should verify the amounts actually due on the date of payment using the applicable version of the Schedule of fees and expenses, published as a Supplement to the Official Journal of the EPO, available on the EPO website (**www.epo.org**) at **www.epo.org/schedule-of-fees**. The "Schedule of fees" table allows the viewing, downloading and searching of individual fee amounts, both current and previous.

6.3 Note to users of the automatic debiting procedure

The fee for grant, including the fee for publication, and any additional claims fees due under Rule 71(4) EPC will be debited automatically on the date of filing of the translations of the claims, or on the last day of the period of this communication. However, if the designation fee(s) become(s) due as set out in Rule 71a(3) EPC and/or a renewal fee becomes due as set out in Rule 71a(4) EPC, these should be paid separately by another permitted way of payment in order not to delay the publication of the mention of the grant. The same applies in these circumstances to the payment of extension and validation fees. The same applies in these circumstances to the payment of extension and validation fees.

Examining Division:

Chairman:	Kakoullis, Marios
2nd Examiner:	Przykutta, Andreas
1st Examiner:	Nielsen, Michael

Acquaviva, Laure
For the Examining Division
Tel. No.: +49 89 2399 - 5656

Enclosures: Text intended for grant

EPO Form 2056

Registered letter
EPO Form 2004C 07.20CXP

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European Patent Office
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Application No.: EP19200766

Intention to grant a European patent

Electronically authenticated

31.08.2022

Date

Marios Kakoullis	Michael Nielsen	Andreas Przykutta
Chairperson	1st examiner	2nd examiner

~~BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD~~

~~CROSS-REFERENCE TO~~ RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING"; and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD".

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with

catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles.

Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination,

20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

[0012a] WO 96/05875 A1 discloses a blood sampling device comprising a bifurcated capillary tube which has a first branch having a cannula shaped end for withdrawing and conveying blood to a blood collection zone for storing a quantity of withdrawn blood and feeding an initial fraction of withdrawn blood to a blood disposal chamber having an air permeable liquid sealed end; and a second branch connected to the blood collection zone which terminates in an opening adapted to receive a blood withdrawal device.

SUMMARY

[0013] This document presents systems and methods 2 ▛ (a method is not claimed) ▟ 2 for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to

accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is 2 ▛ provided, comprising; an inlet port; a junction connected with the inlet port; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with an outlet port; and a housing that houses and defines the inlet port, the junction, the sequestration chamber, the sampling channel, and the outlet port, wherein the sequestration chamber is connected with the inlet port via the junction which is configured to direct a first portion of blood to the sequestration chamber, wherein the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood. ▟ 2 ~~presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable~~

~~blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.~~

[0016] In another aspect, a 2 ▮ system of a blood sequestration device, a blood sampling pathway having a patient needle, and a sample collection device is provided, the blood sequestration device comprising; an inlet port connected with the patient needle; a junction connected with the inlet port opposite the blood sampling pathway; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port; and an outlet port connected with a distal end of the sampling channel and with the sample collection device; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel, wherein the sequestration chamber is connected with the inlet port and the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood. ▮ 2 ~~blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.~~

~~**[0017]** In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration~~

device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is uncoupled by the evacuated blood collection tube.

The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

~~sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.~~

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims. The invention is best illustrated by figures 16A to 19B.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0031] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0032] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0033] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0034] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0035] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0036] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0037] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0038] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0039] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0040] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0041] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

01.10.2019

[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and methods (a method is not claimed) for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient

needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable

blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is

added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone

to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable

blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a

sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can

be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with

one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved,

and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port

1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately ≥ 0.114 cm (0.045 inches), ≥ ~~0.045 inches,~~ but can have a diameter of between ≥ 0.0254 cm (0.01 inches) ≥ ~~0.01 inches~~ or less to ≥ 0.508 cm (0.2 inches) ≥ ~~0.2 inches~~ or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration

chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion

pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately ≥ 0.114 cm (0.045 inches), ≥ ~~0.045 inches,~~ but can have a diameter of between ≥ 0.0254 cm (0.01 inches) ≥ ~~0.01 inches~~ or less to ≥ 0.508 cm (0.2 inches) ≥ ~~0.2 inches~~ or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some

implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port

1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel

1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial

groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not 2 [redacted] shown, not claimed), [redacted] 2 ~~shown),~~

which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure

overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS.

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16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately ≥ 0.114 cm (0.045 inches), ≤ ~~0.045 inches,~~ but can have a diameter of between ≥ 0.0254 cm (0.01 inches) ≤ ~~0.01 inches~~ or less to ≥ 0.508 cm (0.2 inches) ≤ ~~0.2 inches~~ or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need

for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other

pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In 2 [redacted] use (neither use nor method is claimed), [redacted] 2 ~~use,~~ the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-

filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

Amended claims

1. A blood sequestration device (1500) comprising;

an inlet port (1502);

a junction (1607) connected with the inlet port (1502);

a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);

a sampling channel (1506) having a proximal end connected with the inlet port (1502) via the junction (1607), and a distal end connected with an outlet port (1504); and

a housing (1501) that houses and defines the inlet port (1502), the junction (1607), the sequestration chamber (1508), the sampling channel (1506), and the outlet port (1504),

wherein the sequestration chamber (1508) is connected with the inlet port (1502) via the junction (1607) which is configured to direct a first portion of blood to the sequestration chamber (1508),

characterized in that the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.

2. The blood sequestration device (1500) in accordance with claim 1, wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).

3. The blood sequestration device (1500) in accordance with claim 1 or 2, further comprising a blood sampling pathway connected with the inlet port (1502) opposite the junction (1607), and

wherein the inlet port (1502) defined by the housing (1501) has a cross-sectional geometry consistent with the blood sampling pathway.

4. The blood sequestration device (1500) in accordance with one of the preceding claims, wherein the sampling channel (1506) defined by the housing (1501) has a cross-sectional geometry consistent with the inlet port (1502).

5. The blood sequestration device (1500) in accordance with one of claims 2 to 4, wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520)

defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

6. A system of a blood sequestration device (1500), a blood sampling pathway having a patient needle, and a sample collection device, the blood sequestration device (1500) comprising;

an inlet port (1502) connected with the patient needle;

a junction (1607) connected with the inlet port (1502) opposite the blood sampling pathway;

a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);

a sampling channel (1506) having a proximal end connected with the inlet port (1502); and

an outlet port (1504) connected with a distal end of the sampling channel (1506) and with the sample collection device; and a housing (1501) that houses and defines the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506),

characterized in that the sequestration chamber (1508) is connected with the inlet port (1502) and the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with blood.

7. The system in accordance with claim 6, wherein the inlet port (1502) is connected with the patient needle via a first portion of the blood sampling pathway.

8. The system in accordance with claim 6 or 7, wherein the outlet port (1504) is connected with the sample collection device via a second portion of the blood sampling pathway.

9. The system in accordance with one of claims 6 to 8, wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).

10. The system in accordance with claim 9, wherein the sequestration channel has a proximal end connected with the inlet port (1502), and a distal end having the vent (1510) comprising an air permeable blood barrier (1512).

11. The system in accordance with one of claims 6 to 10, wherein the sequestration chamber (1508) and the sampling channel (1506) are connected with

the inlet port (1502) by the junction (1607) that is configured to direct a first portion of blood to the sequestration chamber (1508).

12. The system in accordance with one of claims 6 to 11, wherein the sampling channel (1506) has a substantially uniform cross-sectional geometry that is consistent with the blood sampling pathway.

13. The system in accordance with claim 12, wherein the sequestration chamber (1506) includes a sequestration chamber that has a cross-sectional area that is larger than the cross-sectional geometry of the sampling channel (1506).

14. The system in accordance with claim 7, member (1520), wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520) defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

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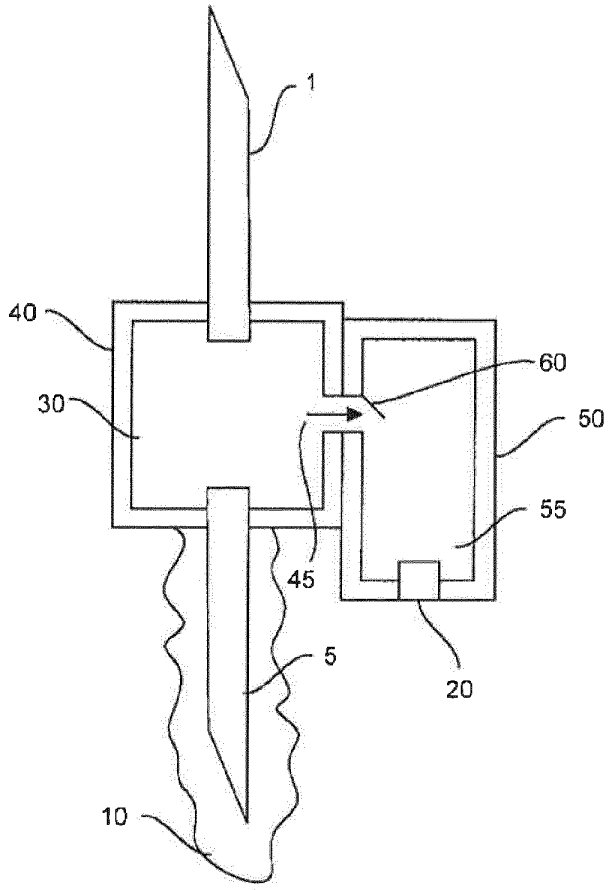

FIG. 1

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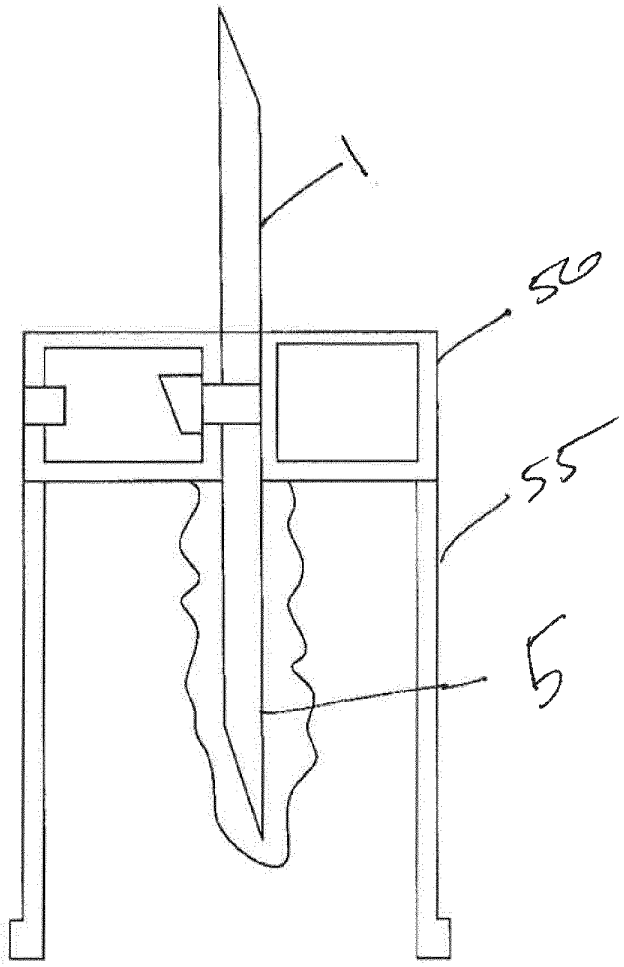

FIG. 2

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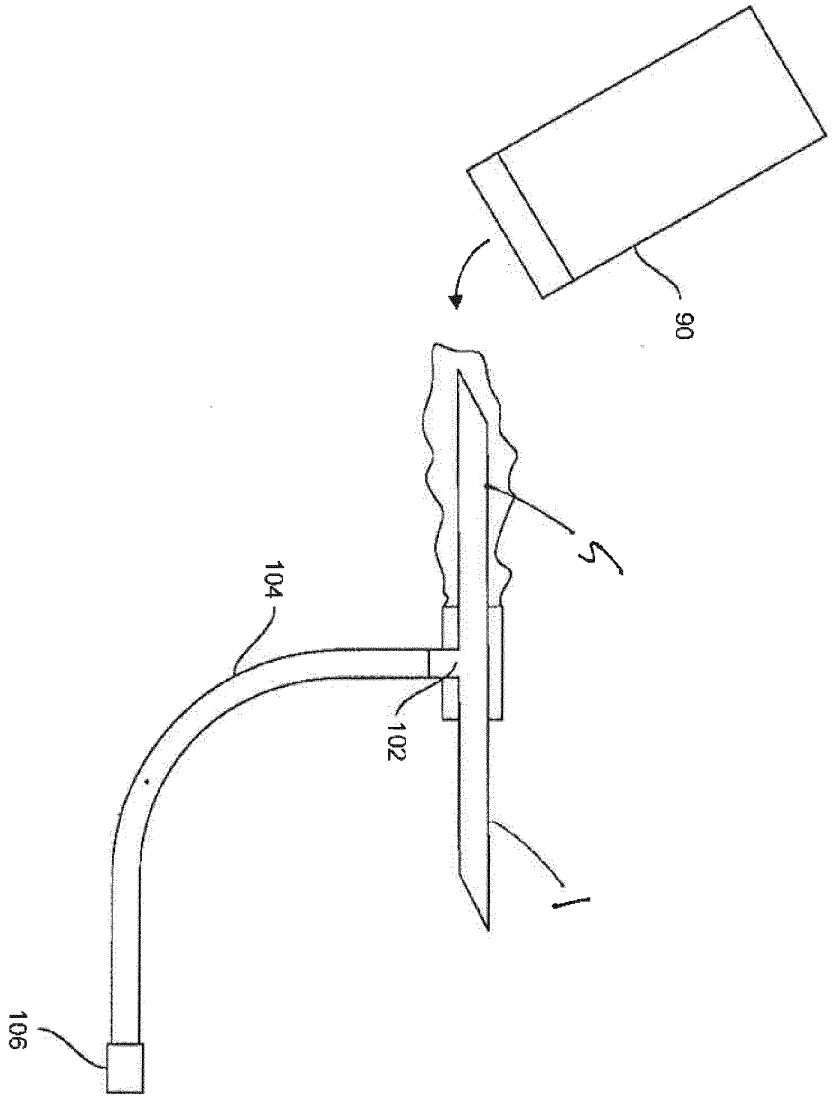

FIG. 3

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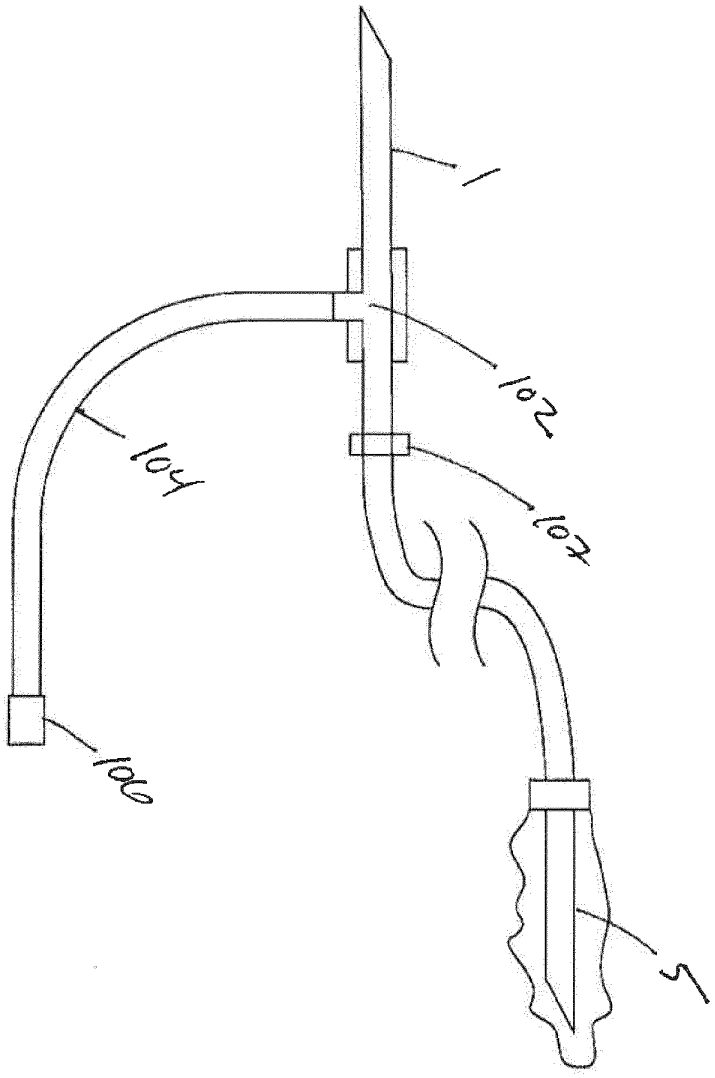

FIG. 4

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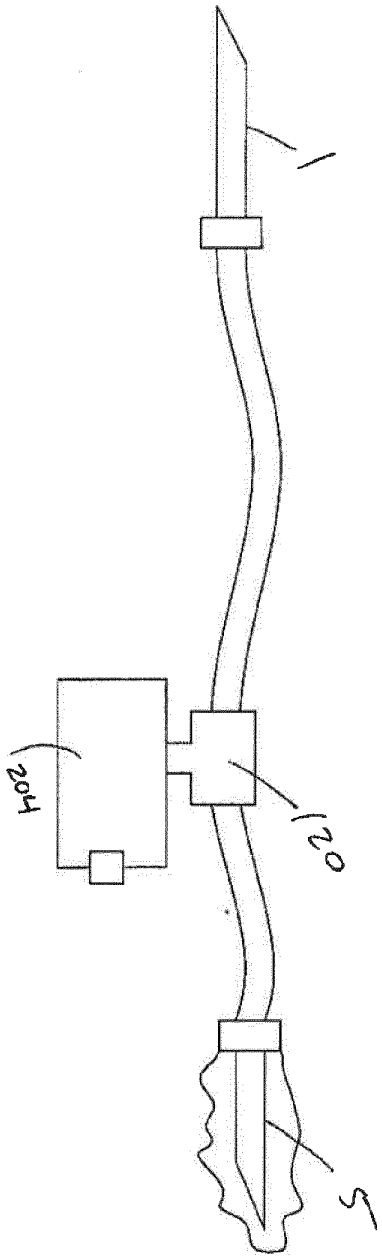

FIG. 5

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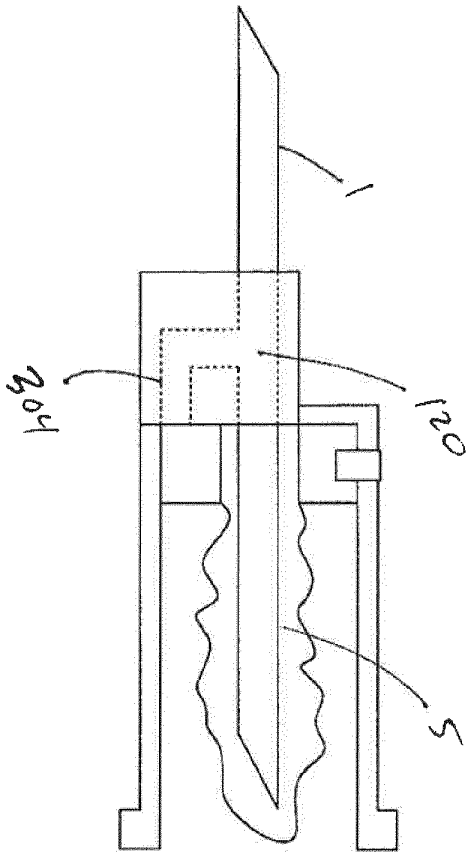
FIG. 6



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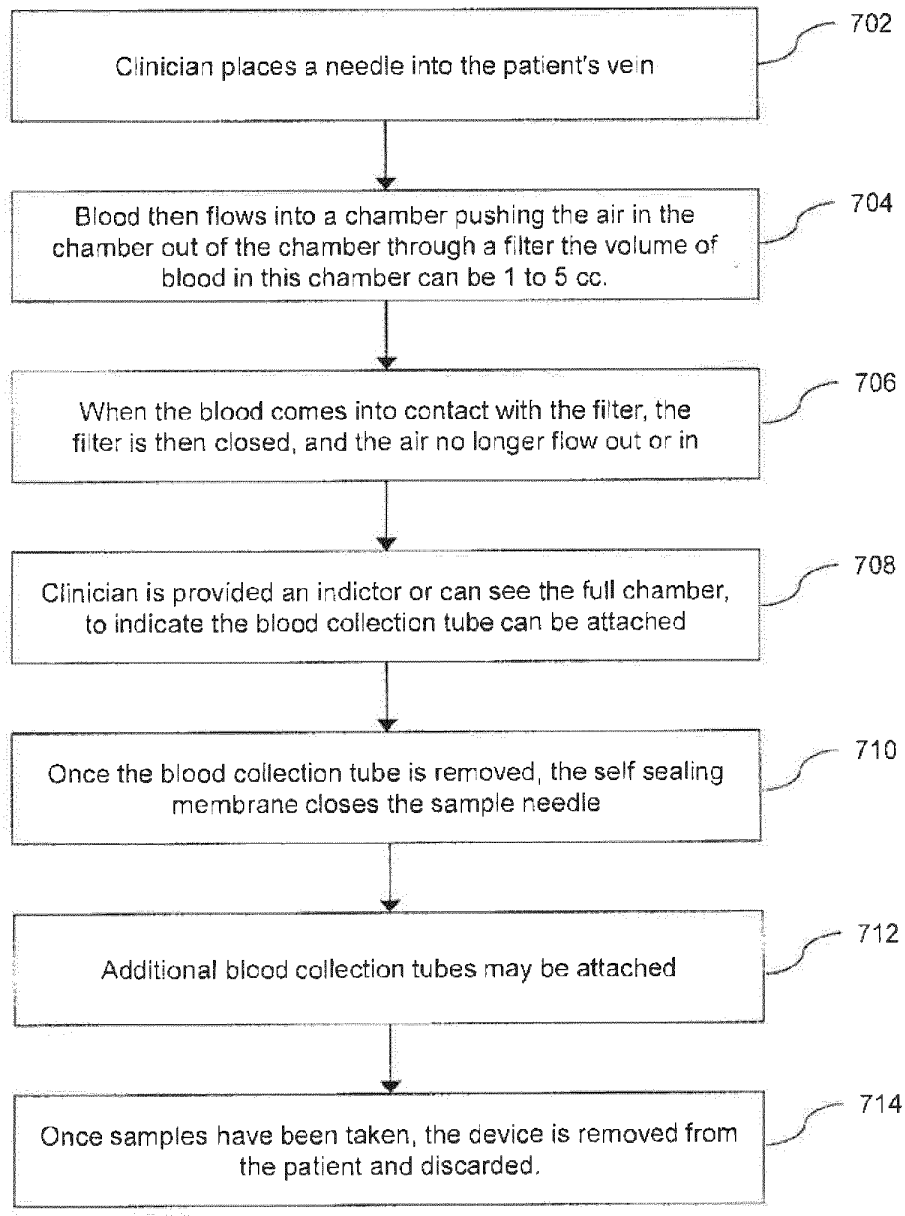
Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
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FIG. 7

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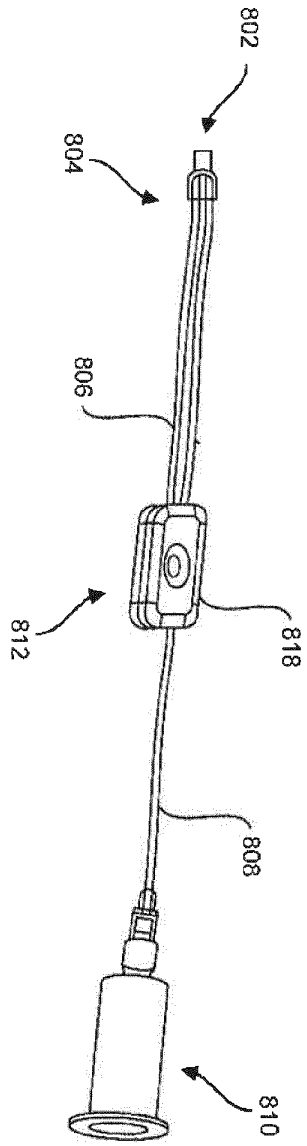

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FIG. 8A

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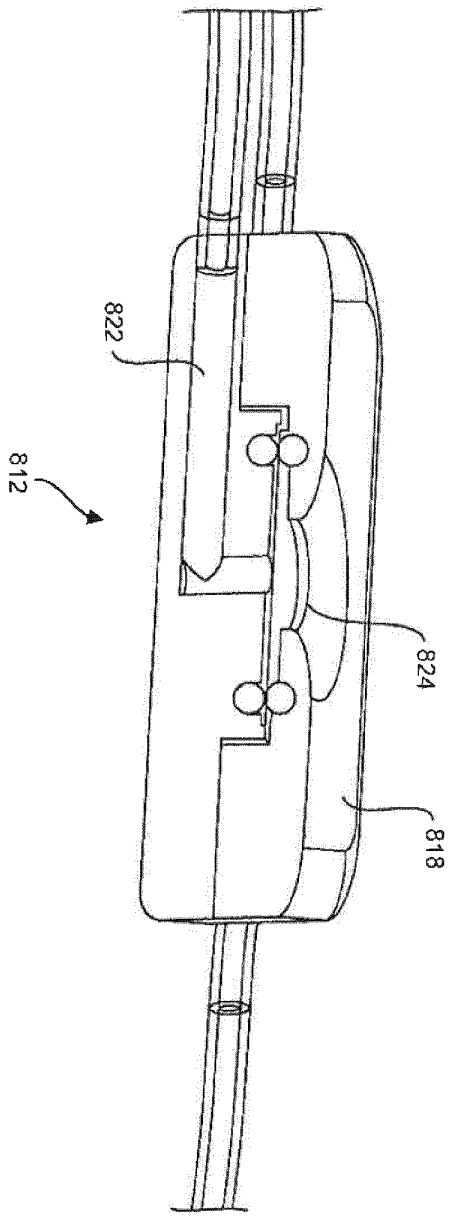

FIG. 8B

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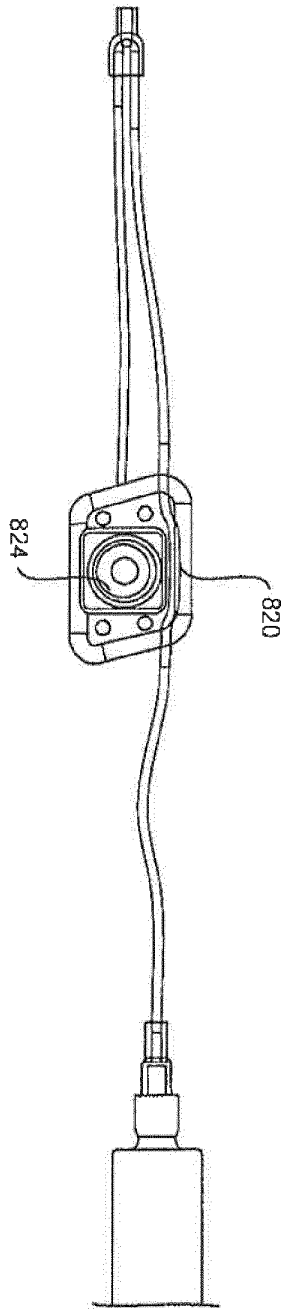
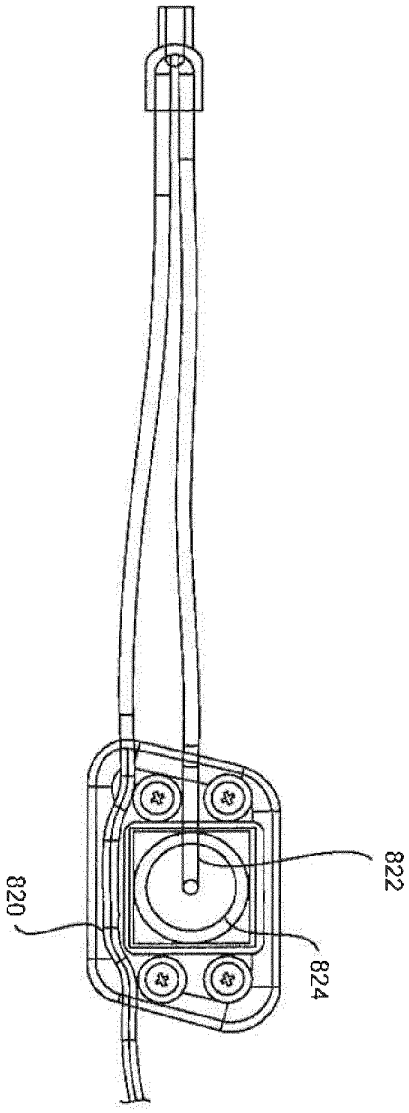


FIG. 8C

FIG. 8D



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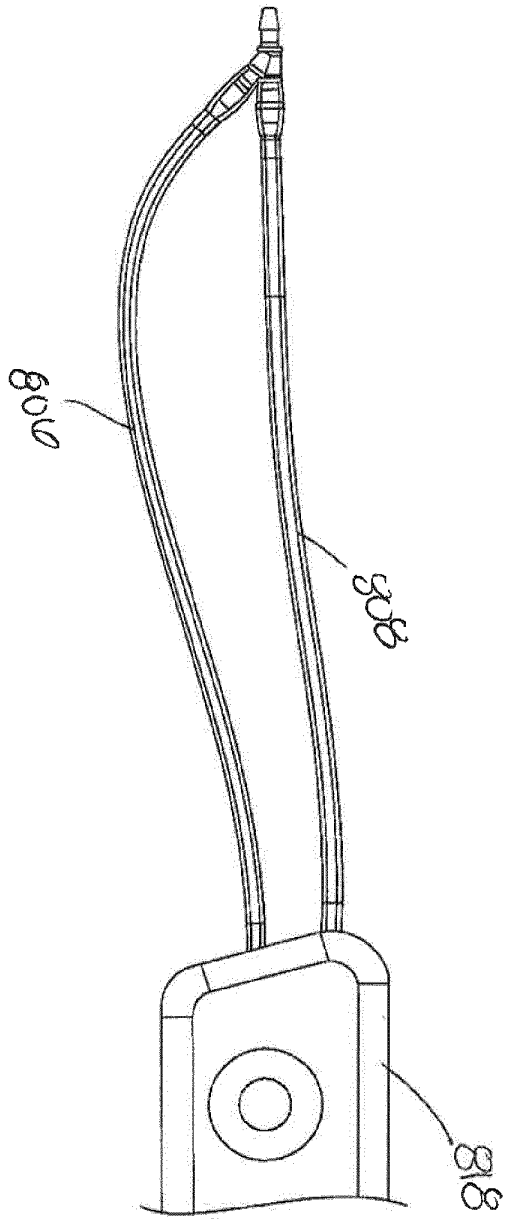

FIG. 8E

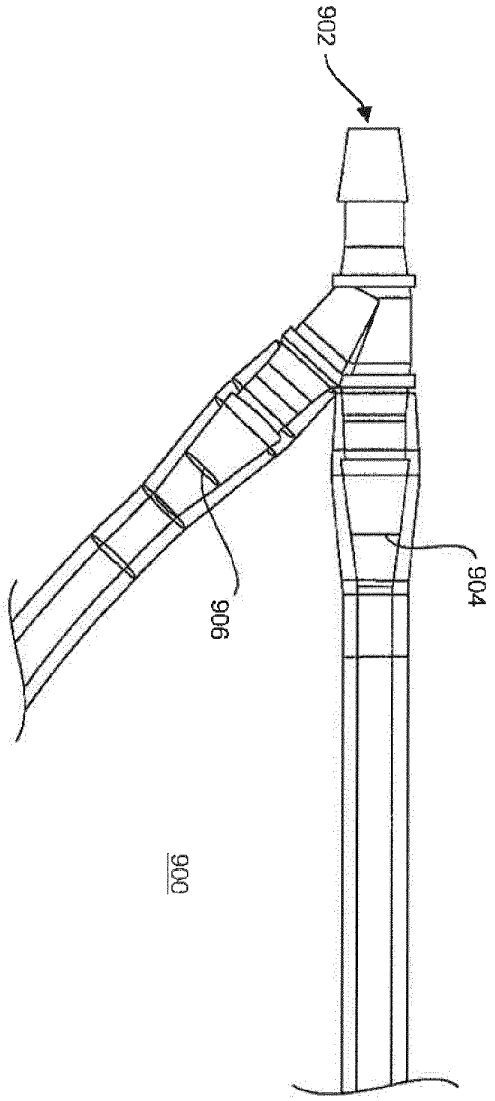

FIG. 9

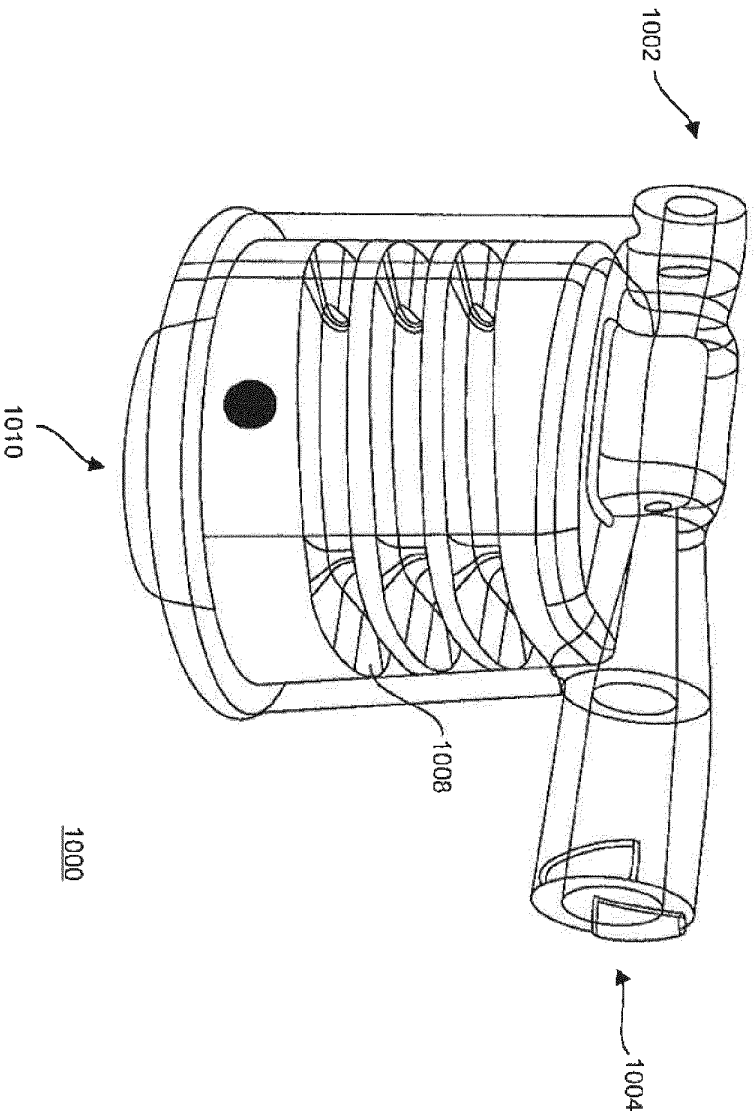

FIG. 10A

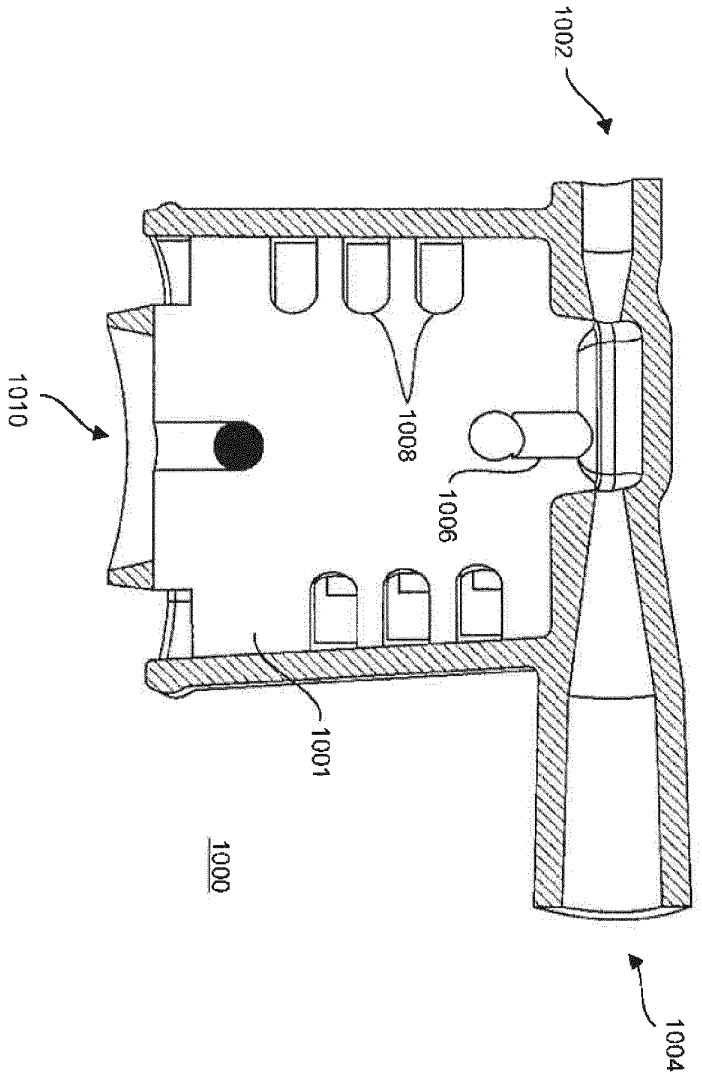

FIG. 10B

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FIG. 10C

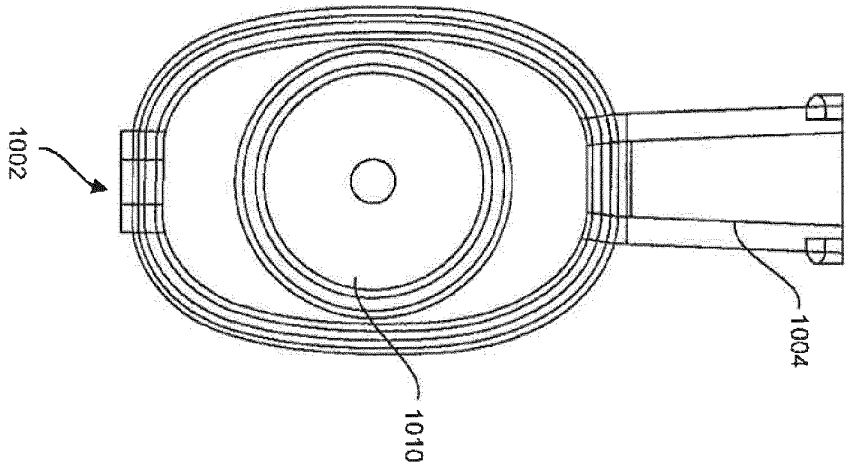
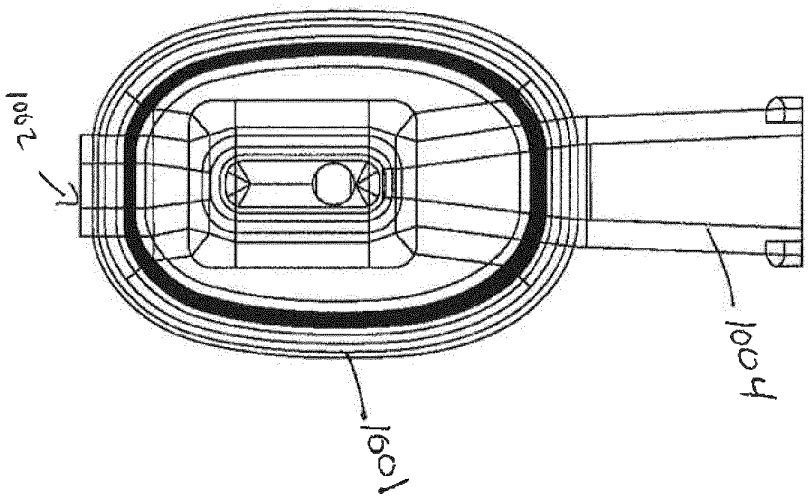


FIG. 10D



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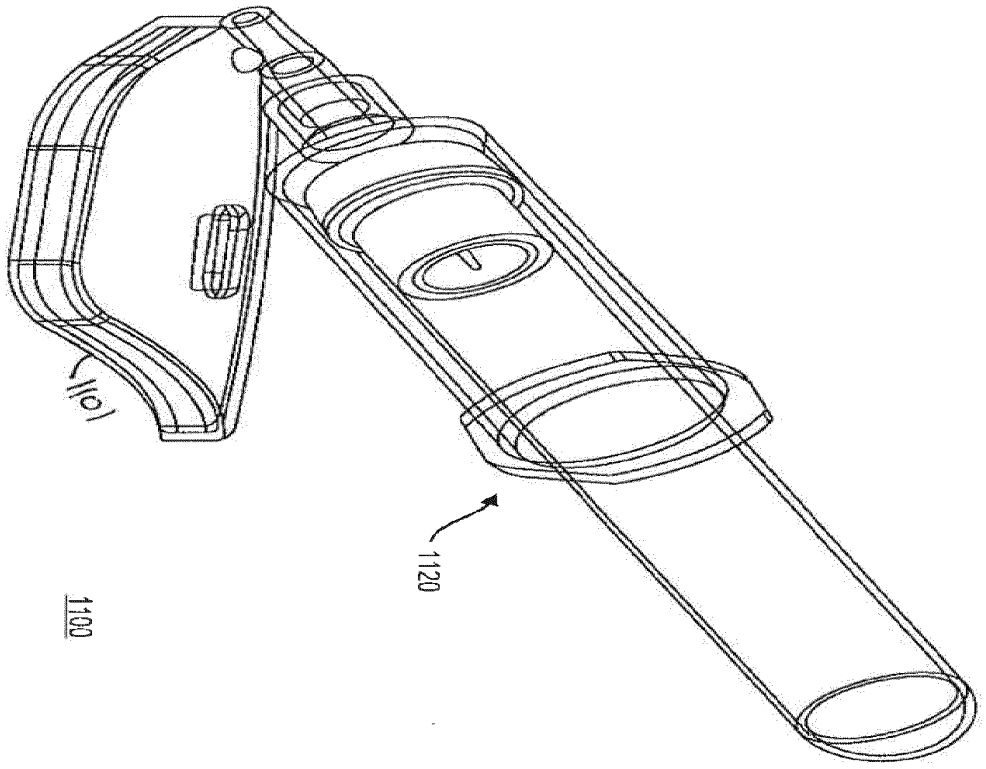

FIG. 11A

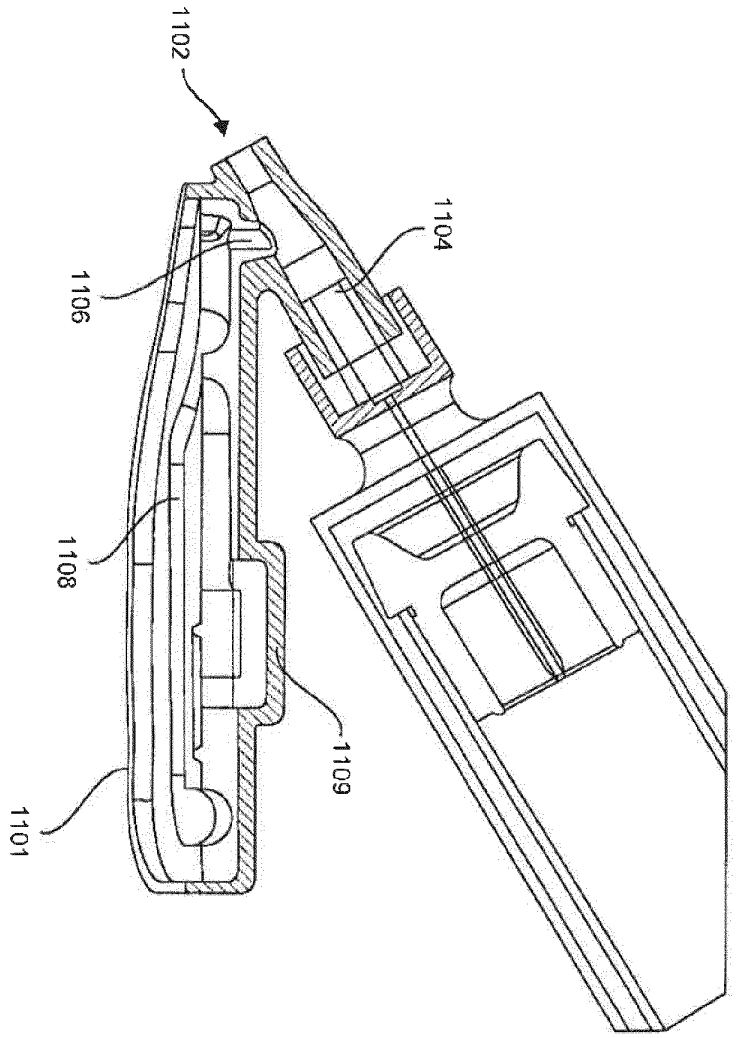

FIG. 11B

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FIG. 11C

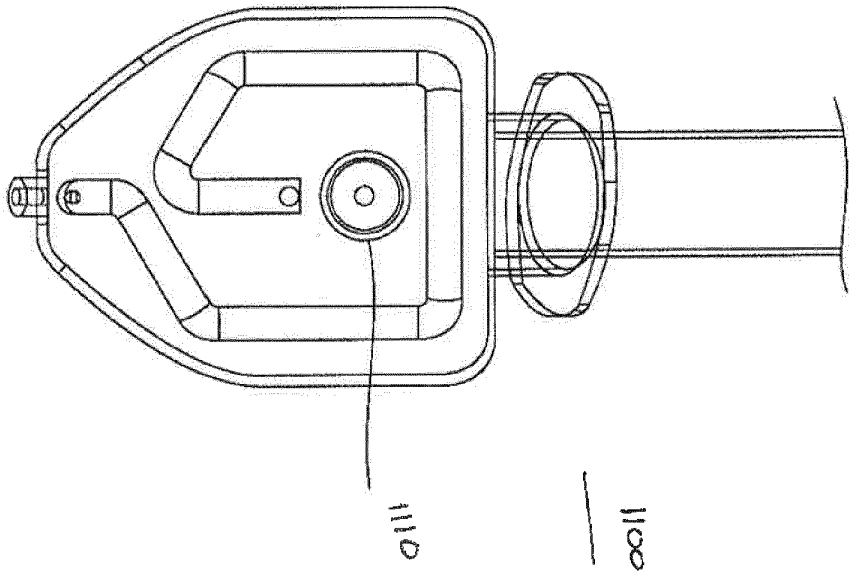
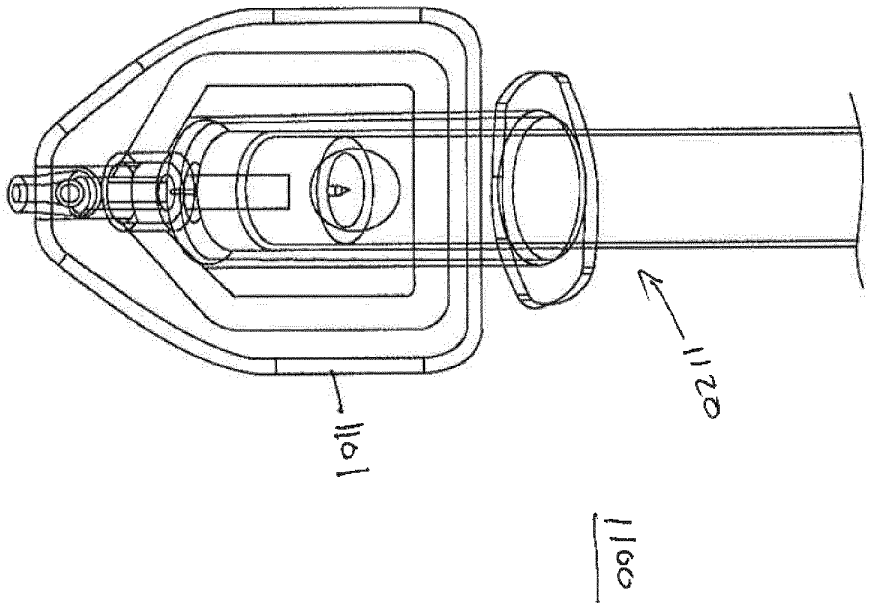


FIG. 11D



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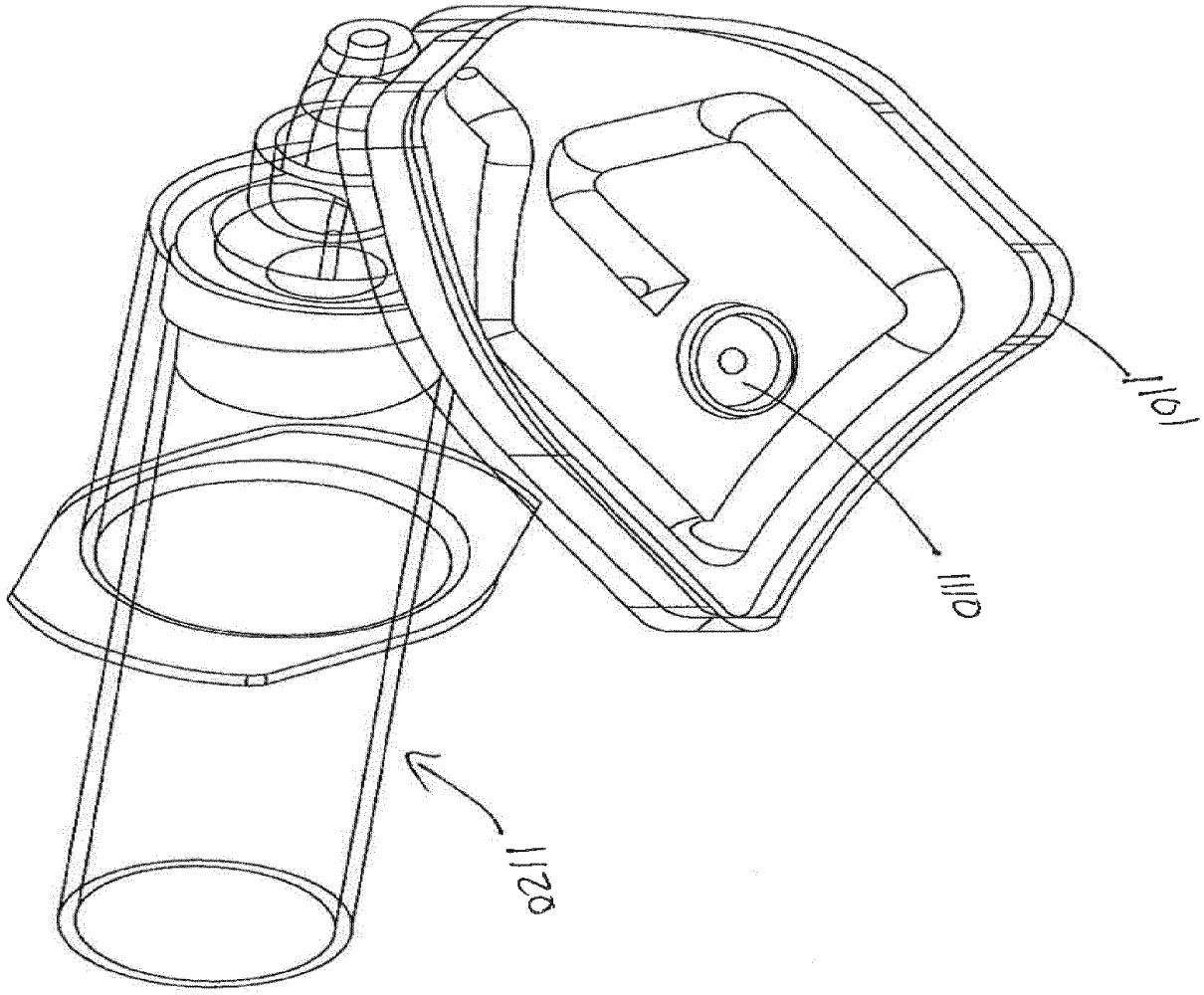

FIG. 11E

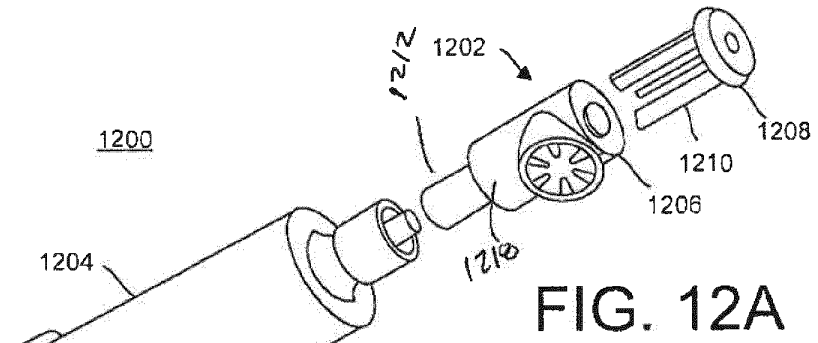

FIG. 12A

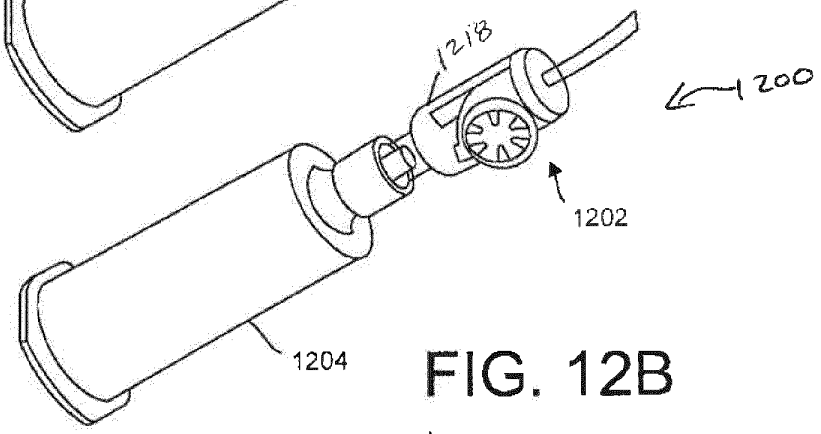

FIG. 12B

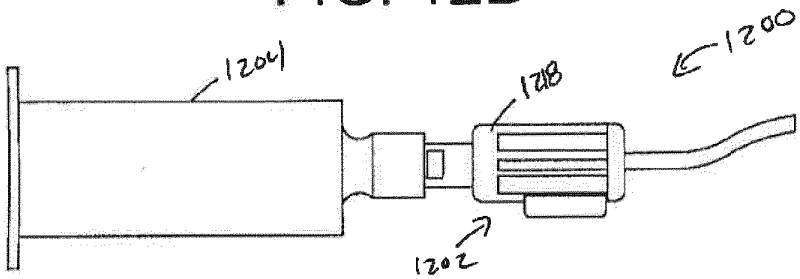

FIG. 12C

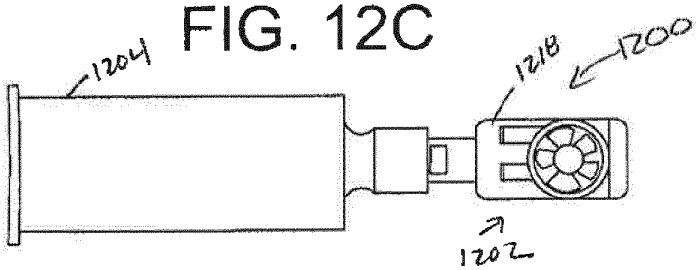

FIG. 12D

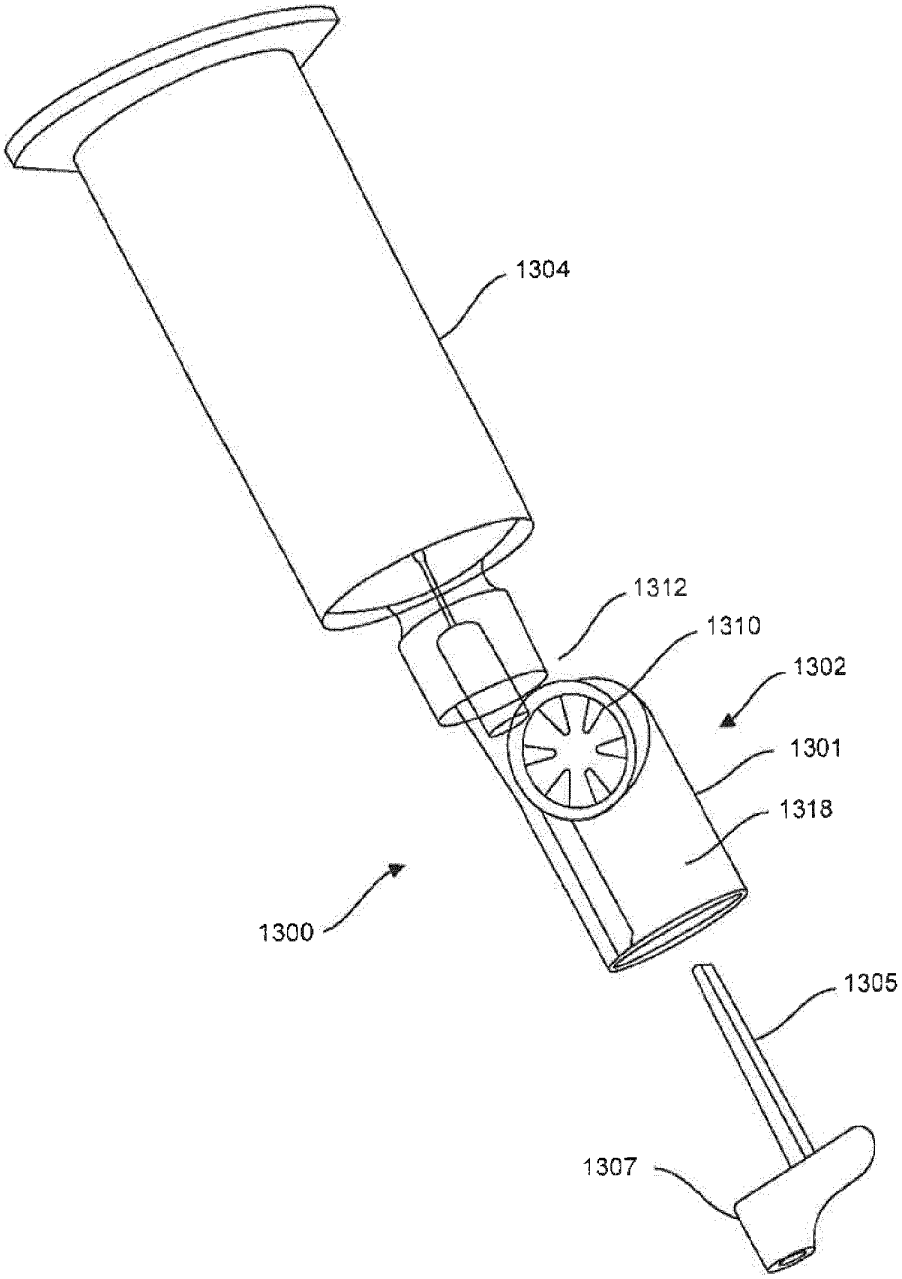

FIG. 13A

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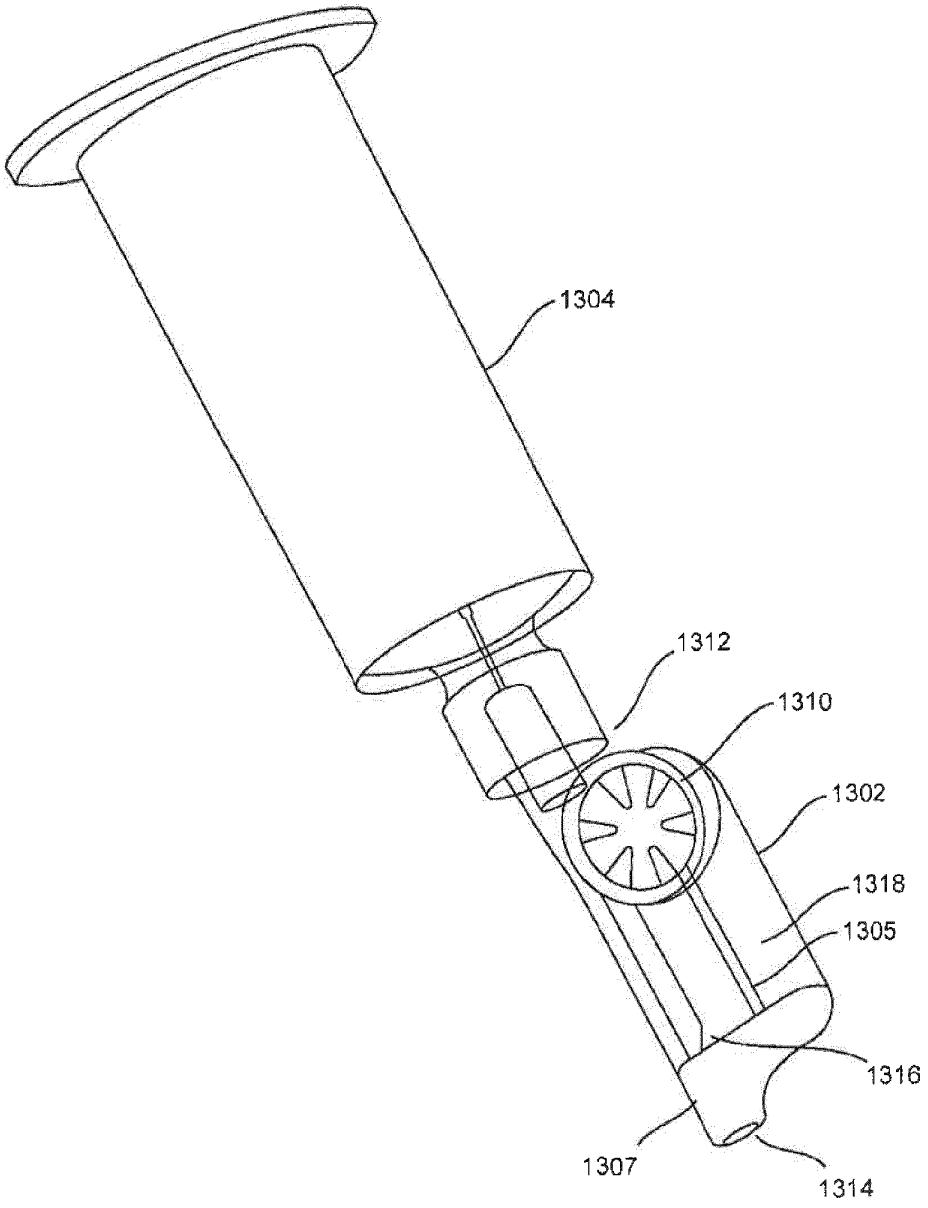

FIG. 13B

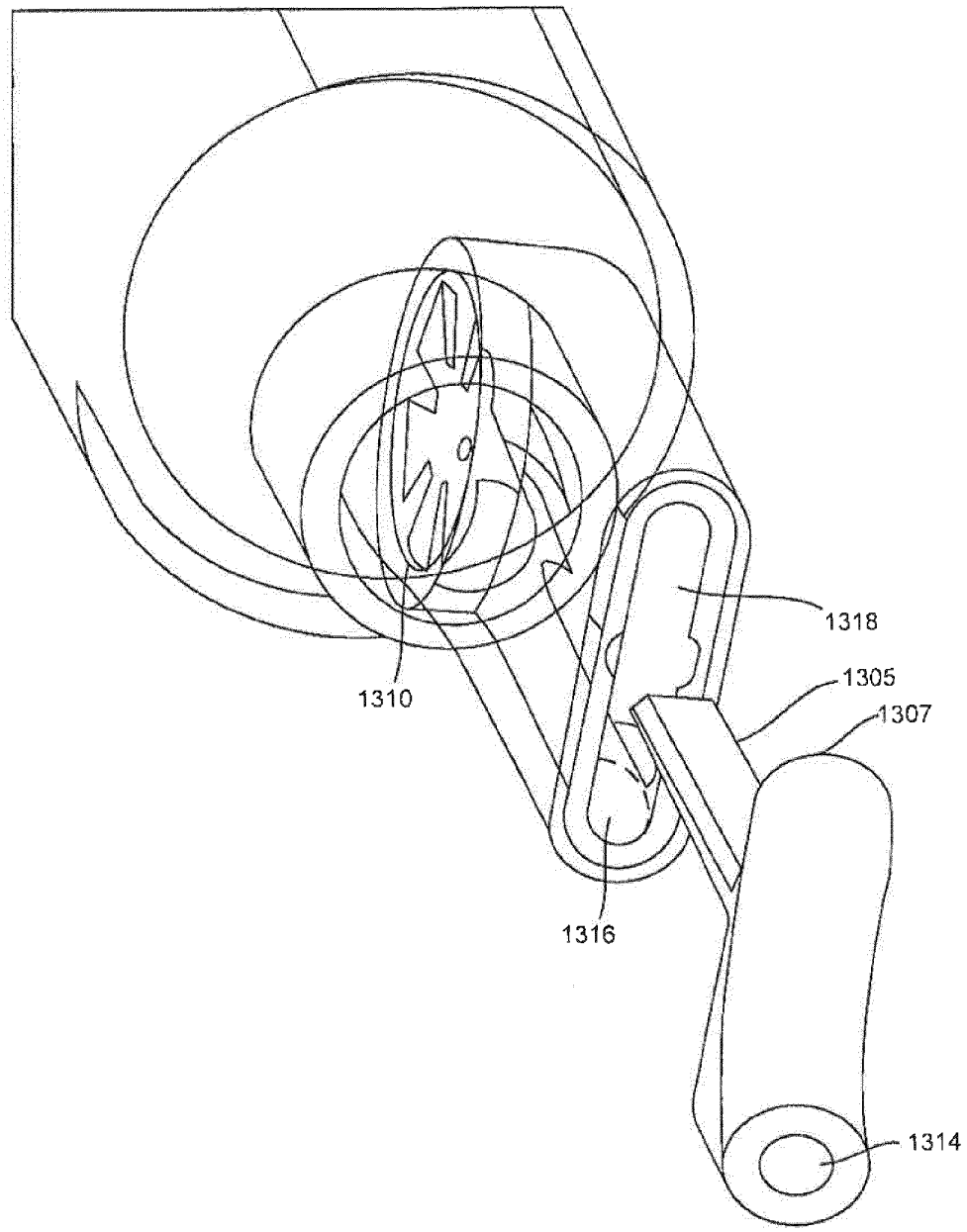

FIG. 13C

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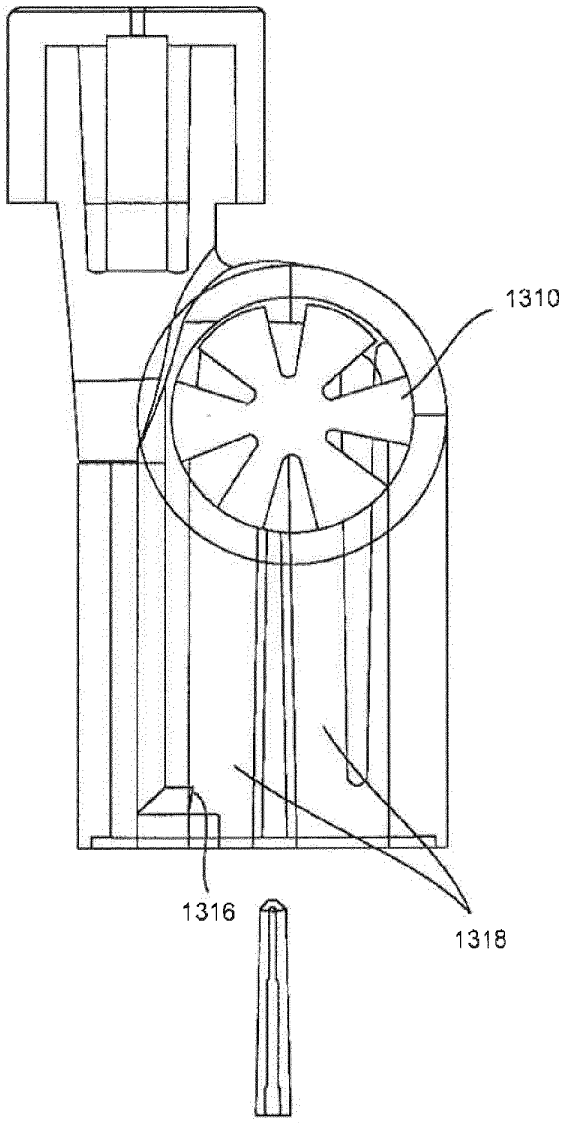

FIG. 13D

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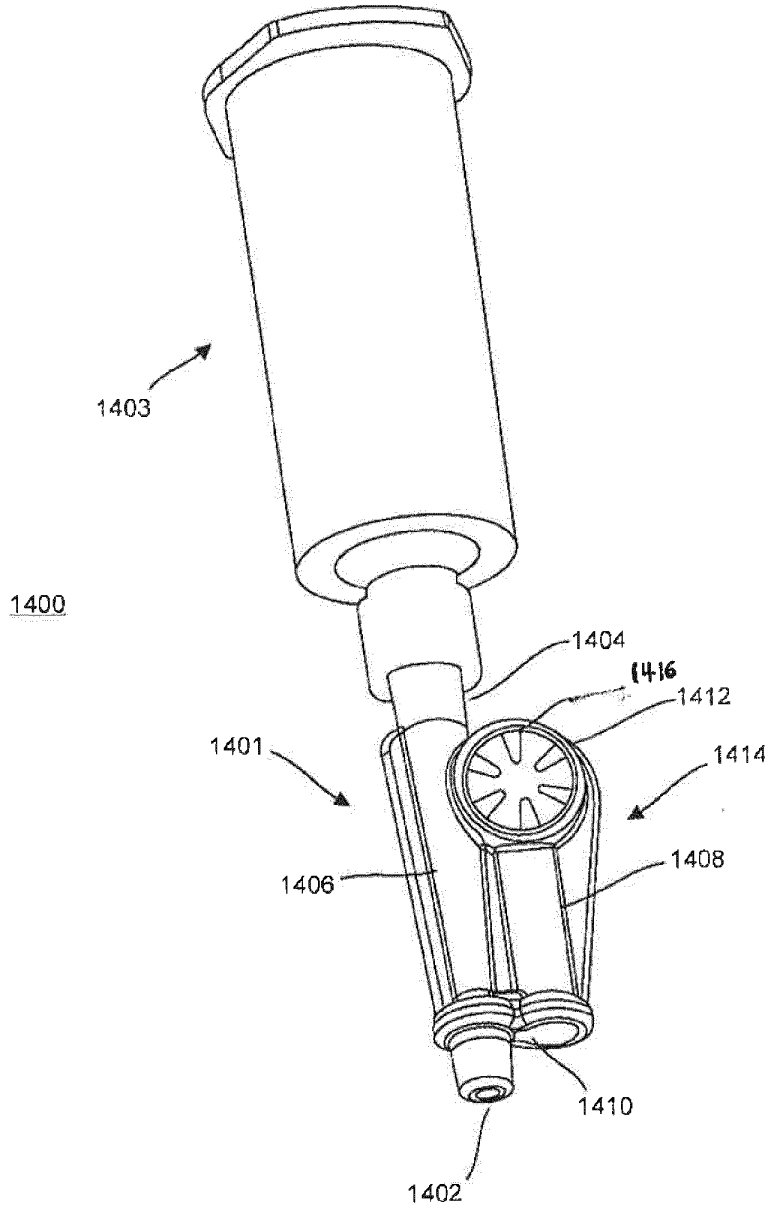

FIG. 14A

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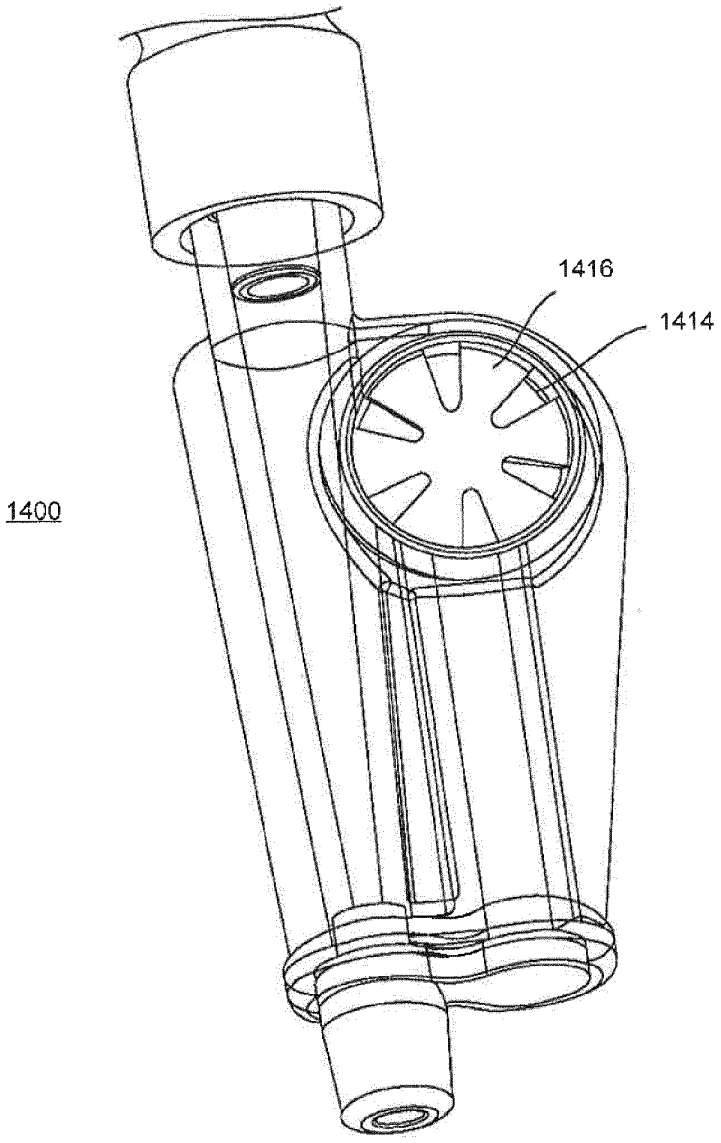

FIG. 14B

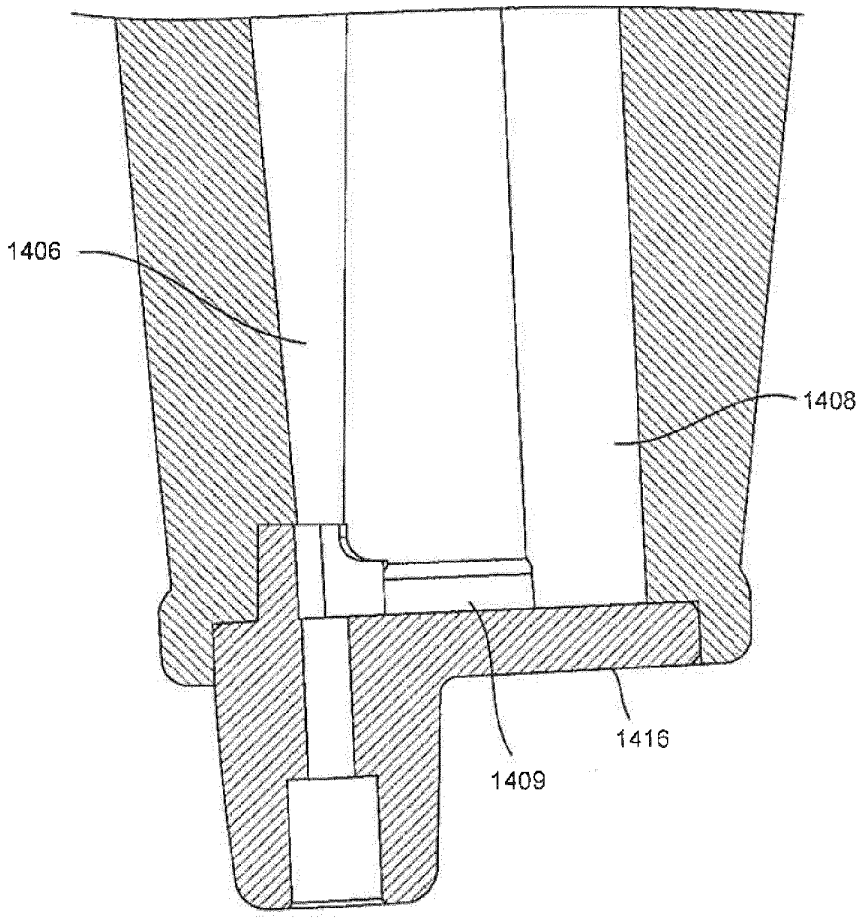

FIG. 14C

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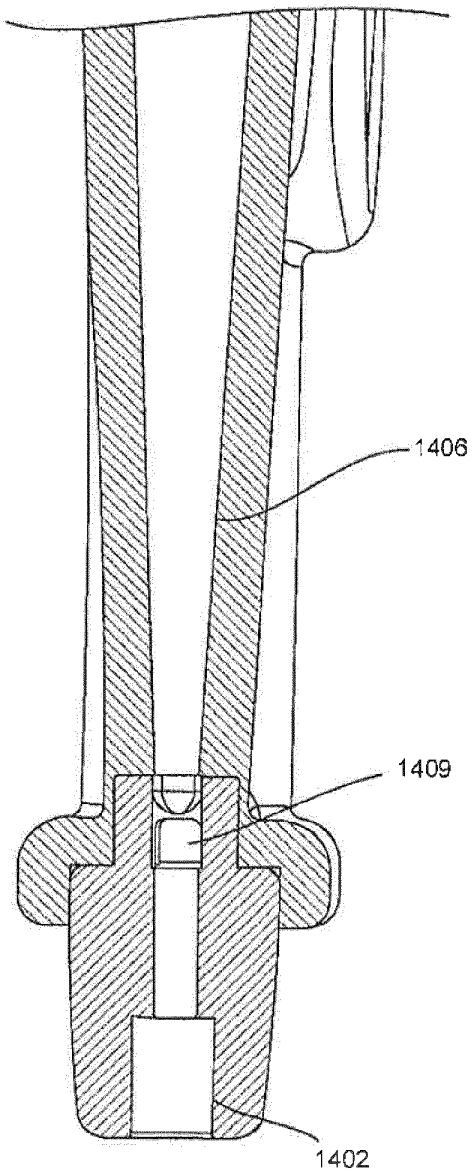

FIG. 14D

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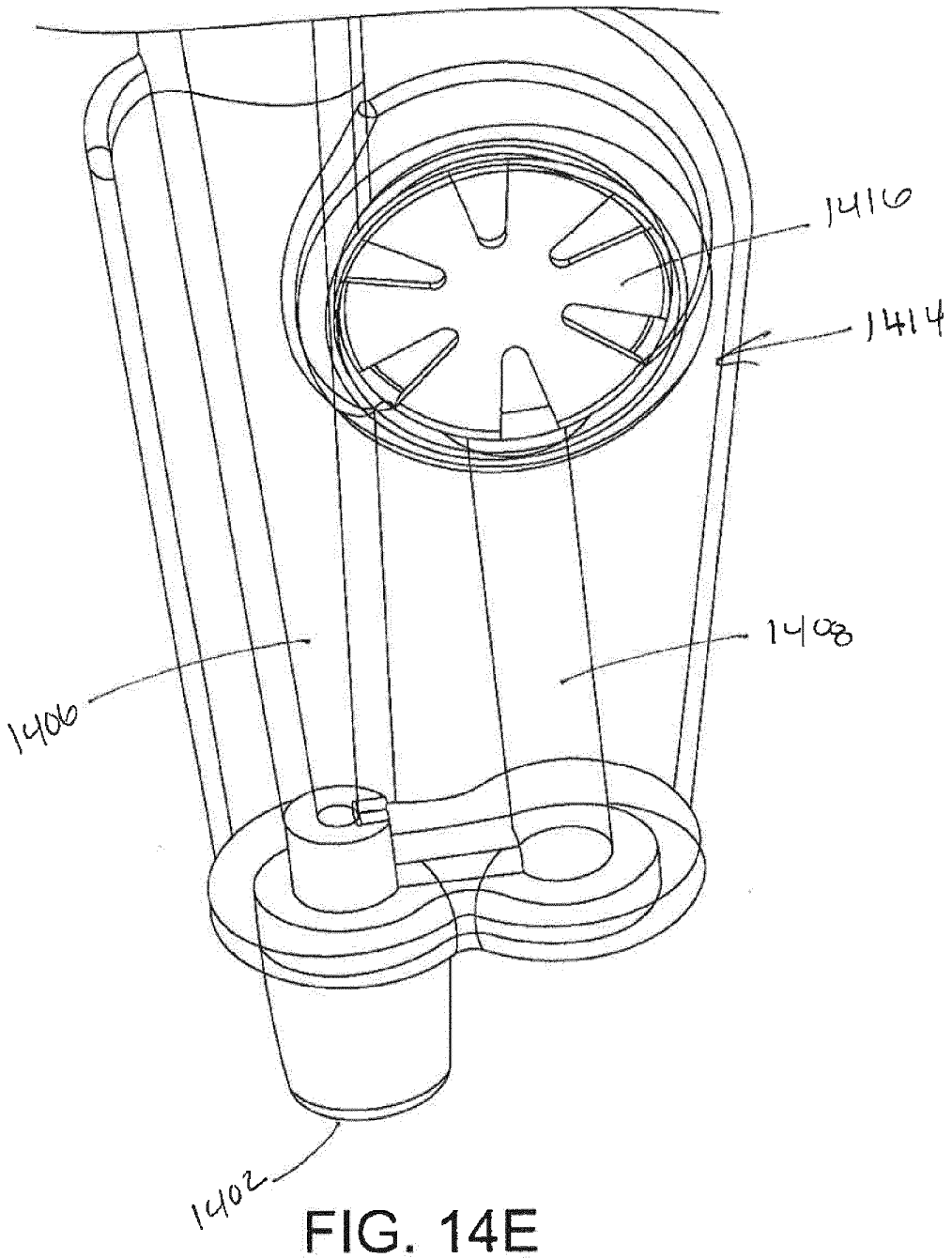

FIG. 14E

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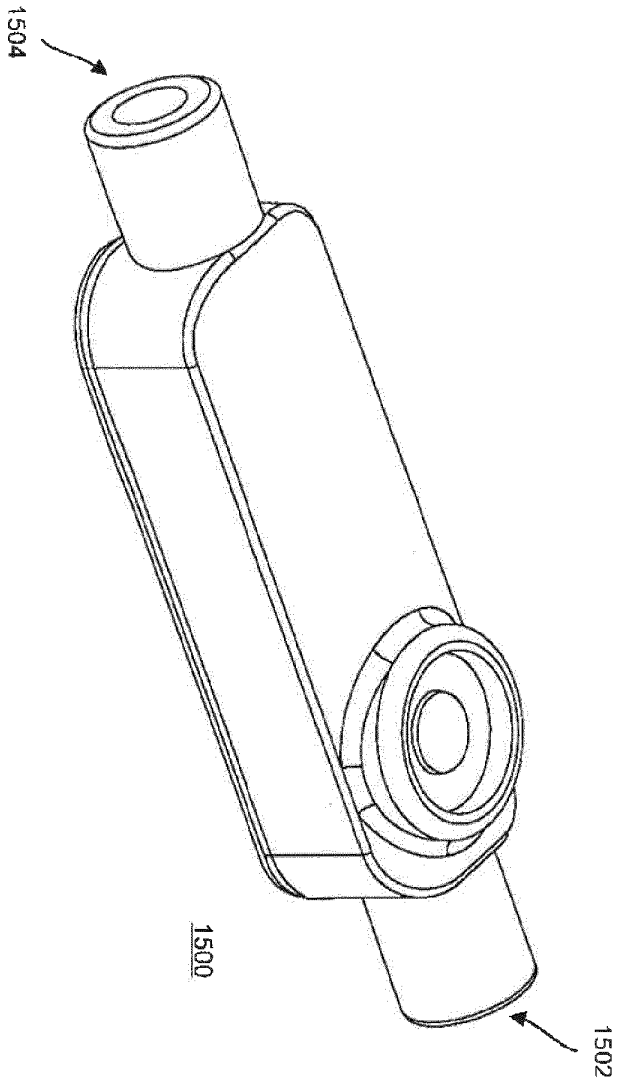

FIG. 15A

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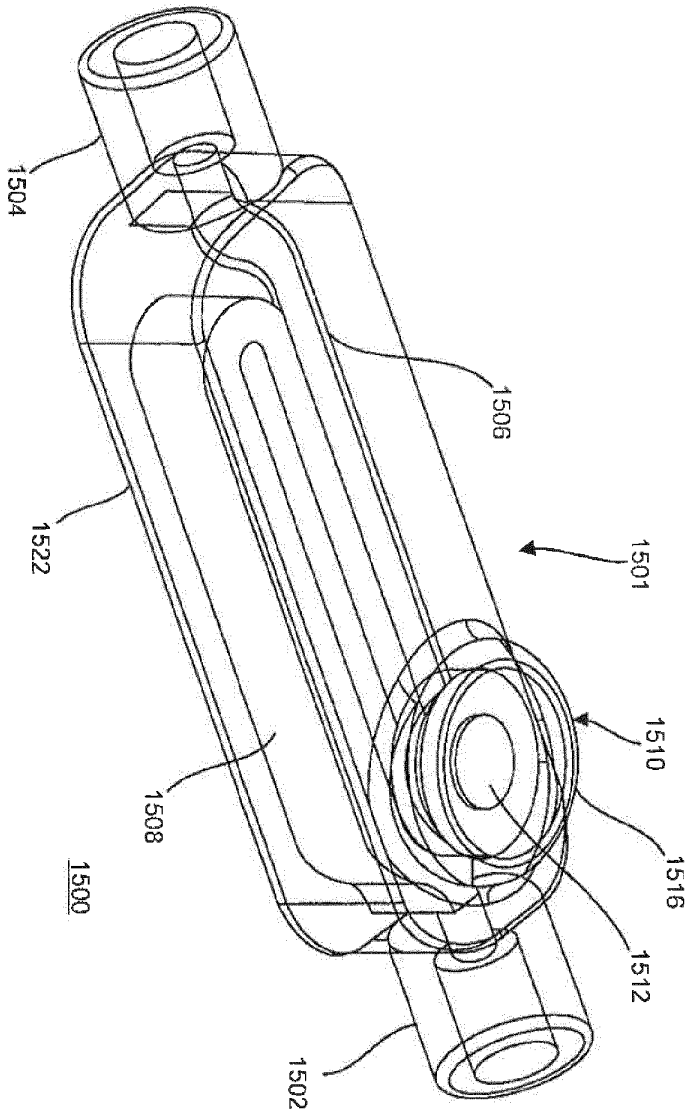

FIG. 15B

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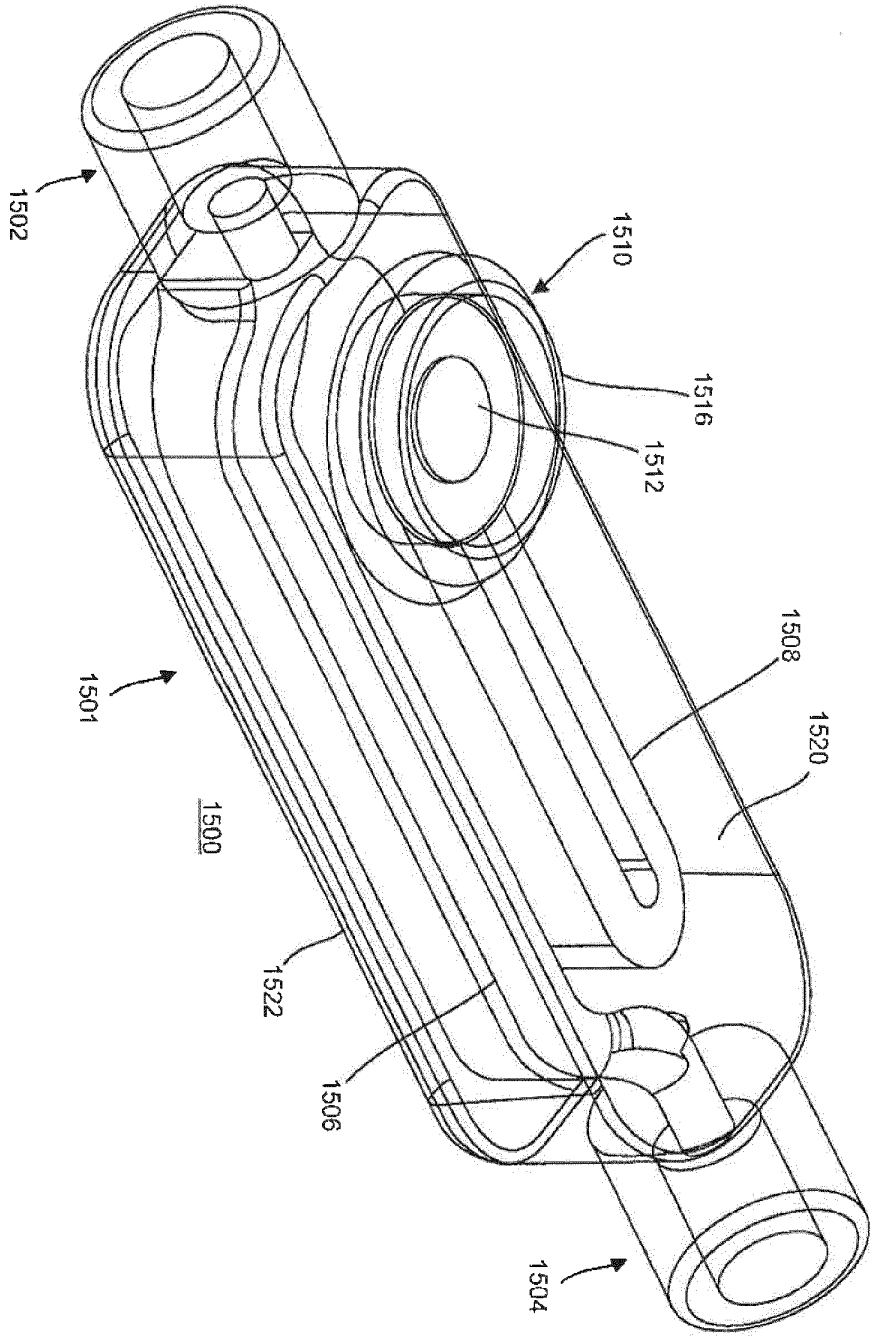

FIG. 15C

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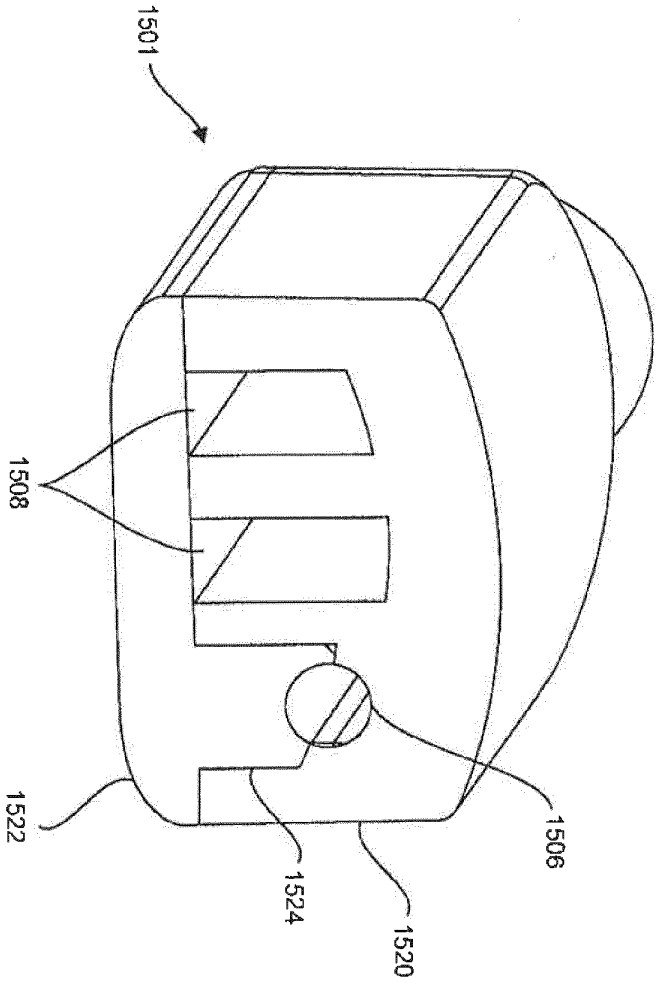

FIG. 15D

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FIG. 15E

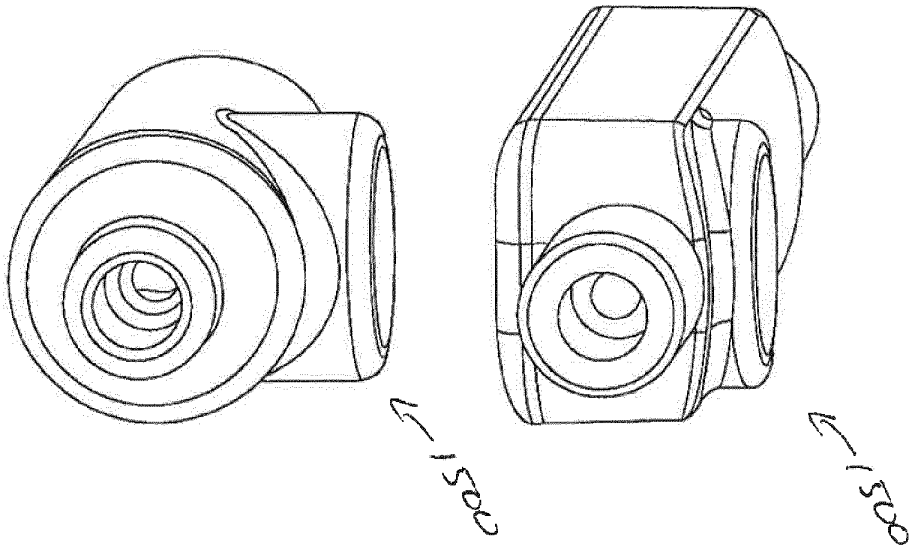
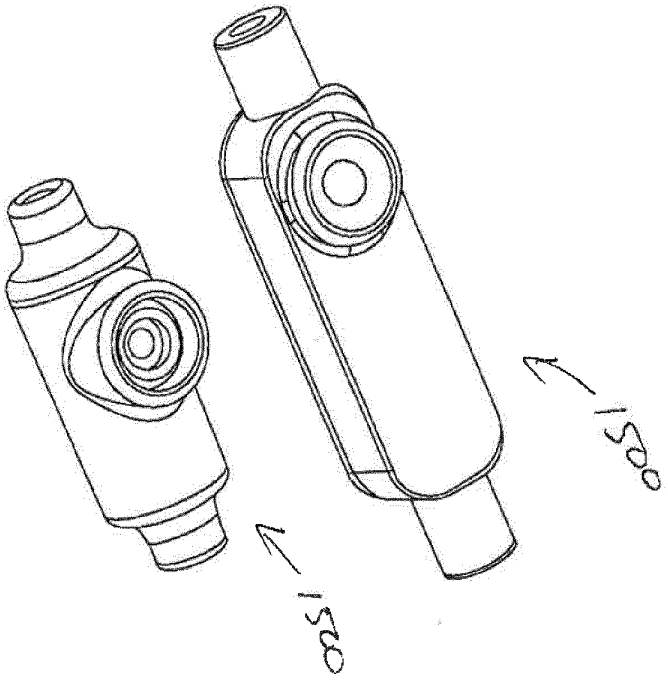


FIG. 15F



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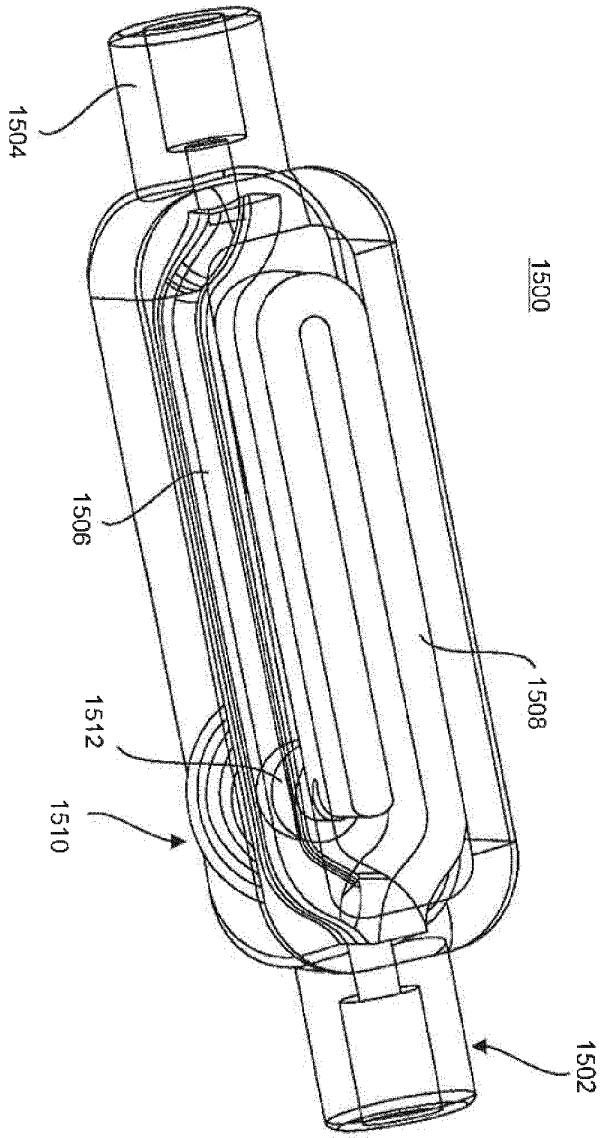

FIG. 15G

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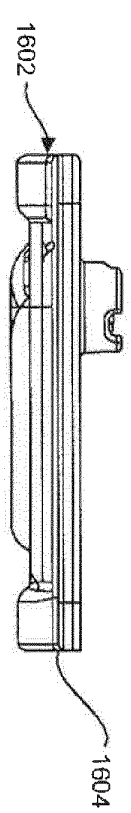

FIG. 16B

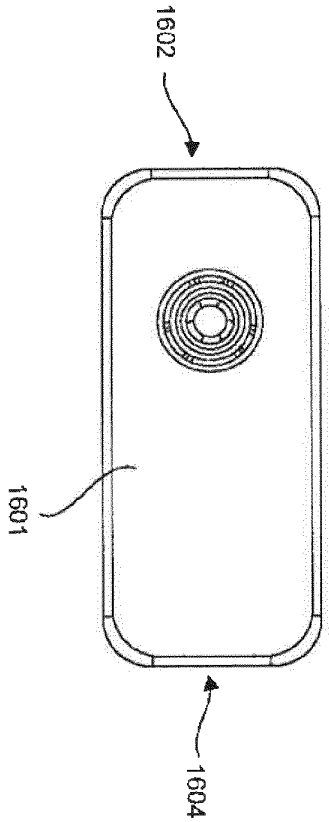

FIG. 16A

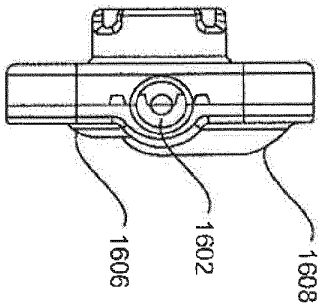

FIG. 16C

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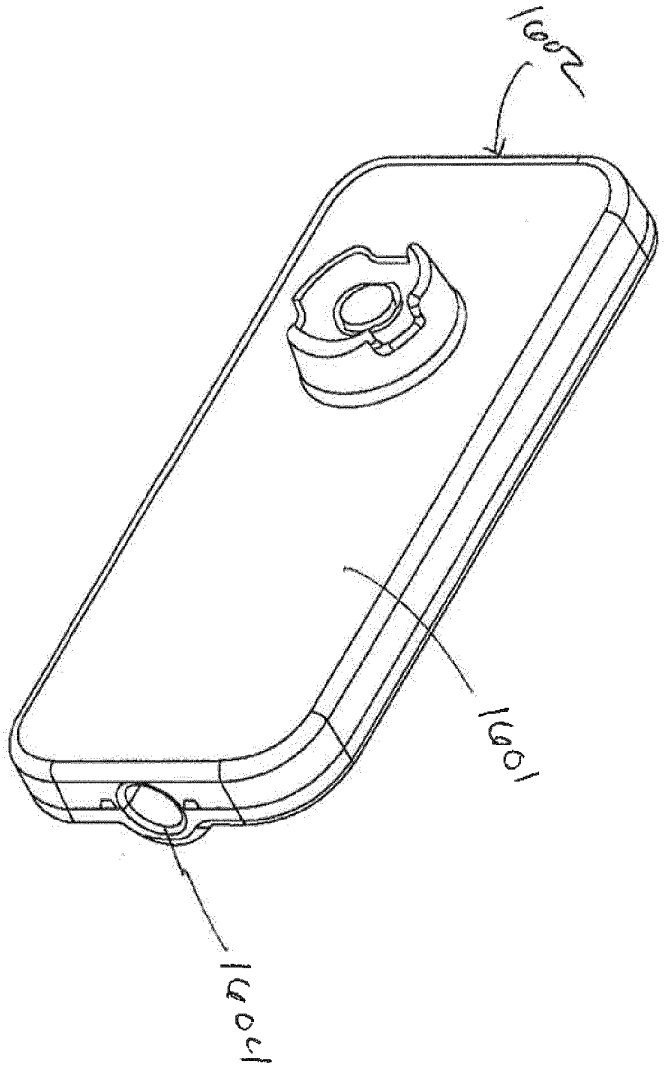

FIG. 16D

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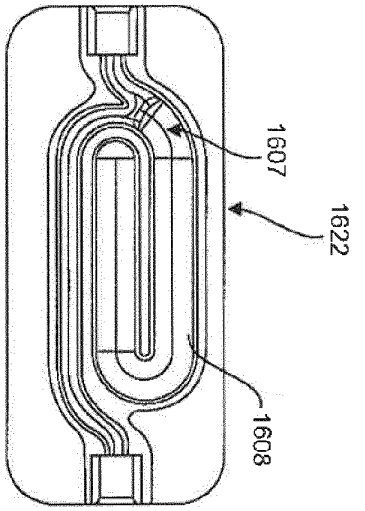

FIG. 17A

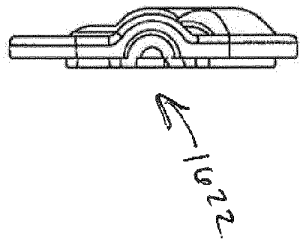

FIG. 17C

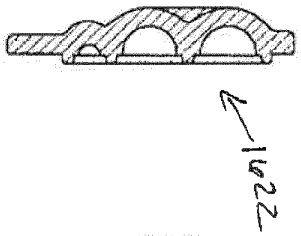

FIG. 17D

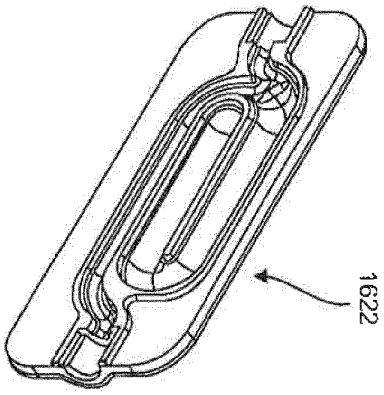

FIG. 17B

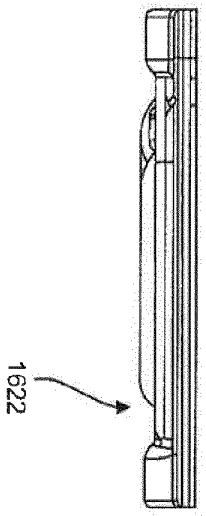

FIG. 17E

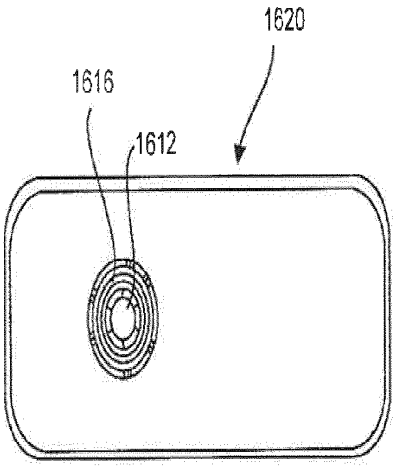

FIG. 18A

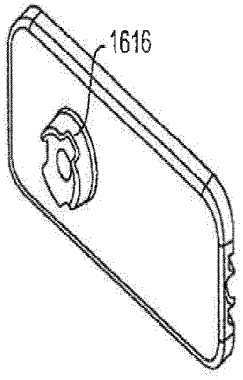

FIG. 18B

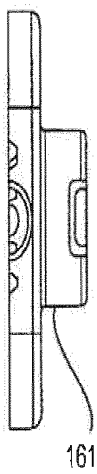

FIG. 18C

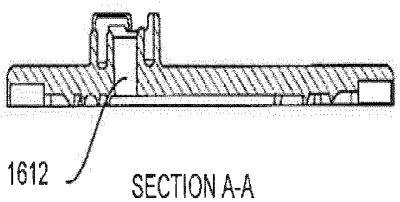

FIG. 18D

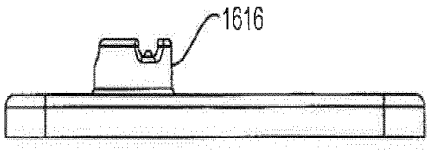

FIG. 18E

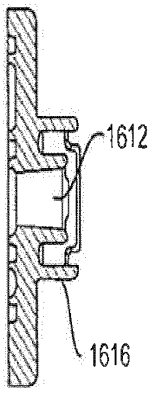

FIG. 18F

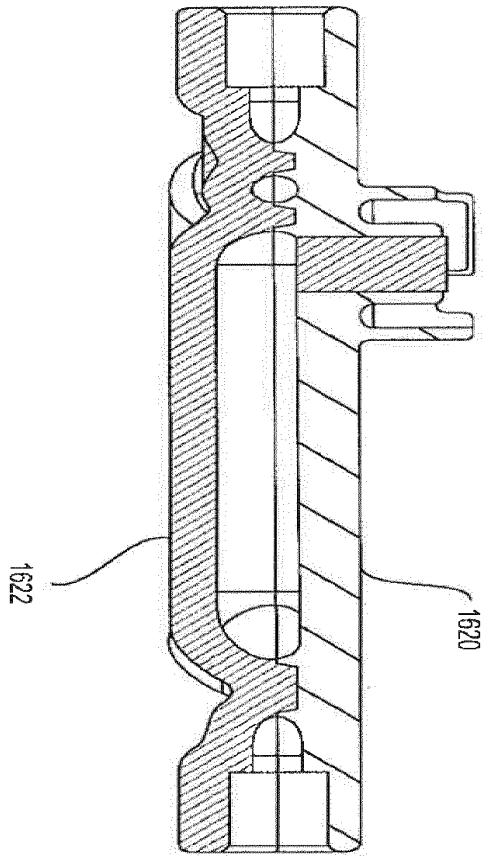

FIG. 19A

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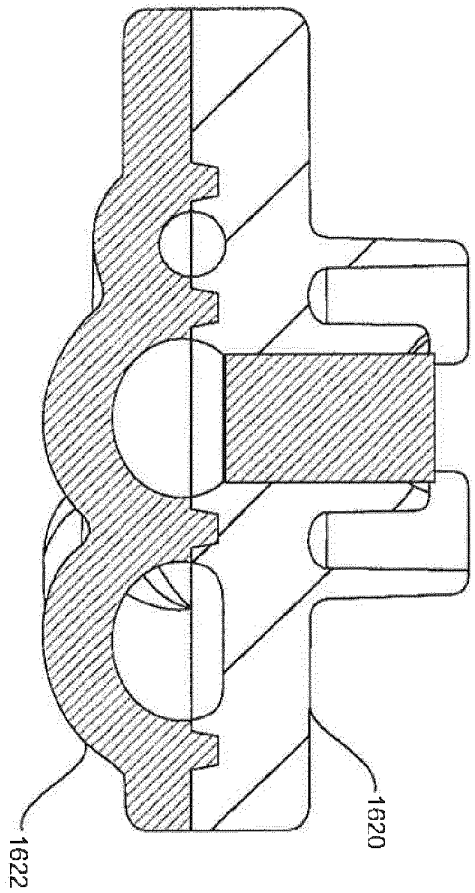

FIG. 19B

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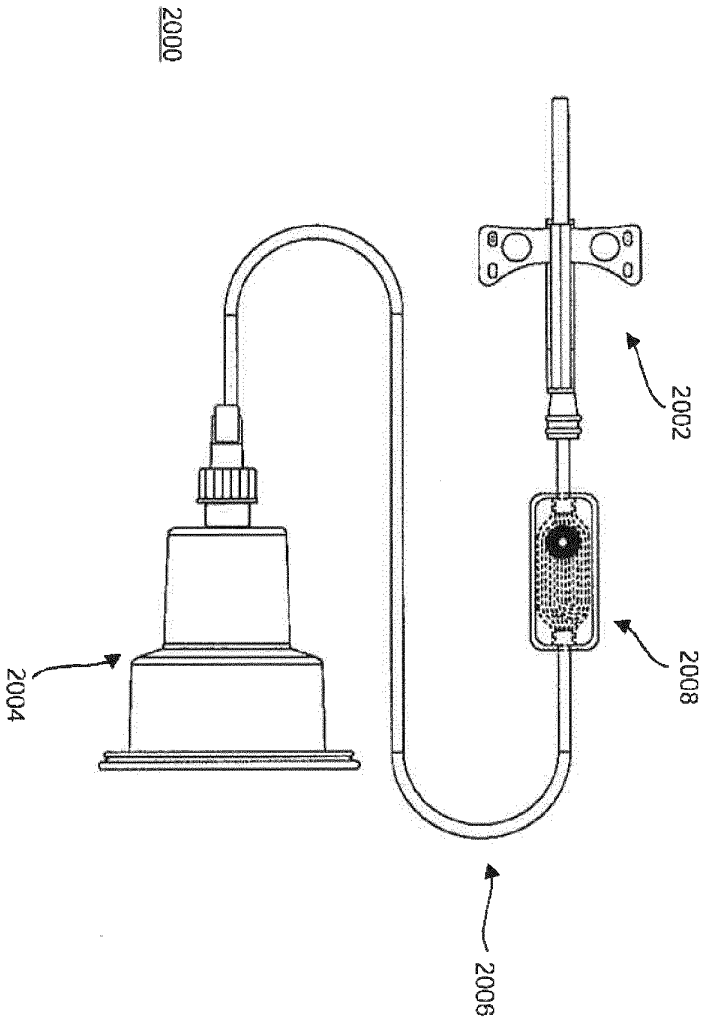

FIG. 20

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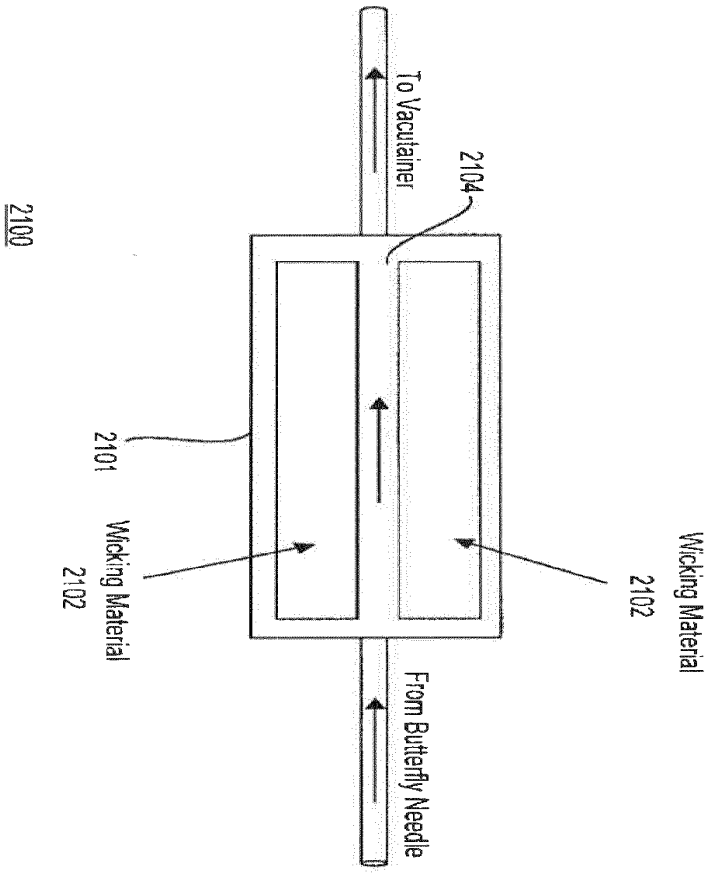

FIG. 21

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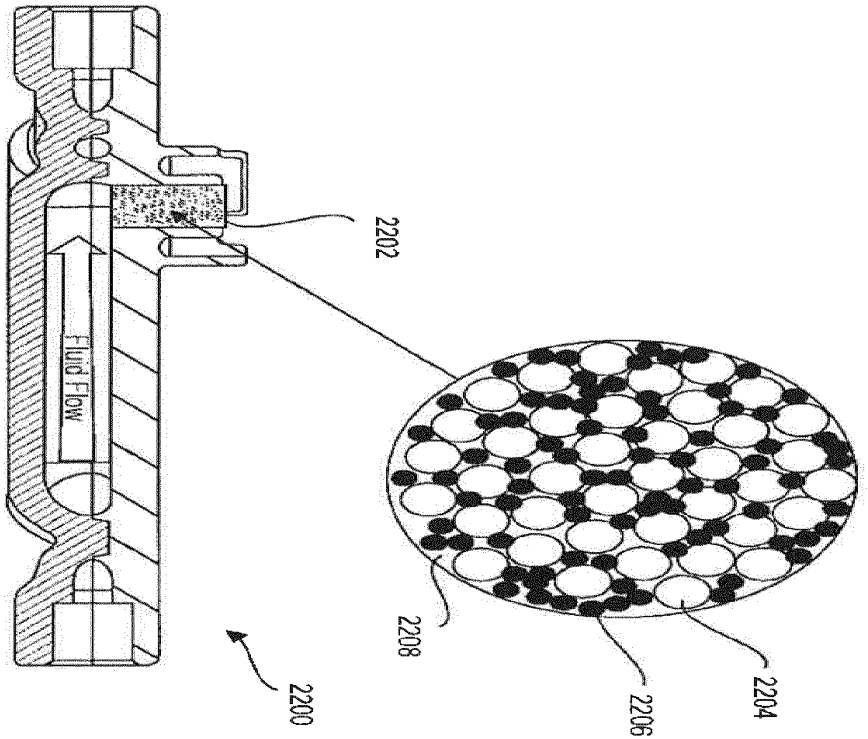

FIG. 22A

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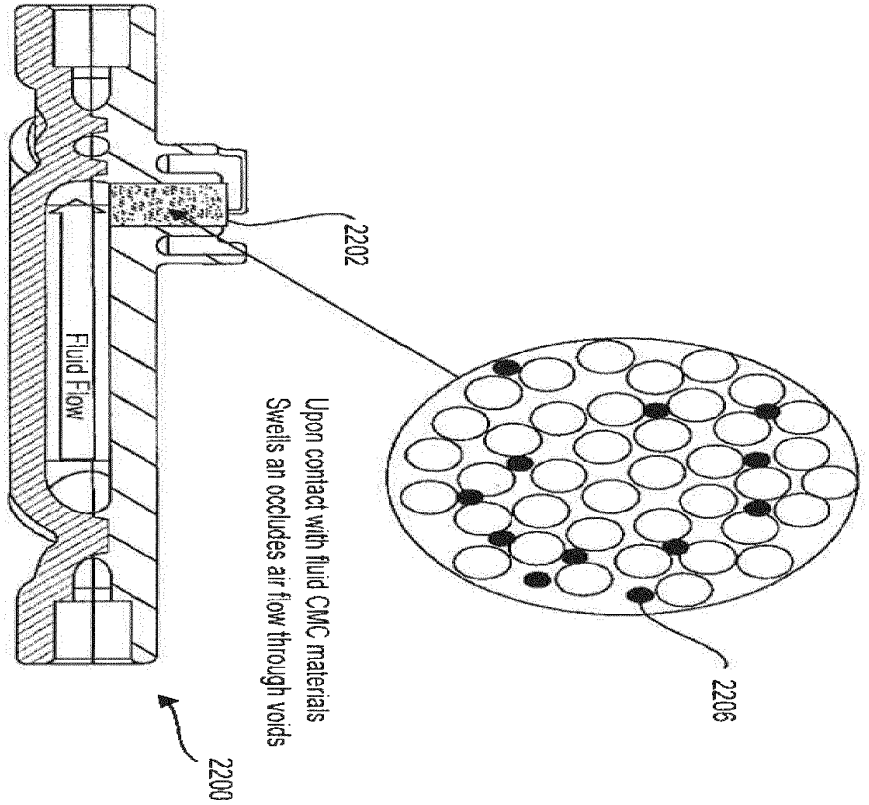

FIG. 22B

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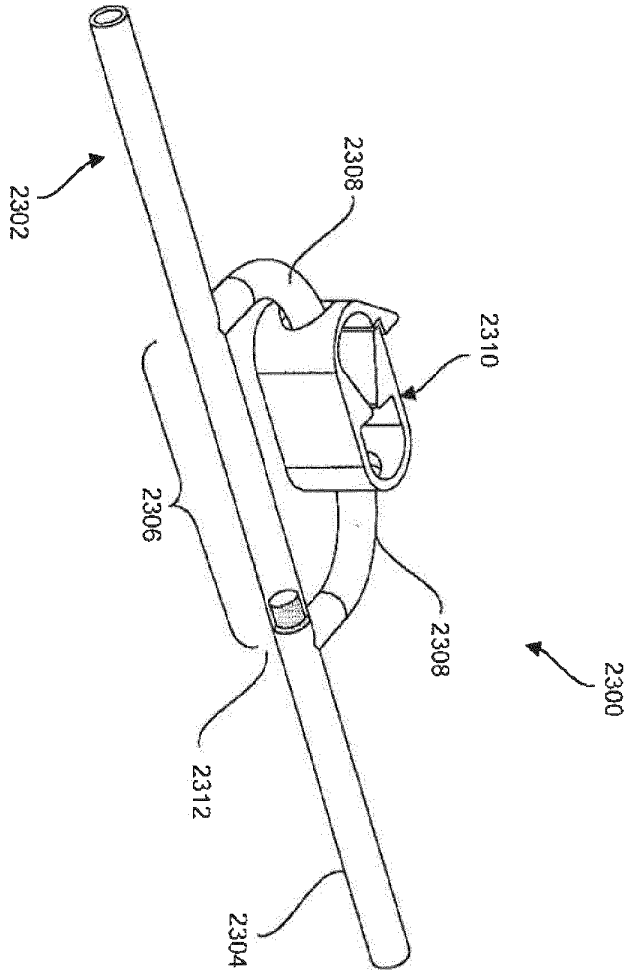

FIG. 23A

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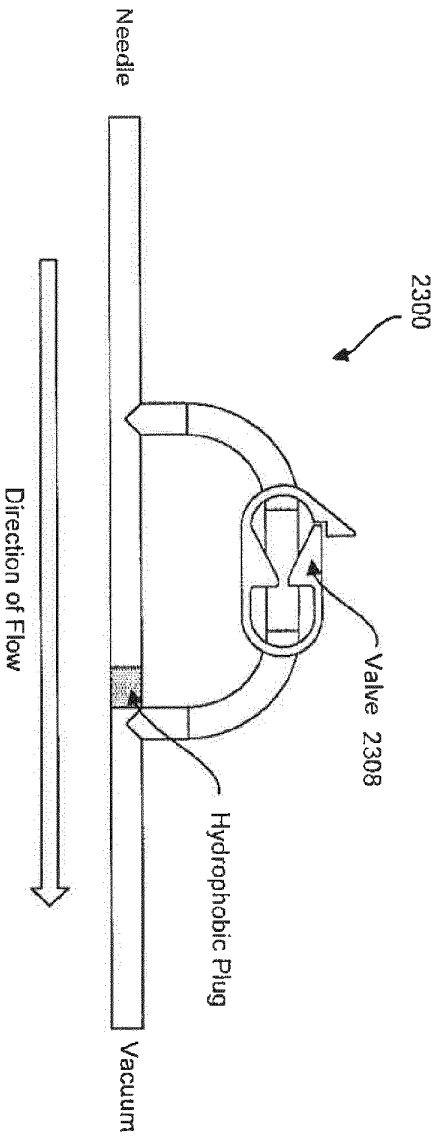

FIG. 23B

RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING"; and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD".

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with

catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles.

Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination,

20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

[0012a] WO 96/05875 A1 discloses a blood sampling device comprising a bifurcated capillary tube which has a first branch having a cannula shaped end for withdrawing and conveying blood to a blood collection zone for storing a quantity of withdrawn blood and feeding an initial fraction of withdrawn blood to a blood disposal chamber having an air permeable liquid sealed end; and a second branch connected to the blood collection zone which terminates in an opening adapted to receive a blood withdrawal device.

SUMMARY

[0013] This document presents systems and methods (a method is not claimed) for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to

accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is provided, comprising; an inlet port; a junction connected with the inlet port; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with an outlet port; and a housing that houses and defines the inlet port, the junction, the sequestration chamber, the sampling channel, and the outlet port, wherein the sequestration chamber is connected with the inlet port via the junction which is configured to direct a first portion of blood to the sequestration chamber, wherein the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.

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[0016] In another aspect, a system of a blood sequestration device, a blood sampling pathway having a patient needle, and a sample collection device is provided, the blood sequestration device comprising; an inlet port connected with the patient needle; a junction connected with the inlet port opposite the blood sampling pathway; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port; and an outlet port connected with a distal end of the sampling channel and with the sample collection device; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel, wherein the sequestration chamber is connected with the inlet port and the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood.

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims. The invention is best illustrated by figures 16A to 19B.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0031] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0032] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0033] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0034] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0035] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0036] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0037] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0038] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0039] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0040] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0041] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

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[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and methods (a method is not claimed)

for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient

needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable

blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is

added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone

to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable

blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a

sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can

be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with

one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved,

and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port

1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.114 cm (0.045 inches), but can have a diameter of between 0.0254 cm (0.01 inches) or less to 0.508 cm (0.2 inches) or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration

chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion

pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.114 cm (0.045 inches),
but can have a diameter of between 0.0254 cm (0.01 inches) or less to 0.508 cm (0.2 inches) or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some

implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port

1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel

1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial

groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not shown, not claimed),

which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure

overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS.

16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.114 cm (0.045 inches), but can have a diameter of between 0.0254 cm (0.01 inches) or less to 0.508 cm (0.2 inches) or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need

for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other

pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In use (neither use nor method is claimed), the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-

filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

Amended claims

1. A blood sequestration device (1500) comprising;

an inlet port (1502);

a junction (1607) connected with the inlet port (1502);

a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);

a sampling channel (1506) having a proximal end connected with the inlet port (1502) via the junction (1607), and a distal end connected with an outlet port (1504); and

a housing (1501) that houses and defines the inlet port (1502), the junction (1607), the sequestration chamber (1508), the sampling channel (1506), and the outlet port (1504),

wherein the sequestration chamber (1508) is connected with the inlet port (1502) via the junction (1607) which is configured to direct a first portion of blood to the sequestration chamber (1508),

characterized in that the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.

2. The blood sequestration device (1500) in accordance with claim 1, wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).

3. The blood sequestration device (1500) in accordance with claim 1 or 2, further comprising a blood sampling pathway connected with the inlet port (1502) opposite the junction (1607), and

wherein the inlet port (1502) defined by the housing (1501) has a cross-sectional geometry consistent with the blood sampling pathway.

4. The blood sequestration device (1500) in accordance with one of the preceding claims, wherein the sampling channel (1506) defined by the housing (1501) has a cross-sectional geometry consistent with the inlet port (1502).

5. The blood sequestration device (1500) in accordance with one of claims 2 to 4, wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520)

defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

6. A system of a blood sequestration device (1500), a blood sampling pathway having a patient needle, and a sample collection device, the blood sequestration device (1500) comprising;

an inlet port (1502) connected with the patient needle;

a junction (1607) connected with the inlet port (1502) opposite the blood sampling pathway;

a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);

a sampling channel (1506) having a proximal end connected with the inlet port (1502); and

an outlet port (1504) connected with a distal end of the sampling channel (1506) and with the sample collection device; and a housing (1501) that houses and defines the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506),

characterized in that the sequestration chamber (1508) is connected with the inlet port (1502) and the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with blood.

7. The system in accordance with claim 6, wherein the inlet port (1502) is connected with the patient needle via a first portion of the blood sampling pathway.

8. The system in accordance with claim 6 or 7, wherein the outlet port (1504) is connected with the sample collection device via a second portion of the blood sampling pathway.

9. The system in accordance with one of claims 6 to 8, wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).

10. The system in accordance with claim 9, wherein the sequestration channel has a proximal end connected with the inlet port (1502), and a distal end having the vent (1510) comprising an air permeable blood barrier (1512).

11. The system in accordance with one of claims 6 to 10, wherein the sequestration chamber (1508) and the sampling channel (1506) are connected with

the inlet port (1502) by the junction (1607) that is configured to direct a first portion of blood to the sequestration chamber (1508).

12. The system in accordance with one of claims 6 to 11, wherein the sampling channel (1506) has a substantially uniform cross-sectional geometry that is consistent with the blood sampling pathway.

13. The system in accordance with claim 12, wherein the sequestration chamber (1506) includes a sequestration chamber that has a cross-sectional area that is larger than the cross-sectional geometry of the sampling channel (1506).

14. The system in accordance with claim 7, member (1520), wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520) defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

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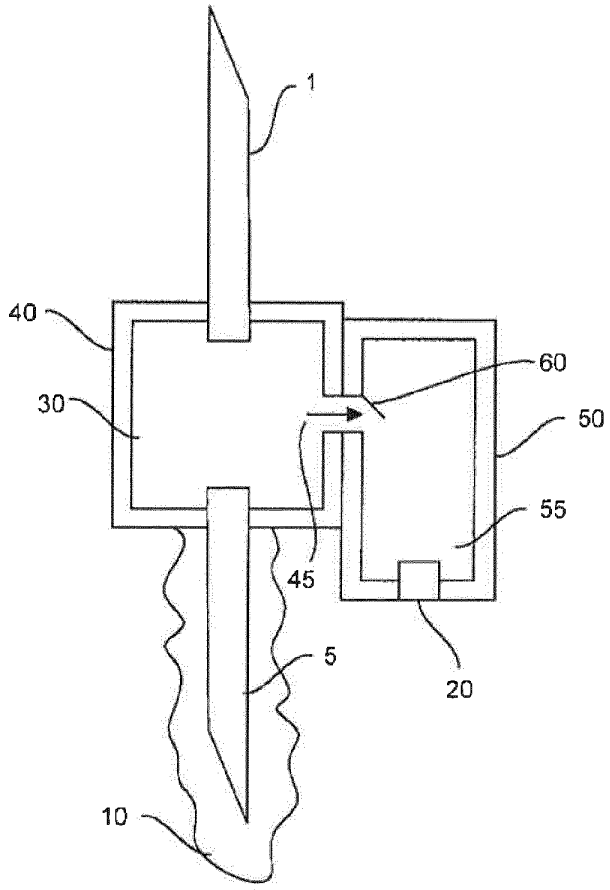

FIG. 1

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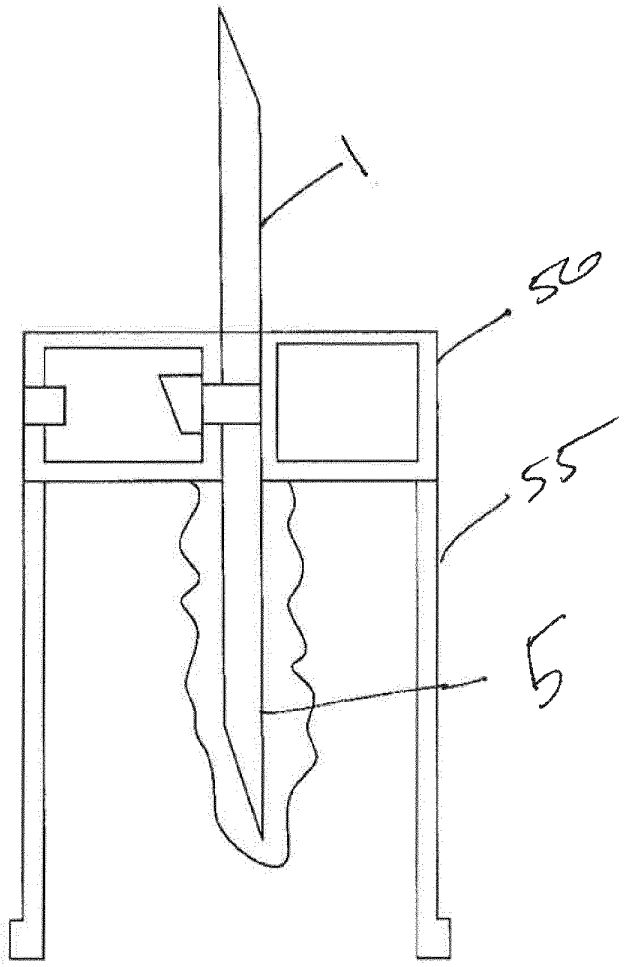

FIG. 2

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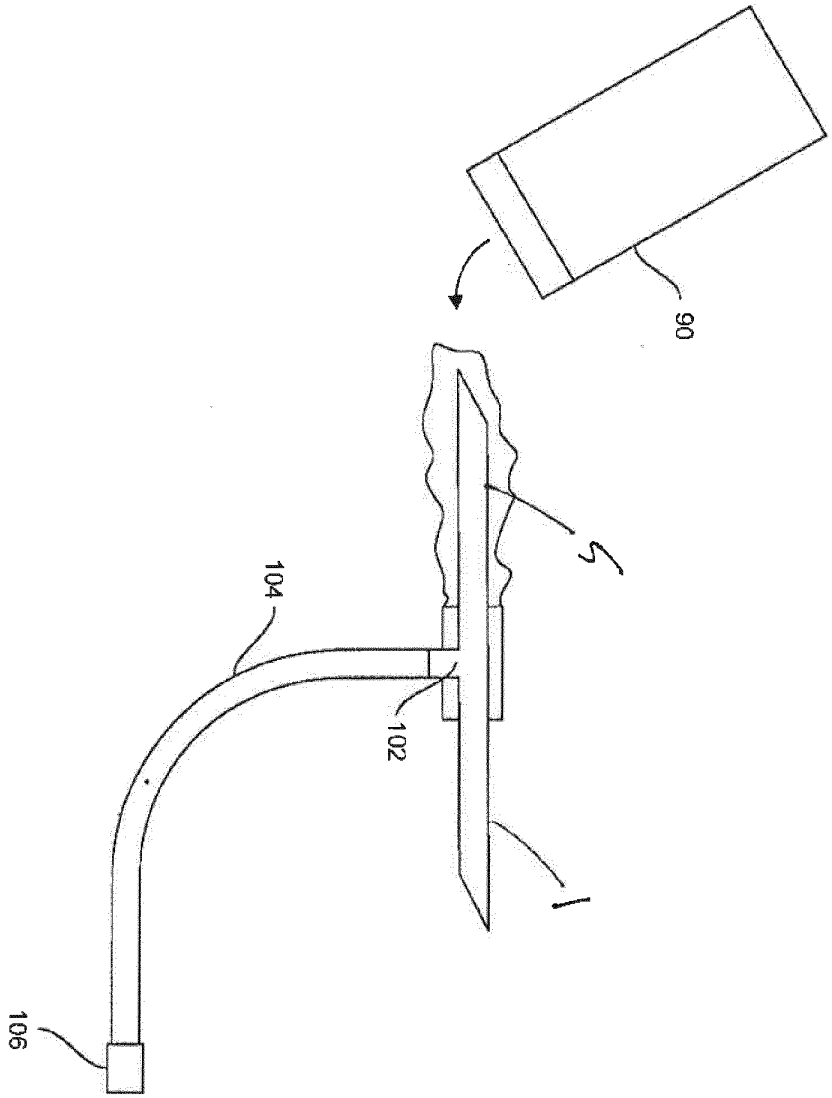

FIG. 3

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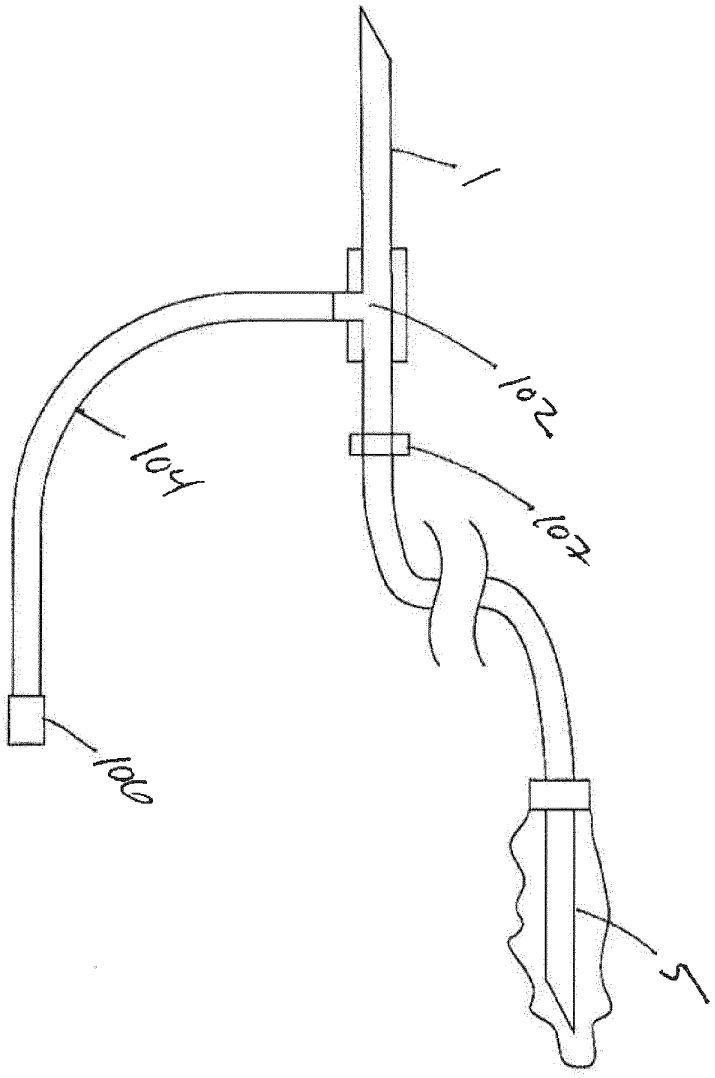

FIG. 4

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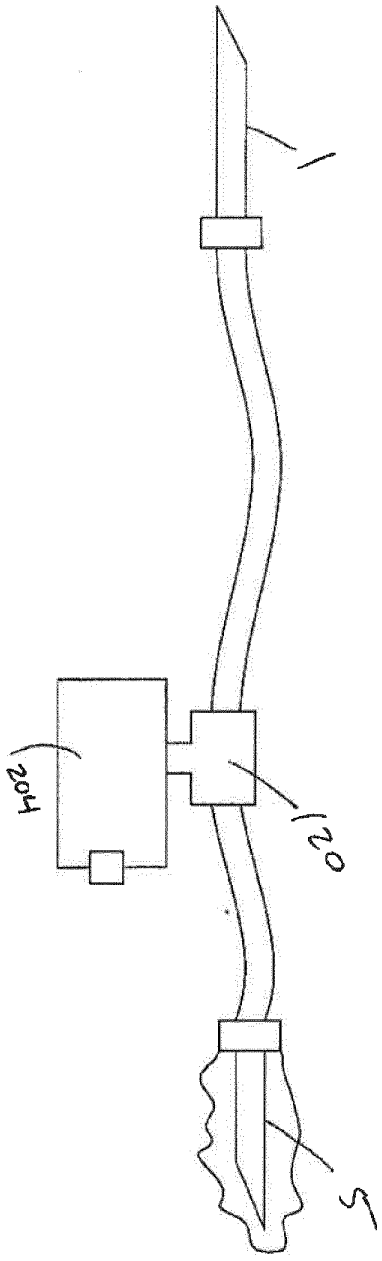

FIG. 5

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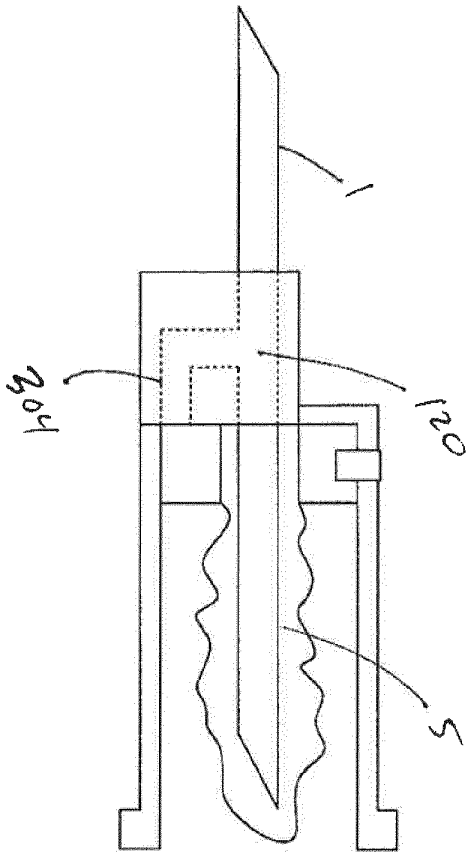
FIG. 6



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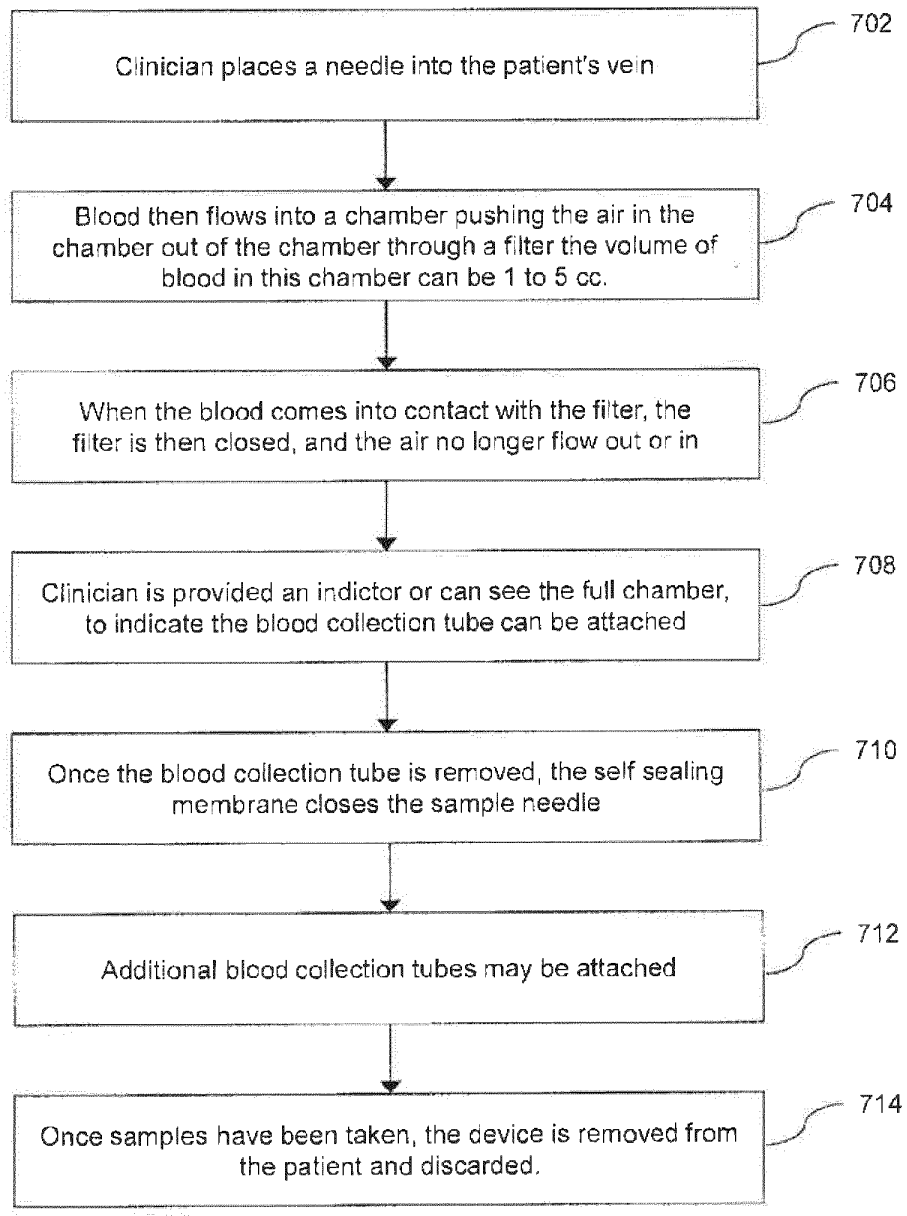
Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

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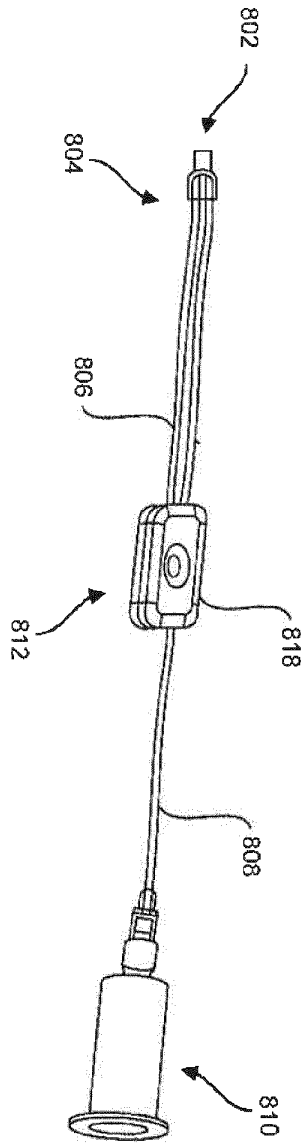

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FIG. 8A

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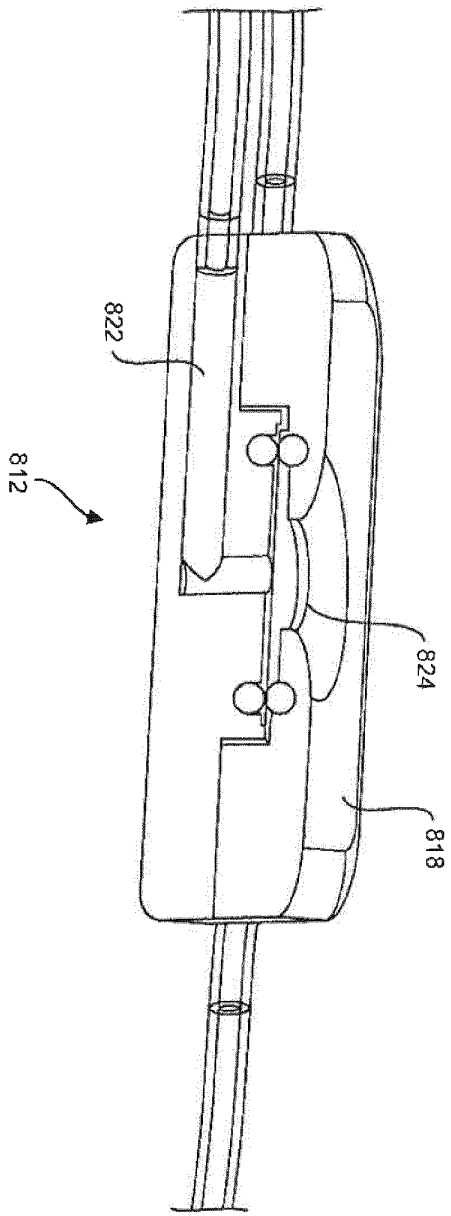

FIG. 8B

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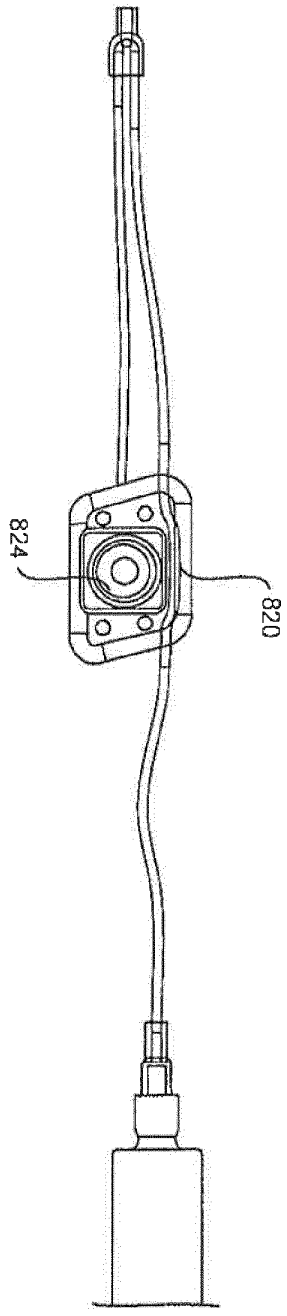
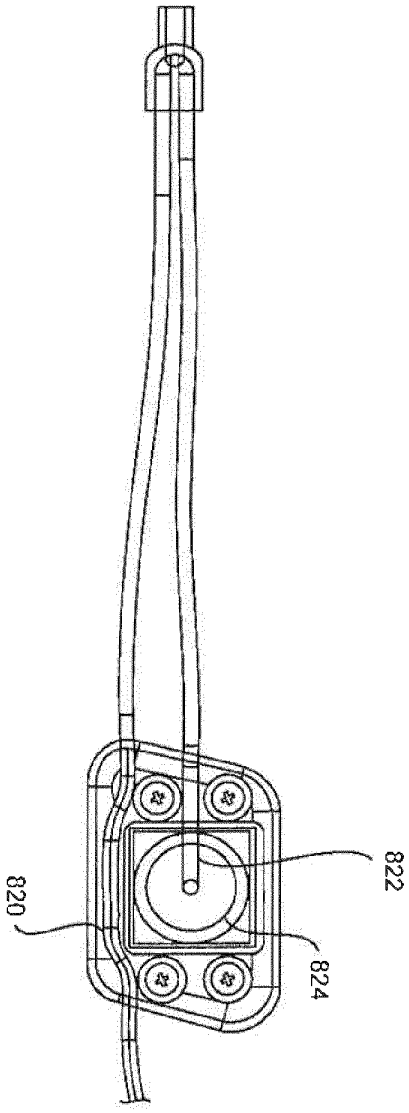


FIG. 8C

FIG. 8D



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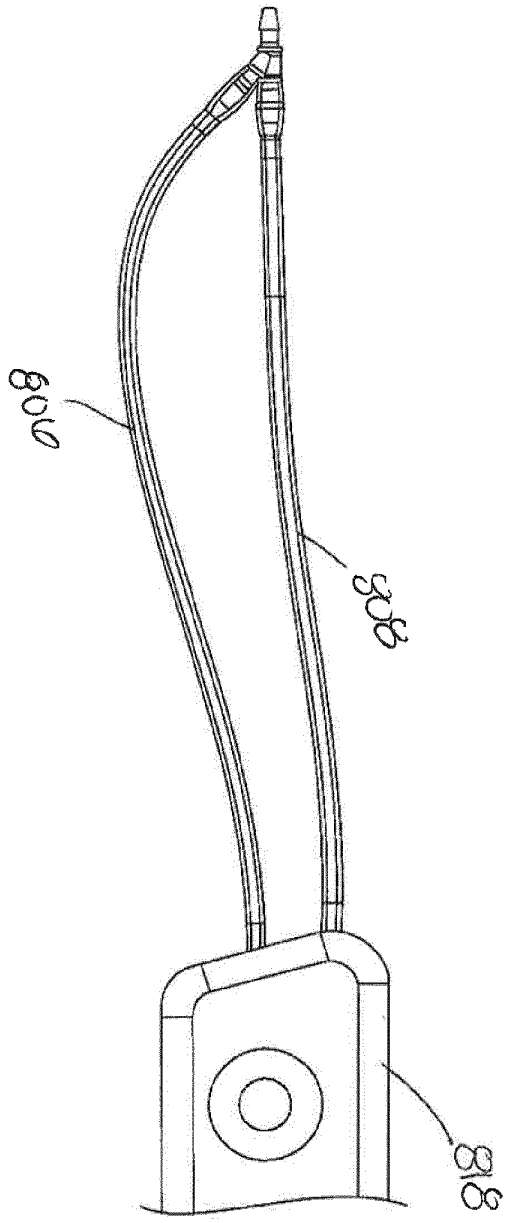

FIG. 8E

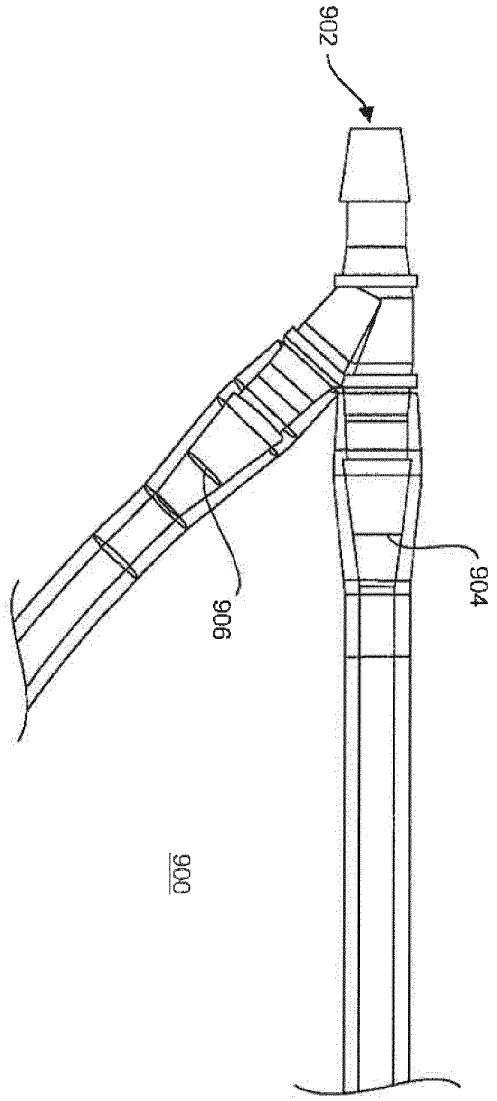

FIG. 9

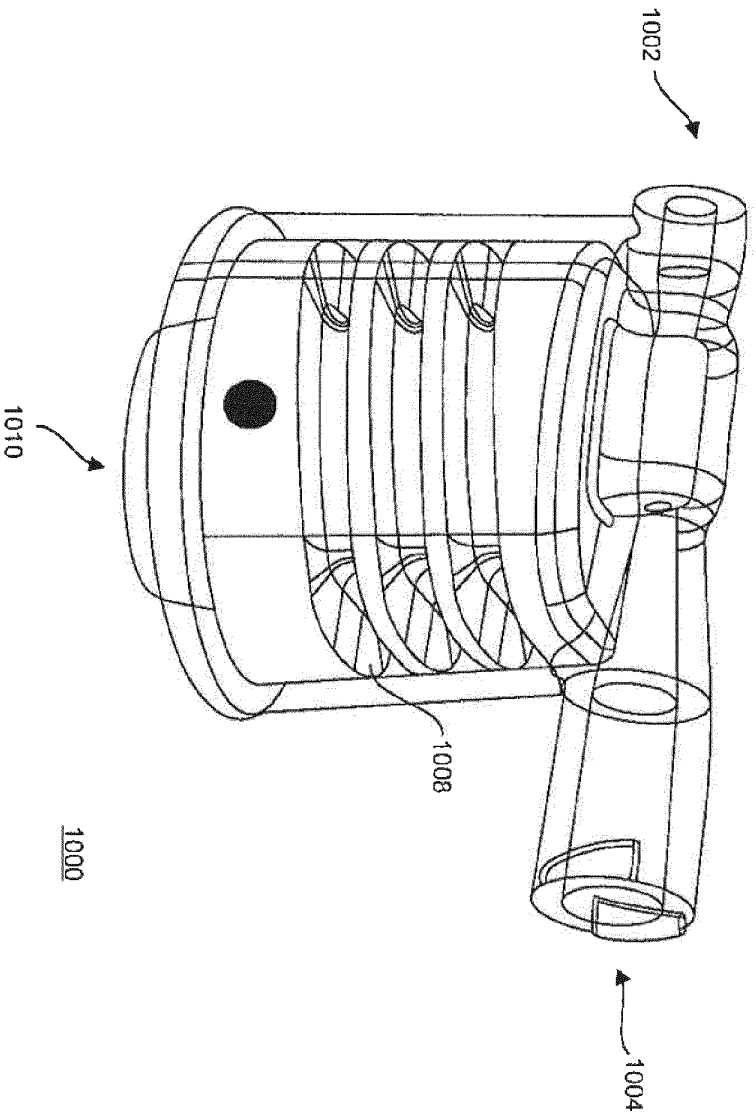

FIG. 10A

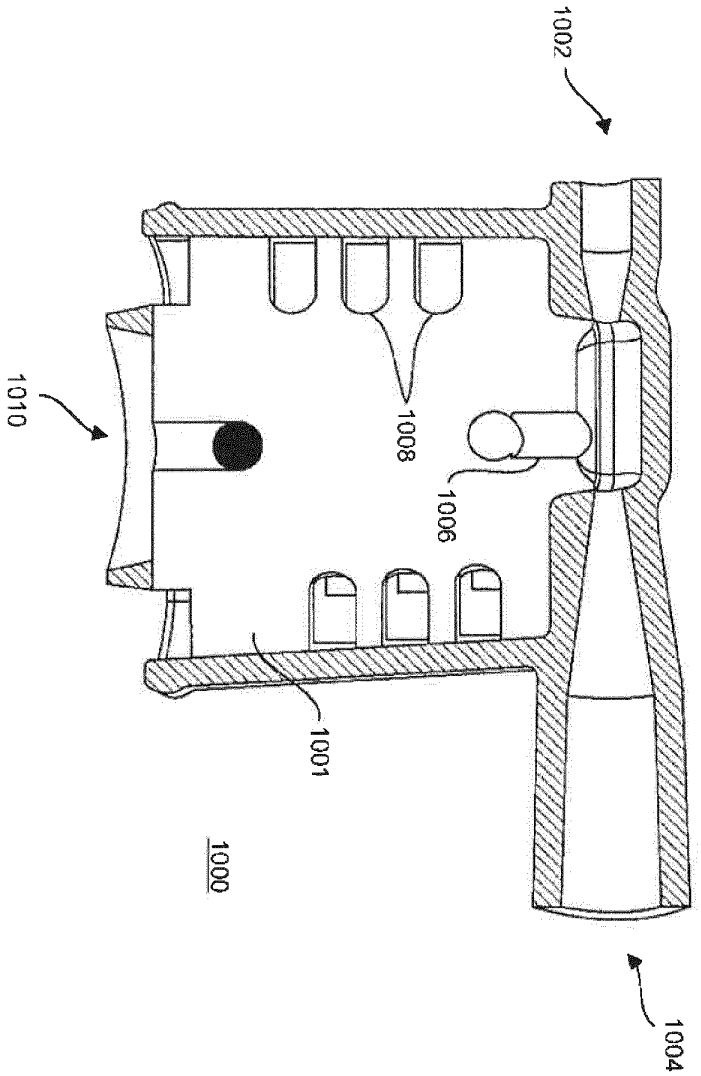

FIG. 10B

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FIG. 10C

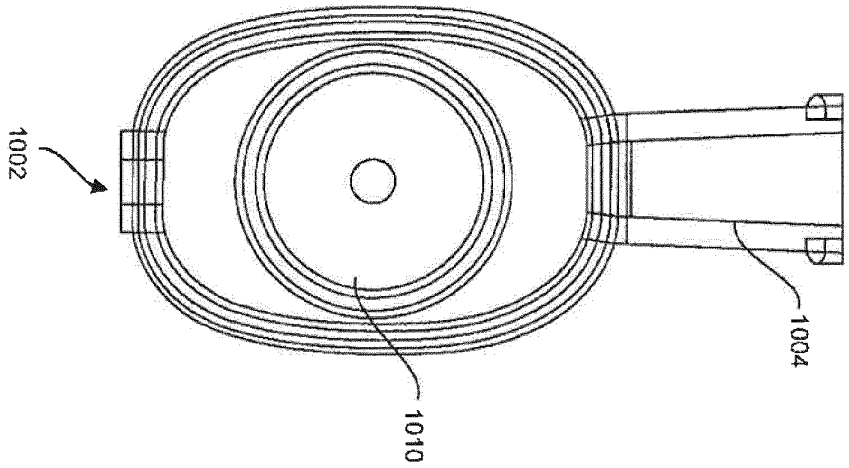
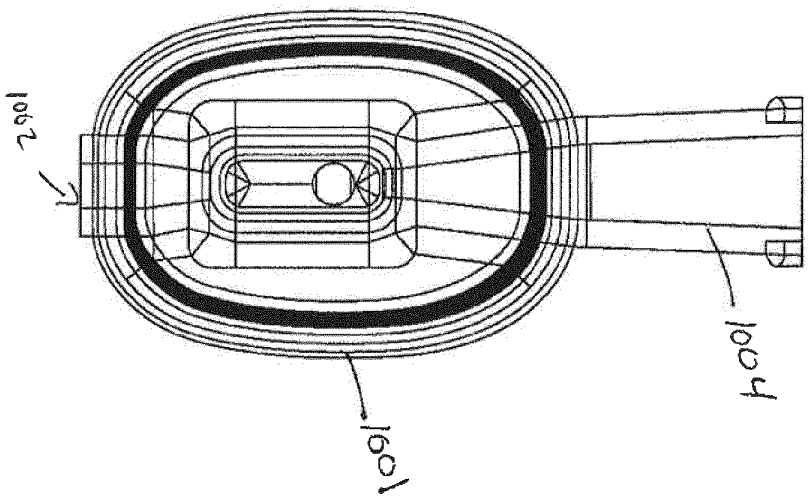


FIG. 10D



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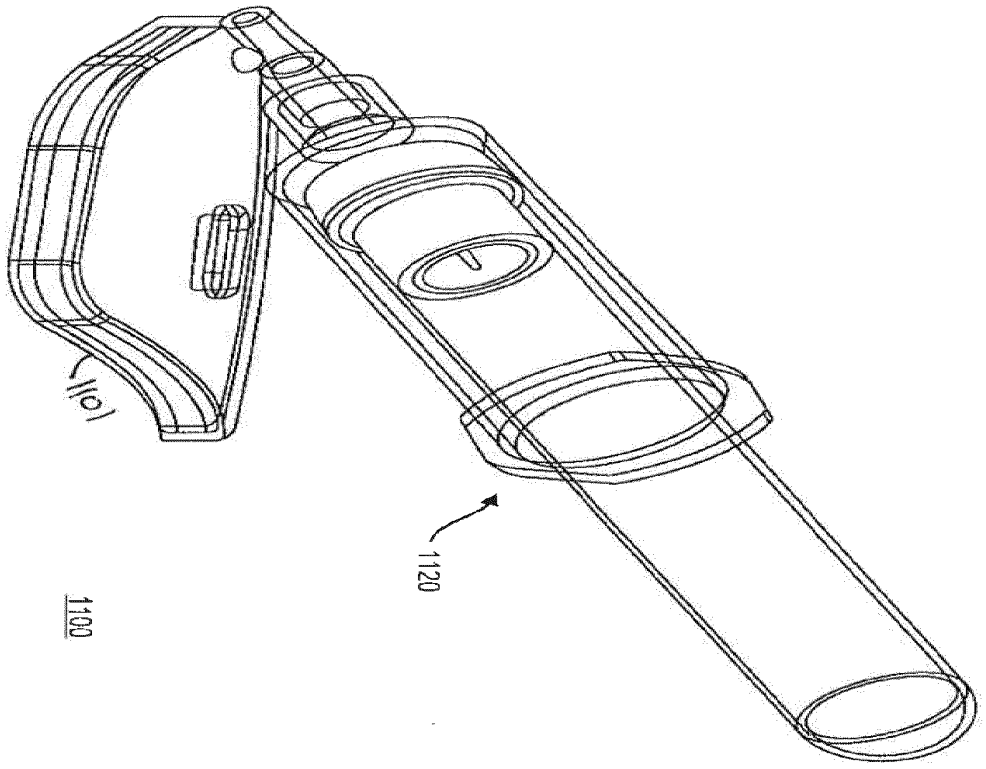

FIG. 11A

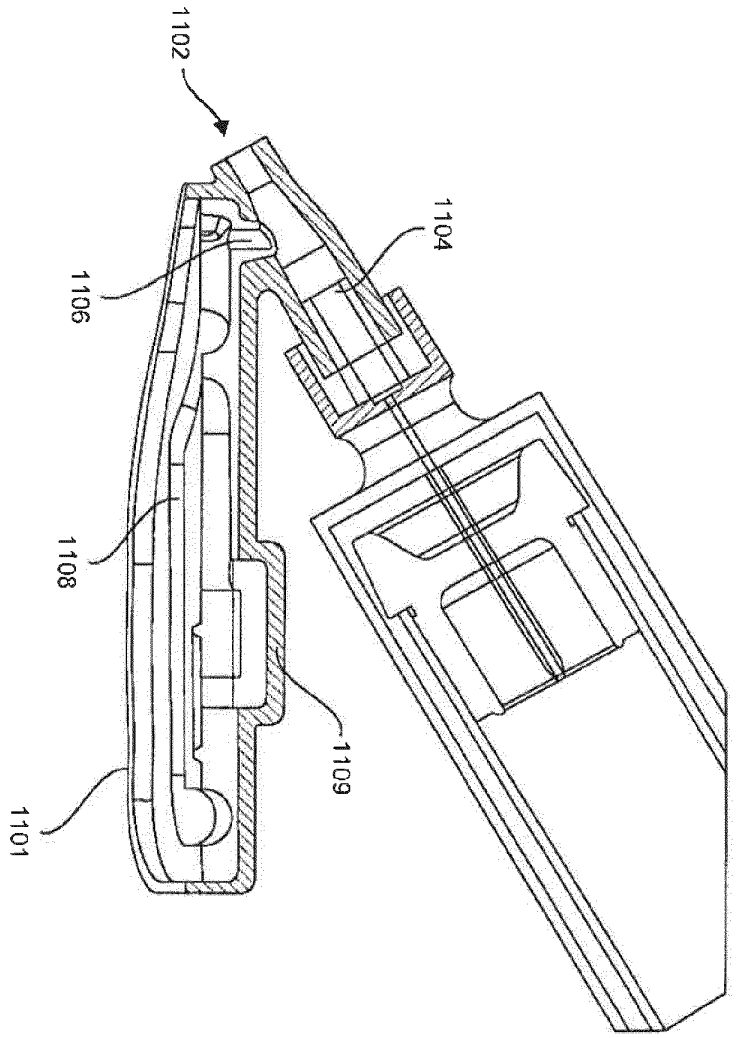

FIG. 11B

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FIG. 11C

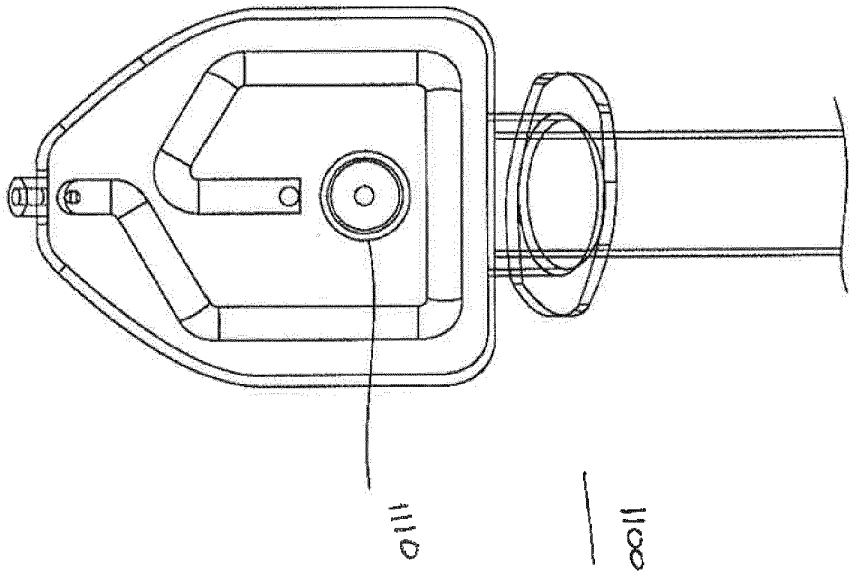
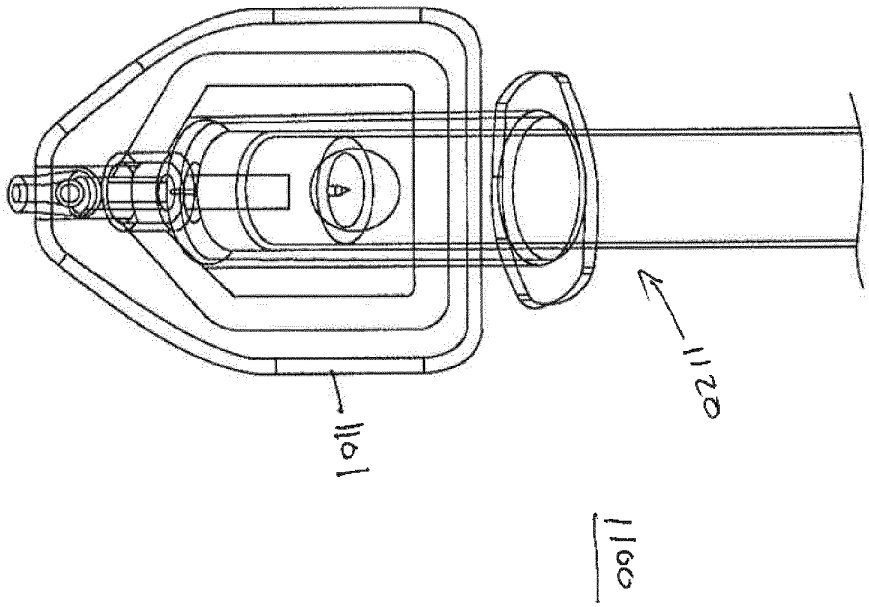


FIG. 11D



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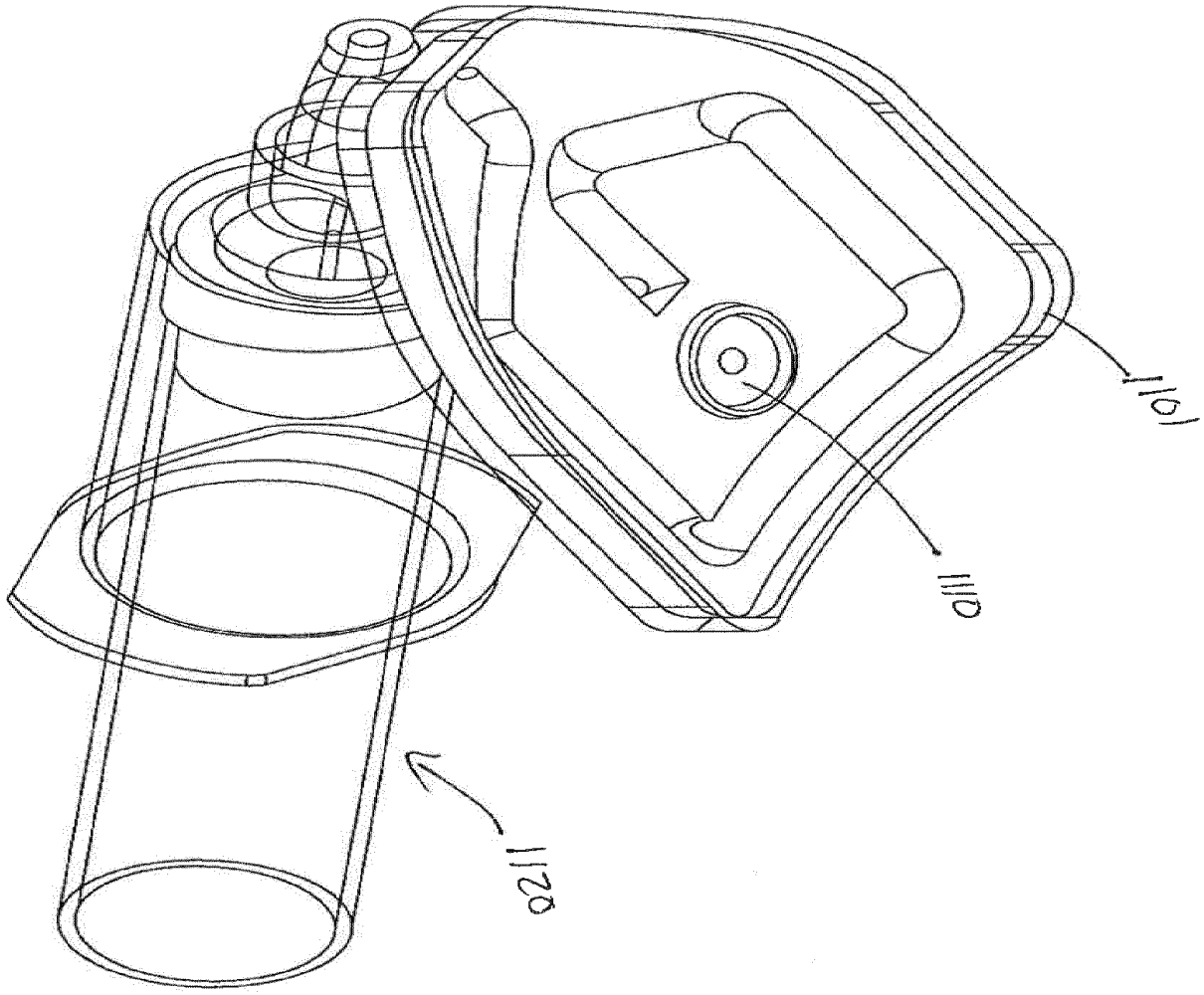

FIG. 11E

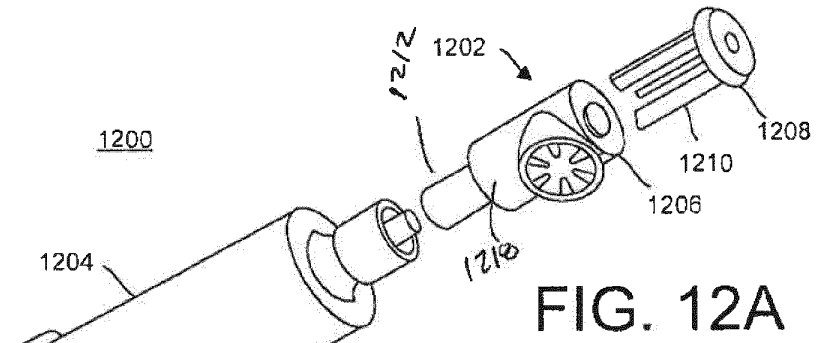

FIG. 12A

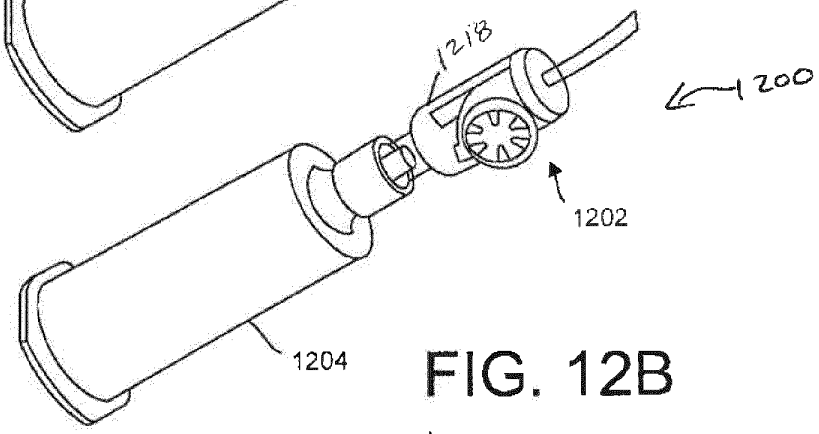

FIG. 12B

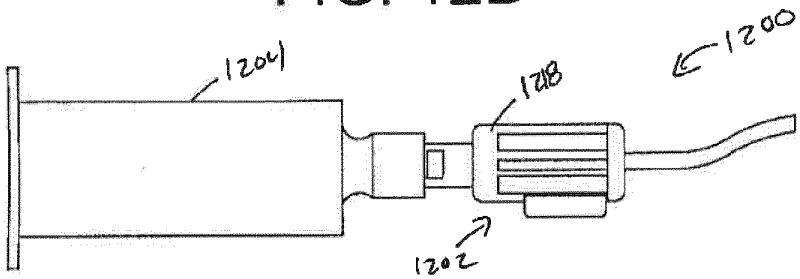

FIG. 12C

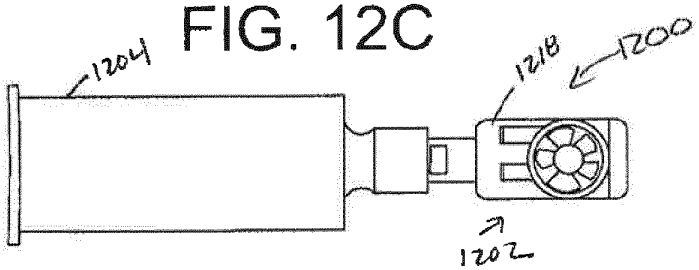

FIG. 12D

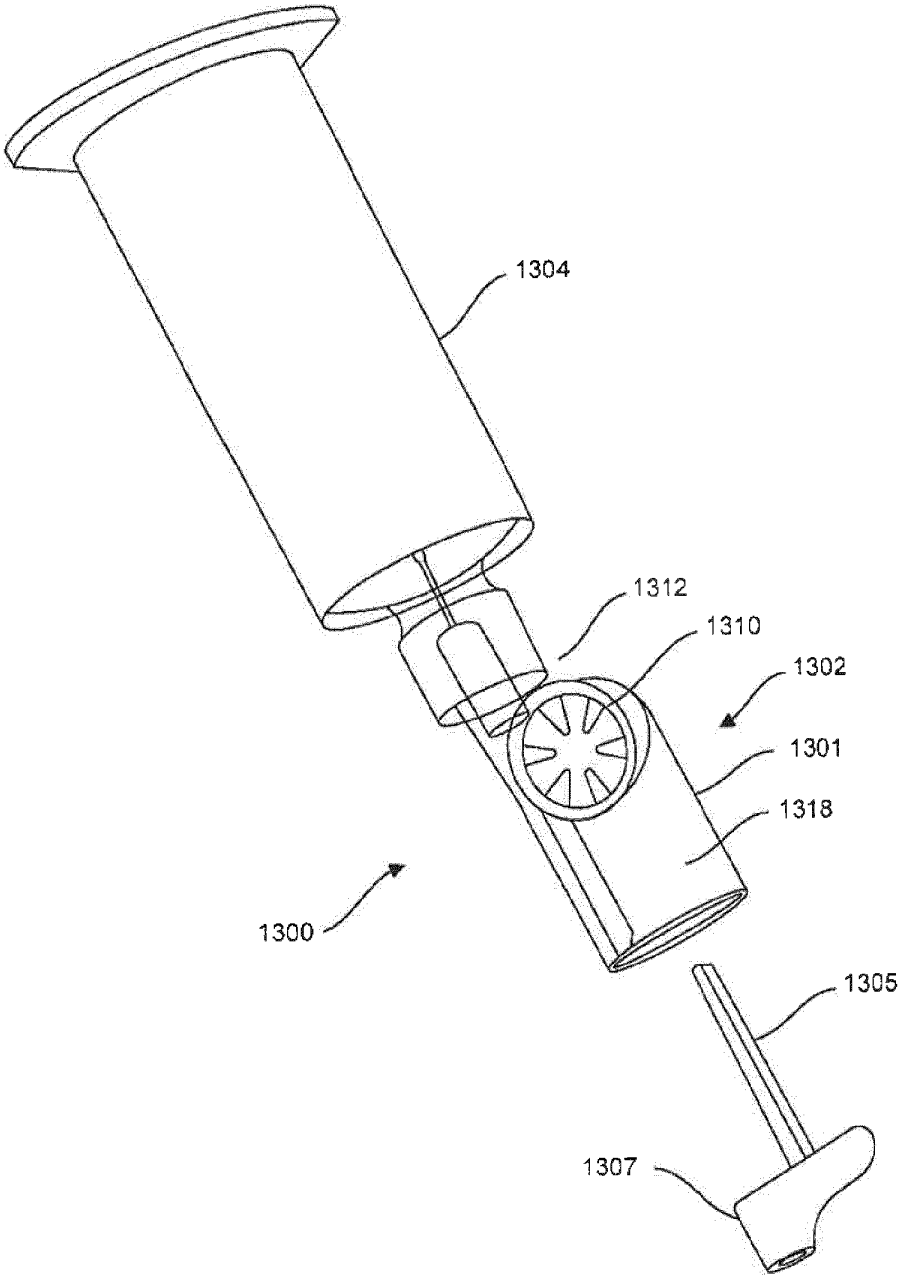

FIG. 13A

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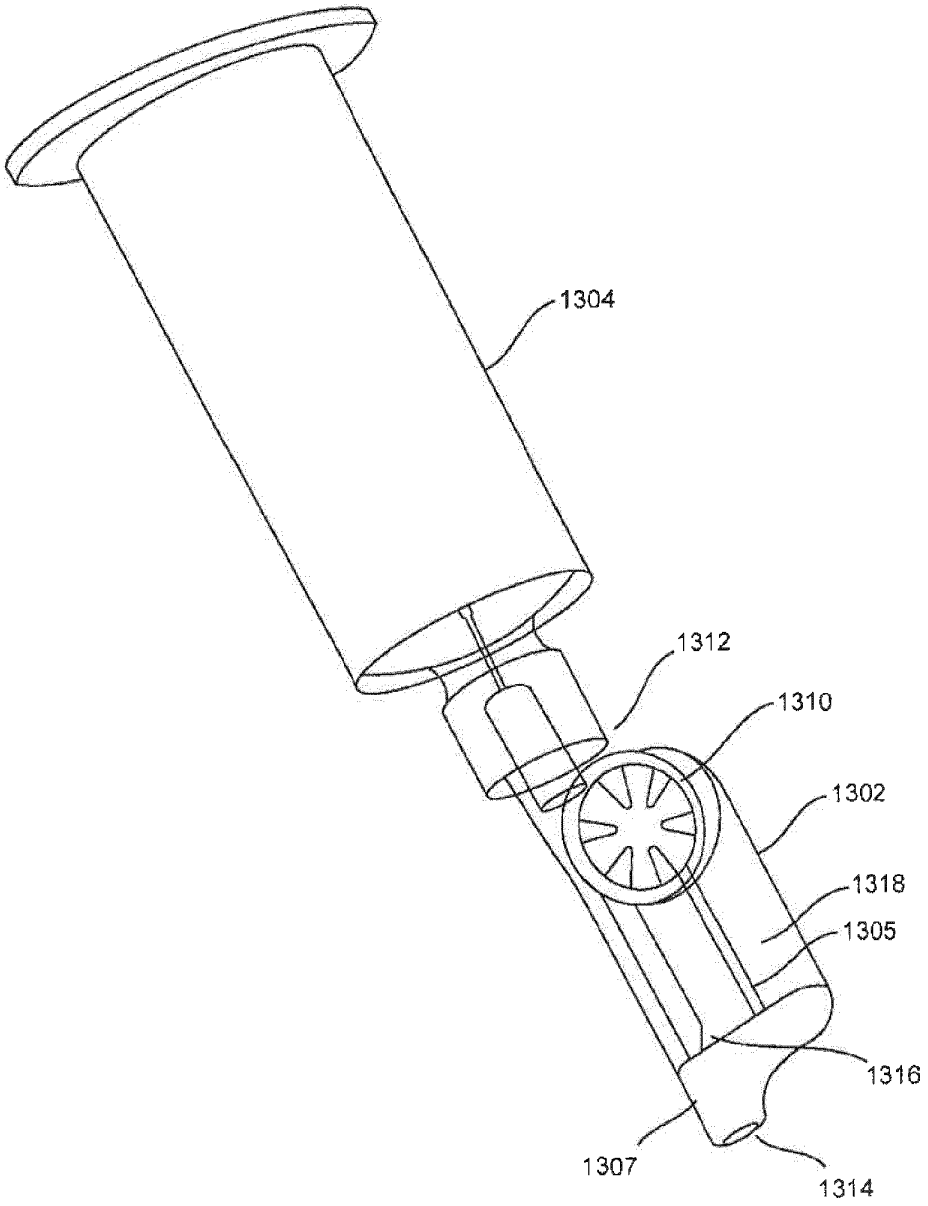

FIG. 13B

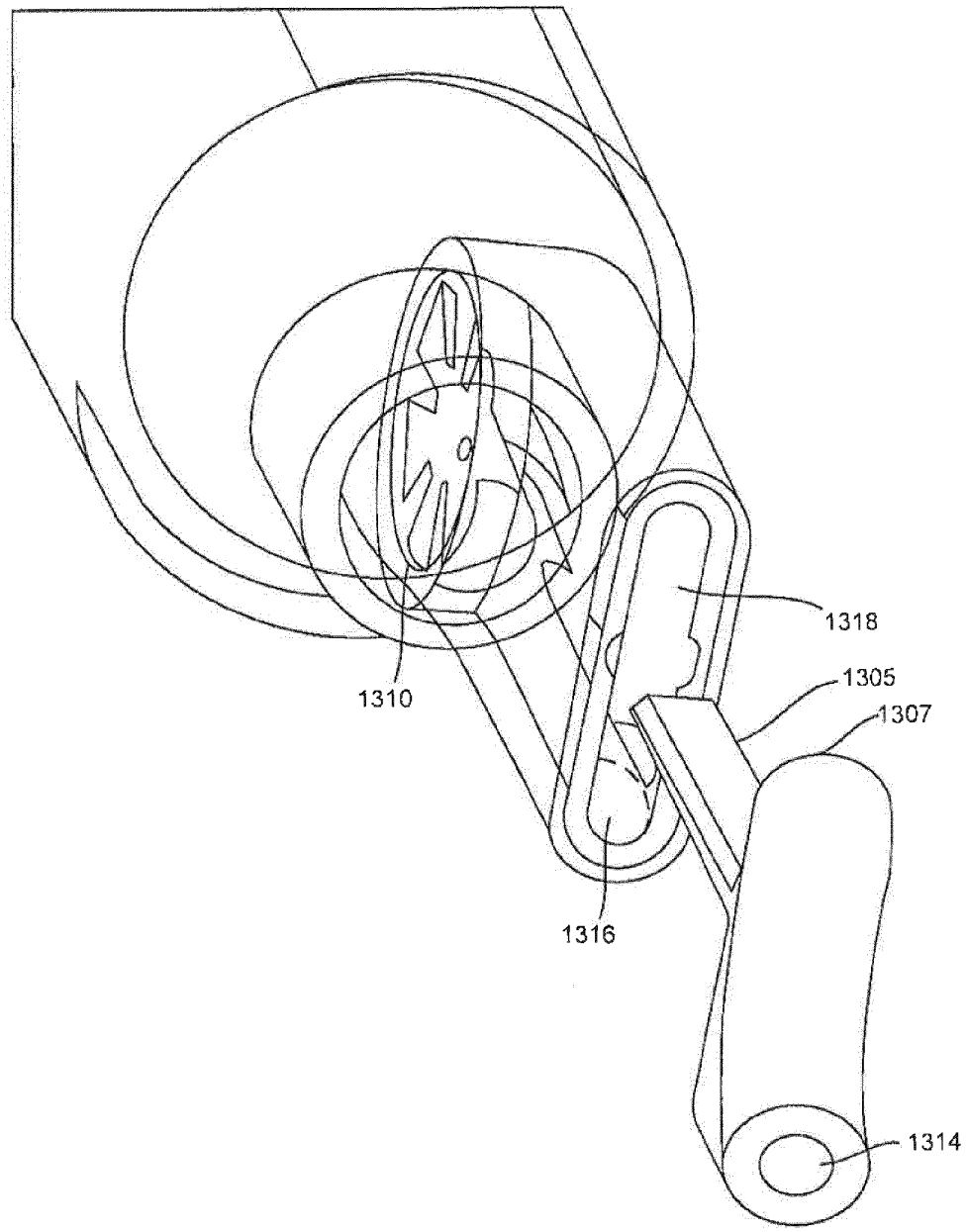

FIG. 13C

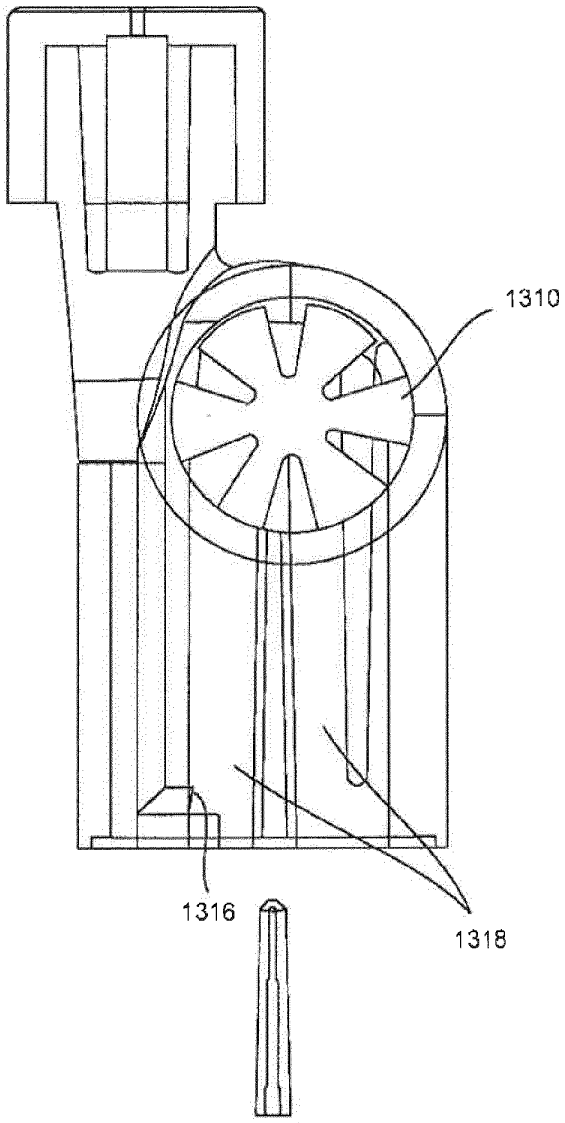

FIG. 13D

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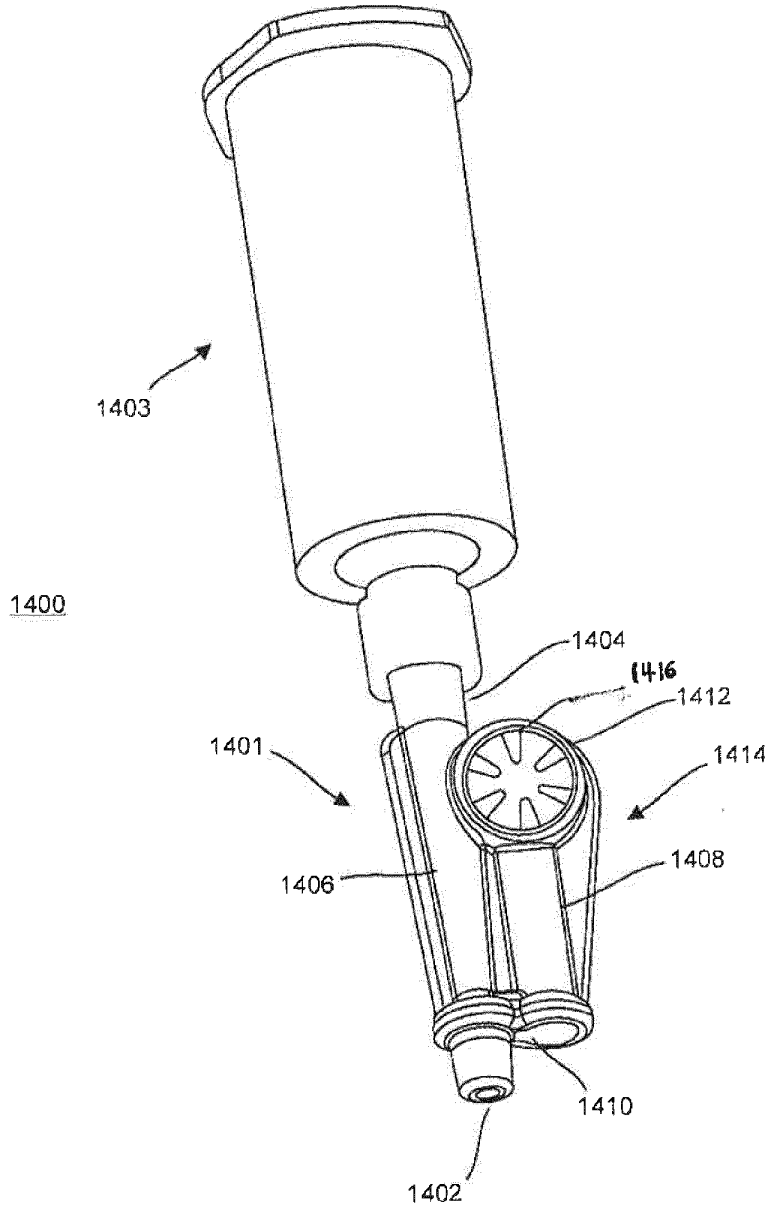

FIG. 14A

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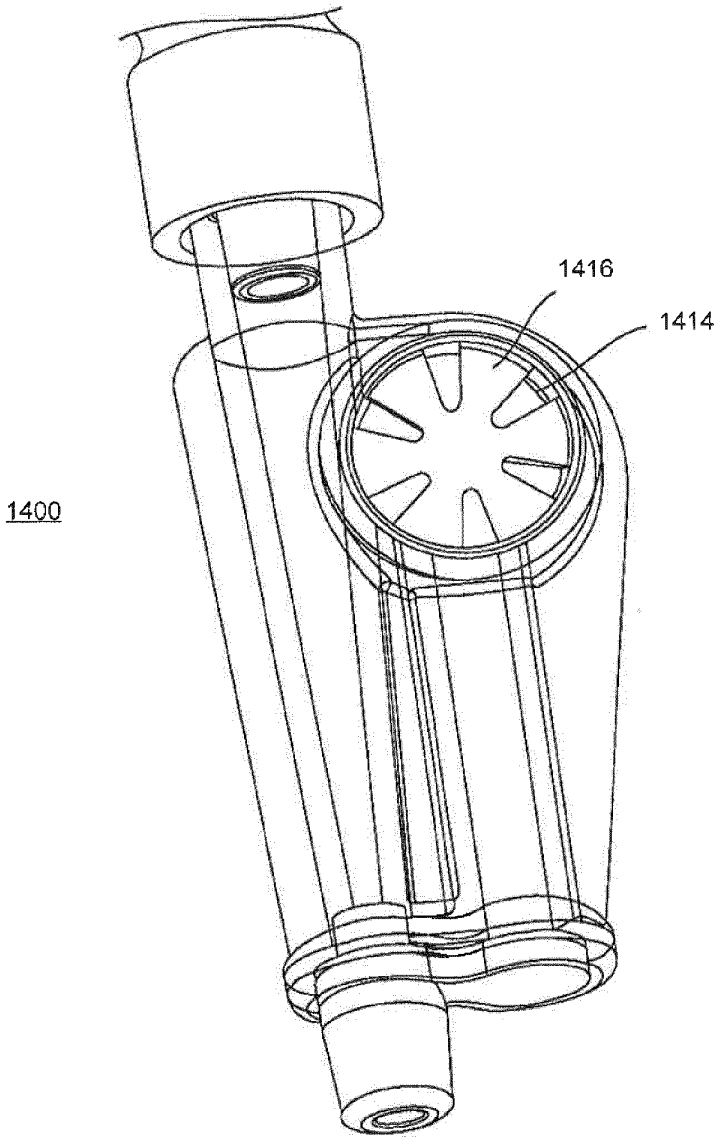

FIG. 14B

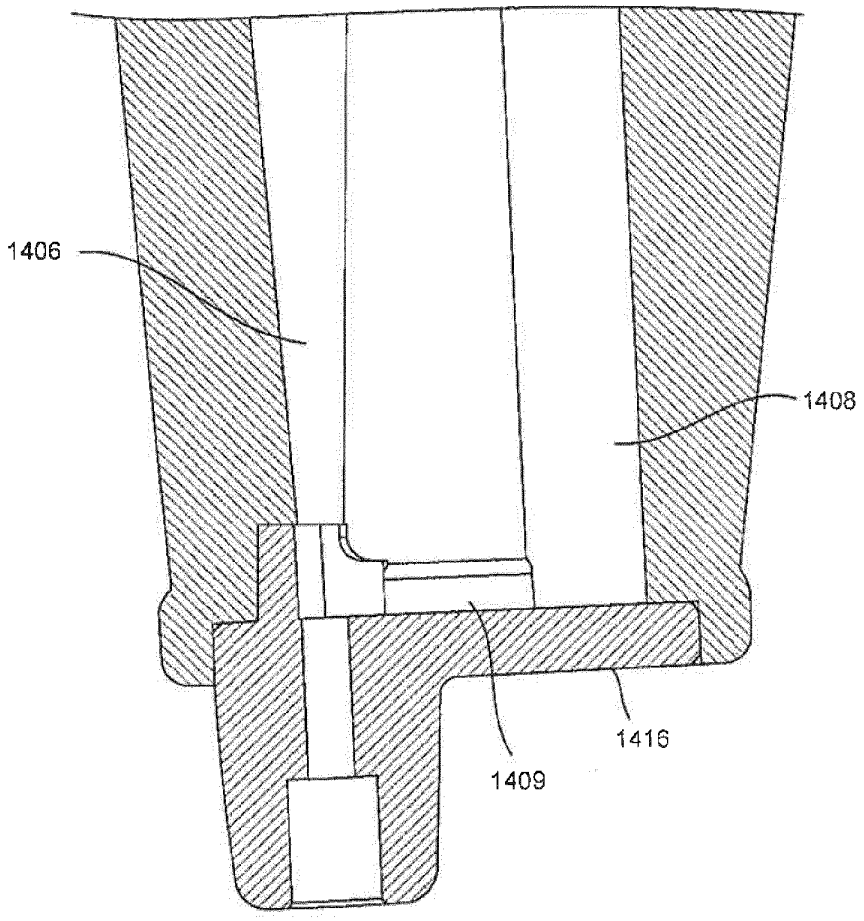

FIG. 14C

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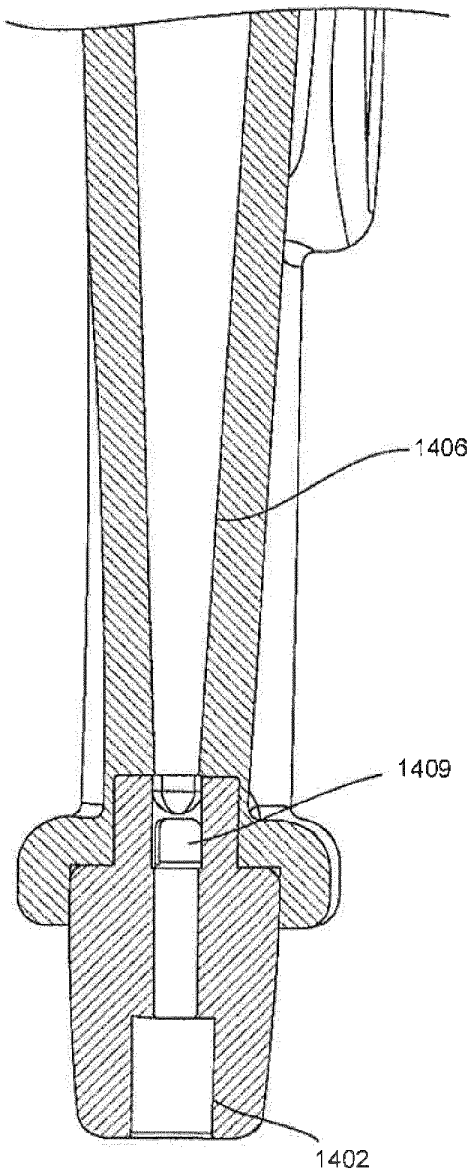

FIG. 14D

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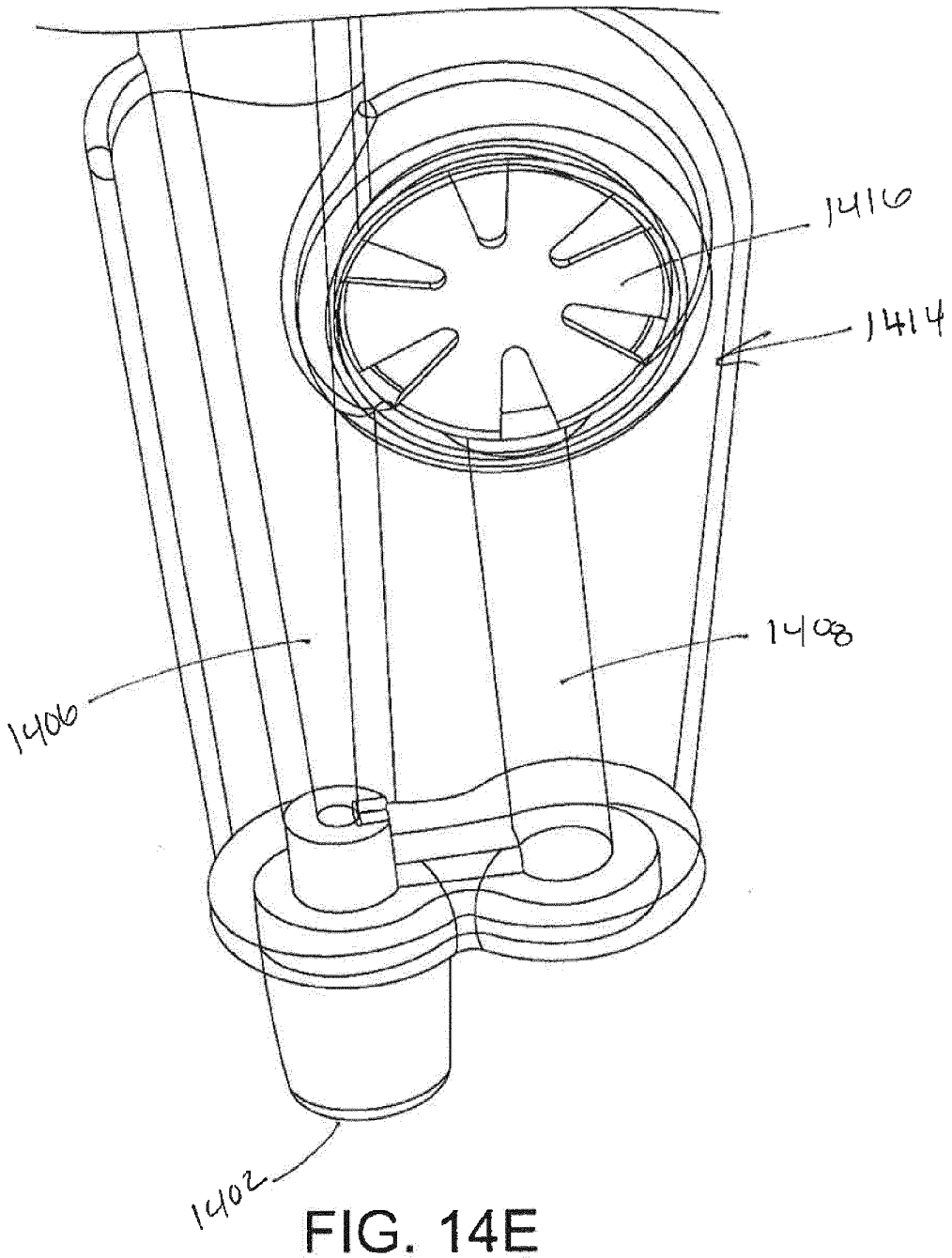

FIG. 14E

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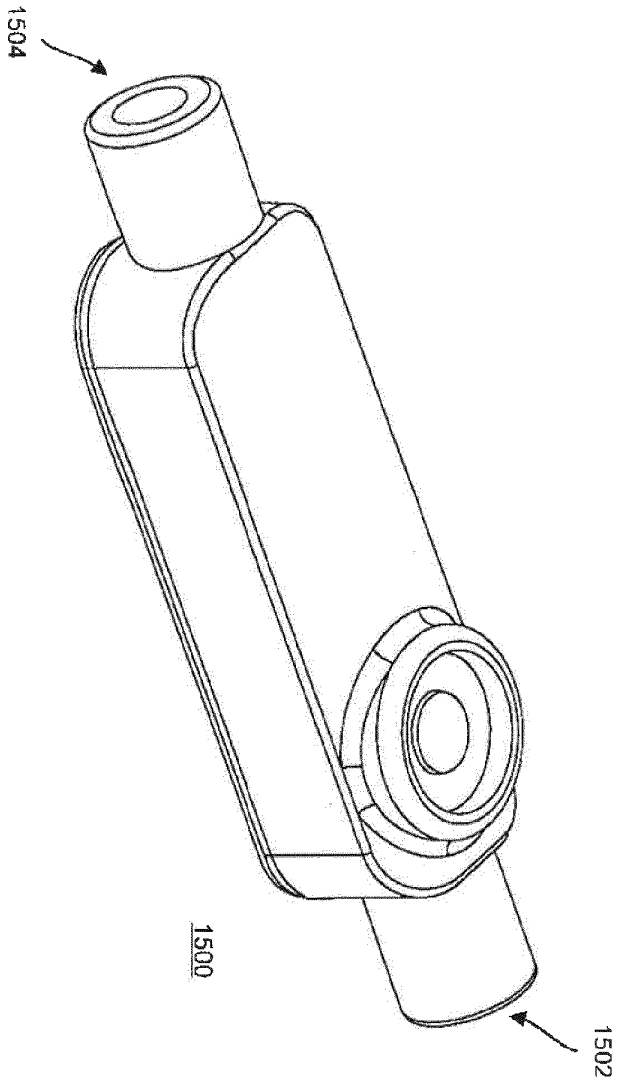

FIG. 15A

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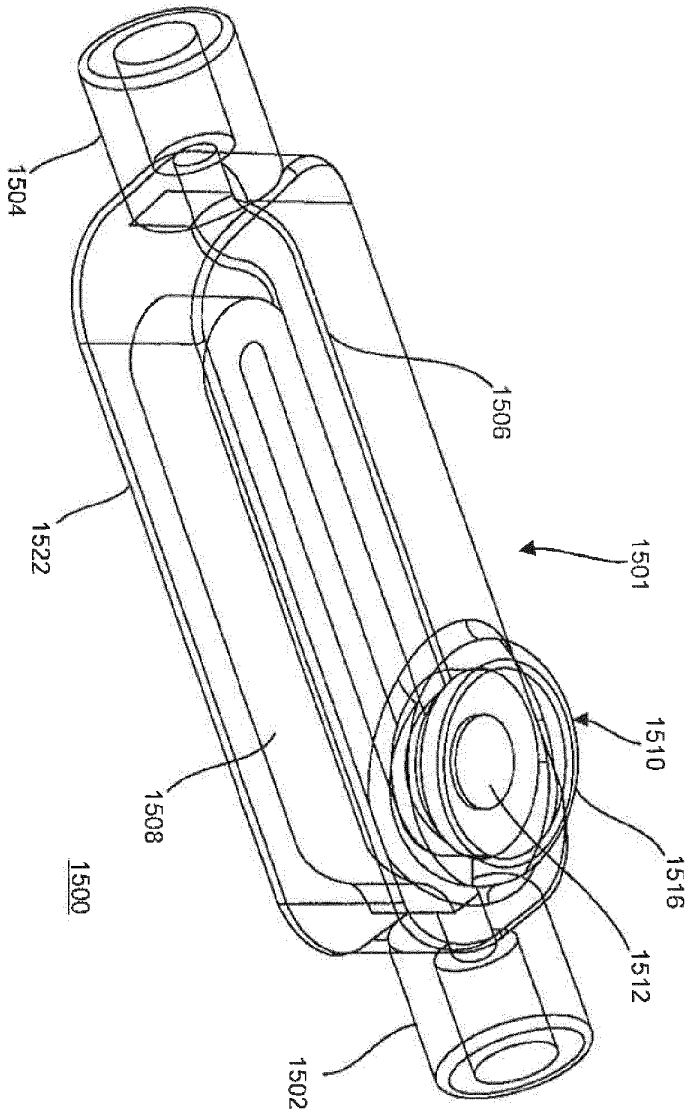

FIG. 15B

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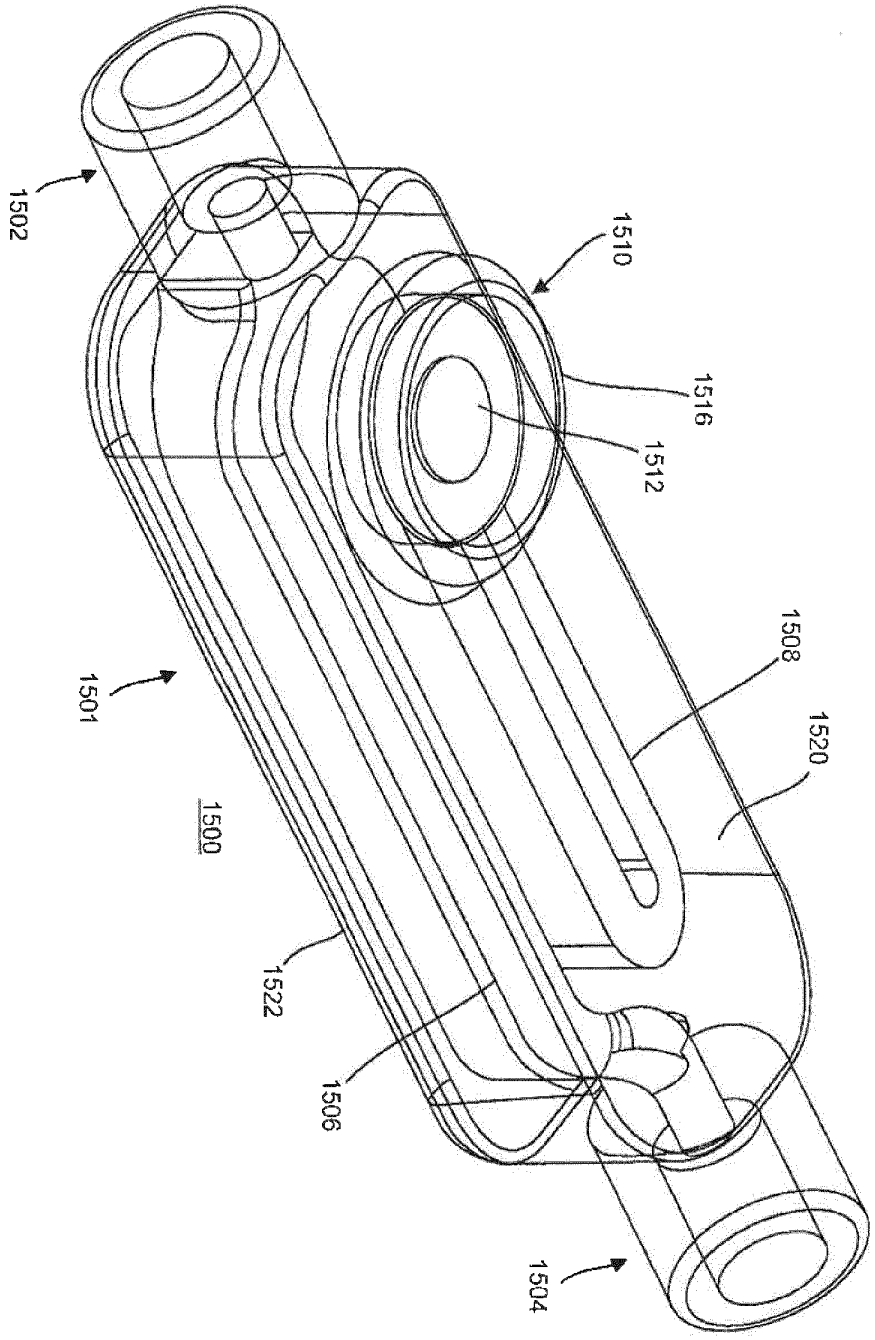

FIG. 15C

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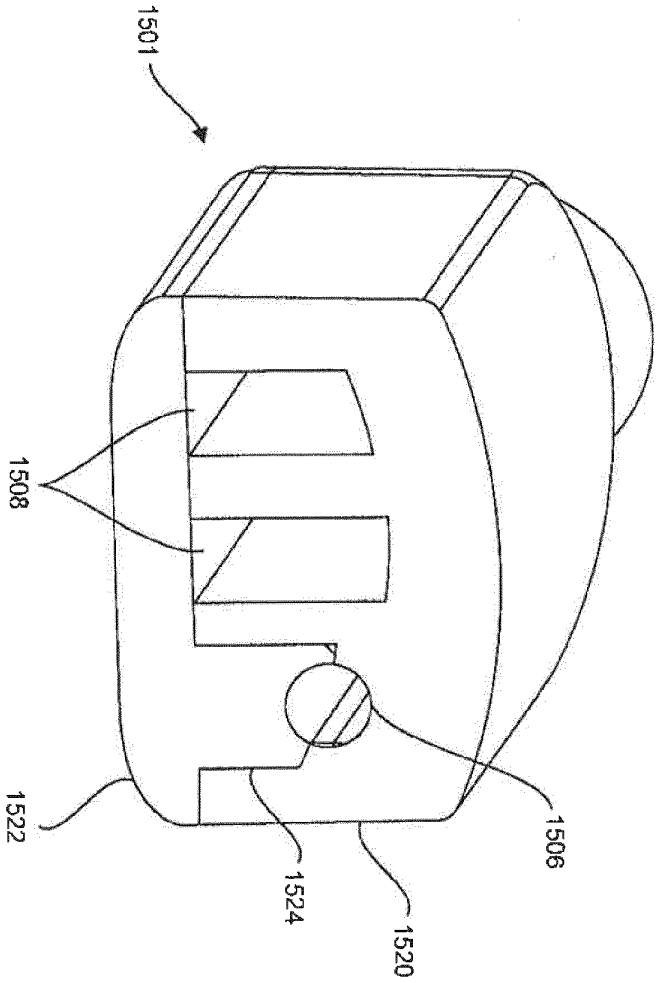

FIG. 15D

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FIG. 15E

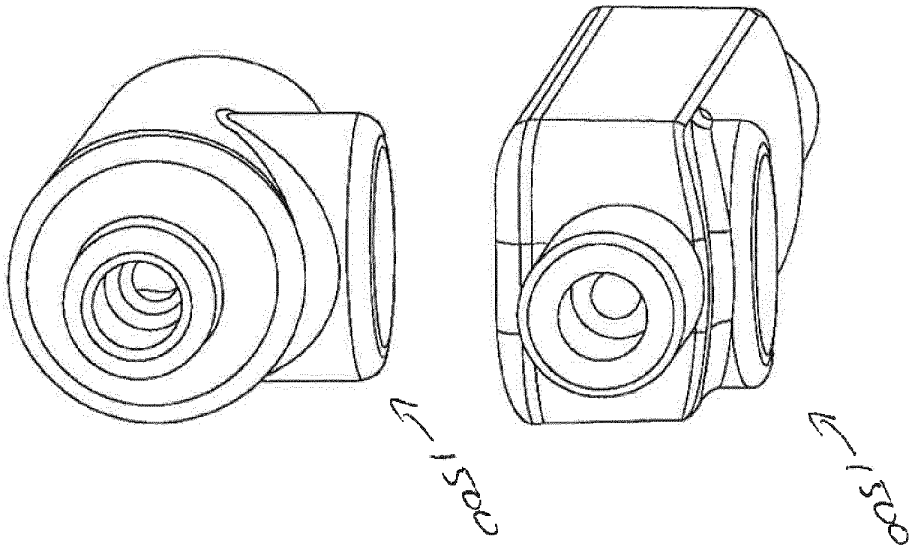
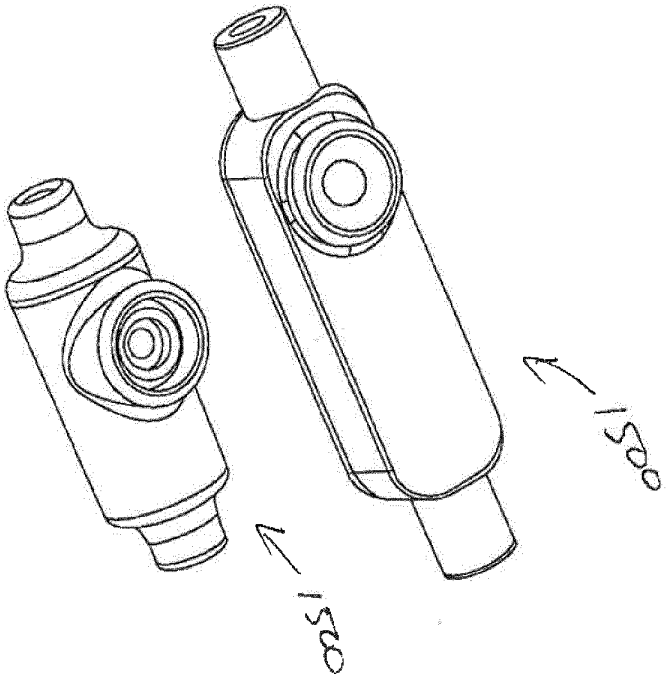


FIG. 15F



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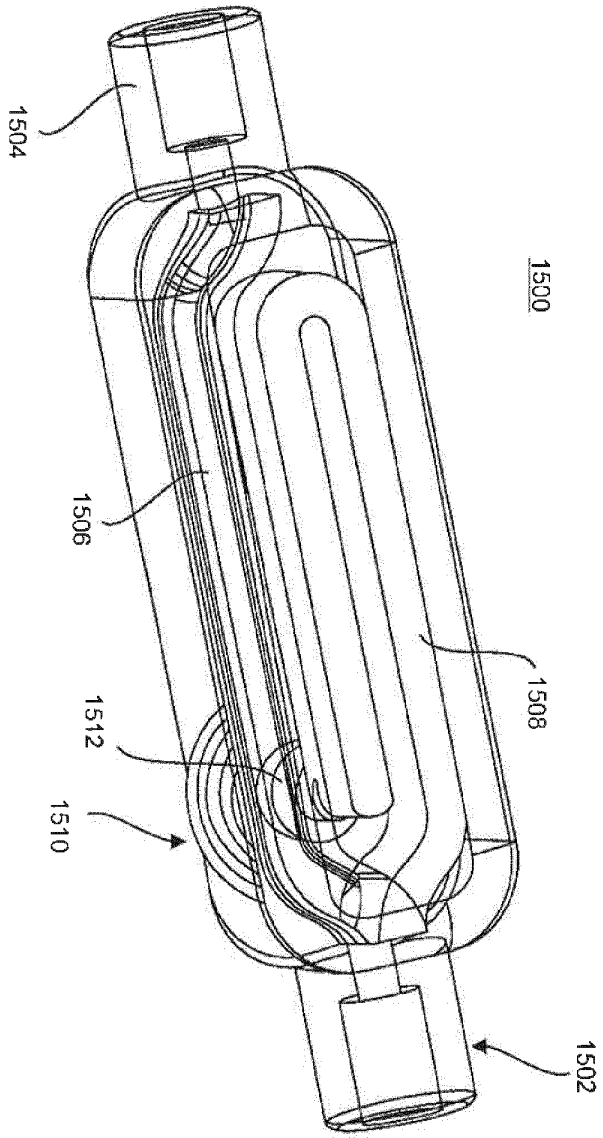

FIG. 15G

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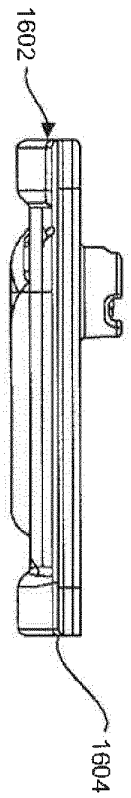

FIG. 16B

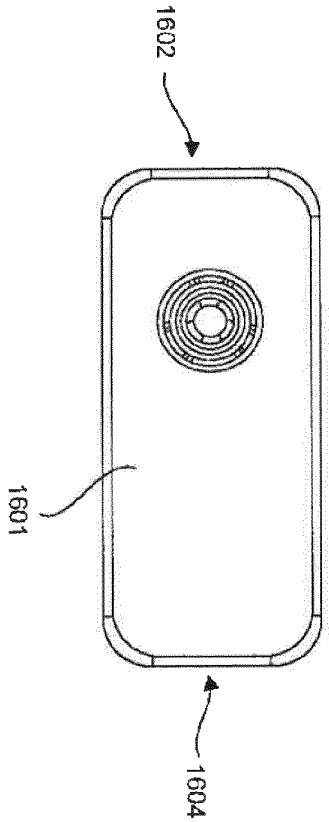

FIG. 16A

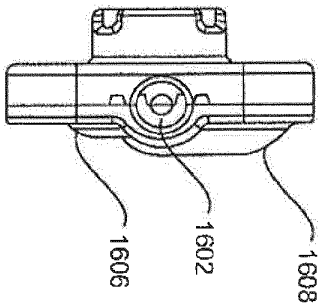

FIG. 16C

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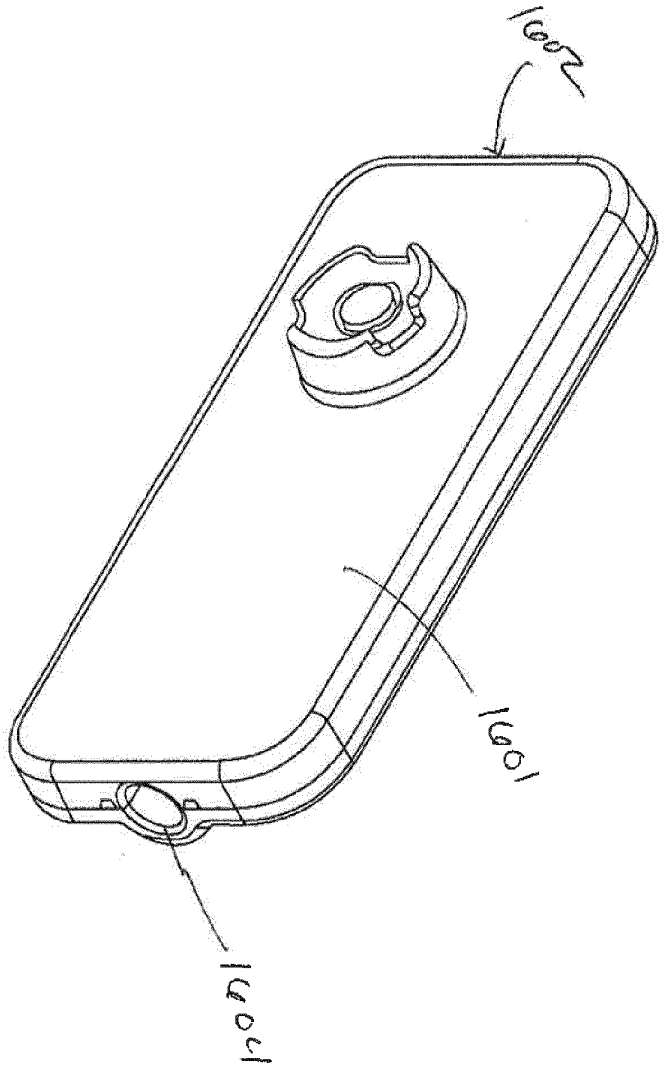

FIG. 16D

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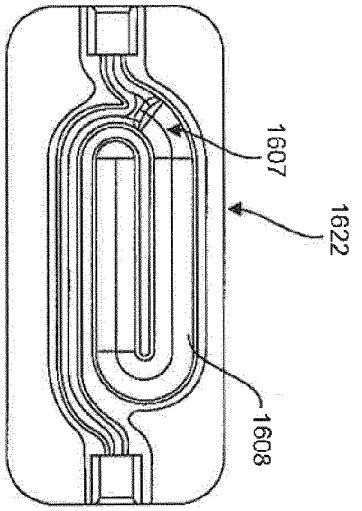

FIG. 17A

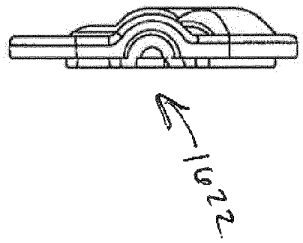

FIG. 17C

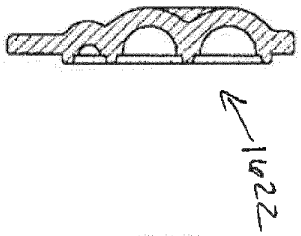

FIG. 17D

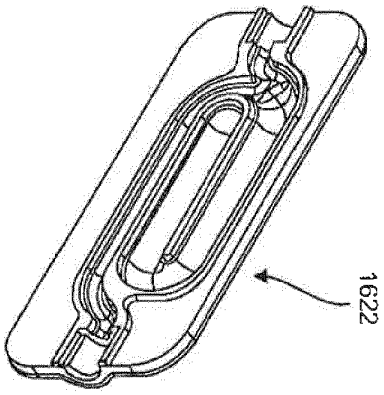

FIG. 17B

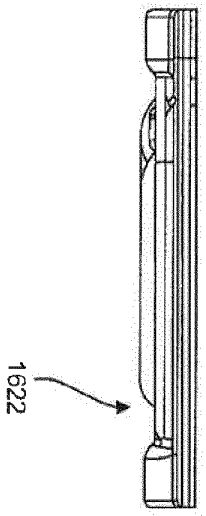

FIG. 17E

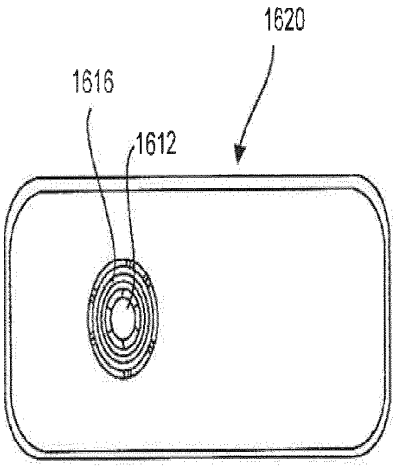

FIG. 18A

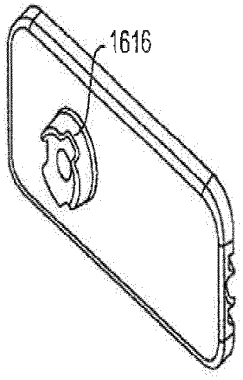

FIG. 18B

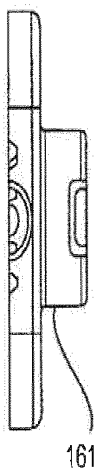

FIG. 18C

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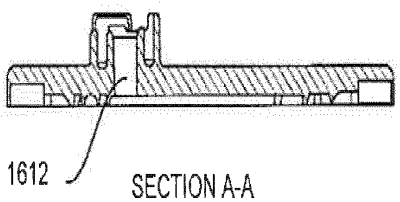

FIG. 18D

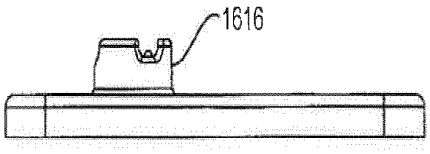

FIG. 18E

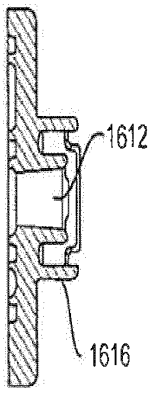

FIG. 18F

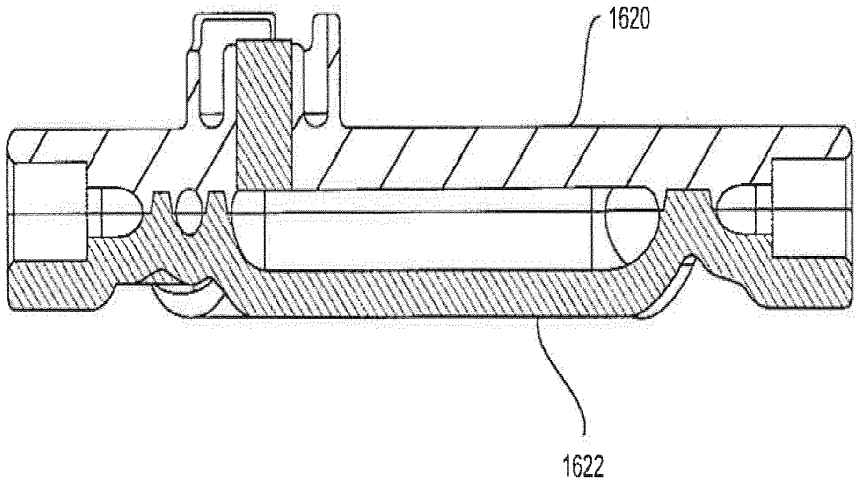

FIG. 19A

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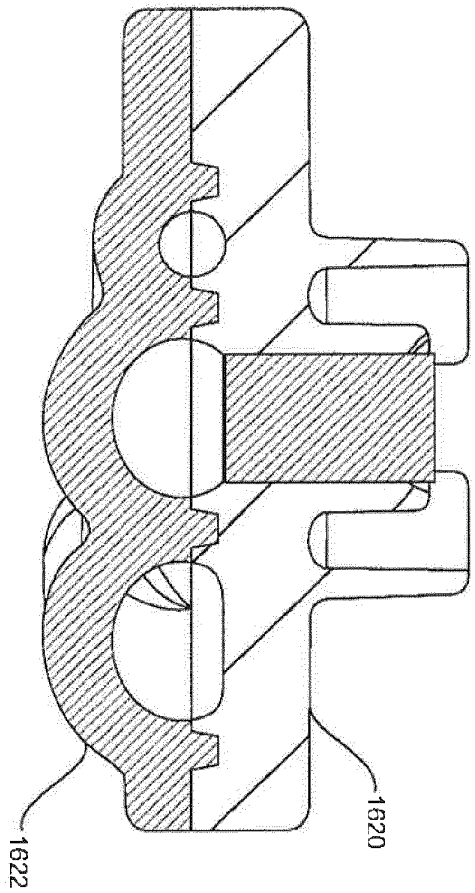

FIG. 19B

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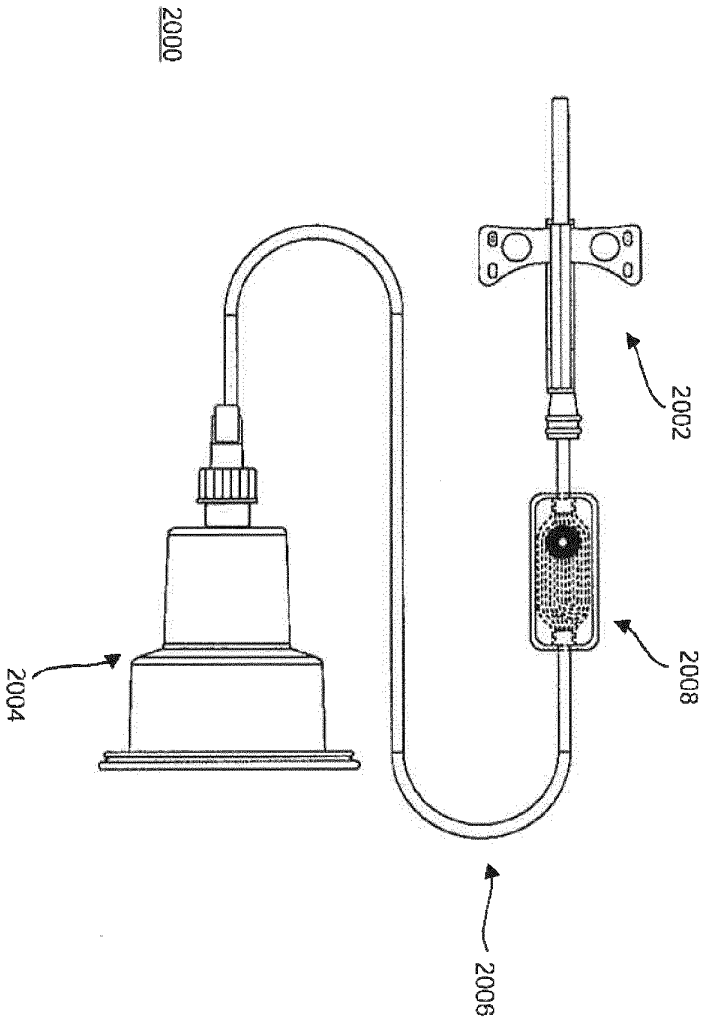

FIG. 20

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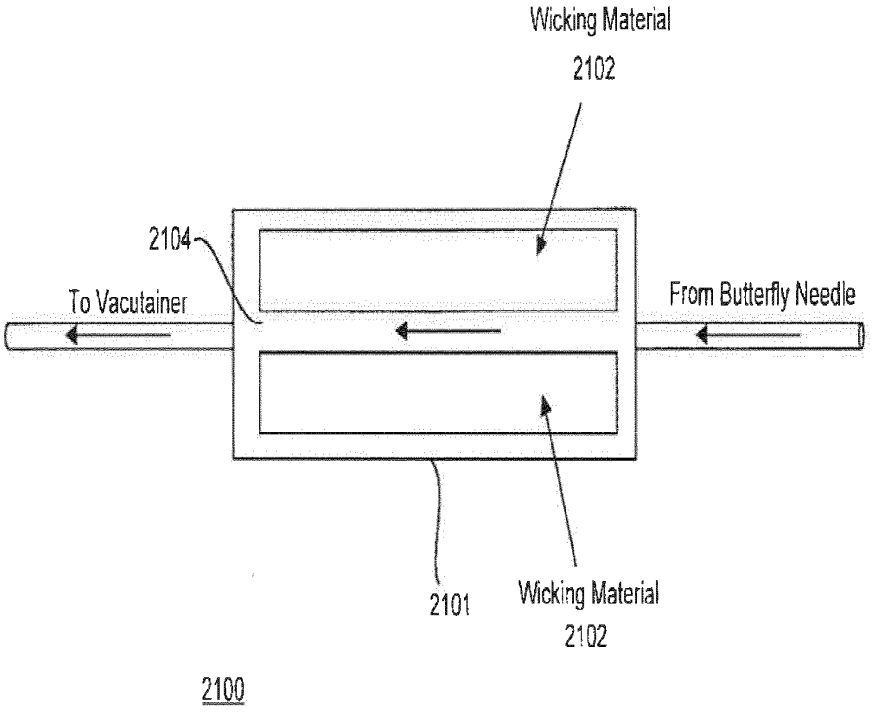
Wicking Material
2102
2104
To Vacutainer
From Butterfly Needle
2101
Wicking Material
2102
2100

FIG. 21

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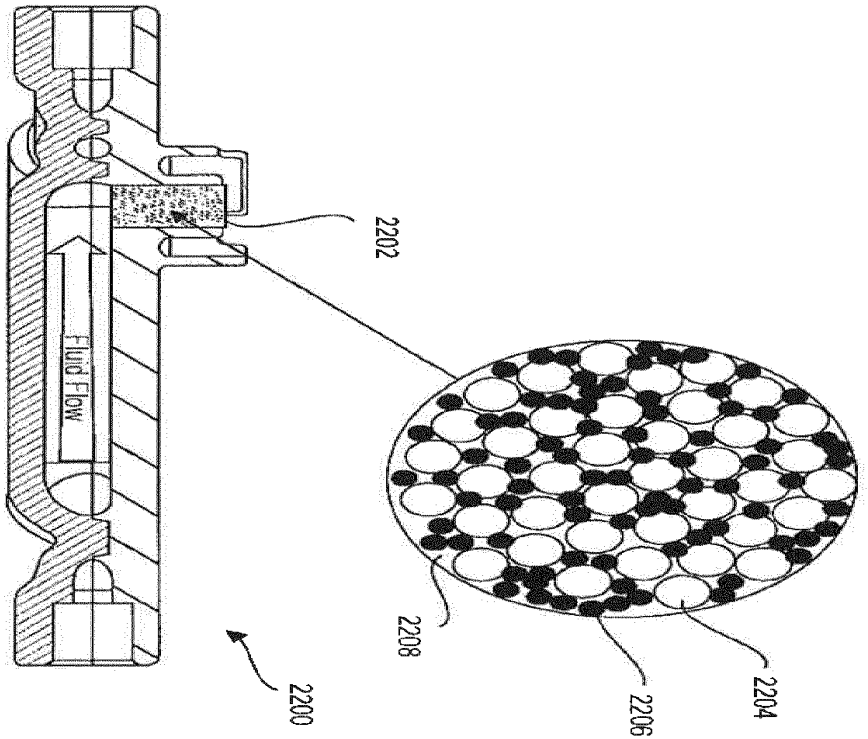

FIG. 22A

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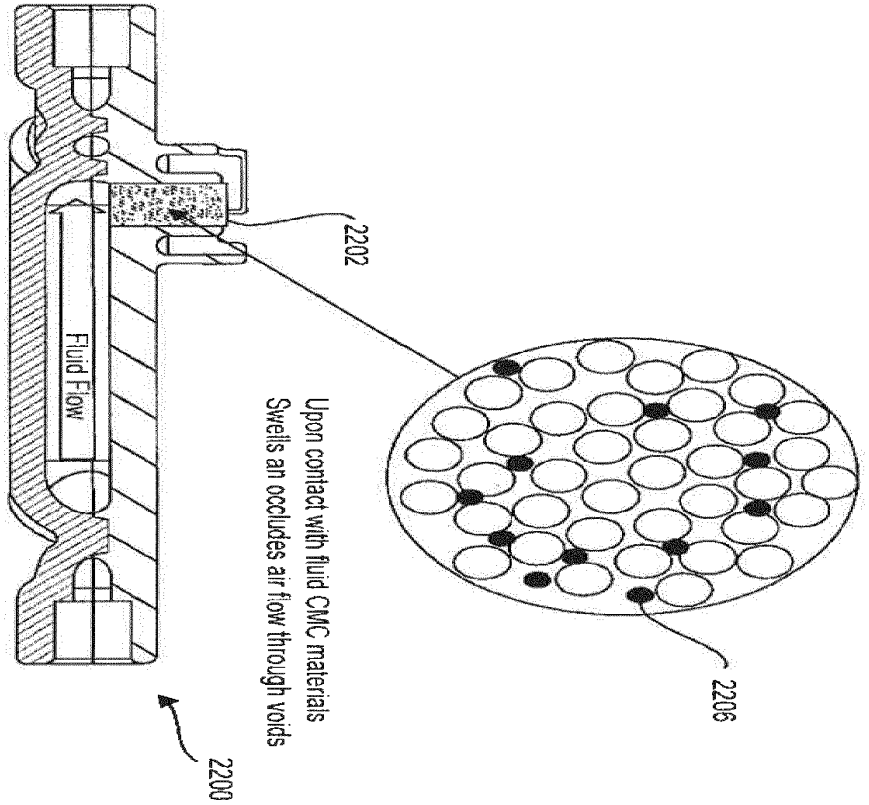

FIG. 22B

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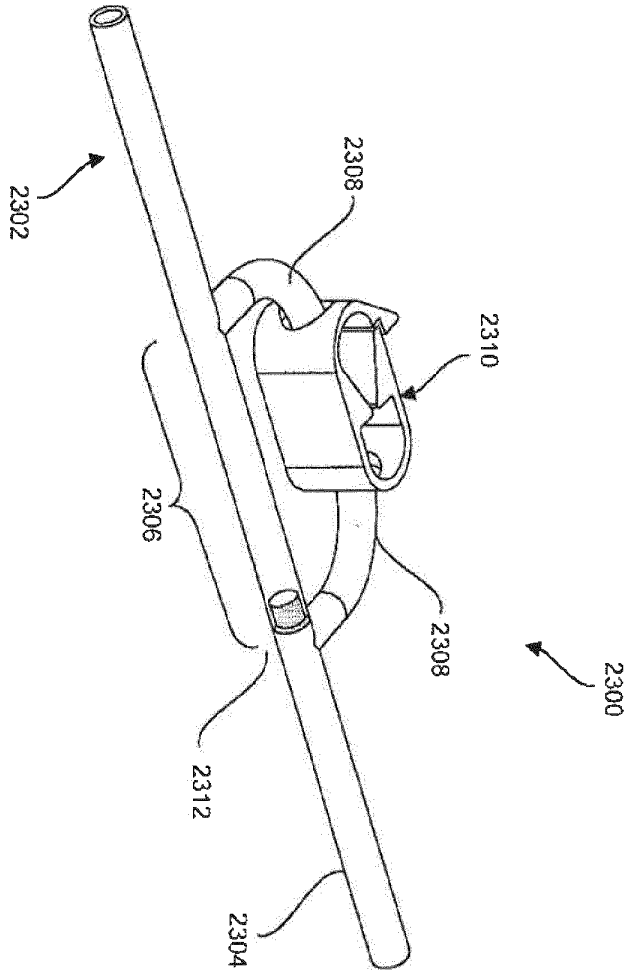

FIG. 23A

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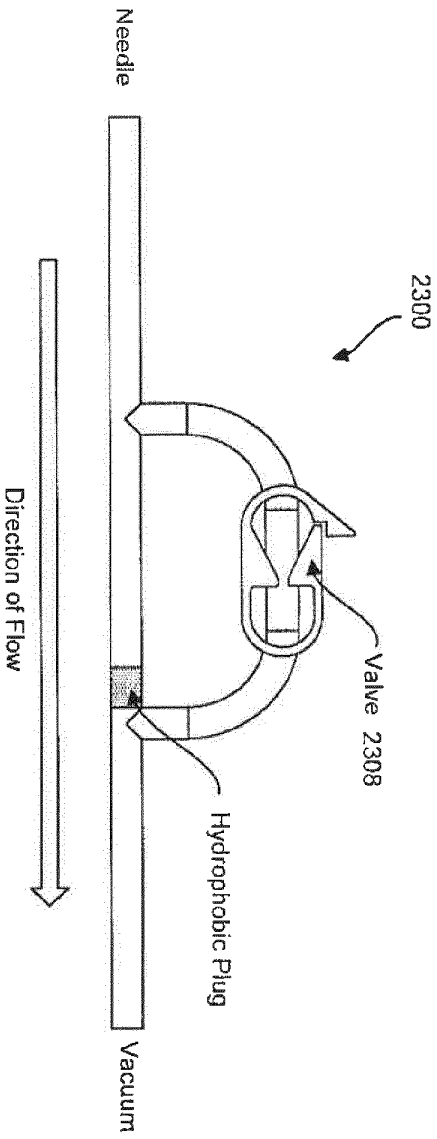


FIG. 23B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715

27500 7590 08/25/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
08/25/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/113,710	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 08/09/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-13 and 16-31 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☑ Claim(s) 17-31 is/are allowed.

7) ☑ Claim(s) 1-13 and 16 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/09/2023, and 05/10/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1, 5, 8-13 and 16 is/are rejected under 35 U.S.C. 102(1)(a) as being anticipated by Christensen et al (US 20100057004).

As to claim 1, Christensen discloses a device comprising:

an inlet port (catheter 14 and the frontal inlet port of device 10 where catheter 14 is connected/inserted therein, par.41-43 and par.47, fig.1-4);

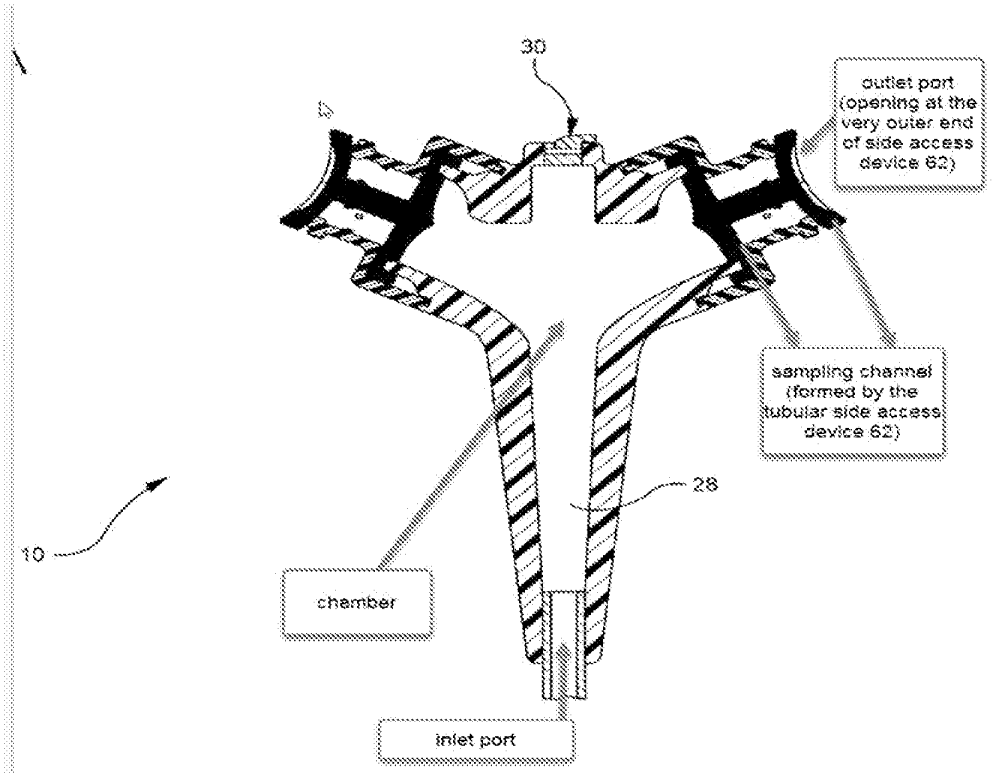
an outlet port (outlet opening at the very outer end of side access device 62 of device 10 where tube 16 is connected to and/or outlet port at the end of tube 16 connected to Y-adapter 18, par.41-43, par.53, fig.1-5);

a chamber (a fluid path 28 filling the interior of the extravascular system 10, par.47, fig.1-4) connected with the inlet port (fluid path 28 within the interior of device 10 is connected to catheter 14 and the frontal inlet port of device 10, fig.1-5) and configured to receive a first portion of blood (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into the system 10 to confirm that the needle 12 is properly located within the vasculature of the patient, par.7, par.42, and blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43)(The Examiner respectfully notes that flashback of blood, is considered the initial portion of blood),

the chamber including an air permeable material (venting material in vent 30, par.48-50, a removable filter plug 50 and a re-seal elastomer 52 in vent 30, par.51-53, or 114 that expands when exposed to liquid from bath 28, and thus seals the vent, par.71-72, fig.1-16, and/or curing material 108 of the vent 30 described with reference to FIGS. 13 and 14 provides a vent capable of venting gas from the system 10 without permitting the escape of liquid after the liquid has come into contact with the material 108, par.69, a porous membrane 110, par.70) that seals at least partially upon contact with a portion of the first portion of blood (par.48-53); and

a sampling channel (tubular channel formed by side access device 62 of device 10 and integrated extension tube 16, par.41-42, fig.1-6) having a proximal end connected with

the inlet port and a distal end connected with the outlet port (tubular channel formed by side access device 62 of device 10 having proximal end connected to frontal inlet port of device 10 at catheter 14, and having a distal end connected to the outlet opening at the very outer end of side access device 62 of device 10, as best seen in fig.1-6)(Examiner respectfully notes that since blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43, so tubular channel formed by side access device 62 is configured to sample and convey blood to tubing 16).



As to claim 5, Christensen discloses the device, wherein the air permeable material is located at a distal end of the chamber (a vent may be placed at or near the start of the fluid path, or the vent may be placed at any point in between the start or end of the fluid path of the extravascular system, par.45, as best seen in fig.1-3).

As to claim 8, Christensen discloses the device, wherein the air permeable material is a hydrophilic membrane (vent 30 includes an expandable vent material 114 that is hydrophilic, par.71, fig.16).

As to claim 9, Christensen discloses the device, wherein the sampling channel further comprises a valve configured to close off the sampling channel (side clamp 20, par.41, slide clamp 20 on the integrated extension tubing 16 is provided to eliminate blood exposure when the vent plug 22 is replaced with another vascular access device, par.42, fig.1).

As to claim 10, Christensen discloses the device, wherein the valve is a clip (clamp 20, par.41, fig.1)

As to claim 11, Christensen discloses the device, further comprising a junction configured to direct an initial blood flow into the chamber (the longitudinal shape at the beginning of fluid path 28 formed in the interior of device 10 forces the flashback blood to enter the interior of device 10, par.43-48, and/or vent 30, vent 30 may be placed at or near the terminus of the system 10 in order to allow fluid, including gas, blood, saline,

and water, to fill the internal chamber of the fluid path directly adjacent any vascular access devices of the system 10, par.51-52, fig.1-6).

As to claim 12, Christensen discloses the device, further comprising a junction configured such that flow out of the inlet port is preferentially directed toward the chamber (the longitudinal shape at the beginning of fluid path 28 formed in the interior of device 10 forces the flashback blood to enter the interior of device 10, par.43-48, and/or vent 30, vent 30 may be placed at or near the terminus of the system 10 in order to allow fluid, including gas, blood, saline, and water, to fill the internal chamber of the fluid path directly adjacent any vascular access devices of the system 10, par.51-52, fig.1-6).

As to claim 13, Christensen discloses the device, wherein the chamber has a larger cross-sectional area than the sampling channel (the cross-sectional area of fluid path 28 of the interior of device 10 is larger than the side tubular channel and tube 16, as best seen in fig.1-3).

As to claim 16, Christensen discloses the device, further comprising a patient needle (needle 12, par.41-43, fig.1) and a sample collection device (Luer access device or port 24, par.41)(Examiner respectfully notes that the luer access device is a device that is connected to obtain blood sample in a sampling container, see link: https://www.medline.com/product/Blood-Transfer-and-Luer-Lock-Access-Device/Z05-PF253812#:~:text=Luer%20lock%20access%20devices%20%28LLAD%20and%20AC

SD%29%20are,reduce%20the%20risk%20of%20transfer-

related%20injuries%20and%20infections).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-4, 6 and 7 is/are rejected under 35 U.S.C. 103 as being obvious over Christensen et al (US 20100057004), in view of Weilbacher et al (US 2008/0167577).

As to claims 2-4, 6 and 7, Christensen discloses the device, wherein the device is further configured such that an initial aliquot of blood will contact the air permeable material and back up into the chamber (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into the system 10 to confirm that the needle 12 is properly located within the vasculature of the patient. The blood travels into and along the catheter 14 and extension tubing The fluid path 28 is in communication with a vent 30, and the vent 30 is capable of venting gas from the fluid path 28 of the system 10, par.47 and par.53), wherein the device is further configured such that follow-on amounts of blood will flow through the sampling channel towards the outlet port (blood travels into and along the catheter 14 and extension tubing 16

because a vent plug 22 permits air to escape the system 10 as blood enters the system 10, par.43).

Christensen discloses the invention substantially as above, but failed to explicitly teach wherein the device is configured such that, when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber, and wherein the air permeable material is a hydrophobic plug/membrane.

However Weilbacher discloses an analogous vascular access needle assembly (abstract, fig.1-3), when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber (collection tube 17 is maintained at a vacuum such that when distal needle portion 20 is properly positioned in a vein 38 of a patient and collection tube 17 is positioned within cavity 34 OF BODY 30, blood will flow through needle 10 into blood collection tube 17, par.33, fig.1)(the Examiner respectfully notes the vacuum applies blood drawing force), and wherein the air permeable material is a hydrophobic plug/membrane (filter material 116 disposed in chamber 112, wherein material includes a hydrophobic material. In an alternate embodiment, the material includes a hydrophilic wicking material. In yet another embodiment, the material includes a hydrophobic plug, par.11 and par.35, fig.2).

As these types of blood drawing force are well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to maintain blood collection devices and/or luer accesses devices connected to port 24 taught by Christensen's invention under vacuum, as tube 17 taught by

Weilbacher's invention, to facilitated blood sampling and prevent unwanted blood exposure/spilling, as taught by Weilbacher's invention (par.33).

Still, as the hydrophobic air permeable filter/material are well known in the art to vent air, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to substitute the hydrophilic material taught by Christensen's invention, with the hydrophobic material taught by Weilbacher's invention, for the same reason of venting air from sampling chamber, as taught by Weilbacher's invention (par.11 and par.35-36).

Allowable Subject Matter

5. Claims 17-31 are allowed.

6. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Christensen et al (US 2010/0057004) teaches a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable.

The prior art does not teach, disclose and/or fairly suggest a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

7. Applicant's arguments claim objections/rejections and double patenting have been fully considered and are persuasive. The claim objections/rejections and double patenting have been withdrawn.

8. Applicant's arguments regarding Christensen's invention does not teach the claimed subject matter "an air permeable material that seals at least partially upon contact with a portion of the first portion of blood" in claim 1 have been fully considered but they are not persuasive, because Christensen's invention explicitly teaches hydrophilic air permeable material 114 that allows air to pass through vent 30, and then expands when exposed to liquid from fluid path 28, and thus seals the vent (par.71-72), similarly materials 108 and 110, par.69-70.

So, Christensen's invention explicitly teaches the claimed subject matter "an air permeable material that seals at least partially upon contact with a portion of the first portion of blood" in claim 1.

9. Still, regarding the Applicant's arguments that Christensen's invention does not teach "a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port" in claim 1 because Christensen's invention is not taking samples. Instead Christensen's invention is used for infusion therapy (see arguments page 5) have been fully considered but are not persuasive, because claim 1 broadly claims "A device comprising" in the preamble, and does not claim a blood sampling/collecting device. Under the broadest reasonable interpretation the claimed

subject matter "sampling channel" may be interpreted as sampling any type of tissue, fluid and/or infusion agents, and does not necessarily means sampling blood.

Device 10 taught by Christensen's invention comprises a fluid path 28 filling the interior of the extravascular system 10 (par.47) configured to receive a portion of blood (operator will insert the needle 12 into the vasculature of a patient and wait for flashback of blood to travel into fluid path 28 to confirm that the needle 12 is properly located within the vasculature of the patient (par.7, par.42), and blood travels into and along the catheter 14 and extension tubing 16 because a vent plug 22 permits air to escape the system 10 as blood enters the system 10 (par.43).

Examiner respectfully notes that since blood travels into and along the catheter 14 and extension tubing 16, so tubular channel formed by side access device 62 is configured to sample and convey blood to tubing 16.

So, it can be fairly interpreted that the tubular channel is a sampling channel that samples blood to and from tubing 16, as claimed in claim 1.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure Burkholz et al (US 20120/016266).

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/113,710	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Filing Date	2023-02-24
First Named Inventor	Bobby E. ROGERS
Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4416291		1983-11-22	KAUFMAN JOSEPH	

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☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-08-09
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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First Named Inventor	Bobby E. ROGERS
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Attorney Docket Number	069366-0574153_KUR2C04US

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	1	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	
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	19	4444203		1984-04-24	ENGELMAN ALLAN	

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	36	9820682		2017-11-21	ROGERS BOBBY E	
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	43	3648684		1972-03-14	BARNWELL CLEORA W	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18113710
	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	08/22/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Reference No.: 0575273
Mailing No.: 092516
Mailing Date: February 27, 2024

Non-final Office Action
(Translation)

Application No.	Japanese Patent Application No. 2023-076490
Drafting Date	February 26, 2024
Examiner	Yoshinori TAKA 9813 2Q00
Representative	Satoshi MURAKOSHI
Applied Articles	Japanese Patent Act, Section 36, Paragraph 6, Item 2 (clearness)
	Japanese Patent Act, Section 36, Paragraph 6, Item 1 (support requirement)
	Japanese Patent Act, Section 29, Paragraph 1, Item 3 (novelty)
	Japanese Patent Act, Section 29, Paragraph 2 (inventive step)

This application has been rejected for the grounds stated below. Applicant is invited to file a Response within three months from the mailing date of this notice.

Grounds

<Ground 1>

(Clearness) This application does not conform to Section 36, Paragraph 6, Item 2 of the Japanese Patent Act in the following points.

<Ground 2>

(Support requirement) This application does not conform to Section 36, Paragraph 6, Item 1 of the Japanese Patent Act in the following points.

<Ground 3>

(Novelty) The claim(s) of this application set forth below was/were anticipated by the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are not entitled to obtain a patent under Section 29, Paragraph 1, Item 3 of the Japanese Patent Act.

<Ground 4>

(Inventive step) The claim(s) of this application set forth below would have been obvious to one ordinarily skilled in the art prior to the filing of this application, based on the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are unpatentable under Section 29, Paragraph 2 of the Japanese Patent Act.

Examiner Notes (the cited references are listed in Reference List below)

• As to Ground 1 (clearness) and Ground 2 (support requirement)

(1) Claims 1 to 15

In claims 1 to 15, the following points are not clear.

(A) The device includes a first junction that connects the inlet port with the sampling channel and the chamber.

(B) The device includes a second junction, different from the first junction, that connects the outlet port with the sampling channel and the chamber.

Thus, the technical relationship is unclear among the inlet port, the outlet port, the sampling channel, and the chamber.

Claim 1 recites that the chamber is "connected with the inlet port and the outlet port." This recitation could only specify that the chamber fluidically communicates with the inlet port and the outlet port (therefore, as in Reference 2 cited below, this recitation encompasses the case where the chamber is connected at only one location with a channel connecting between the inlet port and the outlet port).

Claim 1 also recites that the sampling channel is "connected with the inlet port." This recitation does not indicate that the sampling channel is "connected with the inlet port and the outlet port."

Further, a device lacking in the above features (A) and (B) is not at all described in the Detailed Description of the Invention.

Accordingly, claims 1 to 15 lacking in the above features (A) and (B) are unclear (Ground 1) and are not described in the Detailed Description of the Invention (Ground 2).

If the above features (A) and (B) are clearly recited, "the junction" recited in claim 11 should rightly be "the first junction and the second junction."

(2) Claims 1 to 15

Claim 1 recites that the chamber is "connected with the inlet port and the outlet port." This recitation specifies that the chamber is connected with the outlet port as well as with the inlet port.

According to the Detailed Description of the Invention, the chamber is connected with the outlet port as well as with the inlet port for the purpose that the device is configured such that,

(C) "when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber."

The technical significance of the chamber being connected with the outlet port as well as with the inlet port is clear only when it is specified that the device achieves the above operation (C). The Detailed Description of the Invention does not at all describe a device having a chamber "connected with the inlet port and the outlet port" but not achieving the above operation (C).

The Detailed Description of the Invention describes the following feature for the device to achieve the above operation (C).

(D) "A material that is air permeable and blood impermeable is located at a distal end of the chamber." The Detailed Description of the Invention does not at all describe a device achieving the above operation (C) but lacking in the above feature (D).

However, claim 1 and claims 2 to 15 depending on claim 1 do not specify that the device achieves the above operation (C) and satisfies the above feature (D). Thus, these claims are unclear (Ground 1) and are not described in the Detailed Description of the Invention (Ground 2).

(3) Claim 14

Claim 14 recites "the housing comprises a bottom member mated with a top member." This recitation does not indicate that the housing comprises the top member. If the housing does not comprise the top member, claim 14 is not described in the Detailed Description of the Invention. It is unclear whether this recitation is intended to mean "the housing comprises a top member and a bottom member mated therewith."

Accordingly, claim 14 is unclear (Ground 1) and is not described in the Detailed Description of the Invention (Ground 2).

• As to Ground 3 (novelty) and Ground 4 (inventive step)

- As to Claims: 1, 4, 8, 10, 11, and 15
- Reference cited: Reference 1
- Notes:

Reference 1 (page 3, lower left column, line 15 to page 7, upper left column, line 20 and Figs. 1 to 9) discloses the following.

A device comprising:

an inlet port (an inner end (inner opening 30) of a first puncture needle 14 that communicates with a chamber 28, or an inner end 39 of a second puncture needle 15 protruding into the chamber 28) for receiving a blood sample;

an outlet port (a tip end of an outer extension portion of the second puncture needle 15);

a chamber (the space containing the porous plug (porous member that is gas permeable and liquid impermeable) 52 and the space between the hole 48 and the porous plug 52, in the inner cavity 51 of the second puncture needle 15) connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable (the porous plug (porous member that is gas permeable and liquid impermeable) 52); and

a sampling channel (cavity 46) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

As to claim 8, the sleeve valve 41 of Reference 1 corresponds to the "valve" of claim 8.

As to claims 10 and 11, the location of the hole 48 of the inner cavity 51 corresponds to the "junction" of claims 10 and 11.

As to claim 15, the first puncture needle 14 of Reference 1 corresponds to the "patient needle" of claim 15, and the vessel holder 19 and the vacuum blood collection vessel 16 of Reference 1 correspond to the "sample collection device" of claim 15.

Accordingly, claims 1, 4, 8, 10, 11, and 15 are disclosed in Reference 1.

Also, claims 1, 4, 8, 10, 11, and 15 could have been readily devised by those skilled in the art

bead on Reference 1.

- As to Claims: 1, 4 to 6, 8, 13, and 15
- Reference cited: Reference 2
- Notes:

Reference 2 (paragraphs 0004 to 0015, Figs. 1 to 4, and the claims) discloses the following.

A device comprising:

an inlet port (one end 1a of the needle tube 1) for receiving a blood sample;

an outlet port (the other end 1b of the needle tube 1);

a chamber (the passage 21 in the needle tube support 2) connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable (air permeable and blood impermeable member 23); and

a sampling channel (the needle tube 1) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

For the features recited in claims 5 and 6, see Reference 2 (in particular, paragraph 0011).

As to claim 8, the rubber cap 4 or (D) that covers and seals the edge surface of the other end 1b of the needle tube 1 in Reference 2 (paragraphs 0014 and 0006) corresponds to the "valve" of claim 8.

As to claim 13, the needle tube support 2 of Reference 2 corresponds to the "housing" of claim 13.

As to claim 15, the needle tube 1 of Reference 2 corresponds to the "patient needle" of claim 15, and the vacuum blood collection tube of Reference 2 (paragraphs 0004, 0005, and 0012) corresponds to the "sample collection device" of claim 15.

Accordingly, claims 1, 4 to 6, 8, 13, and 15 are disclosed in Reference 2.

Also, claims 1, 4 to 6, 8, 13, and 15 could have been readily devised by those skilled in the art based on Reference 2.

• As to Ground 4 (inventive step)

- As to Claims: 9 and 12 to 14
- Reference cited: Reference 1
- Notes:

The features of claims 9 and 12 to 14 could have been devised as necessary by those skilled in the art, and thus claims 9 and 12 to 14 could have been readily devised by those skilled in the art based on Reference 1.

- As to Claims: 5 to 7
- References cited: References 1 to 3
- Notes:

In a blood sample collection device, use of an air permeable and blood impermeable material that is hydrophobic or hydrophilic is conventional. See Reference 2 (disclosing the hydrophobic material

in paragraph 0011 and a hydrophilic material in paragraph 0013) and Reference 3 (paragraph 0023 and Fig. 3). Claims 5 to 7 could have been readily devised by those skilled in the art based on References 1 to 3.

- As to Claims: 9, 12, and 14
- Reference cited: Reference 2
- Notes:

The features of claims 9, 12, and 14 could have been devised as necessary by those skilled in the art, and thus claims 9, 12, and 14 could have been readily devised by those skilled in the art based on Reference 2.

- As to Claim: 7
- References cited: References 2 and 3
- Notes:

In a blood sample collection device, use of an air permeable and blood impermeable material that is hydrophilic is conventional. See Reference 2 (disclosing a hydrophilic material in paragraph 0013) and Reference 3 (paragraph 0023 and Fig. 3). Claim 7 could have been readily devised by those skilled in the art based on References 2 and 3.

<Reference List>

1. Japanese Patent Application Publication No. Sho 58-25146
2. Japanese Patent Application Publication No. 2001-424
3. Japanese Patent Application Publication No. 2013-240628

Record of Search for Prior Art Literature

- Searched Field IPC A61B 5/06 – 5/22
- Prior Art Literature

U.S. Patent Application Publication No. 2008/0145933

This record of search for prior art literatures does not constitute grounds for refusal.

拒絶理由通知書

特許出願の番号	特願２０２３－０７６４９０
起案日	令和　６年　２月２６日
特許庁審査官	▲高▼　芳徳　　９８１３　２Ｑ００
特許出願人代理人	村越　智史　様
適用条文	第３６条第６項第２号（明確性） 第３６条第６項第１号（サポート要件） 第２９条第１項第３号（新規性） 第２９条第２項（進歩性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第２号に規定する要件を満たしていない。
２．（サポート要件）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第１号に規定する要件を満たしていない。
３．（新規性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明であるから、特許法第２９条第１項第３号に該当し、特許を受けることができない。
４．（進歩性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第２９条第２項の規定により特許を受けることができない。

記　　（引用文献等については引用文献等一覧参照）

●理由１（明確性）および理由２（サポート要件）について

（１）請求項１～１５
　請求項１～１５において、

（A）装置が、入口ポートとサンプリング流路とチャンバとを接続する第１の分岐点を備えること
（B）装置が、出口ポートとサンプリング流路とチャンバとを接続する、前記第１の分岐点とは異なる第２の分岐点を備えること
が明らかでなく、入口ポート、出口ポート、サンプリング流路、チャンバの間の技術的な関係が明らかでない。
請求項１における、チャンバに関する「前記入口ポートと前記出口ポートとに接続され」との記載は、チャンバが、前記入口ポートと前記出口ポートとに流体的に連通していれば足りる（したがって、後出の引用文献２のように、入口ポートと出口ポートとを結ぶ流路上に、チャンバが、１箇所のみで接続される場合を含む）との疑義を生じている。
また、請求項１における、サンプリング流路に関する「前記入口ポートと接続されており」との記載からは、そもそも、サンプリング流路が「前記入口ポートと前記出口ポートとに接続されて」いることが明らかでない。
また、上記（A）および（B）の事項を欠く装置は、発明の詳細な説明に何ら記載されていない。
したがって、上記（A）および（B）の事項を欠く請求項１～１５に係る発明は、明確でない（理由１）と共に、発明の詳細な説明に記載されたものとはいえない（理由２）。
尚、上記（A）および（B）の点を明確化した場合、請求項１１における「前記分岐点」は、正しくは、「前記第１の分岐点および前記第２の分岐点」であるものと認められる。

（２）請求項１～１５
請求項１には、チャンバに関して、「前記入口ポートと前記出口ポートとに接続され」と記載されており、チャンバが、前記入口ポートのみならず、前記出口ポートにも接続されていることが特定されている。
発明の詳細な説明によれば、チャンバが入口ポートのみならず出口ポートにも接続されているのは、装置が、
（C）「出口ポートで吸引力が加えられると、血液が入口ポートに吸い込まれ、チャンバ内に流入する」
という動作を実現するためであり、装置が上記（C）の動作を実現することを特定することにより、はじめて、チャンバが入口ポートのみならず出口ポートにも接続されていることの技術的意味が明らかになる。また、発明の詳細な説明には、チャンバが「前記入口ポートと前記出口ポートとに接続され」る装置として、上記（C）の動作を実現しないものは、何ら記載されていない。
また、装置が上記（C）の動作を実現するための構成として、発明の詳細な説明には、
（D）「空気透過性であり血液不透過性である材料が、チャンバの遠位端に配置

されること」
が記載されており、上記（C）の動作を実現する装置として、上記（D）の事項を欠くものは、発明の詳細な説明に何ら記載されていない。
しかしながら、請求項１とこれに従属する請求項２～１５に係る発明は、装置が上記（C）の動作を実現すること、および、上記（D）の事項を満足することが特定されておらず、明確でない（理由１）と共に、発明の詳細な説明に記載されたものとはいえない（理由２）。

（３）請求項１４
請求項１４における、「前記ハウジングは、上部部材と嵌合する下部部材を備え・・・」との記載からは、ハウジングが上部部材を備えることが明らかでない。また、ハウジングが上部部材を備えない場合の請求項１４に係る発明は、発明の詳細な説明に記載されたものとはいえない。「前記ハウジングは、上部部材とこれに嵌合する下部部材とを備え・・・」ということなのか。
したがって、請求項１４に係る発明は、明確でない（理由１）と共に、発明の詳細な説明に記載されたものとはいえない（理由２）。

●理由３（新規性）および理由４（進歩性）について

・請求項：１，４，８，１０，１１，１５
・引用文献等：１
・備考：
引用文献１（第３頁左下欄第１５行～第７頁左上欄第２０行、第１～９図）には、
血液サンプルを受け入れるための入口ポート（室２８に連通する第１の穿刺針１４の内方端（内部開口３０）、または、室２８に突出する第２の穿刺針１５の内方端３９）と、
出口ポート（第２の穿刺針１５の外方延長部の尖端）と、
前記入口ポートと前記出口ポートとに接続され、前記血液サンプルの第１の部分を集めるように構成されたチャンバ（第２の穿刺針１５の内腔５１のうち、多孔性プラグ（ガス透過性液不透過性の多孔性部材）５２が置かれたスペース、および、孔４８と多孔性プラグ５２との間のスペース）であって、空気透過性であり血液不透過性である材料（多孔性プラグ（ガス透過性液不透過性の多孔性部材）５２）を含む、チャンバと、
前記入口ポートと接続されており、前記チャンバを迂回しながら前記出口ポートに前記血液サンプルの後続の部分を運ぶように構成されたサンプリング流路（キャビティー４６）と、
を備える装置

が記載されている。

請求項８に関して、引用文献１におけるスリーブ弁４１が、請求項８でいう「弁」に相当する。

請求項１０，１１に関して、引用文献１における、内腔５１の孔４８がある位置が、請求項１０，１１でいう「分岐点」に相当する。

請求項１５に関して、引用文献１における第１の穿刺針１４が、請求項１５でいう「患者針」に相当し、引用文献１における容器ホルダー１９および真空血液収集容器１６が、請求項１５でいう「サンプル採取装置」に相当する。

したがって、請求項１，４，８，１０，１１，１５に係る発明は、引用文献１に記載された発明である。

また、請求項１，４，８，１０，１１，１５に係る発明は、引用文献１に基づき、当業者が容易に想到し得るものである。

・請求項：１，４～６，８，１３，１５
・引用文献等：２
・備考：

引用文献２（［０００４］～［００１５］、図１～４、特許請求の範囲）には、

血液サンプルを受け入れるための入口ポート（針管１の一端１ａ）と、

出口ポート（針管１の他端１ｂ）と、

前記入口ポートと前記出口ポートとに接続され、前記血液サンプルの第１の部分を集めるように構成されたチャンバ（針管支持体２内の通路２１）であって、空気透過性であり血液不透過性である材料（空気透過性血液不透過性部材２３）を含む、チャンバと、

前記入口ポートと接続されており、前記チャンバを迂回しながら前記出口ポートに前記血液サンプルの後続の部分を運ぶように構成されたサンプリング流路（針管１）と、

を備える装置

が記載されている。

請求項５，６の限定事項については、引用文献２の特に［００１１］を参照のこと。

請求項８に関して、引用文献２における、針管１の他端１ｂの刃面を密封的に覆うゴム状キャップ４または（D）（［００１４］、［０００６］）が、請求項８でいう「弁」に相当する。

請求項１３に関して、引用文献２における針管支持体２が、請求項１３でいう「ハウジング」に相当する。

請求項１５に関して、引用文献２における針管１が、請求項１５でいう「患者針」に相当し、引用文献２における真空採血管（［０００４］、［０００５］、［００１２］）が、請求項１５でいう「サンプル採取装置」に相当する。

したがって、請求項１，４～６，８，１３，１５に係る発明は、引用文献２に記載された発明である。

また、請求項１，４～６，８，１３，１５に係る発明は、引用文献２に基づき、当業者が容易に想到し得るものである。

●理由４（進歩性）について

・請求項：９，１２～１４
・引用文献等：１
・備考：

請求項９，１２～１４の限定事項は、いずれも、当業者が適宜なし得ることであり、　請求項９，１２～１４に係る発明は、引用文献１に基づき、当業者が容易に想到し得るものである。

・請求項：５～７
・引用文献等：１～３
・備考：

血液サンプル収集装置において、空気透過性かつ血液不透過性の材料を、疎水性または親水性とすることは、引用文献２（［００１１］には、前記材料を疎水性とすることが記載されており、［００１３］に記載された材料は、親水性である。）、引用文献３（［００２３］、図３）に記載のとおり、通常のことであり、請求項５～７に係る発明は、引用文献１～３に基づき、当業者が容易に想到し得るものである。

・請求項：９，１２，１４
・引用文献等：２
・備考：

請求項９，１２，１４の限定事項は、いずれも、当業者が適宜なし得ることであり、　請求項９，１２，１４に係る発明は、引用文献２に基づき、当業者が容易に想到し得るものである。

・請求項：７
・引用文献等：２，３
・備考：

血液サンプル収集装置において、空気透過性かつ血液不透過性の材料を、親水性とすることは、引用文献２（［００１３］に記載された材料は、親水性である。）、引用文献３（［００２３］、図３）に記載のとおり、通常のことであり、請求項７に係る発明は、引用文献２，３に基づき、当業者が容易に想到し得るも

のである。

＜引用文献等一覧＞

１．特開昭５８－２５１４６号公報
２．特開２００１－４２４号公報
３．特開２０１３－２４０６２８号公報

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

＜先行技術文献調査結果の記録＞

・調査した分野　　ＩＰＣ　Ａ６１Ｂ　　５／０６　　－　　５／２２
・先行技術文献　　米国特許出願公開第２００８／０１４５９３３号明細書

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません。

この拒絶理由通知の内容に関する問い合せ先は以下のとおりです。補正案等の送付を希望される際は、その旨を事前にご連絡ください。

電子メールにて連絡する際は、氏名、所属、出願番号、電話番号、下記審査官名を記載していただき、下記メールアドレス（※）までご連絡ください。電子メールの連絡内容について不明な点等がある場合、電話で確認させていただく場合があります。

審査第一部　分析診断（医学診断）高　芳徳　（たか　よしのり）
ＴＥＬ．０３－３５８１－１１０１内線３２９１
※ ●●●●@jpo.go.jp （上記「●●●●」に置き換えて、「PA2J」と入力ください。）

Date: 20 December 2023

Your ref: 1000-016-04

Attn.

Katz, Presenti & Co.

14 Abba Hillel Rd.

Ramat Gan 52506

Greetings,

Re: **Notice prior to an Examination of Patent Application no. 309380 pursuant to Section 18 of the Law and Regulation 36 of the Regulations**

Please be advised: any reference to the Law, shall mean a reference to the Patents Law, 5727-1967; any reference to the Regulations, shall mean a reference to the Patents Regulations (Office Practices, Rules of Procedure, Documents and Fees), 5728-1968.

Please note: you must reply to this notice (even if all the answers are negative) within 4 months from the date hereof; however, you may request to extend the period in accordance with the rules prescribed in the Patents Registrar's Circular 035/2017-Patents. **In accordance with this circular, an extension of up to six months shall be granted for a notice prior to an examination.** Upon filing such an application prior to the end of the period, a fee at the sum of NIS 208 shall be paid for each month of delay or any part thereof.

1. List of References and Publications

Pursuant to the provisions of Section 18 of the Law and Regulation 36 of the Regulations, the following documents must be provided to the Patent Office:

a) The list of references relied on by the patent offices of the countries in which patent applications were filed with respect to the invention subject of the application contemplated herein during their examination of such applications (Section 18(a)(1) of the Law).

The applicant must enclose a copy of publications that are neither patents nor patent applications, which are specified in the list above mentioned.

b) In a separate list, publications that were published prior to the application date, which are known to the applicant and pertain directly to the invention. It is not required to include in this list any publications explicitly mentioned in the patent application (Section 18(a)(2) of the Law).

Pursuant to the provisions of Patents Registrar's Circular 035-2017-Patents, the following should also be specified as part of the said list:

- Any publications published or submitted by the applicant itself or by its predecessor in holding the right of ownership, including patent applications, patents and researches that directly pertain to the claimed invention;
- In the event of filing an application in Israel while claiming a priority right under an application of continuation or continuation in part (as the same are known in the U.S.), it will be required to submit a notice to the Patent Office regarding the publication dates of the applications in the chain of the applications of continuation or continuation in part and the numbers of such applications.

c) A list of the countries in which protection was sought for the invention subject of the application, by the applicant or by its predecessor in holding the right of ownership and the numbers of the applications filed in the said countries (**Regulation 36 of the Regulations**).

Please note: pursuant to Regulation 36(4) of the Regulations, if the applicant failed to respond to this requirement, it shall be deemed to have failed to remove deficiencies for which it was given notice under Section 20 of the Law.

2) **The Details of the Application**

a) **Please be advised:** each claim beyond the first 50 claims shall require a payment of an additional fee. If the application includes more than 50 claims, you must pay the fee; alternatively, you may reduce the number of claims. If the said fees have not been paid or if the number of claims was not reduced, this notice shall be deemed a notice of deficiencies. An applicant who fails to rectify the said deficiency upon filing its response to this notice will receive a notice prior to abandonment of the application, and if no payment was made - the application will be abandoned (the Patents Registrar notice dated December 3, 2012).

b) With respect to patent applications in the field of biotechnology, you must submit the list of sequences in a *.txt file only, and in accordance with the WIPO ST.25 standard. If the sequences file has already been submitted to the Patent Office in a *.txt file as of the application submission date, there is no need to submit it again.

c) Please be advised: in accordance with the provisions of the Patents Registrar Circular 0034/2017-Patents, if it will be determined that more than one invention was claimed under the application, the examiner will examine the first one among them according to the order of claims.

With respect to some fields, it is possible that the examination of the application shall not commence immediately after the Patent Office's requirements listed herein have been satisfied.

Please be advised: the examination of this application may be accelerated based on a parallel application, for which a positive report/patent was granted by an equivalent patent authority that has entered into a PPH arrangement vis-à-vis the Israeli Patent Office, thus free of any additional fees. For further details, please review the PPH webpage (the Patent Department) on the Israeli Patent Office website.

Respectfully,
Cohen Carmela
On behalf of the Patents Registrar

תאריך: ח' טבת תשפ"ד
20/12/2023
סימוכין: 1000-016-04

לכבוד
כץ, פרזנטי ושות'
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א.ג.נ.,

<u>הודעה לפני בחינת הבקשה לפטנט מס' 309380 בהתאם לסעיף 18 לחוק ותקנה 36 לתקנות</u>

לתשומת לבכם: מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ"ז – 1967.
מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות , סדרי דין, מסמכים ואגרות), התשכ"ח – 1968.
<u>הערה:</u> עליכם להשיב על הודעה זו (אף אם כל התשובות הן שליליות) תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה בהתאם לכללים שנקבעו בחוזר הרשם 035/2017 – פטנטים. **בהתאם לחוזר זה לא יינתנו יותר משישה חודשי ארכה בגין הודעה לפני בחינה.** עם בקשה כאמור שתוגש לפני תום התקופה יש לשלם אגרה בסך 218 בעד כל חודש איחור או חלק ממנו.

1. רשימת פירסומים

בהתאם לאמור בסעיף 18 לחוק ובתקנה 36 לתקנות, יש להמציא לרשות את המסמכים הבאים:

(א) רשימת פירסומים (אסמכתאות) עליהם הסתמכו רשויות הפטנטים בארצות בהן הוגשו בקשות לפטנט על האמצאה מושא הבקשה דנן בשעת הבחינה של בקשות אלה (סעיף 18 (א)(1) לחוק).
על המבקש לצרף עותק של פרסומים שאינם פטנטים או בקשות לפטנט המצוינים ברשימה הנ"ל.

(ב) ברשימה נפרדת, פרסומים שפורסמו לפני תאריך הבקשה, הידועים למבקש והנוגעים במישרין לאמצאה. אין צורך לכלול ברשימה זו פרסומים שאוזכרו במפורש בבקשת הפטנט (סעיף 18(א)(2) לחוק).
על פי הוראות חוזר רשם 035/2017 - פטנטים במסגרת רשימה זו יש להודיע בין היתר גם על:

- פרסומים שפרסם או הגיש המבקש עצמו או מי שקדם לו בזכות בעלות, לרבות בקשות לפטנט, פטנטים, מחקרים הנוגעים במישרין לאמצאה הנתבעת;
- בקשה שהוגשה בישראל תוך תביעת דין קדימה מבקשת המשך או המשך בחלקה (Continuation, Continuation In Part כפי שאלה נעשות בארה"ב) תחייב הודעה לרשות אודות תאריכי הפרסום של הבקשות בשרשרת בקשות ההמשך או בקשות המשך בחלקן ומספרי הבקשות.

(ג) רשימת הארצות שבהן נתבקשה הגנה על האמצאה נושא הבקשה על ידי המבקש או מי שקדם לו בזכות בעלות ואת מספרי הבקשות שהוגשו באותן ארצות **(תקנה 36 לתקנות).**

לתשומת לבכם, בהתאם לתקנה 36(4) לתקנות אם לא השיב המבקש על דרישה זו, יהיה דינו כדין מי שלא סילק ליקויים שעליהם נמסרה לו הודעה לפי סעיף 20 לחוק.

2. פירוט הבקשה

(א) **תשומת לבכם** כי כל תביעה שמעבר ל-50 התביעות הראשונות מחייבת בתשלום אגרה נוספת. ככל שהבקשה כוללת מעל 50 תביעות עליכם לשלם את האגרה, לחלופין באפשרותכם לצמצם את מספר התביעות. לא שולמה האגרה כאמור או לא צומצם מספר התביעות, יראו בהודעה זו מכתב ליקויים. מבקש שלא יתקן את הליקוי האמור במועד תשובתו להודעה זו יקבל הודעה לפני סגירת הבקשה ובהעדר תשלום תיסגר הבקשה (הודעת הרשם מיום 3/12/2012).

(ב) בבקשה לפטנט בתחום הביוטכנולוגיה הכוללת רשימת רצפים:
עבור בקשה שתאריכה מאוחר מ- 1/7/2022 עליכם להגיש את רשימת הרצפים בקובץ מסוג XML ערוך בהתאם לתקן ST.26 של WIPO;
עבור בקשה שתאריכה מוקדם מתאריך זה עליכם להגיש את רשימת הרצפים בקובץ מסוג TXT ערוך בהתאם לתקן ST.25 של WIPO;
במידה וקובץ הרצפים הוגש לרשות בסוג הקובץ הנדרש במועד הגשת הבקשה, אין צורך להגישו בשנית.

(ג) **לתשומת לבכם בהתאם להוראות חוזר רשם 0034/2017 - פטנטים, באם יקבע כי נתבעו בבקשה יותר מאמצאה אחת, הבוחן יבחן את <u>הראשונה</u> מביניהן לפי סדר התביעות.**

ייתכן כי בתחומים מסויימים בחינתה של בקשה לא תחל מייד עם מילוי דרישות הרשות המפורטות בהודעה זו.

נבקש לידע שניתן לזרז את בחינת בקשה זו על סמך בקשה מקבילה אשר קיבלה דוח חיובי/פטנט ברשות מקבילה שיש לה הסדר PPH עם רשות הפטנטים הישראלית וזאת ללא צורך בתשלום אגרה נוספת. לפרטים נוספים נא לפנות לדף ה-PPH (מחלקת פטנטים) באתר רשות הפטנטים.

בכבוד רב,
רשות הפטנטים

טופס פר' 34 (12) 15.05.2023

מדינת ישראל
משרד המשפטים

רשות הפטנטים

פ.ק 13

תאריך : כ״ח אלול תשפ״ג
14/09/2023
מספרכם : 1000-016-03

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה לפני קיבול בקשת פטנט מספר 300848</u>**

סימוכין : מכתבכם מיום 14/07/2023

לתשומת לבכם : מקום בו הנכם מופנים ל״חוק״, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים ל״תקנות״, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. בהתאם לחוזר רשם 035/2017 – פטנטים **לא ניתן להשהות פרסום בקשות פטנט לפי סעיף 26 לחוק.**

<u>הודעה זו מבוססת על המסמכים הבאים :</u>

שרטוטים מתאריך : 21/02/2023
תביעות מתאריך : 27/07/2023
פרטי הבקשה מתאריך : 27/07/2023

<u>הריני להודיעכם כי בחינת הבקשה הנ״ל הושלמה לפי הוראות סעיף 48ו(ג)(1) ו- (2) לחוק.</u>

1. <u>בחינת הבקשה מבוססת על ההודעות הבאות :</u>

1.1 הריני להודיעכם כי :

תאריך הבקשה הנוכחית, שהינה בקשת חלוקה מן הבקשה מס׳ 286030, הוקדם לתאריך 22/07/2016 , שהוא תאריך הבקשה ההורה, וזאת בהתאם ל**סעיף 24(ג) לחוק**.

<u>תשלום אגרת קיבול</u>

1. הבקשה תתקבל בהתאם לסעיף 26 לחוק לאחר תשלום אגרת הקיבול.
2. יש לשלם את האגרה תוך 3 חודשים מתאריך הודעה זו.
3. סכום האגרה נכון למועד הודעה זו הינו 764.00 ש״ח. הסכום כפוף לעדכונו על פי המדד בהתאם לתקנה 6א.

<u>הפניה בפירוט למסמך הבכורה</u>

לפי הוראות **סעיף 20 לחוזר הרשם 034/2017-פטנטים** במידה ופירוט הבקשה מכיל הפניה למסמך בכורה באמצעות הביטוי ״incorporated by reference״ ובמידה וחלפו 14 חודשים ממועד דין הקדימה (אם נדרש) לא

רחוב אגודת ספורט הפועל מס׳ 1,
הגן הטכנולוגי מלחה בנין מס׳ 5
ירושלים, מיקוד 9695101
טל׳ : 972-73-3927100 פקס : 972-2-6467774
https://www.gov.il/he/departments/ilpo

ניתן עוד להוסיף דבר מתוך מסמך הבכורה והמבקש לא יכול להסתמך על האמור במסמך הבכורה לצורך סעיפים 12 ו-13 לחוק.

<u>עדכון רשימות האסמכתאות והפרסומים לפי סעיף 18א לחוק</u>

לתשומת לבכם, בהתאם להוראות פרק ג' בחוזר רשם 035/2017-פטנטים חובת המבקש לעדכן את הרשות בכל שינוי שחל ברשימת הפרסומים בהתאם לסעיף 18 לחוק נמשכת עד קיבול הבקשה.

באם ברצונכם להחזיר את הבקשה לבחינה בעקבות שינוי ברשימת הפרסומים שהתרחש מאז עדכנתם לאחרונה את תשובתכם לדרישה לפי סעיף 18 לחוק , עליכם להגיש בקשה לבחינה חוזרת בה עליכם לציין מהו השינוי ברשימת הפרסומים ומתי נודע על שינוי זה.

בקשה לבחינה חוזרת יש להגיש באמצעות פניה ל-"בקשה לתיקונים לאחר פ.ק. 13".

<u>הגשת בקשות חלוקה</u>

בהתאם להוראות סעיף 24(א) לחוק זכאי המבקש כל עוד לא קובלה הבקשה לדרוש את חלוקת הבקשה לבקשות אחדות. לפיכך, באם ברצונכם להגיש בקשות חלוקה מבקשה זו עליכם לעשות זאת בטרם מועד הקיבול. לא נוכל להכיר בבקשות שיוגשו לאחר מועד הקיבול של הבקשה הנוכחית כבקשות חלוקה לעניין סעיף 24(ג) לחוק.

<u>בדיקה פורמלית</u>

להודעה הנוכחית מצורף העתק פירוט הבקשה המעודכן - אם נפלו טעויות נא להודיע עליהן לרשות לפני מועד תשלום אגרת הקיבול.

לצורך אימות פרטי הפרסום בהתאם לסעיף 26 לחוק ניתן לעיין בנסח הבקשה באתר הרשות בקישור הבא:

https://israelpatents.justice.gov.il/#/en/patent-extract/300848

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

https://israelpatents.justice.gov.il/#/en/patent-file/details/300848

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
טלפון: 073-3927233
דואר אלקטרוני: albertak@justice.gov.il
ראש צוות: מוריה שלמה לוי

Claims

1. A device comprising:

an inlet port for receiving a blood sample;

an outlet port;

a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable; and

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

2. The device in accordance with claim 1, wherein the device is configured such that, when a drawing force is applied at the outlet port, blood is drawn into the inlet port and into the chamber.

3. The device in accordance with claim 2, wherein the device is further configured such that an initial aliquot of blood will contact the material and back up into the chamber.

4. The device in accordance with claim 1, wherein the material is located at a distal end of the chamber.

5. The device in accordance with claim 1, wherein the material is a hydrophobic plug.

6. The device in accordance with claim 1, wherein the material is a hydrophobic membrane.

7. The device in accordance with claim 1, wherein the material is a hydrophilic membrane.

8. The device in accordance with claim 1, wherein the sampling channel further comprises a valve configured to close off the sampling channel.

9. The device in accordance with claim 8, wherein the valve is a clip.

10. The device in accordance with claim 1, further comprising a junction connecting the inlet port and the sampling channel and the chamber.

11. The device in accordance with claim 10, wherein the junction is configured to convey the subsequent portion of the blood sample to the outlet port while bypassing the chamber.

12. The device in accordance with claim 1, wherein the chamber has a larger cross-sectional area than the sampling channel.

13. The device in accordance with claim 1, further comprising a housing that defines the chamber and the sampling channel.

14. The device in accordance with claim 13, wherein the housing comprises a bottom member mated with a top member, each of the bottom member and the top member defining a part of each of the inlet port, the outlet port, the chamber, and the sampling channel.

15. The device in accordance with claim 1, further comprising a patient needle and a sample collection device.

BLOOD SAMPLE OPTIMIZATION DEVICE

ABSTRACT

Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING"; and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD," the disclosures of which are incorporated by reference in their entirety.

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by

antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0013] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0016] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port

connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0017] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0018] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0019] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a

sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0020] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0021] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0031] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0032] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0033] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0034] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0035] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0036] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0037] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0038] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0039] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0040] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0041] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and methods for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other

sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of

coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such

as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a

certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the

ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate

valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle

from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the

sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration

device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main

outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In

other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that

sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations,

tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood

sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the

sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the

blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the

sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent

material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood

sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by

the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber

2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00126] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel before the initial aliquot of blood is sequestered in the sequestration chamber 2306.

[00127] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

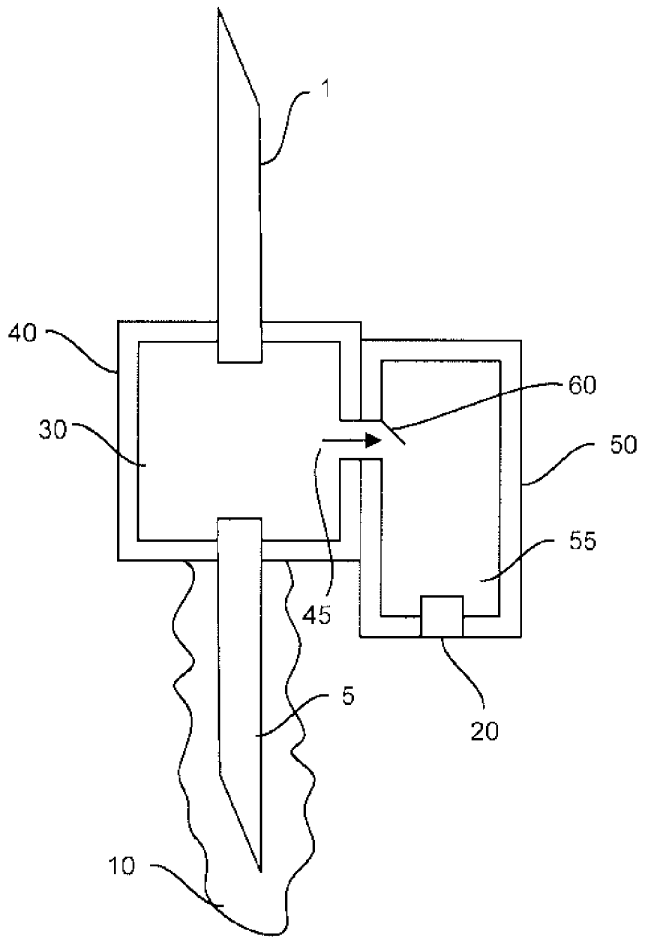


FIG. 1

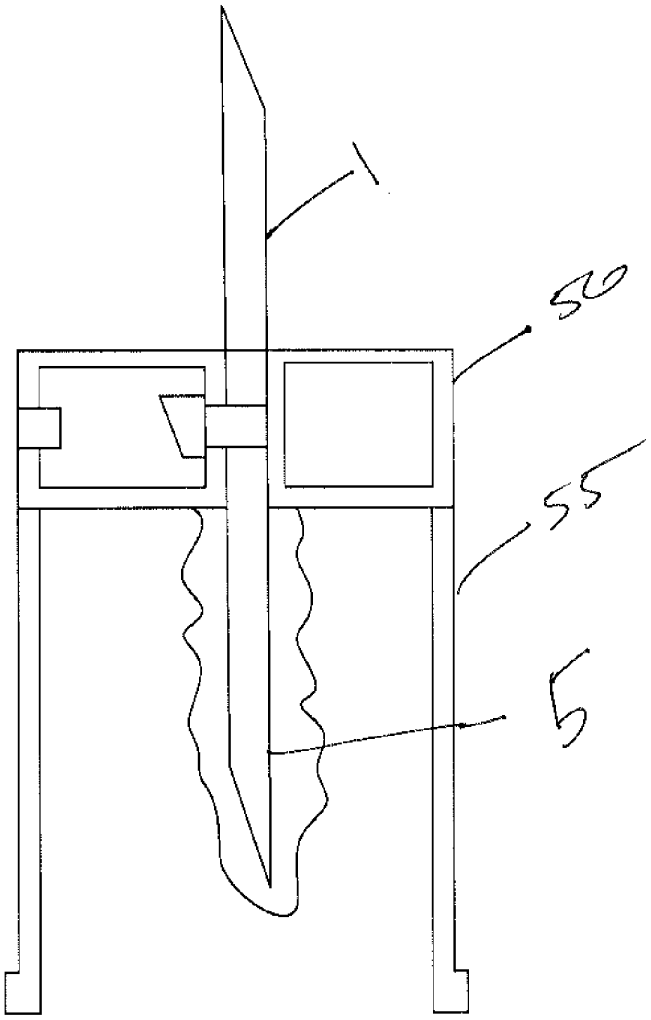


FIG. 2

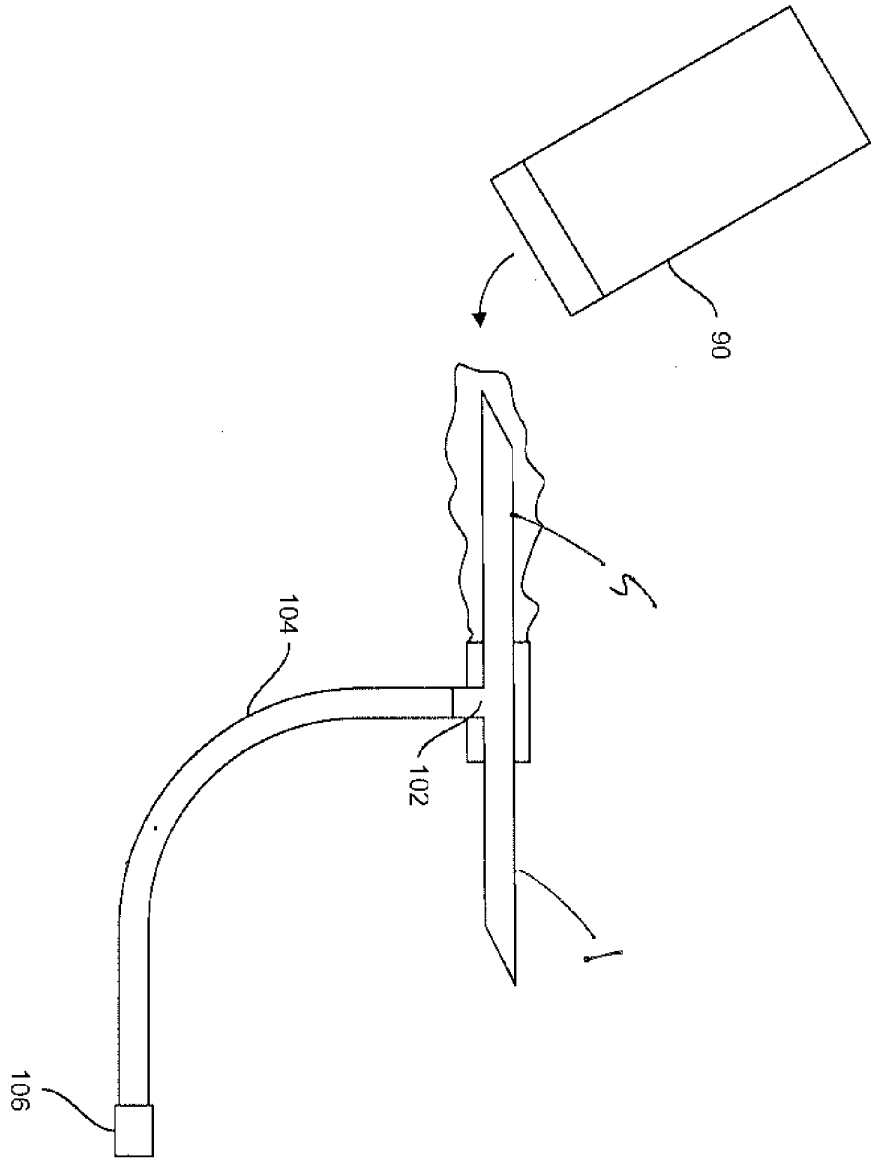


FIG. 3

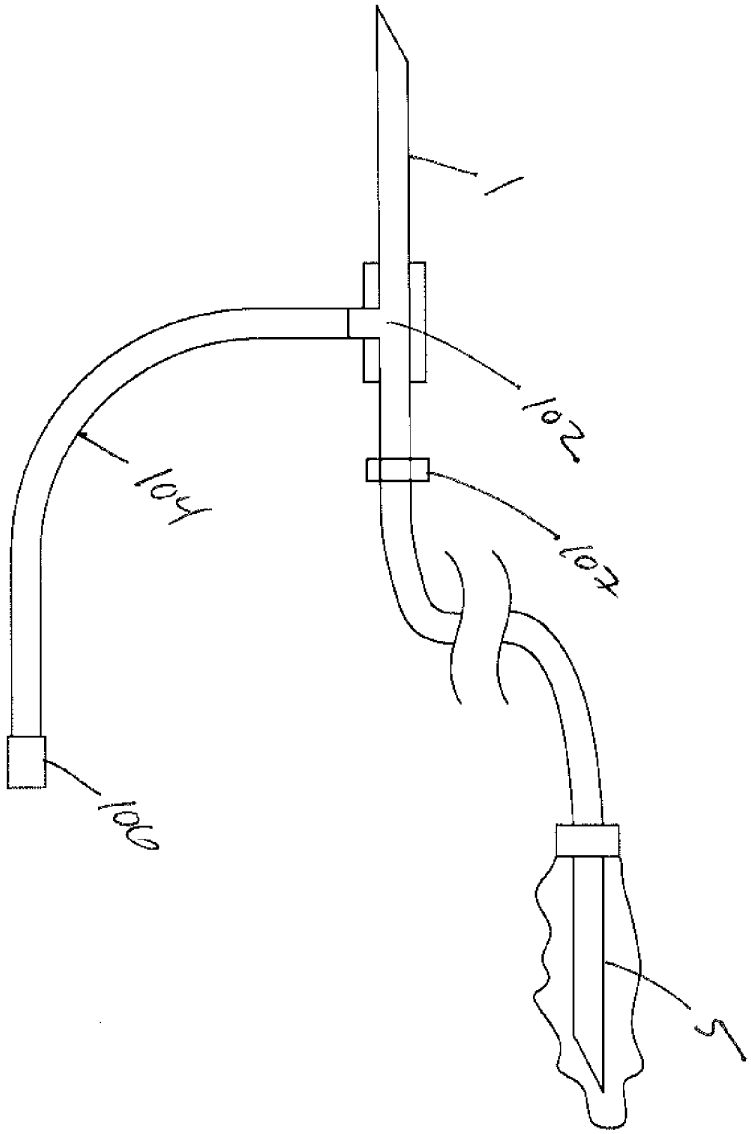


FIG. 4

FIG. 5

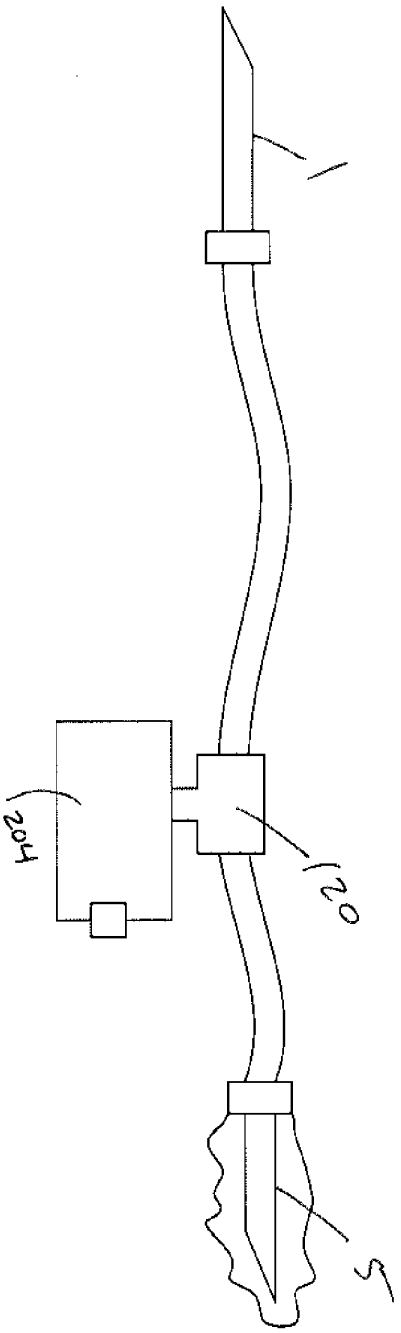
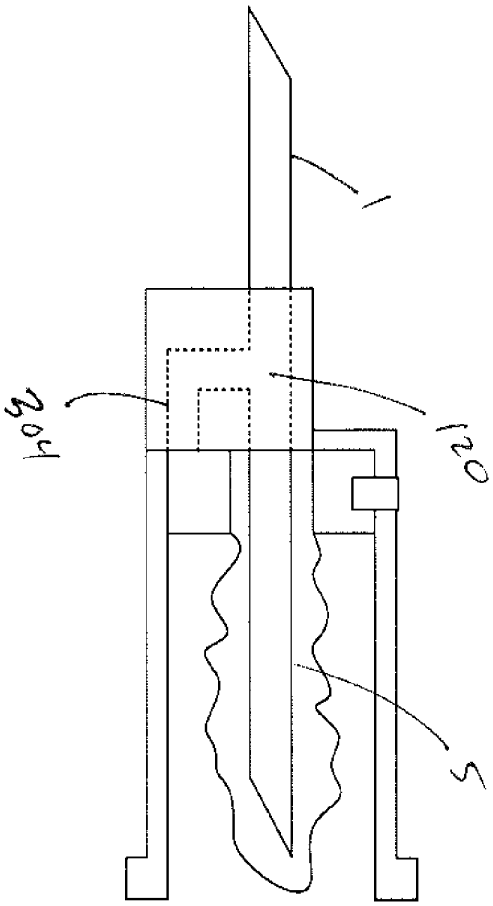


FIG. 6



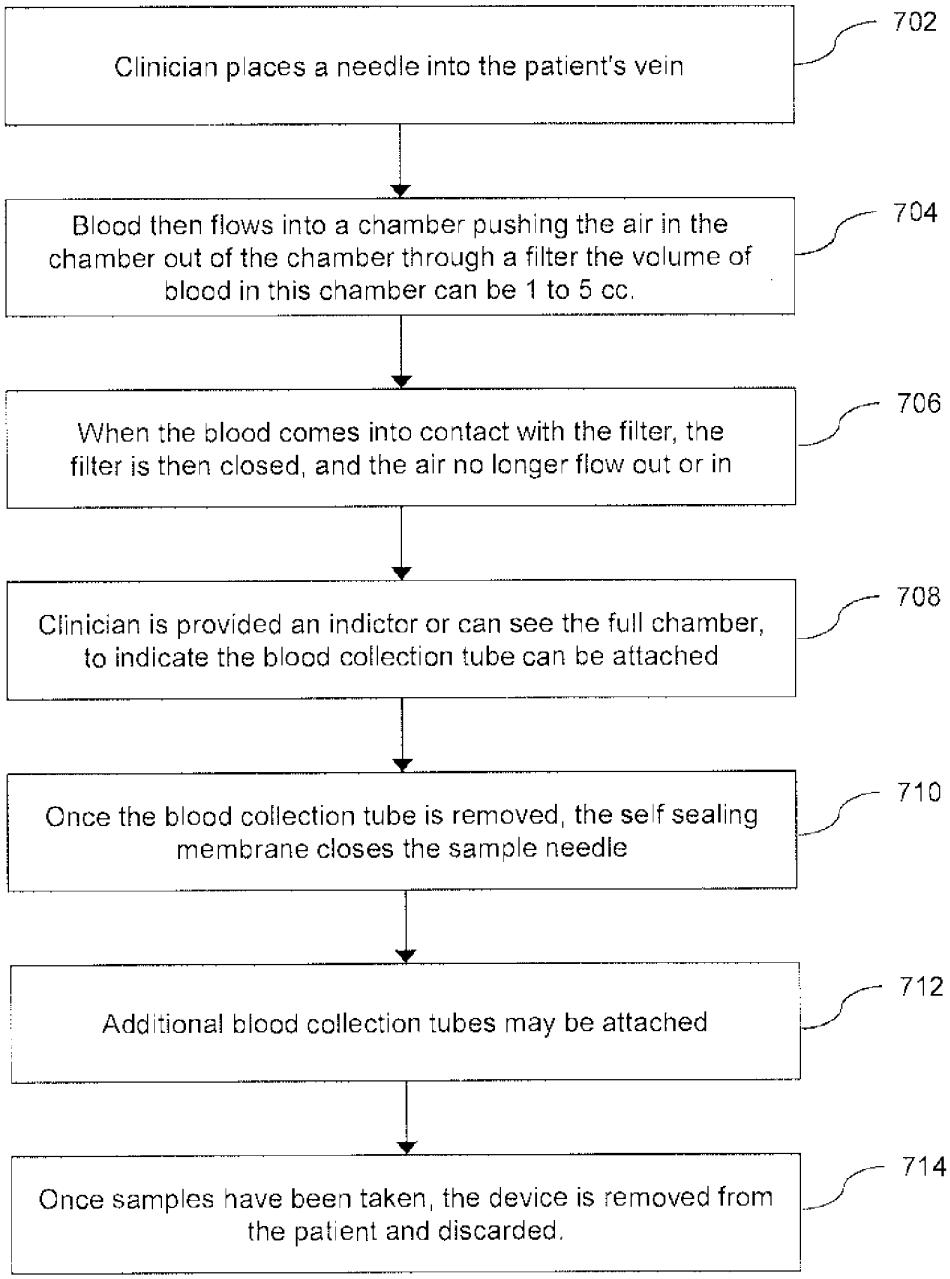

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

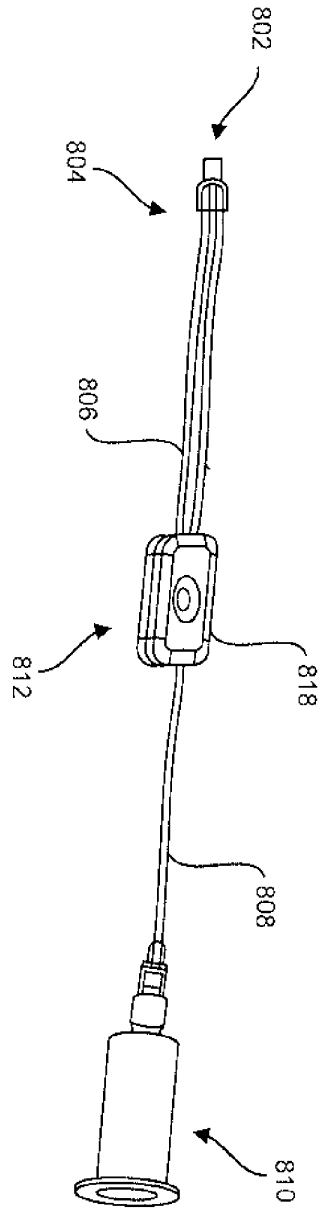


FIG. 8A

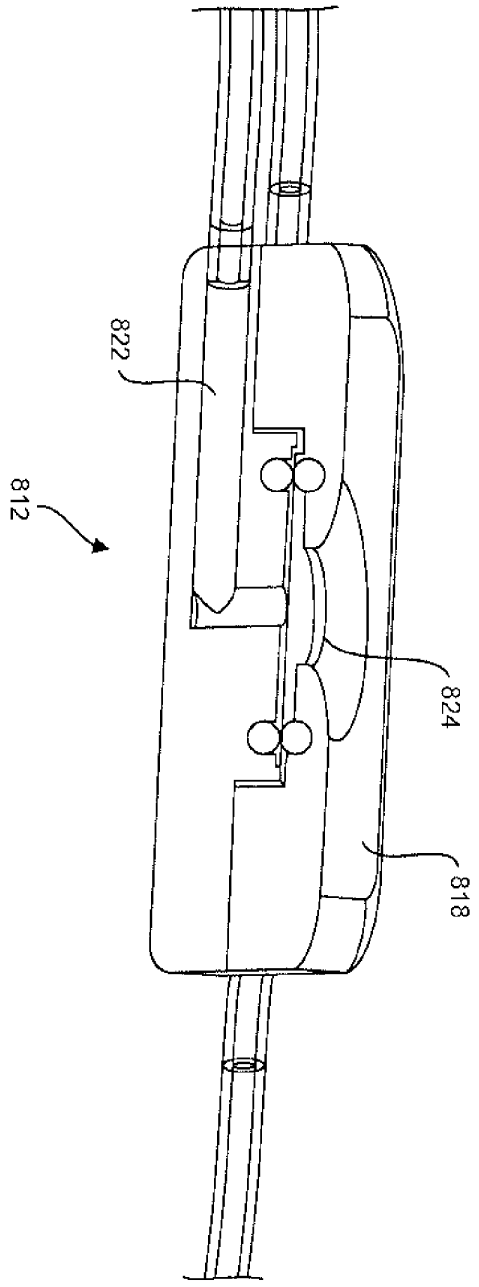


FIG. 8B

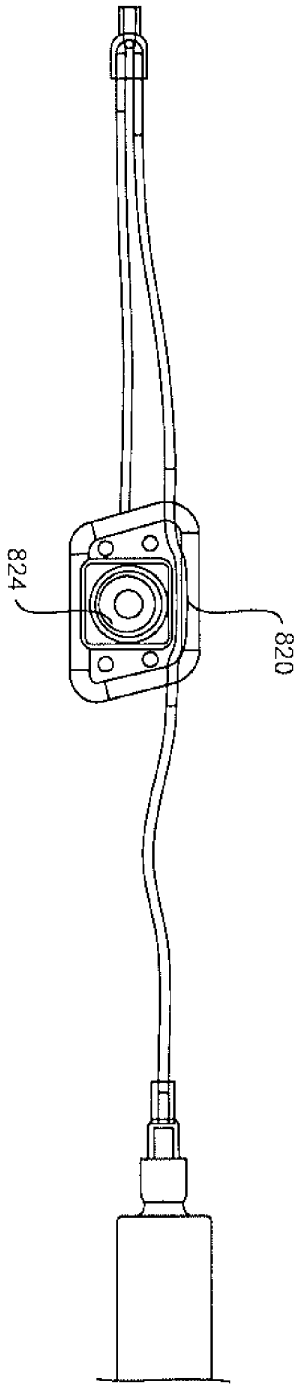


FIG. 8C

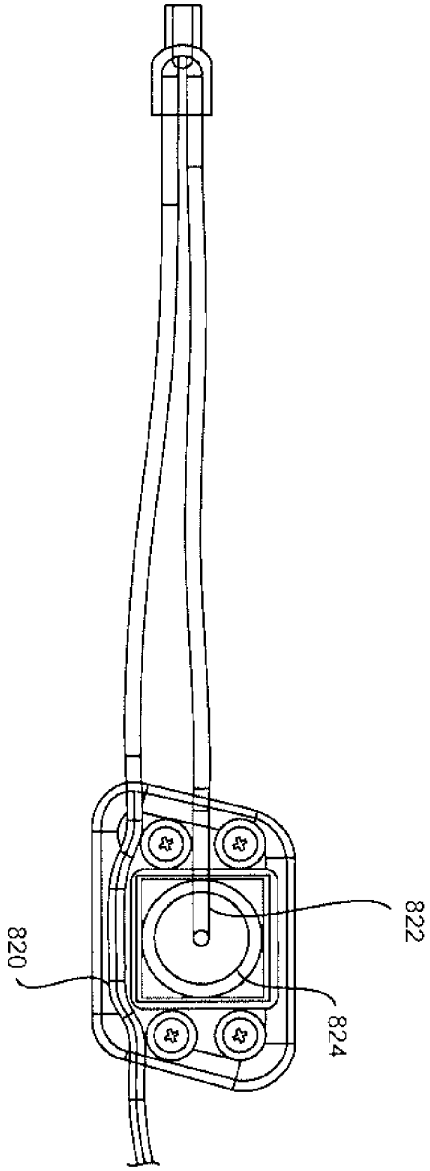


FIG. 8D

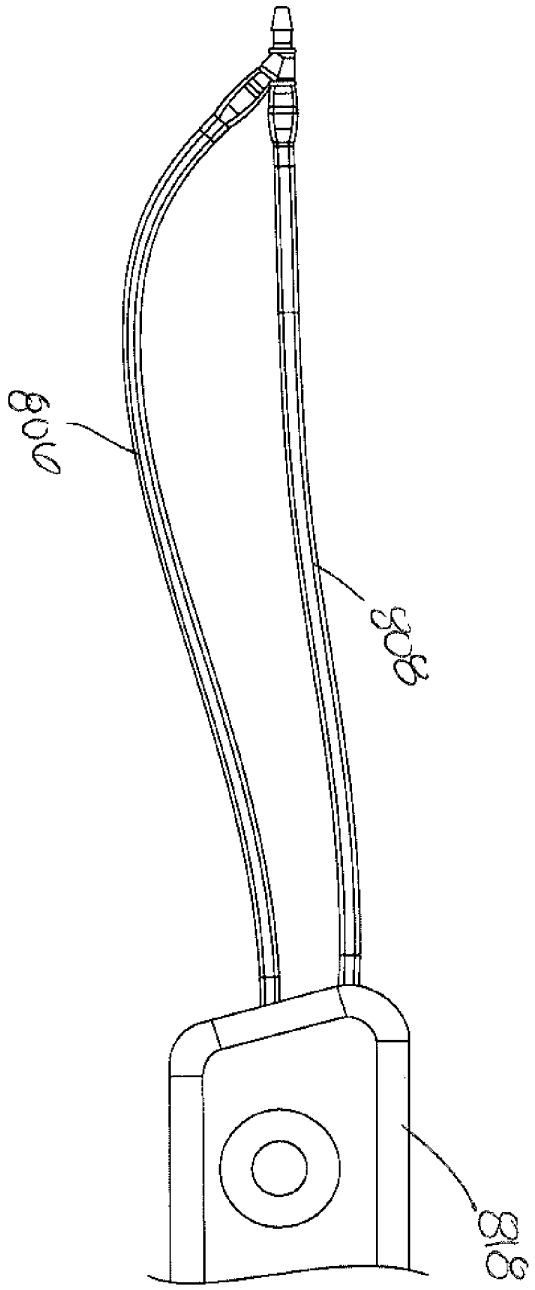


FIG. 8E

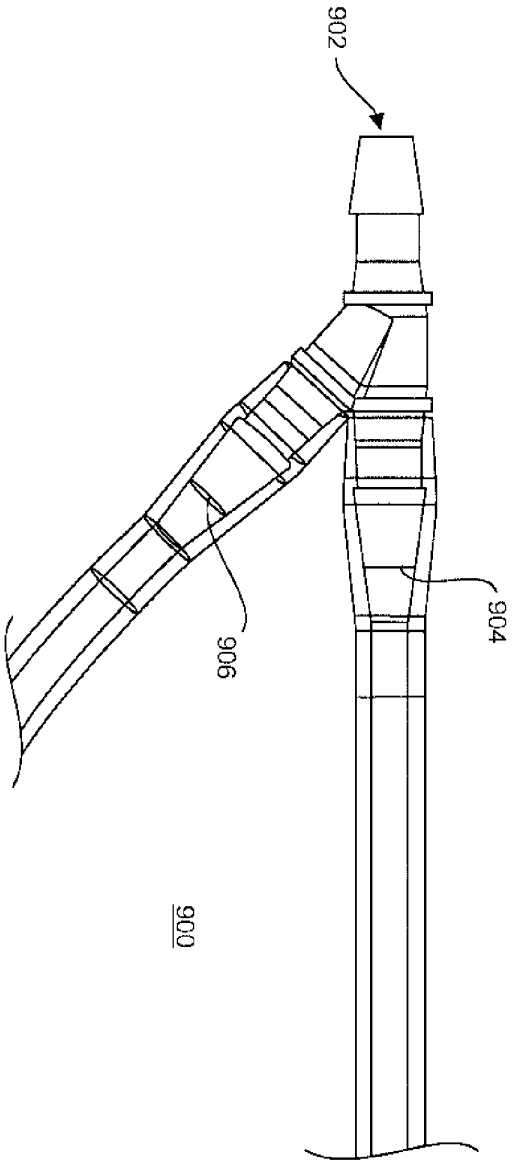


FIG. 9

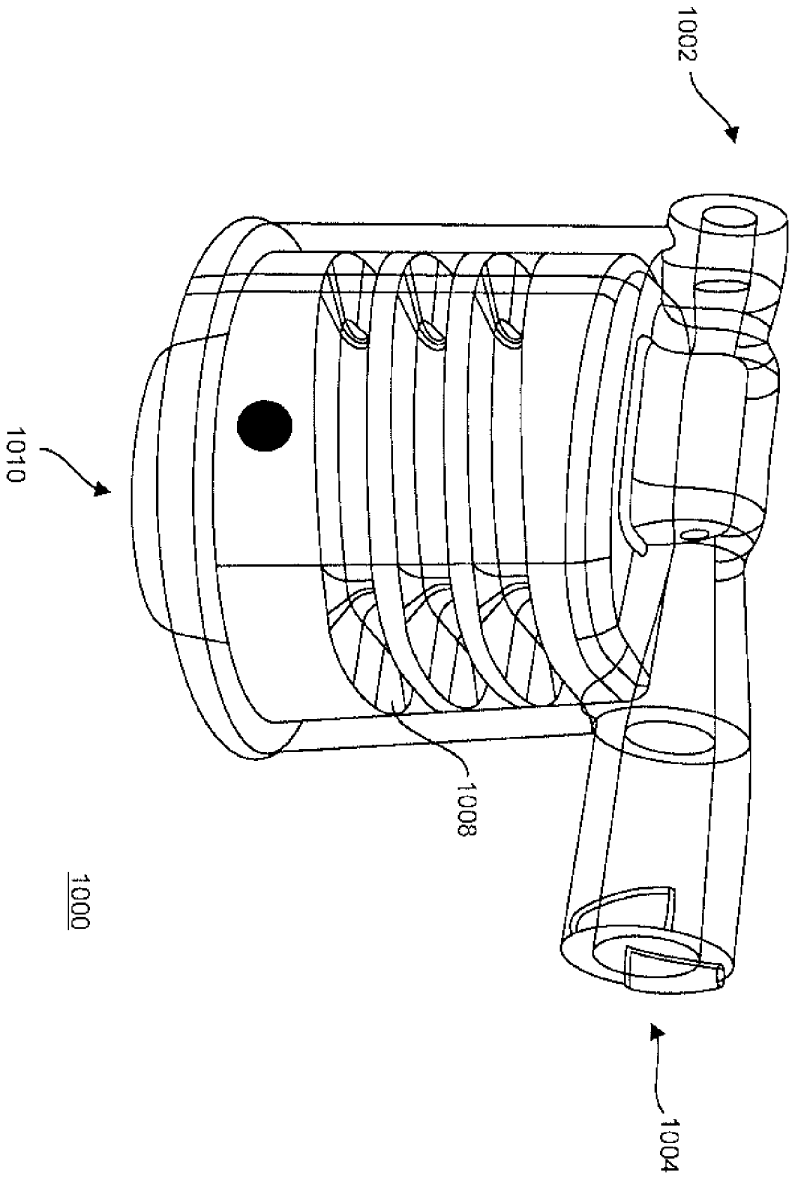


FIG. 10A

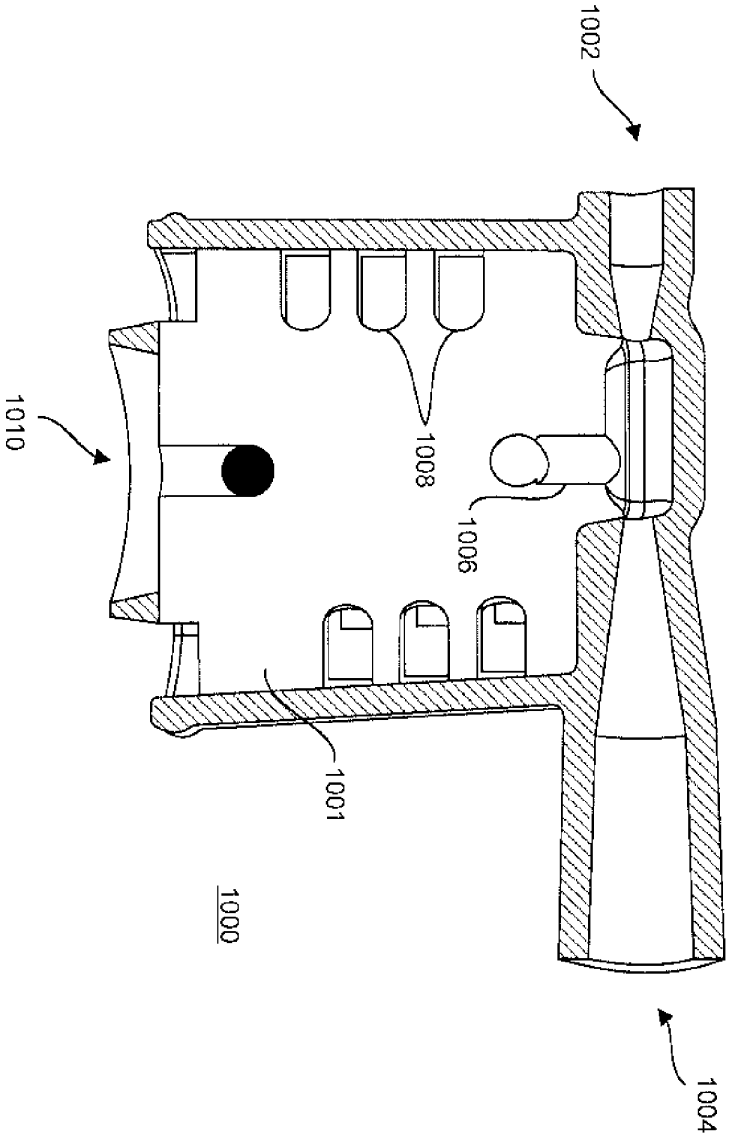


FIG. 10B

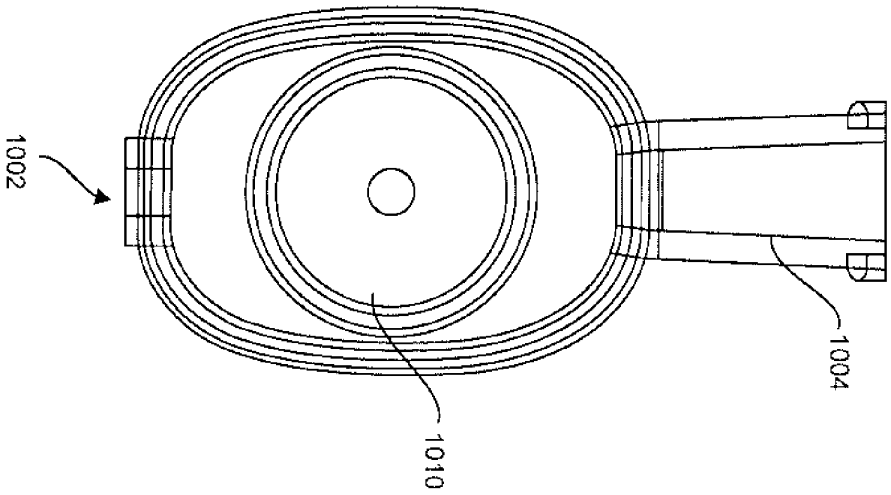


FIG. 10C

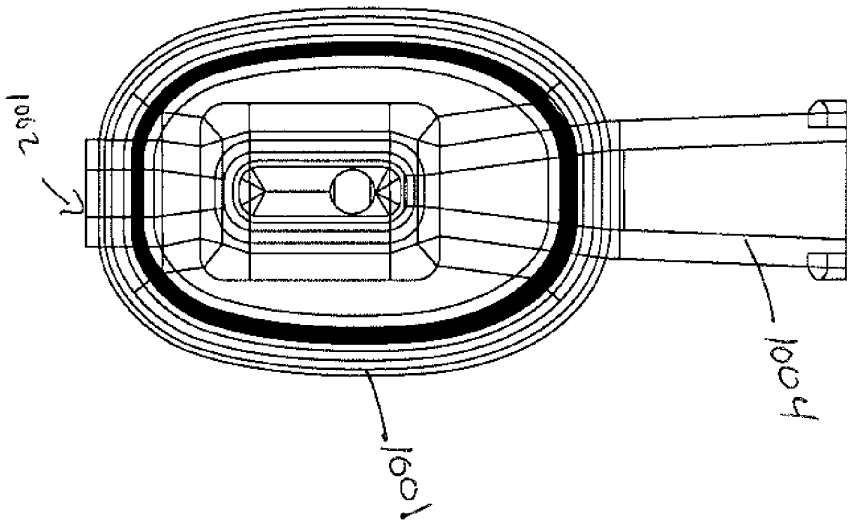


FIG. 10D

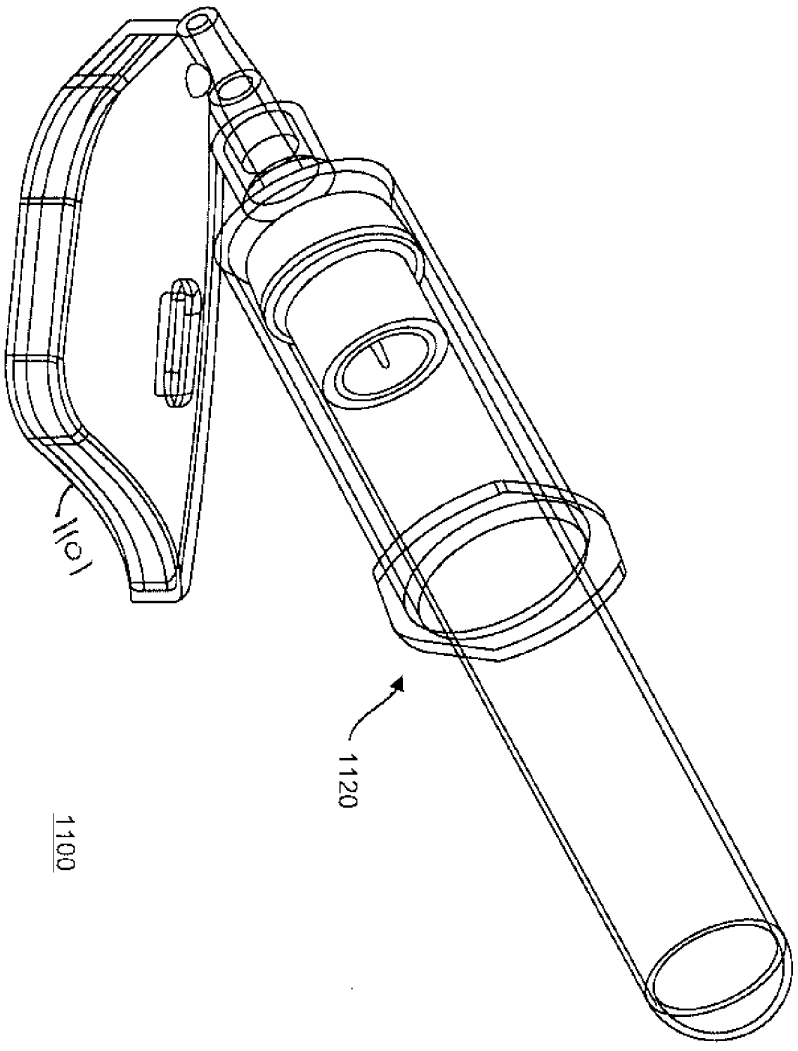


FIG. 11A

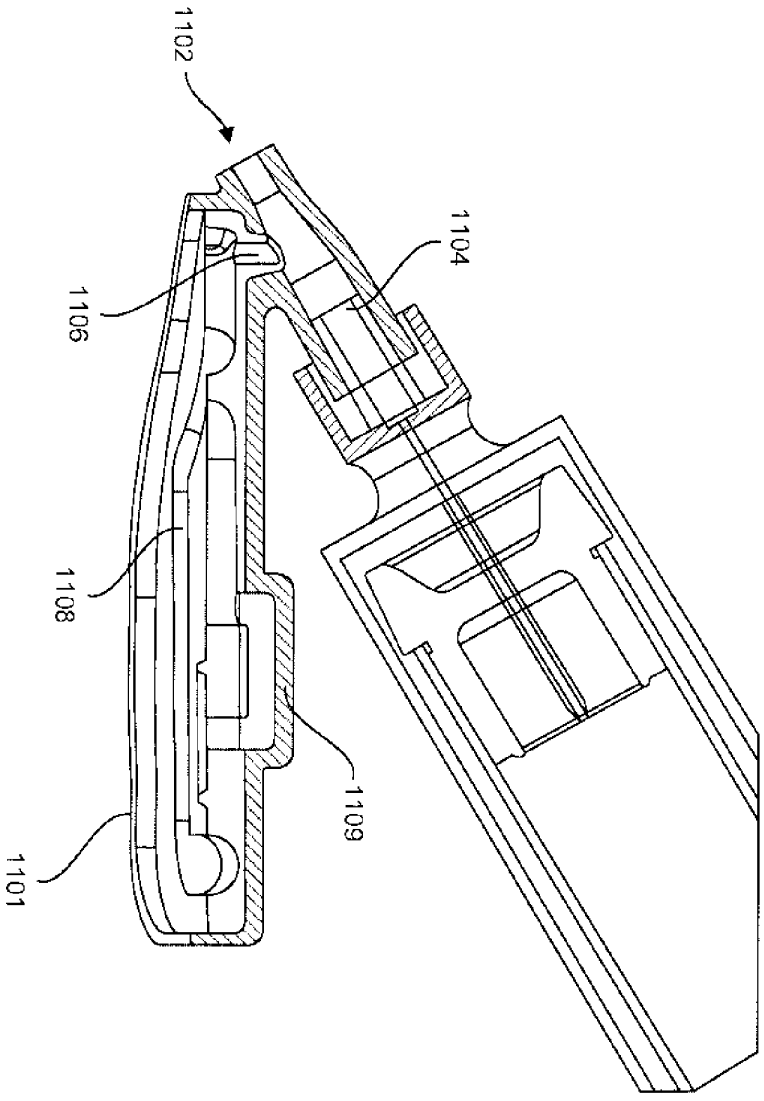
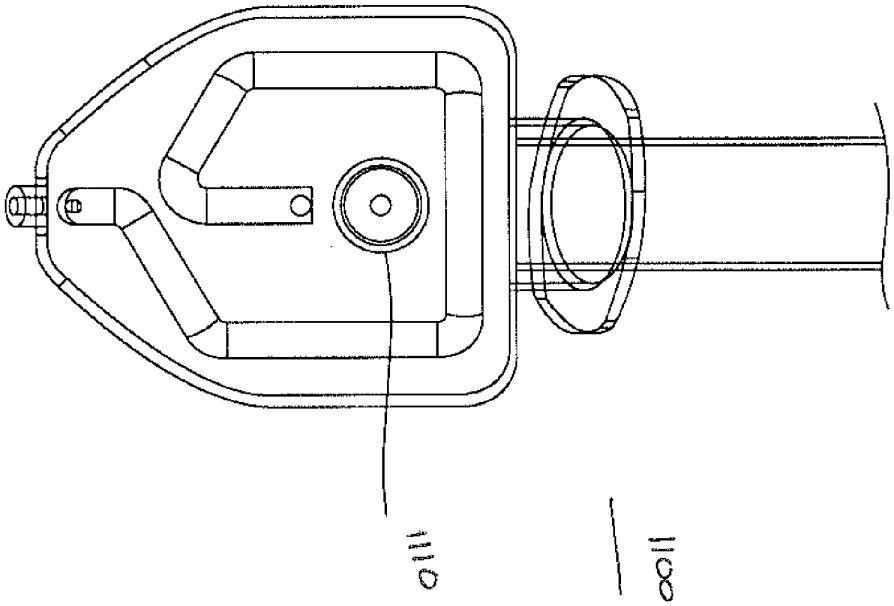


FIG. 11B

FIG. 11C



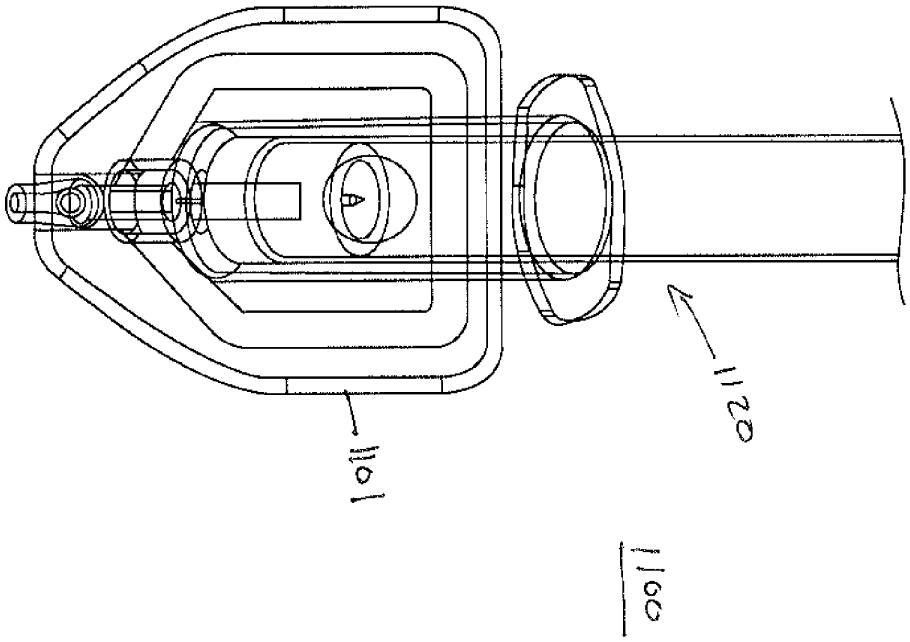


FIG. 11D

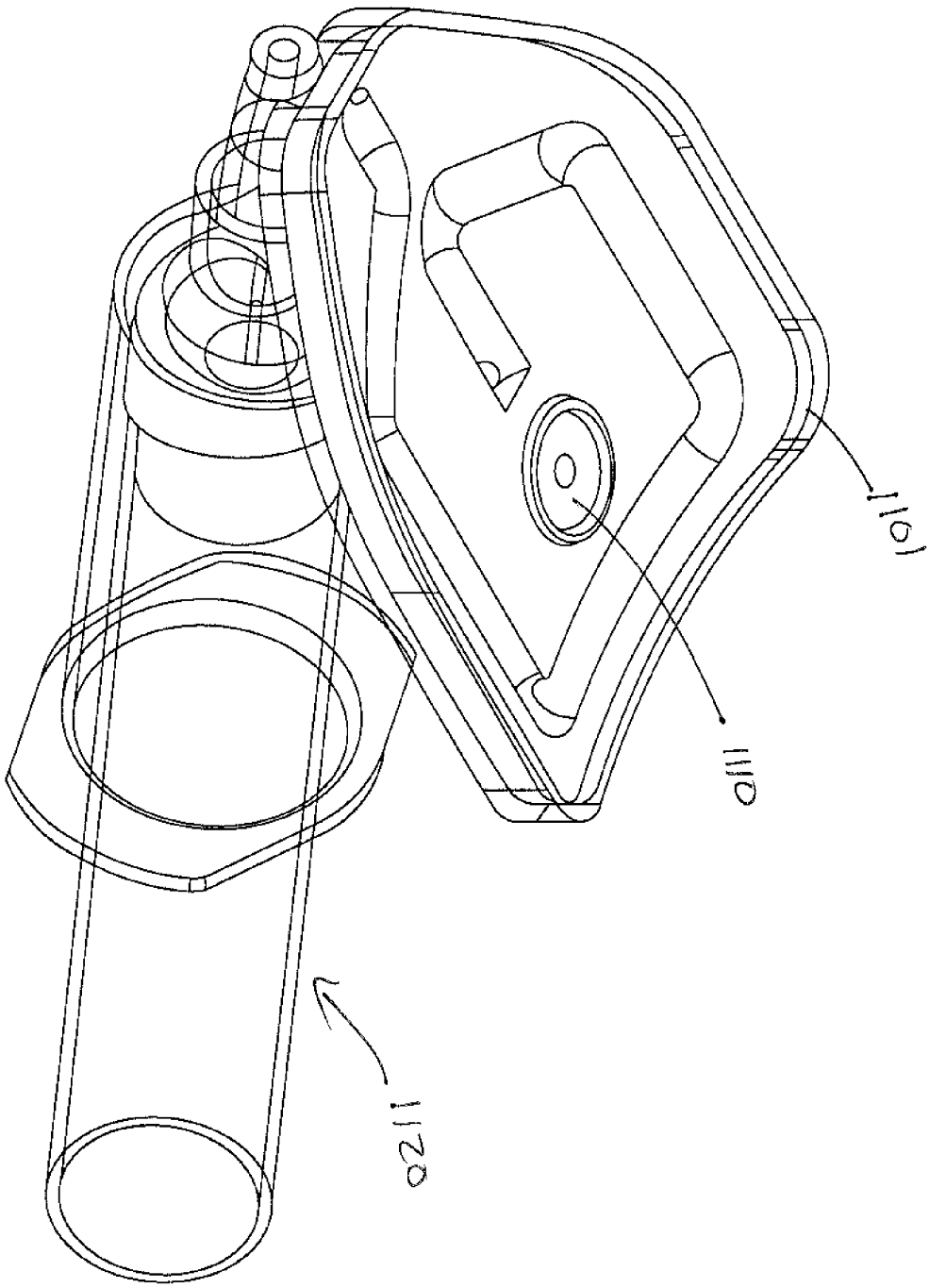


FIG. 11E

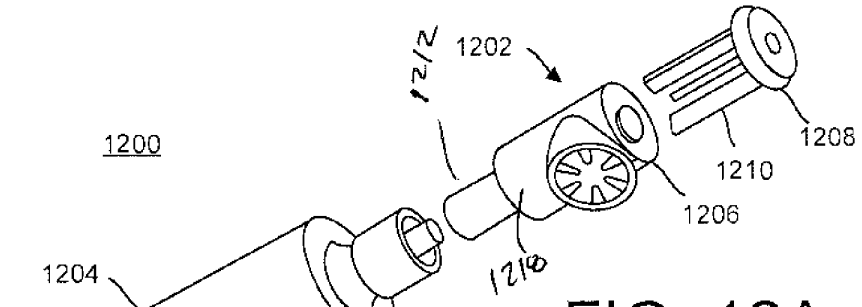


FIG. 12A

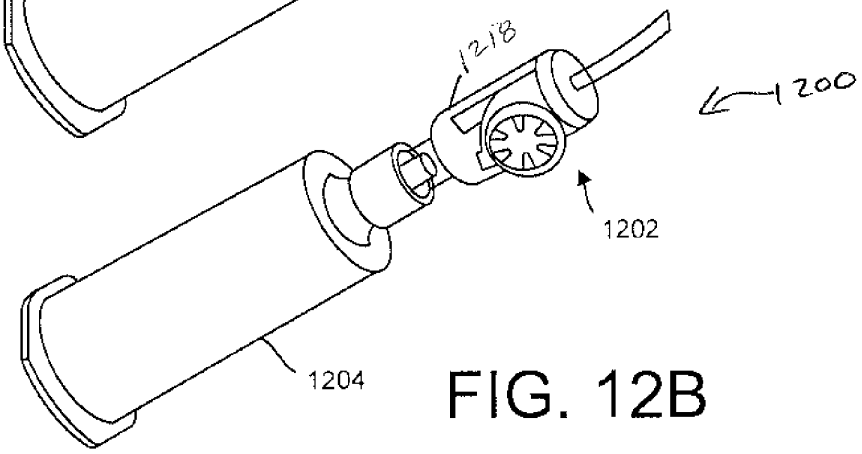


FIG. 12B

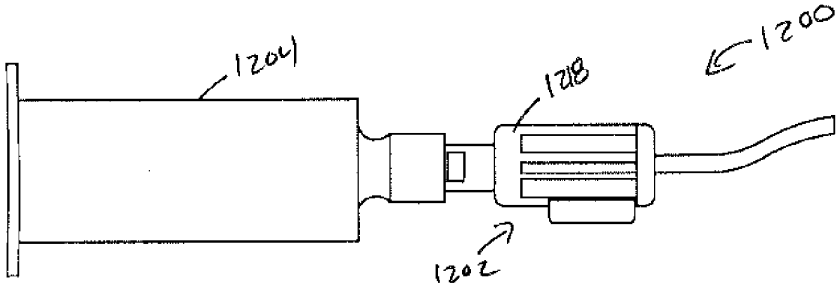


FIG. 12C

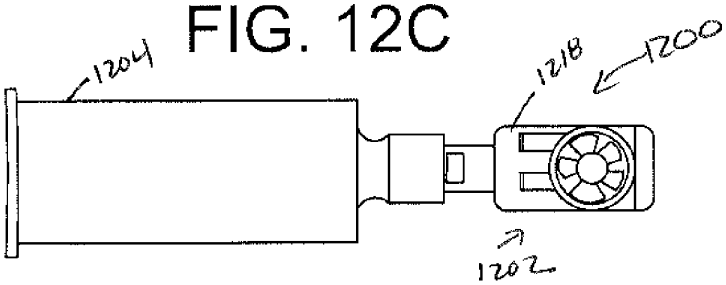


FIG. 12D

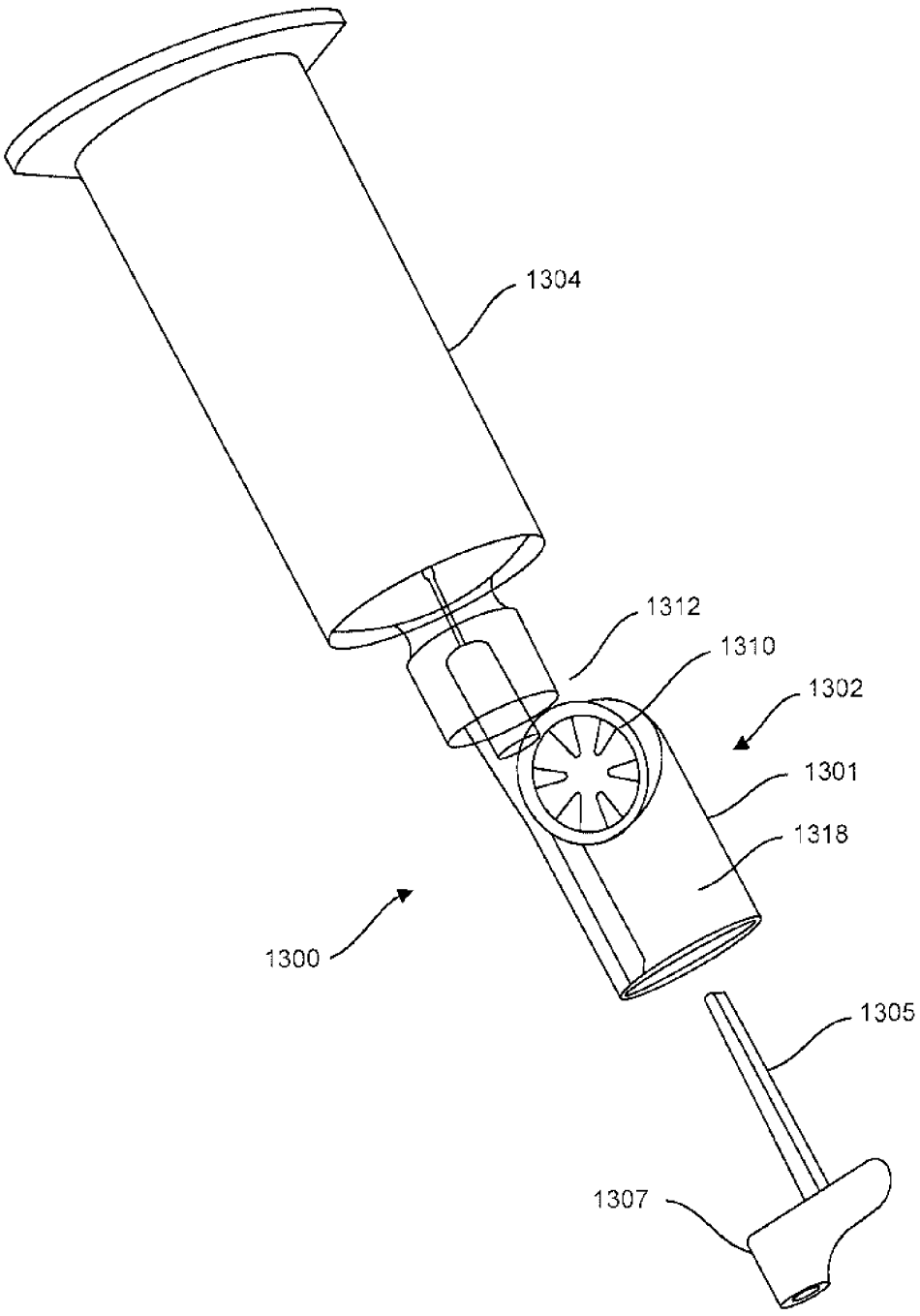


FIG. 13A

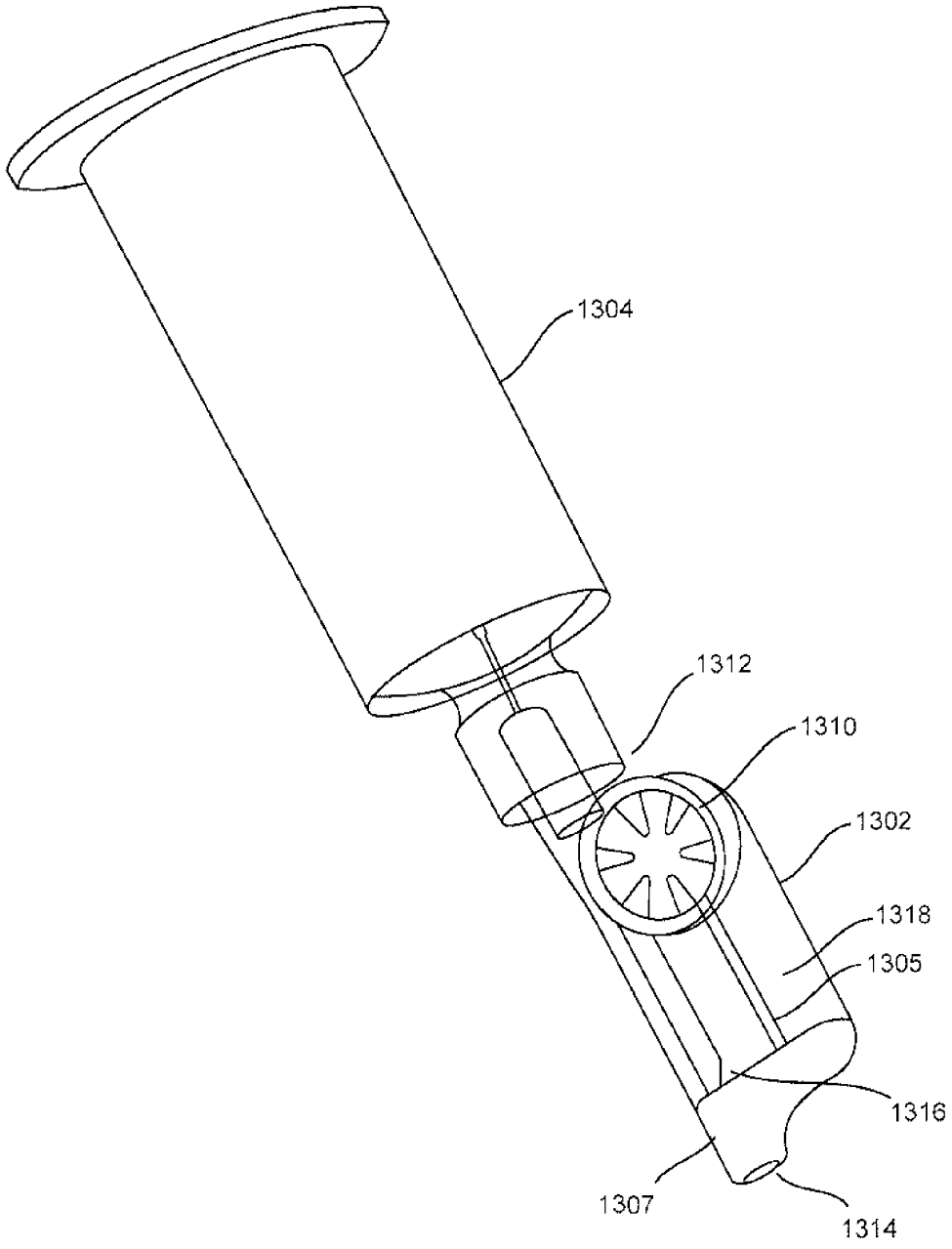


FIG. 13B

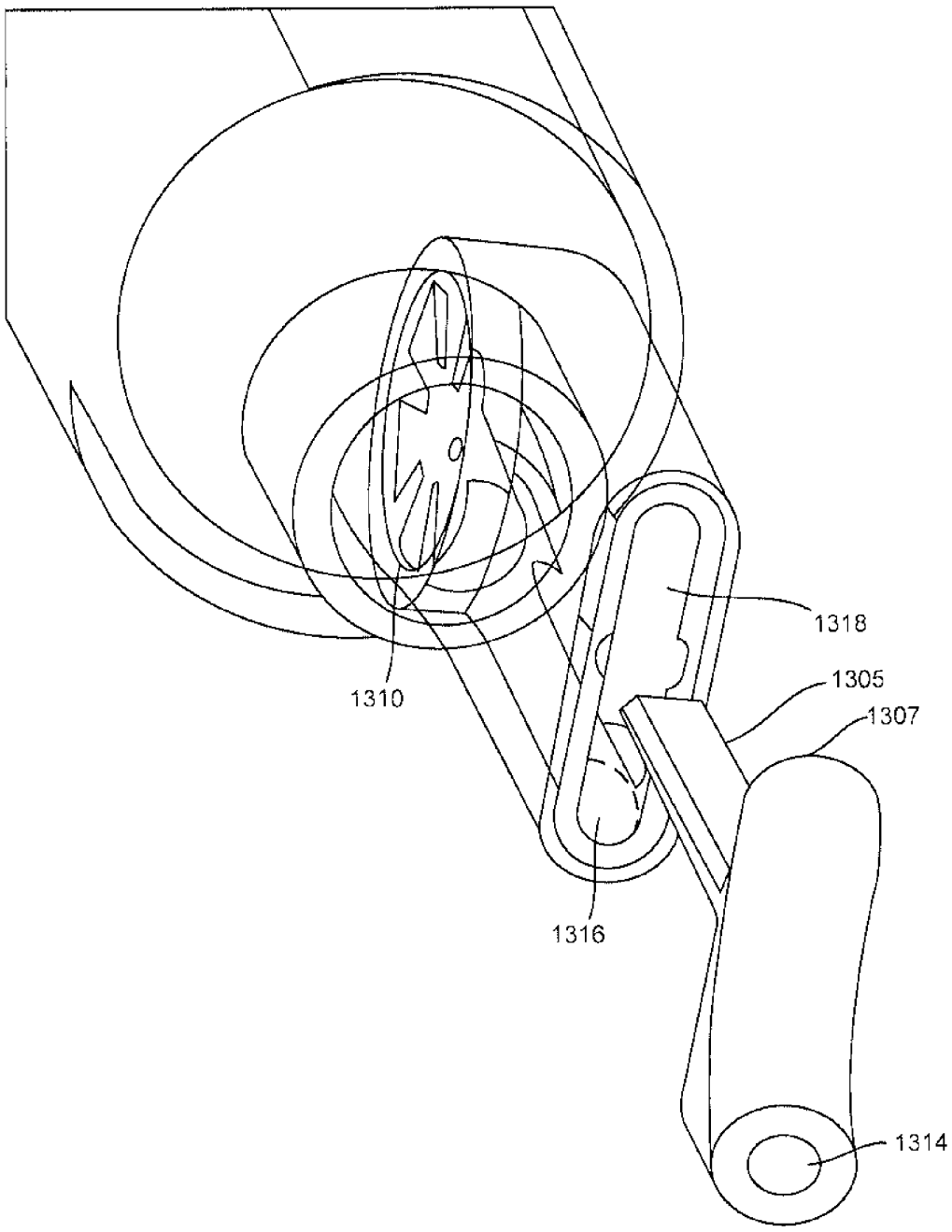


FIG. 13C

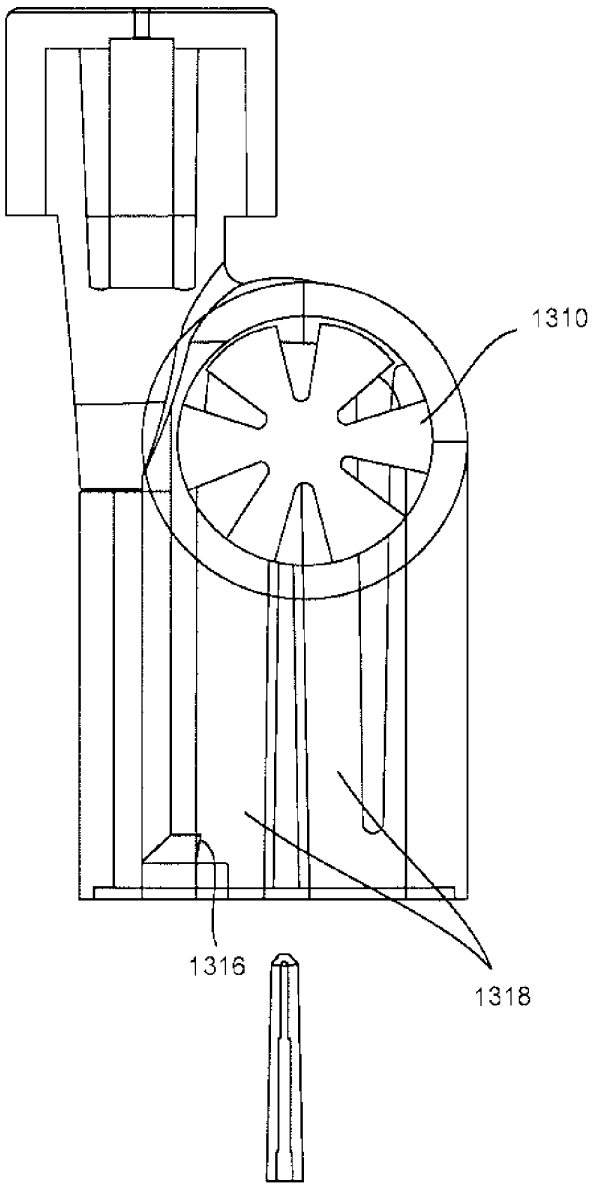


FIG. 13D

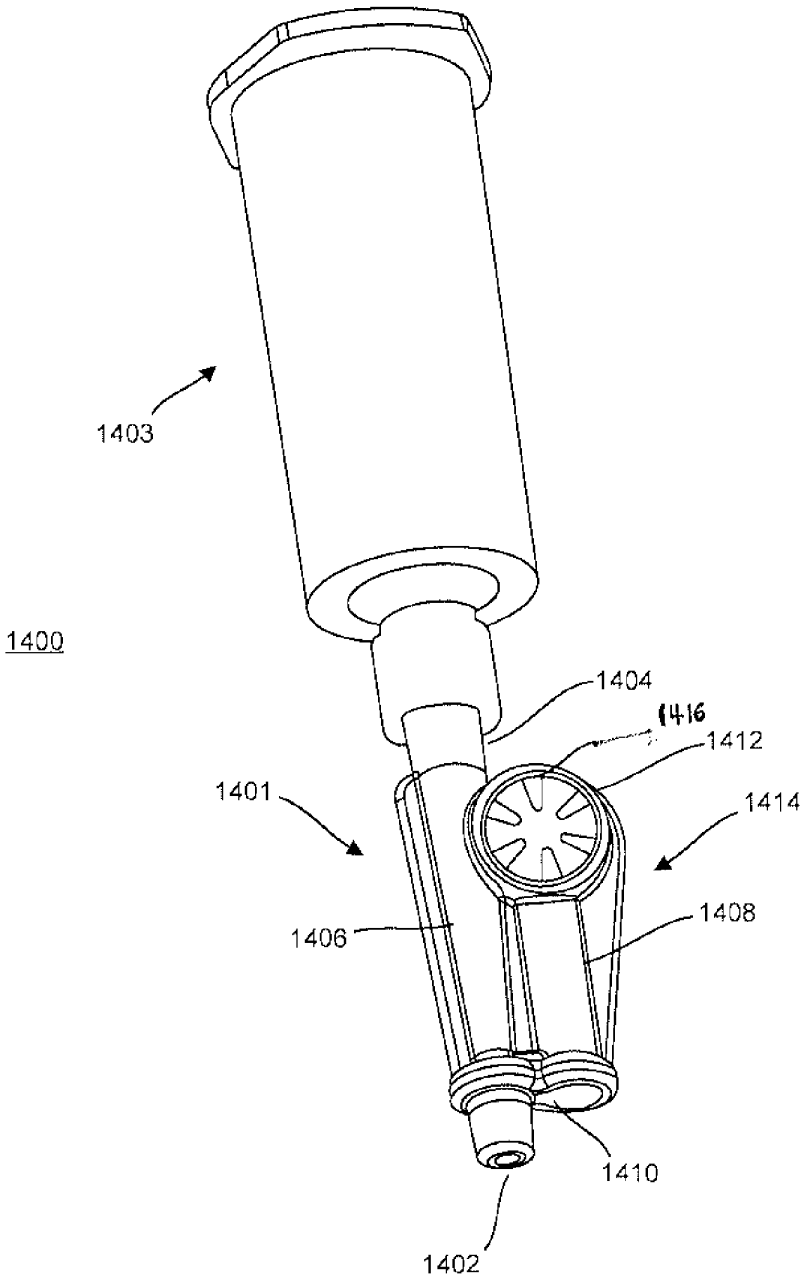


FIG. 14A

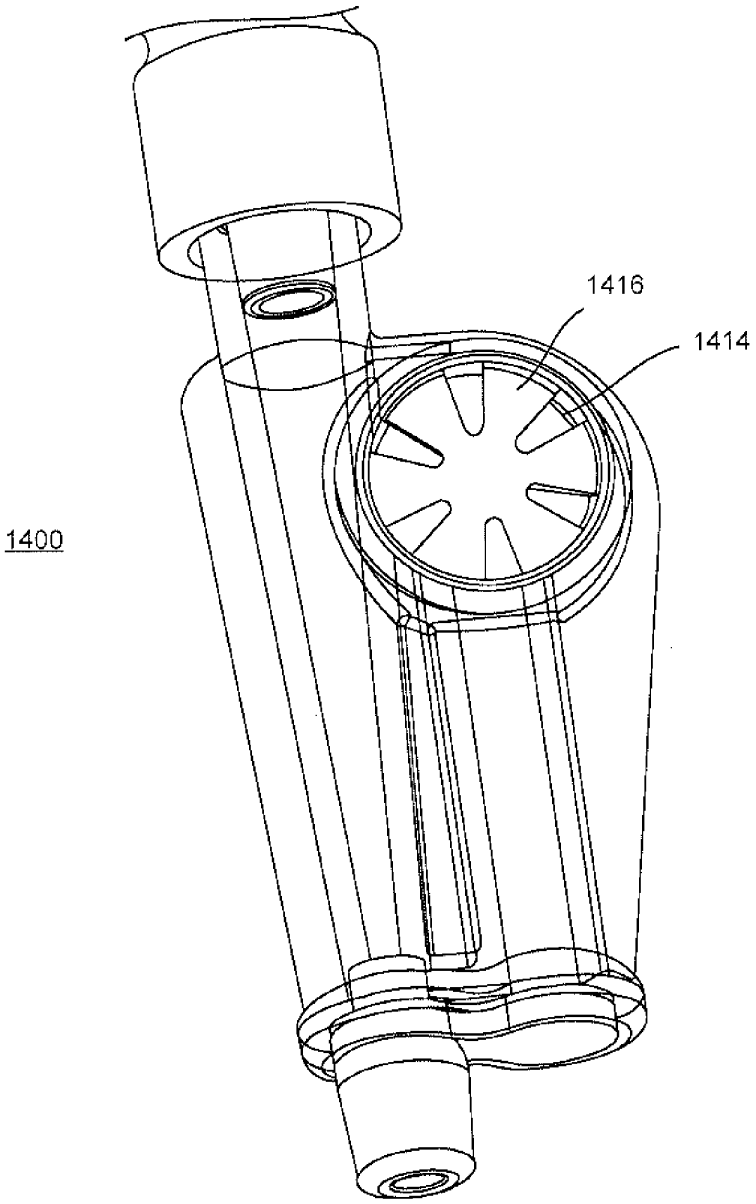


FIG. 14B

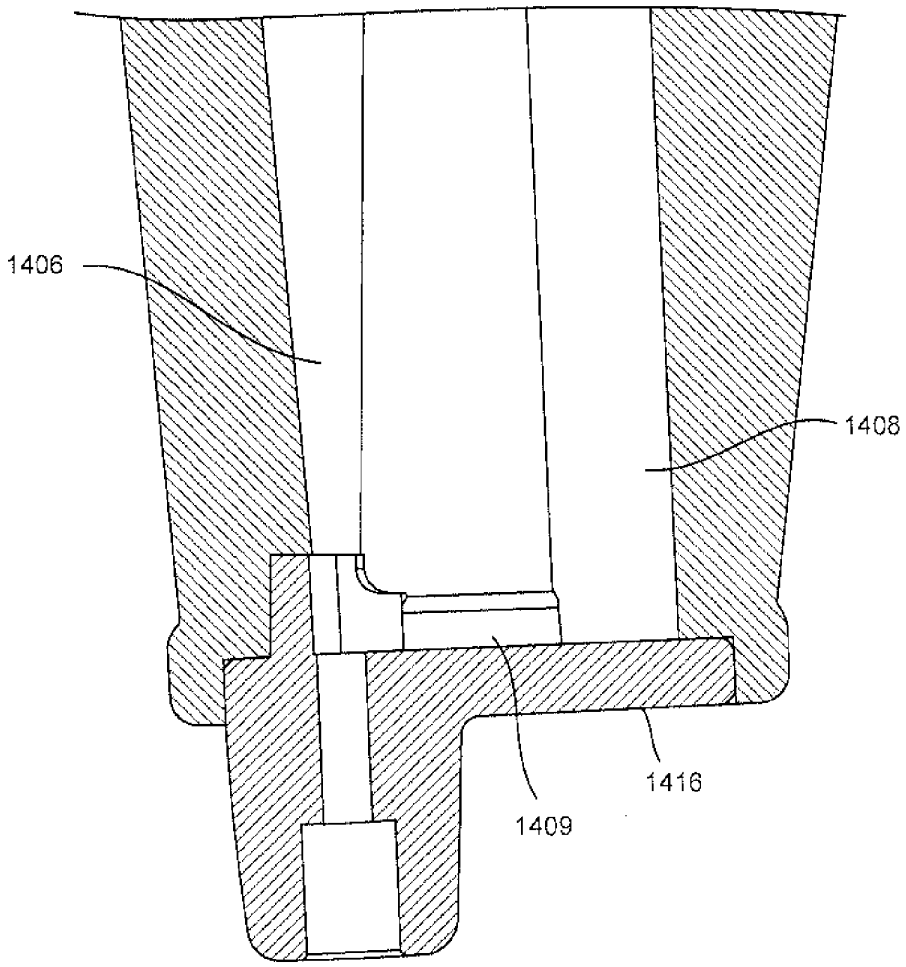


FIG. 14C

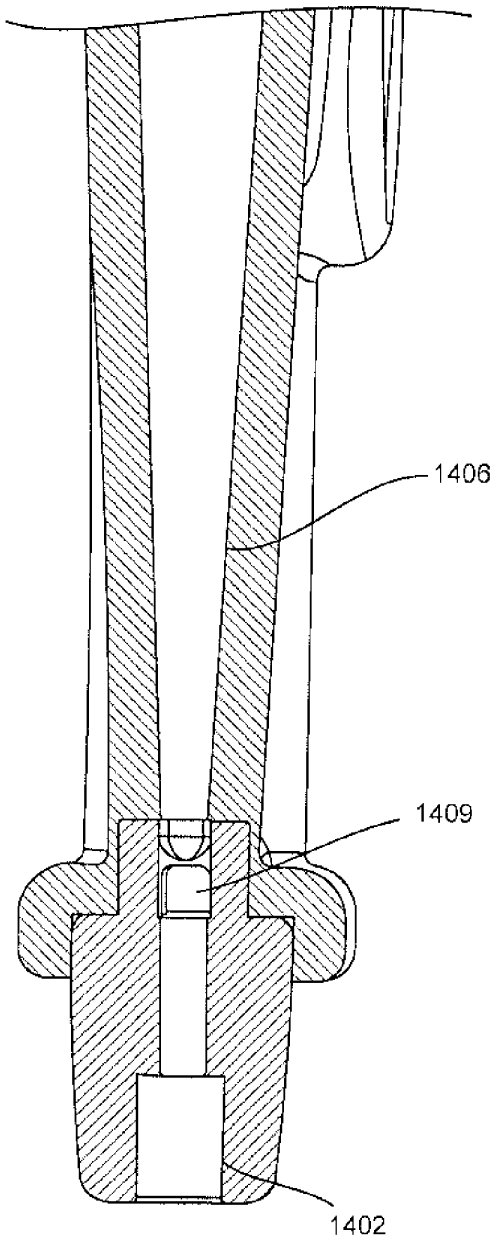


FIG. 14D

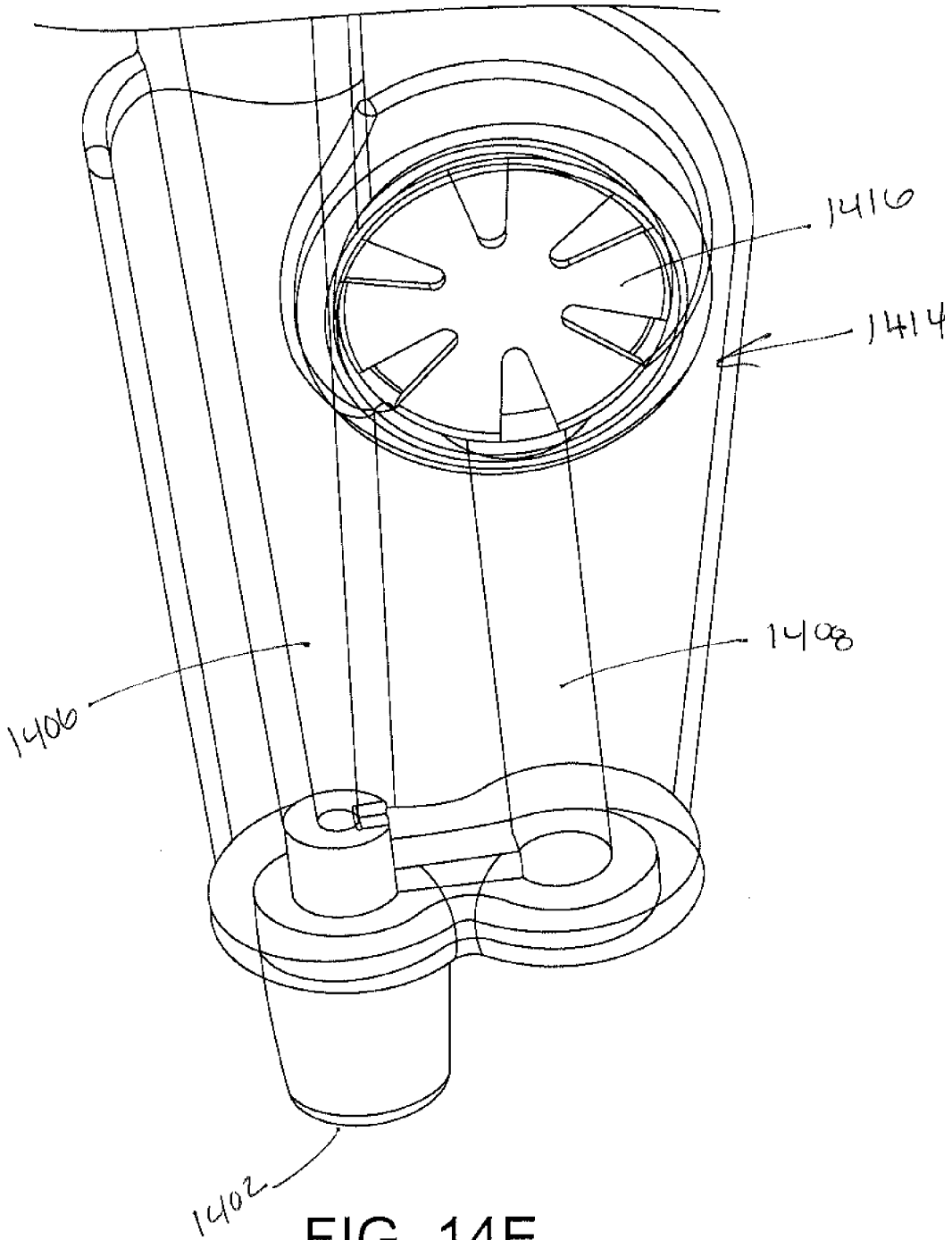


FIG. 14E

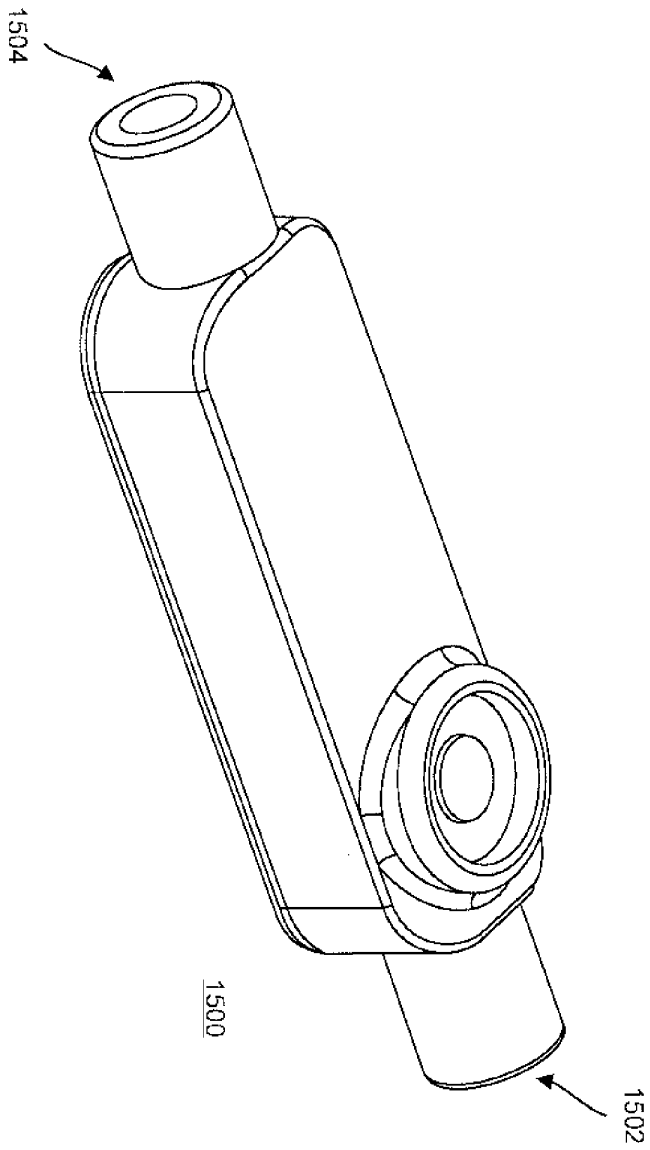


FIG. 15A

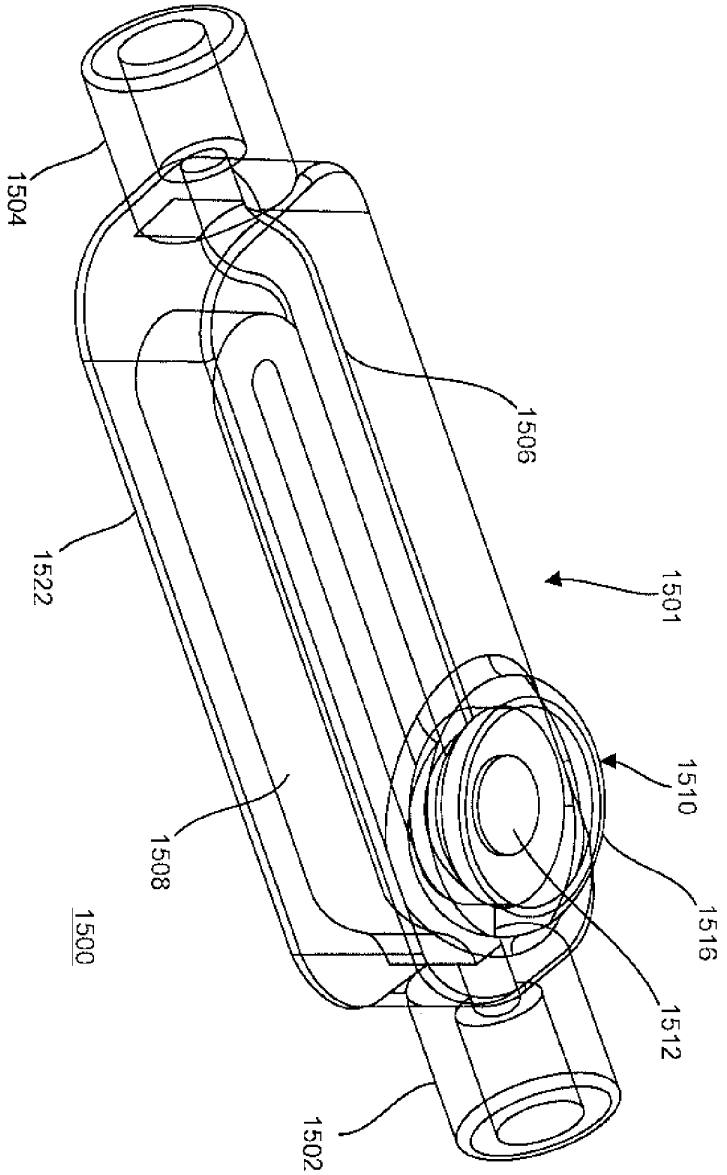


FIG. 15B

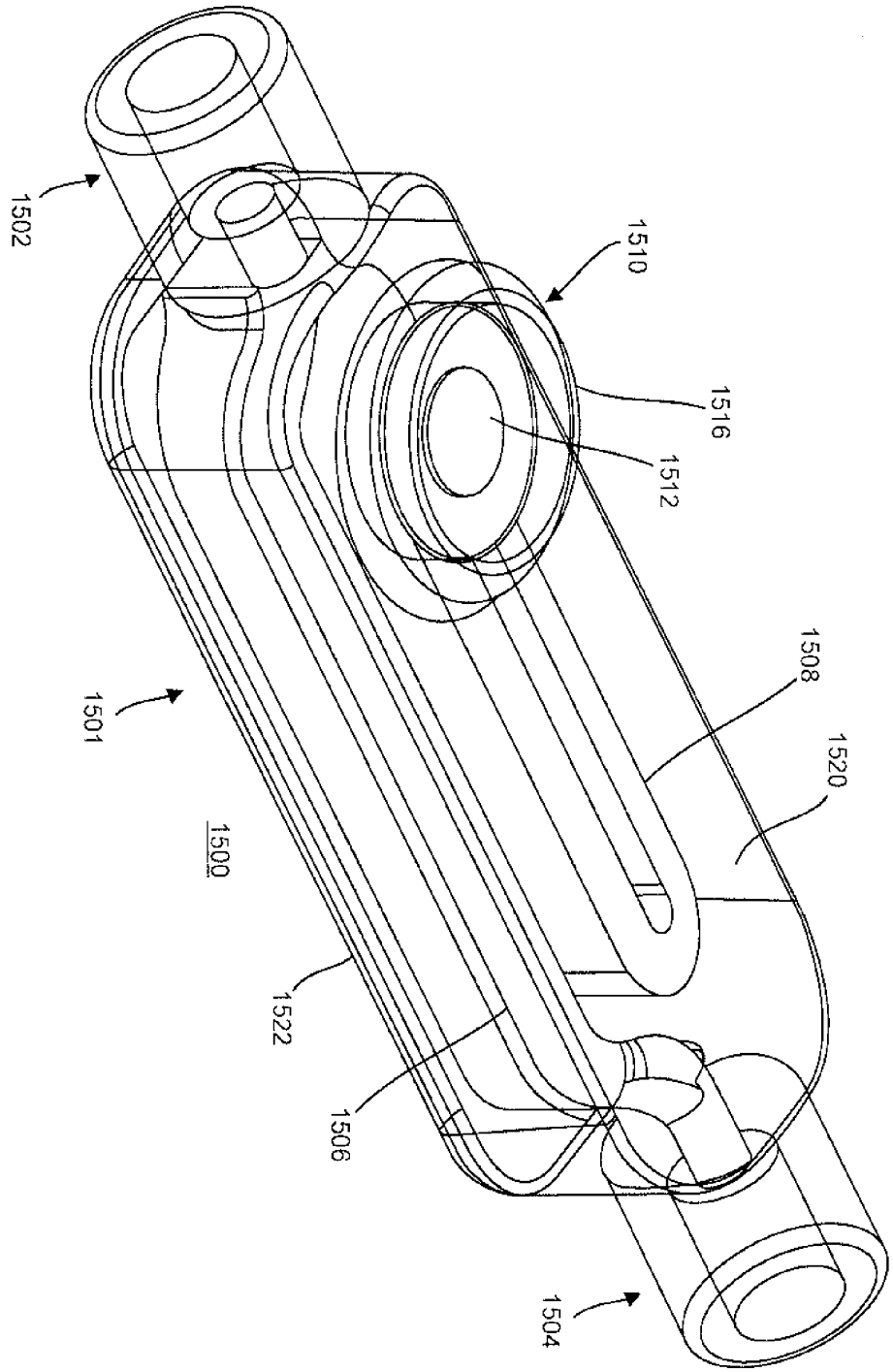


FIG. 15C

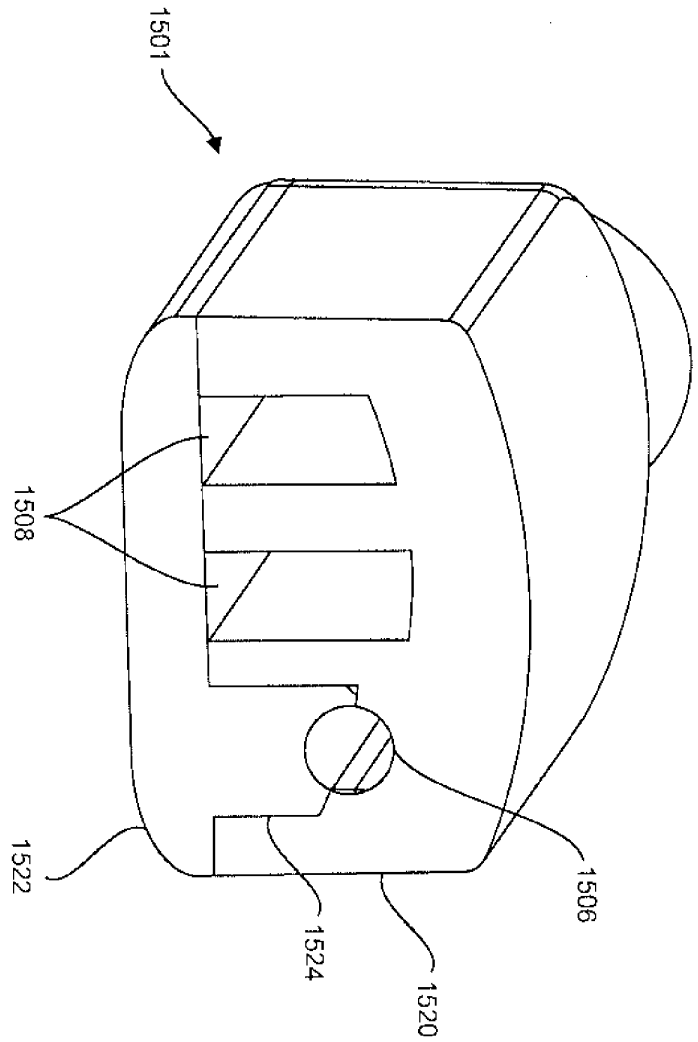


FIG. 15D

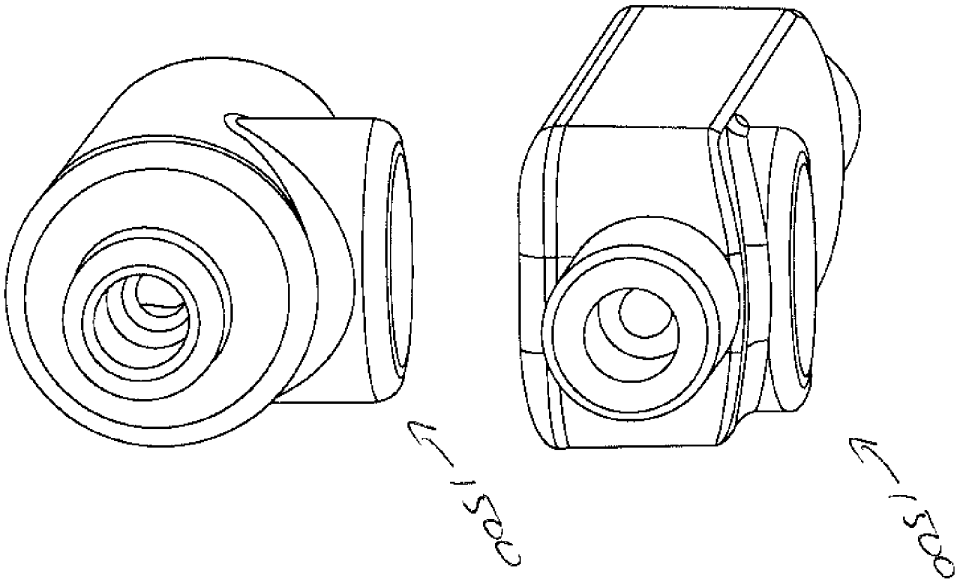


FIG. 15E

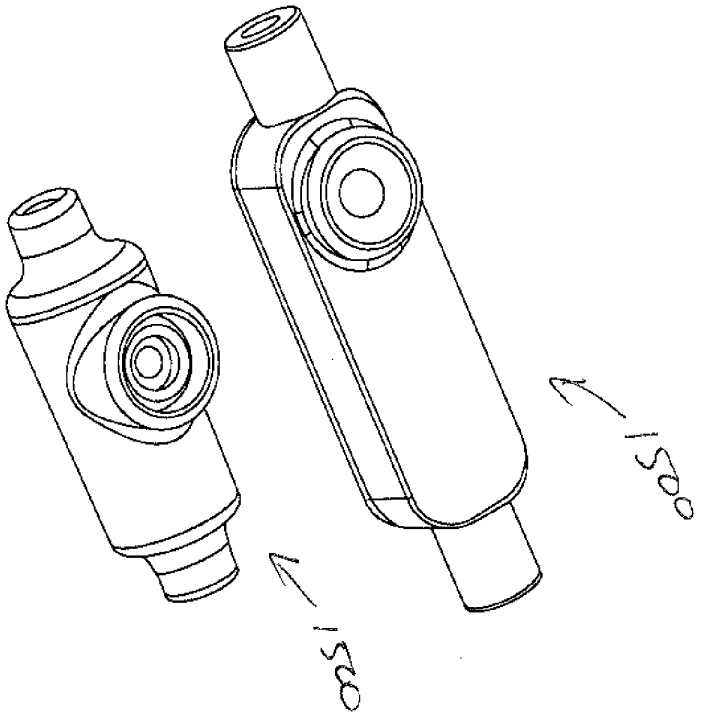


FIG. 15F

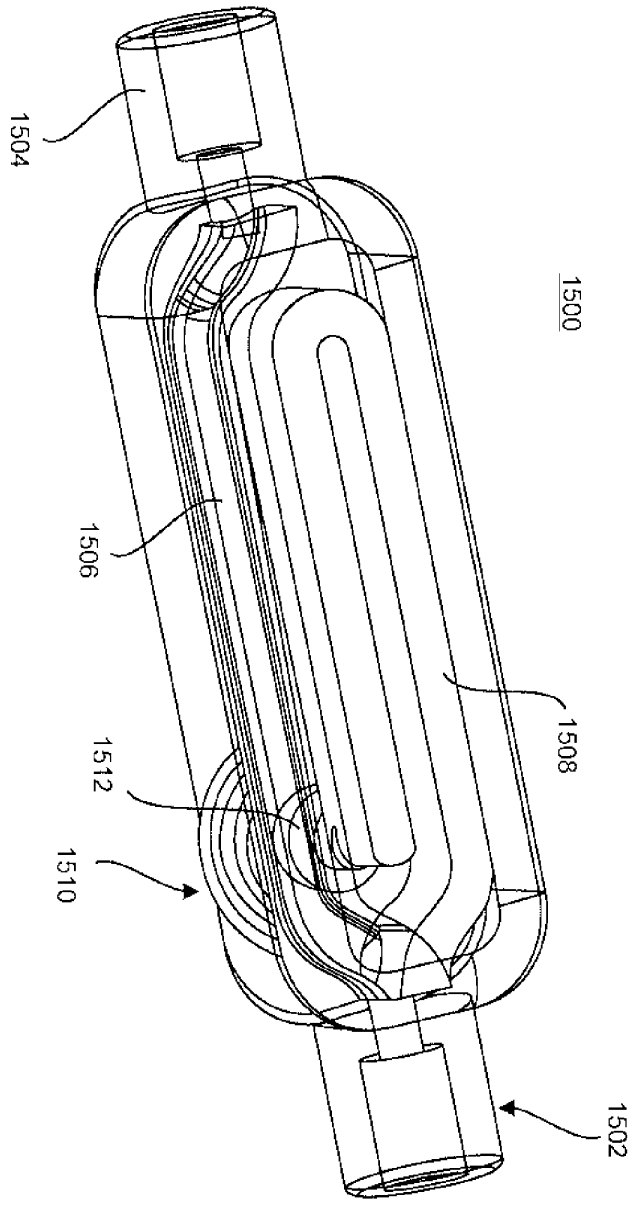


FIG. 15G

FIG. 16B

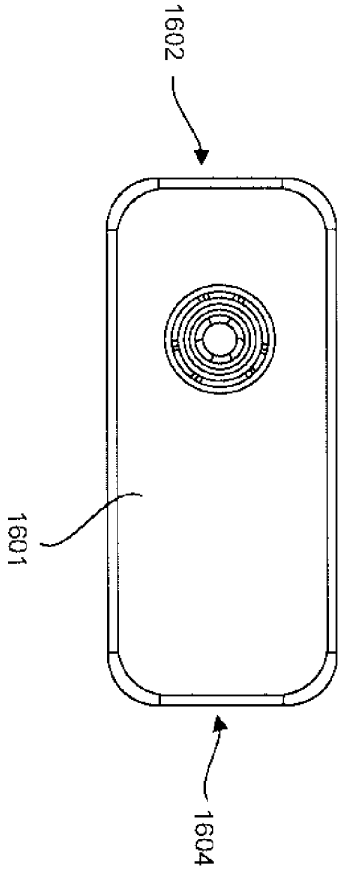


FIG. 16A

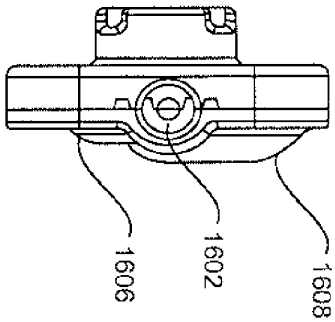


FIG. 16C

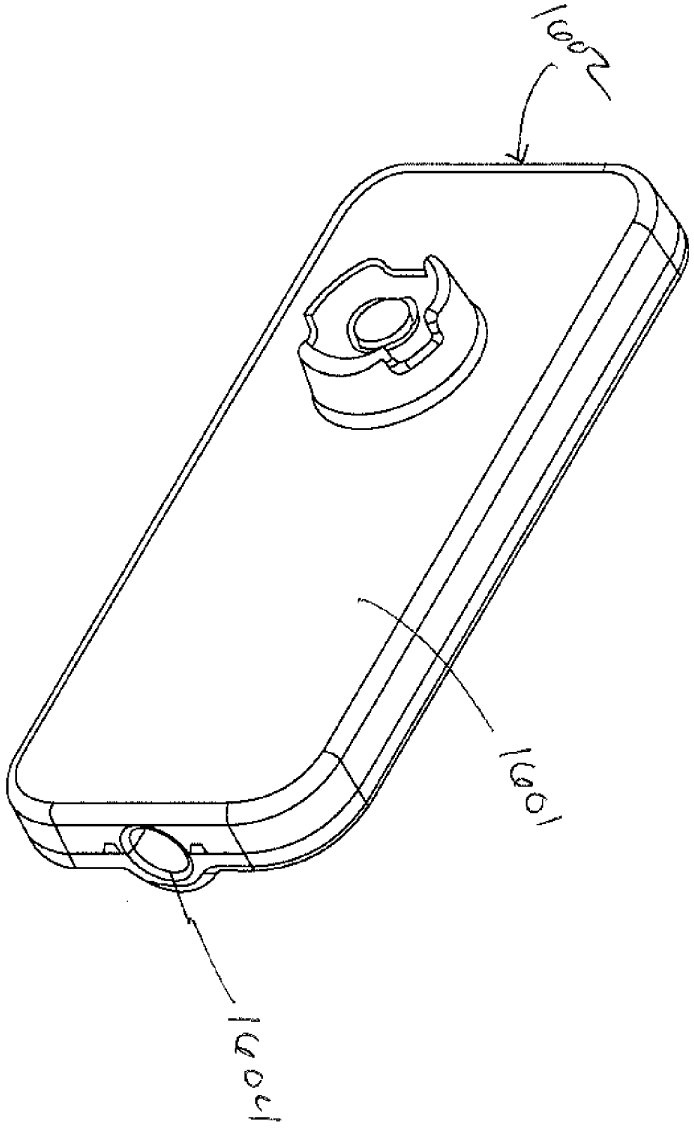


FIG. 16D

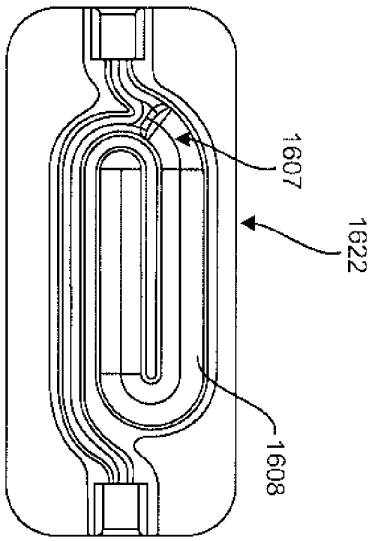


FIG. 17A

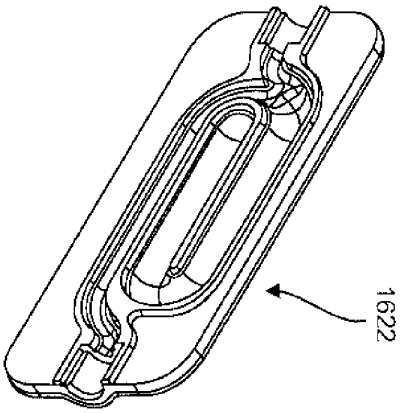


FIG. 17B

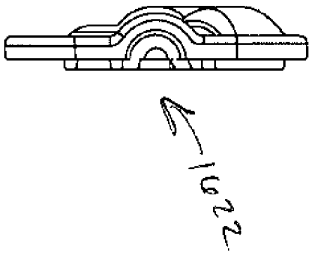


FIG. 17C

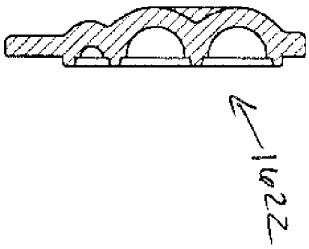


FIG. 17D

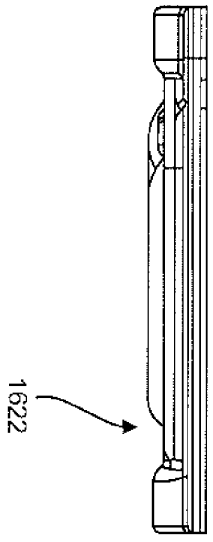


FIG. 17E

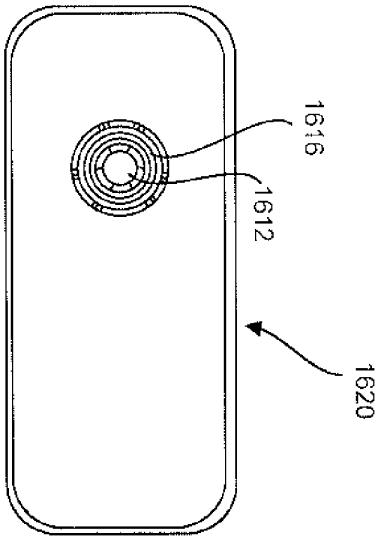


FIG. 18A

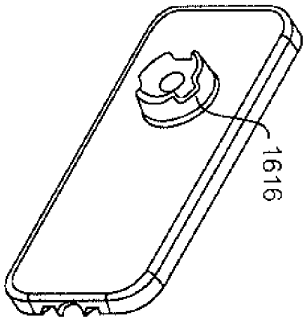


FIG. 18B

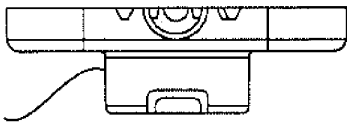


FIG. 18C

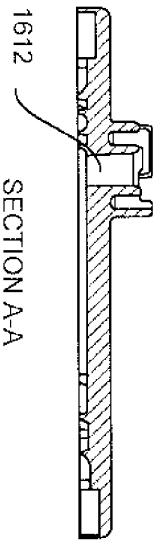


FIG. 18D

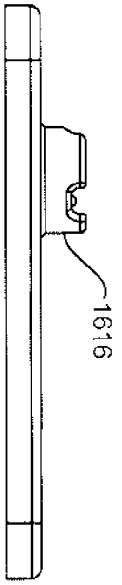


FIG. 18E

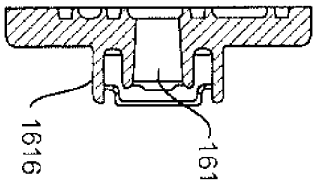


FIG. 18F

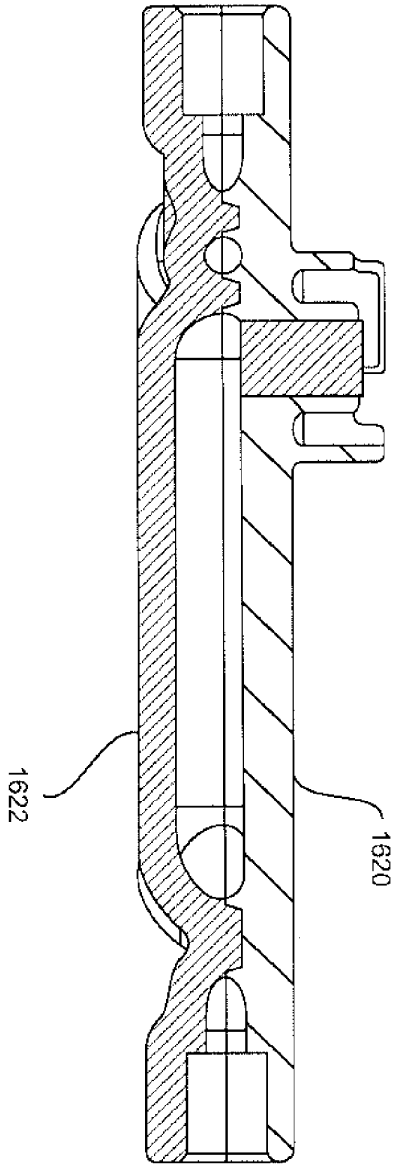


FIG. 19A

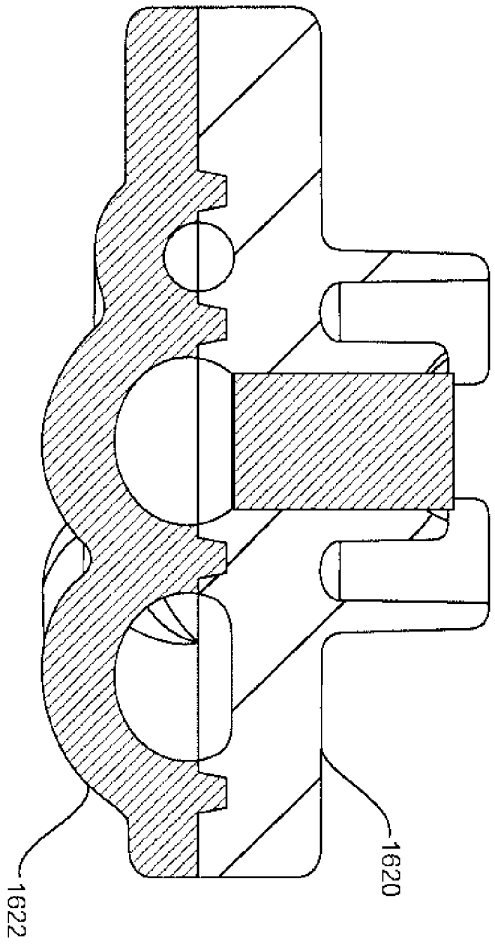


FIG. 19B

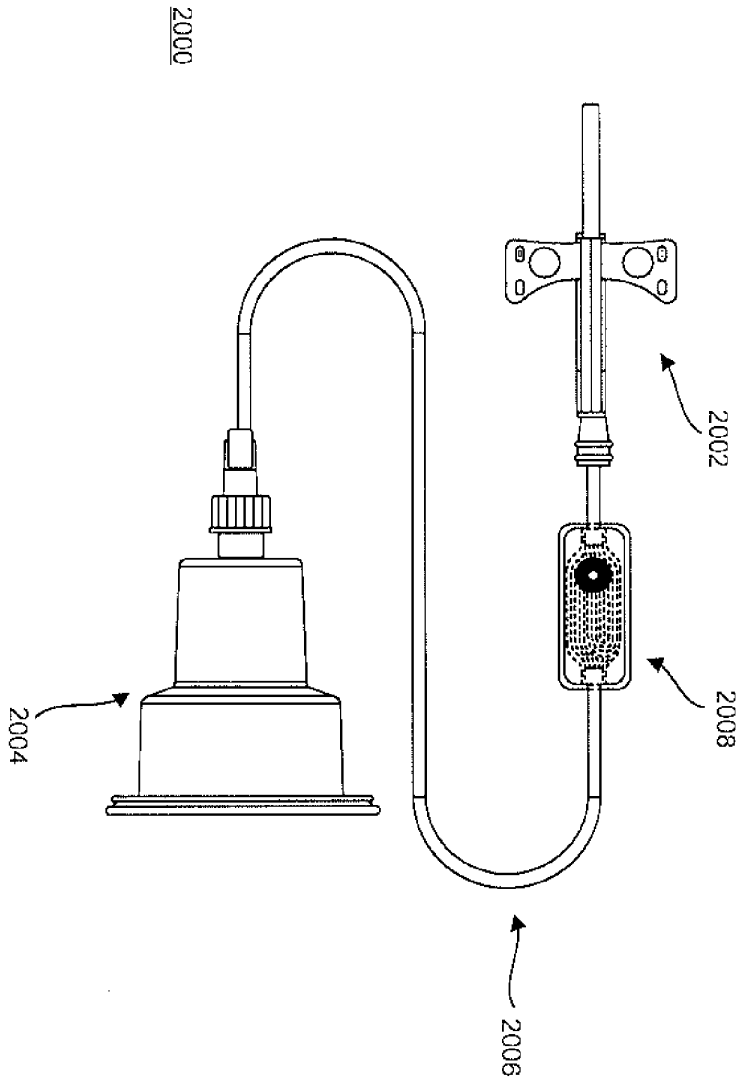


FIG. 20

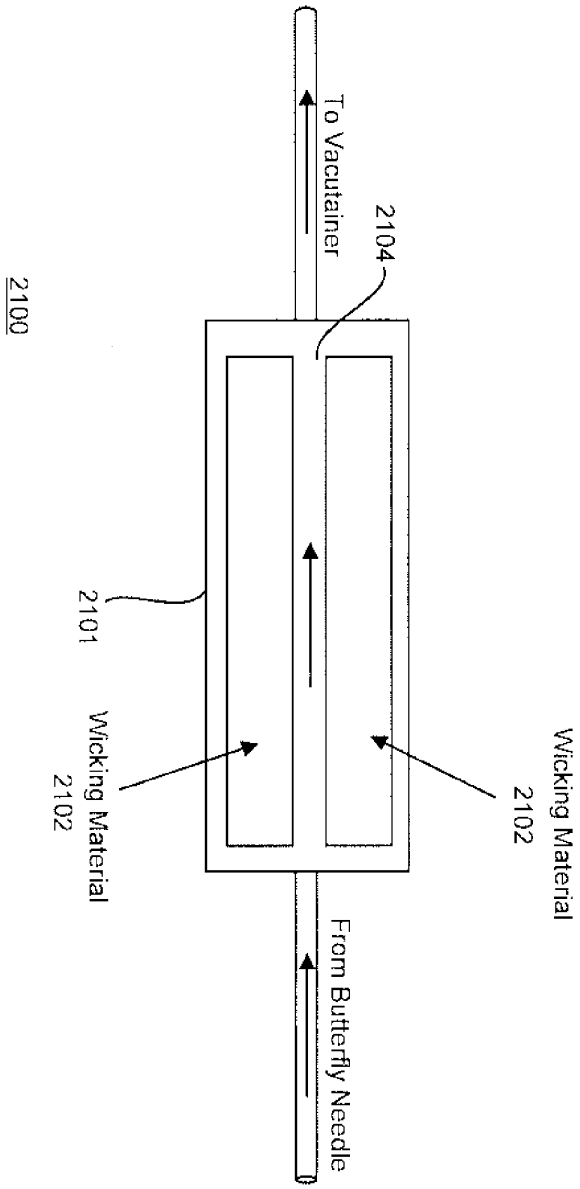

2100
To Vacutainer
2104
2101
Wicking Material
2102
Wicking Material
2102
From Butterfly Needle

FIG. 21

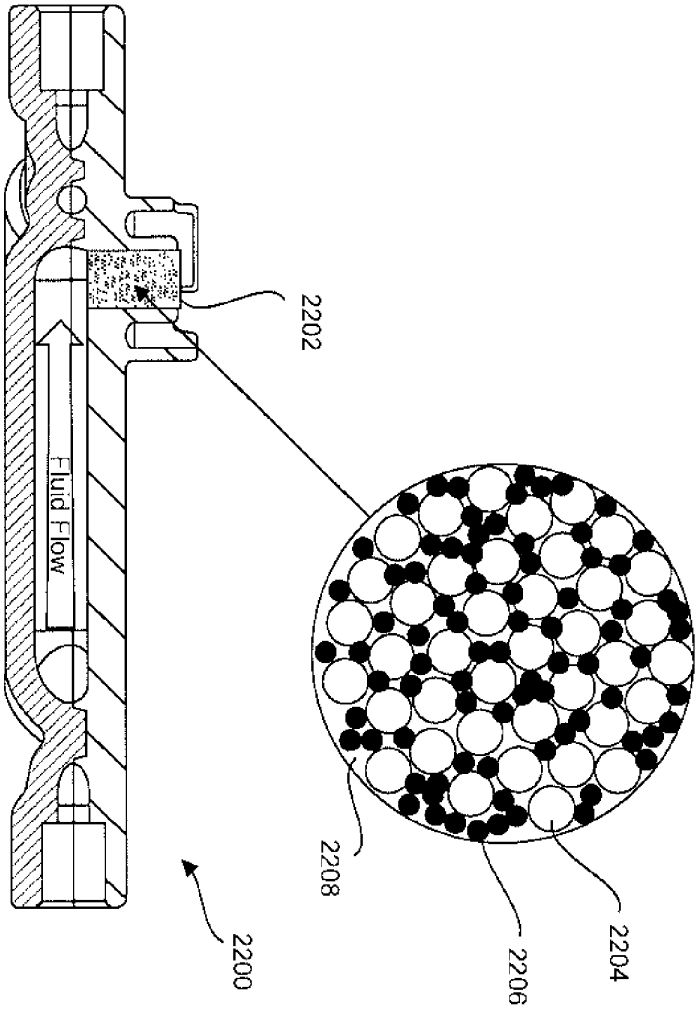


FIG. 22A

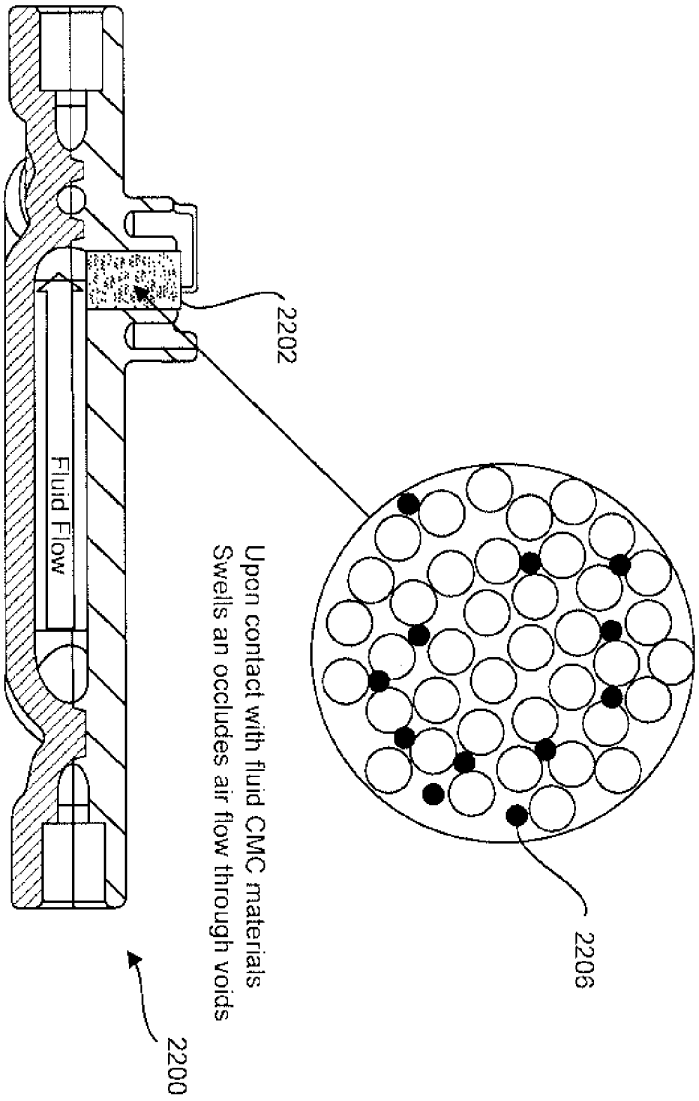

2202
Fluid Flow
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
2206
2200

FIG. 22B

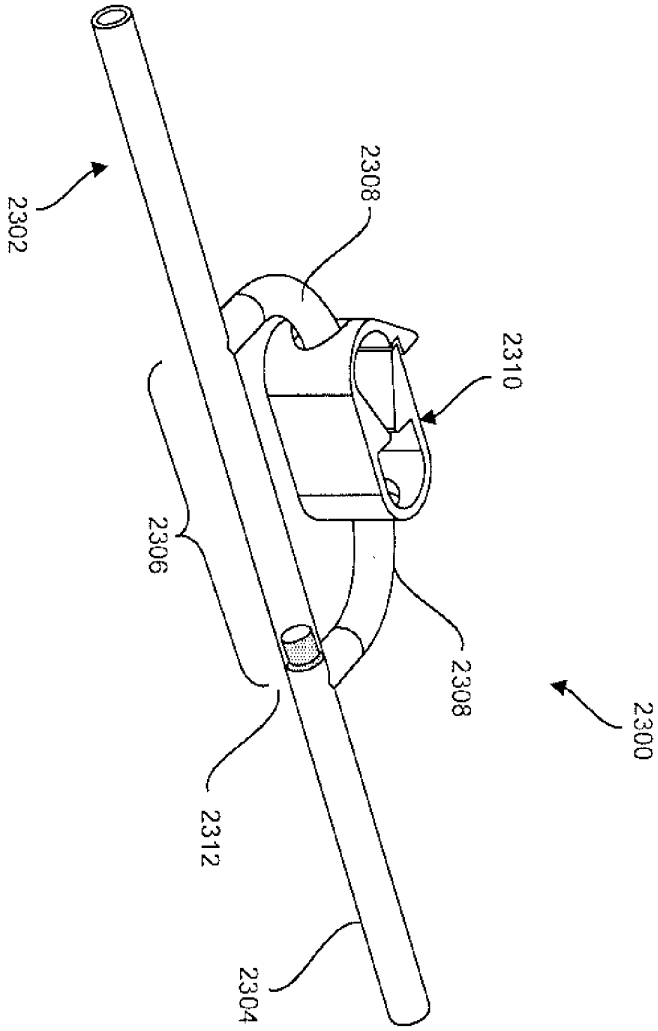


FIG. 23A

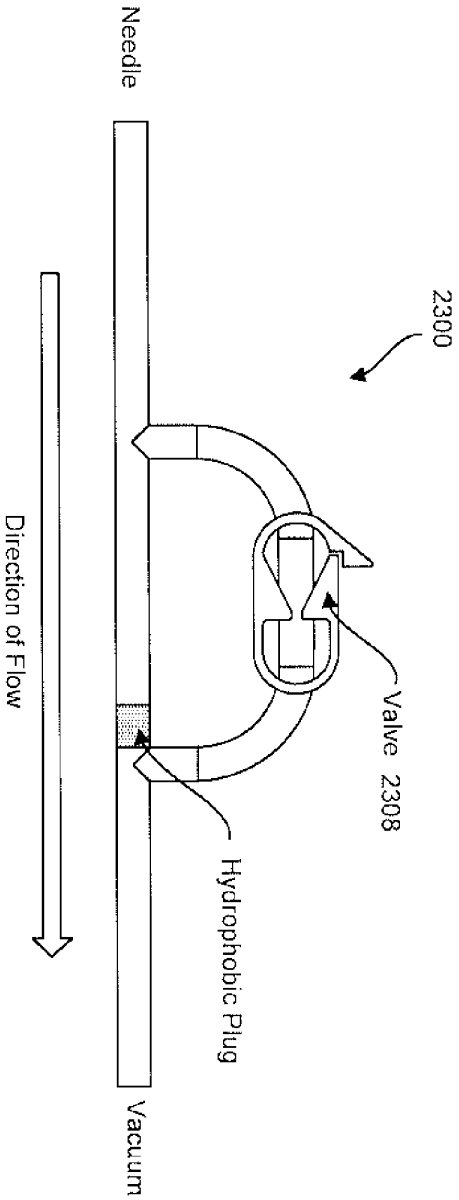

Needle
2300
Valve 2308
Hydrophobic Plug
Vacuum
Direction of Flow

FIG. 23B

katz Presenti & CO

14 September 2023

PILLSBURY WINTHROP SHAW PITTMAN, LLP
P.O. BOX 10500
McLean, VA 22102
USA

By Email Only:
james.conley@pillsburylaw.com
benjamin.hudson@pillsburylaw.com
suzanne.simpson@pillsburylaw.com
Docket_ip@pillsburylaw.com

To the attention of Jim Conley

P.K. 13 - Notice of Acceptance of:

IL Patent Application No.: 300848
a divisional application of IL 286030
Title: BLOOD SAMPLE OPTIMIZATION DEVICE
Filing Date: 21 February 2023
App. date: 22 July 2016
IL NP of PCT Patent Application No.: PCT/US2016/043709
Applicant(s): KURIN, INC.

Dear Jim:

1 We are pleased to report that the above identified Israel Patent Application has been accepted by the Israel Patent Office (ILPO), which issued the herein attached Notice before allowance dated **14 September 2023**.

The Applicant is now required to pay the Allowance Fee, by the due date of **14 December 2023**.

After the payment of the allowance fee the application shall be published for 3rd party opposition for a period of 3 months, after which if no opposition is filed the Certificate of patent will be issued.

This notice of acceptance is based on the following documents:

Drawings dated 21 February 2023
Claims dated 27 July 2023
Description dated 27 July 2023

1. The examination of the above application was based on the following points:
   1.1. The date of the present application, which is a divisional application of IL 286030, has been put forward to the date of 22 July 2016, which is the application

רח' אבא הלל סילבר 14, בית עתן, קומה 11, רמת-גן, 5250607 | info@patents-il.com | 03-9093614 | 03-9326393
+972-3-9326393 | +972-3-9093614 | info@patents-il.com | 14 Abba Hillel Rd. Beit OZ, 11th floor, Ramat Gan 5250607, Israel
www.patents-il.com

date of the parent application. And this in accordance with Section 24(3) of the law.

Attached for your kind attention are:

- The allowed Description
- The allowed Claims
- The allowed Drawings

Please review the attached documents, namely the allowed description, claims and drawings before authorizing us to pay the allowance fee. Of course, we will review the documents as well.

We additionally remind you of the continuing responsibility of the Applicant to update the ILPO with information of cited art and/or opposition procedure and/or cancellation procedures in corresponding Applications under Section 18 of the Israel Patent Law - until the payment of the allowance fee. When the Applicant becomes aware of publications or other citations that may be relevant information/material to the examination of this application, such information/material must be forwarded to us for reporting to the ILPO. Failure to disclose such information to the ILPO may result in cancellation of an issued IL patent.

2

Publications filed after this notice will not be reviewed but will be on record. Should the applicant wish to receive continued examination based on new publications, a request to file for re-examination must be filed along with an update of the list of publications.

Divisional Applications

Please be advised that pursuant to Art. 24(a) of the Act, divisional applications may be filed after the payment of the Allowance fee but before the publication. We highly recommend filng divisional applications before the payment of the allowance fee.

We look forward to receiving your instructions in due course.

Yours sincerely,

Ronen Presenti

רח' אבא הלל סילבר 14, בית עוז, קומה 11, רמת-גן, 5250607 | info@patents-il.com | 03-9093614 | 03-9326393
+972-3-9326393 | +972-3-9093614 | info@patents-il.com | 14 Abba Hillel Rd. Beit OZ, 11th floor, Ramat Gan 5250607, Israel
www.patents-il.com

Submitted herewith

> The original notice in Hebrew.

> The publication documents, namely, Description, Claims, Drawings.

> Our invoice number 3264.

דרך אבא הלל סילבר 14, בית עוז, קומה 11, רמת-גן, 5250607 | info@patents-il.com | 03-9093614 | 03-9326393
+972-3-9326393 | +972-3-9093614 | info@patents-il.com | 14 Abba Hillel Rd. Beit OZ, 11th floor, Ramat Gan 5250607, Israel

www.patents-il.com

Reference No.: F1729JP01
Mailing No.: 662004
Mailing Date: January 16, 2024

Non-final Office Action
(Translation)

Application No.	Japanese Patent Application No. 2021-558648	
Drafting Date	January 5, 2024	
Examiner	Koji ISONO	3411 2Q00
Representative	Satoshi MURAKOSHI, et al.	
Applied Articles	Japanese Patent Act, Section 29, Paragraph 1, Item 3 (novelty)	
	Japanese Patent Act, Section 29, Paragraph 2 (inventive step)	

This application has been rejected for the grounds stated below. Applicant is invited to file a Response within three months from the mailing date of this notice.

Grounds

<Ground 1>

(Novelty) The claim(s) of this application set forth below was/were anticipated by the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are not entitled to obtain a patent under Section 29, Paragraph 1, Item 3 of the Japanese Patent Act.

<Ground 2>

(Inventive step) The claim(s) of this application set forth below would have been obvious to one ordinarily skilled in the art prior to the filing of this application, based on the invention(s) disclosed in the publication(s) below distributed in Japan or foreign countries or the invention(s) made available to the public through electrical communication lines prior to the filing of this application. Therefore, the claim(s) is/are unpatentable under Section 29, Paragraph 2 of the Japanese Patent Act.

Examiner Notes (the cited references are listed in Reference List below)

• Ground 1 (novelty) and Ground 2 (inventive step)

- As to Claims: 1 to 5, 6 to 10, and 14 to 18
- Reference cited: Reference 1
- Notes:

Reference 1 (see particularly paragraphs 0062 and 0140 to 0149 and Figs. 24A to 24B) discloses the following invention.

"A fluid sample optimization device (blood sample optimization system 2400) for optimizing a

fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants (see paragraphs 0062, 0141, etc.), the fluid sample optimization device comprising:

an inlet (inlet port 2412) configured to connect with the fluid source;

an outlet (outlet port 2414) configured to connect with the fluid collection device;

a sample path (blood sample channel 2422) connected between the inlet and the outlet; and

a contaminant containment reservoir (blood sequestration chamber 2418) connected between the inlet and the outlet, the contaminant containment reservoir having an air permeable fluid resistor (air permeable blood barrier 2420) proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (see paragraph 0148 disclosing as follows: 'As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position' and 'Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418')."

Therefore, claims 1 and 14 are disclosed in Reference 1.

As for claim 2, Reference 1 discloses a housing (housing 2416) in paragraph 0146.

As for claim 3, see paragraph 0140 of Reference 1.

As for claim 4, see Figs. 29C and 30A to 30G of Reference 1.

As for claim 5, see paragraph 0144 of Reference 1.

As for claims 6 to 10, Reference 1 discloses in paragraph 0148 "a sample path (blood sample channel 2422) ..., the sample path further having a resistive plug (apertures 2424; see also the first sentence of paragraph 0148) that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path."

Claims 14 to 18 correspond to the "sample optimization devices" of claims 1, 6, and 2 to 4, respectively, having the "fluid source" removed therefrom. Therefore, claims 14 to 18 are disclosed in Reference 1.

Accordingly, claims 1 to 5, 6 to 10, and 14 to 18 are disclosed in Reference 1.

< Allowable Subject Matters >

As to claims 11 to 13 and 19 to 20, no grounds for refusal have been found so far. Applicant would receive an additional Office Action upon finding of any other ground(s) for refusal.

<Reference List>
1. U.S. Patent Application Publication No. 2018/0271425

Record of Search for Prior Art Literature

- Searched Field IPC A61B 5/15 – 5/157
G01N 1/00

- Prior Art Literature
International Publication No. WO 2019/055487

This record of search for prior art literatures does not constitute grounds for refusal.

拒絶理由通知書

特許出願の番号	特願２０２１－５５８６４８
起案日	令和　６年　１月　５日
特許庁審査官	磯野　光司　３４１１　２Ｑ００
特許出願人代理人	村越　智史（ほか　４名）　様
適用条文	第２９条第１項第３号（新規性） 第２９条第２項（進歩性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（新規性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明であるから、特許法第２９条第１項第３号に該当し、特許を受けることができない。

２．（進歩性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第２９条第２項の規定により特許を受けることができない。

記　　（引用文献等については引用文献等一覧参照）

●理由１（新規性）、理由２（進歩性）について

・請求項　１－５，６－１０，１４－１８
・引用文献等　１
・備考
引用文献１（特に、段落[0062],[0140]-[0149]、図24A-24B参照）には、以下の発明が記載されている。
「流体源から流体収集装置によって収集された流体サンプルを最適化するための流体サンプル最適化装置（blood sample optimization system 2400）であって

、前記流体サンプルの第１の部分が汚染物質を潜在的に有しており（段落[0062],[0141]等参照）、
前記流体源と接続するように構成される入口（inlet port 2412）と、
前記流体収集装置に接続するように構成される出口（outlet port 2414）と、
前記入口と前記出口との間に接続されるサンプル経路（blood sample channel 2422）と、
前記入口と前記出口との間に接続される汚染物質封じ込めリザーバ（blood sequestration chamber 2418）と
を備え、
前記汚染物質封じ込めリザーバは、前記出口に近接して空気透過性流体抵抗器（air permeable blood barrier 2420）を有し、
前記汚染物質封じ込めリザーバは、前記入口と前記出口との間に圧力差が印加されたとき、前記流体源から前記流体サンプルの第１の部分を受け取って、前記空気透過性流体抵抗器及び前記出口を通ってその中の空気を移動させるように配置され、それによって、前記汚染物質封じ込めリザーバ内に、前記流体サンプルの前記第１の部分が受け取られ、かつ前記汚染物質が封じ込められると、前記流体サンプルの後続の部分は、前記入口と前記出口との間に後続の圧力差が印加されたときに、前記サンプル経路によって前記入口から前記出口へと搬送され得る（段落[0148]の"As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position."、及び、"Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418."の記載を参照されたい。）、流体サンプル最適化装置。」
よって、請求項１，１４に係る発明は、引用文献１に記載されている。

請求項２について、引用文献１の段落[0146]には、ハウジング（housing 2416）が記載されている。
請求項３については、引用文献１の段落[0140]を参照されたい。
請求項４については、引用文献１の図29C,30A-G等を参照されたい。
請求項５については、引用文献１の段落[0144]を参照されたい。
請求項６－１０について、引用文献１の段落[0148]には、「流体サンプルの前記第１の部分の少なくとも一部及び前記汚染物質が前記サンプル経路に入ることを阻止するように構成される抵抗プラグ（apertures 2424；段落[0148]冒頭の一文も参照されたい。）をさらに有するサンプル経路（blood sample channel 2422）」が記載されている。

請求項１４－１８について、これら請求項に係る発明は、それぞれ請求項１，６，２－４に係る「サンプル最適化装置」の発明から「流体源」を除いたものにあたり、そのため、引用文献１に記載されているといえる。

したがって、請求項１－５，６－１０，１４－１８に係る発明は、引用文献１に記載されている。

＜拒絶の理由を発見しない請求項＞

請求項（１１－１３，１９－２０）に係る発明については、現時点では、拒絶の理由を発見しない。拒絶の理由が新たに発見された場合には拒絶の理由が通知される。

＜引用文献等一覧＞

１．米国特許出願公開第２０１８／０２７１４２５号明細書

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

＜先行技術文献調査結果の記録＞

・調査した分野　　ＩＰＣ　　A61B 5/15-5/157
G01N 1/10

・先行技術文献
国際公開第２０１９／０５５４８７号

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません。

この拒絶理由通知の内容に関するお問合せ又は面接のご希望がありましたら次の連絡先までご連絡ください。電子メール等で補正案等の送付を希望される場合は、その旨を電話でお知らせください。

審査第一部分析診断（医学診断）（PA2J）　磯野光司（いその　こうじ）
ＴＥＬ．０３－３５８１－１１０１　内線３２９１

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18783088
Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1							☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

PC 6.1.24

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783088
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580418_KUR2C06US

	1	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
	2	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
	3	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
	4	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
	5	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
	6	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	7	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
	8	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
	9	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
	10	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐
	11	Office Action (Non-Final Rejection) mailed 04/16/2024 for Application No. 16838017, pages 1-19.	☐

PC 6.1.24

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783088
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580418_KUR2C06US

	12	Second Office Action dated 04/28/2024 for CN Application No. 202080000666.0, pages 1-28.	☐
	13	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	14	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	15	European Patent Office, Examination Report for European Patent Application 21818838.1, dated April 22, 2024, pages 1-11.	☐
	16	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐
	17	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PC 6.1.24

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783088
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	First Named Inventor	Bobby E. ROGERS
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	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580418_KUR2C06US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PC 6.1.24

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

פ.ק 13

תאריך : כ״ג שבט תשפ״ג
14/02/2023
מספרכם : 1000-018-01

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה לפני קיבול בקשת פטנט מספר 267684</u>**

סימוכין : מכתבכם מיום 23/10/2022

לתשומת לבכם: מקום בו הנכם מופנים ל״חוק״, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים ל״תקנות״, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. בהתאם לחוזר רשם 035/2017 – פטנטים **לא ניתן להשהות פרסום בקשות פטנט לפי סעיף 26 לחוק.**

<u>הודעה זו מבוססת על המסמכים הבאים:</u>
שרטוטים מתאריך : 26/06/2019
פרטי הבקשה מתאריך : 26/06/2019
תביעות מתאריך : 23/10/2022

<u>מענה לטיעוני המבקש</u>
מערכת התביעות המוצעת מתקבלת.

<u>הריני להודיעכם כי בחינת הבקשה הנ״ל הושלמה לפי הוראות סעיף 48ו(ג)(1) ו- (2) לחוק.</u>

<u>תשלום אגרת קיבול</u>
1. הבקשה תתקבל בהתאם לסעיף 26 לחוק לאחר תשלום אגרת הקיבול.
2. יש לשלם את האגרה תוך 3 חודשים מתאריך הודעה זו.
3. סכום האגרה נכון למועד הודעה זו הינו 764.00 ש״ח. הסכום כפוף לעדכונו על פי המדד בהתאם לתקנה 6א.

<u>הפניה בפירוט למסמך הבכורה</u>
לפי הוראות **סעיף 20 לחוזר הרשם 034/2017-פטנטים** במידה ופירוט הבקשה מכיל הפניה למסמך בכורה באמצעות הביטוי ״incorporated by reference״ ובמידה וחלפו 14 חודשים ממועד דין הקדימה (אם נדרש) לא ניתן עוד להוסיף דבר מתוך מסמך הבכורה והמבקש לא יכול להסתמך על האמור במסמך הבכורה, לצורך סעיפים 12 ו-13 לחוק.

<u>עדכון רשימות האסמכתאות והפרסומים לפי סעיף 18א לחוק</u>

לתשומת לבכם, בהתאם להוראות פרק ג' בחוזר רשם 035/2017-פטנטים חובת המבקש לעדכן את הרשות בכל שינוי שחל ברשימת הפרסומים בהתאם לסעיף 18 לחוק נמשכת עד קיבול הבקשה.

באם ברצונכם להחזיר את הבקשה לבחינה בעקבות שינוי ברשימת הפרסומים שהתרחש לאחר תשובתכם להודעת הליקויים האחרונה, עליכם להגיש בקשה לבחינה חוזרת בה עליכם לציין מהו השינוי ברשימת הפרסומים ומתי נודע על שינוי זה.

בקשה לבחינה חוזרת יש להגיש באמצעות פניה ל-"בקשה לתיקונים לאחר פ.ק. 13".

<u>הגשת בקשות חלוקה</u>

בהתאם להוראות סעיף 24(א) לחוק זכאי המבקש כל עוד לא קובלה הבקשה לדרוש את חלוקת הבקשה לבקשות אחדות. לפיכך, באם ברצונכם להגיש בקשות חלוקה מבקשה זו עליכם לעשות זאת בטרם מועד הקיבול. לא נוכל להכיר בבקשות שיוגשו לאחר מועד הקיבול של הבקשה הנוכחית כבקשות חלוקה לעניין סעיף 24(ג) לחוק.

<u>בדיקה פורמלית</u>

להודעה הנוכחית מצורף העתק פירוט הבקשה המעודכן - אם נפלו טעויות נא להודיע עליהן לרשות לפני מועד תשלום אגרת הקיבול.

לצורך אימות פרטי הפרסום בהתאם לסעיף 26 לחוק ניתן לעיין בנסח הבקשה באתר הרשות בקישור הבא:

https://israelpatents.justice.gov.il/#/en/patent-extract/267684

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

https://israelpatents.justice.gov.il/#/en/patent-file/details/267684

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
טלפון: 073-3927233
דואר אלקטרוני: albertak@justice.gov.il
ראש צוות: מוריה שלמה לוי

katz Presenti & CO

20 February 2023

PILLSBURY WINTHROP SHAW PITTMAN, LLP
P.O. BOX 10500
McLean, VA 22102
USA

By Email Only:
james.conley@pillsburylaw.com
benjamin.hudson@pillsburylaw.com
suzanne.simpson@pillsburylaw.com
Docket_ip@pillsburylaw.com

To the attention of Jim Conley

P.K. 13 - Notice of Acceptance of:

IL Patent Application No.: 267684
Title: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
Filing Date: 26 June 2019
App. date: 27 December 2017
IL NP of PCT Patent Application No.: PCT/US2017/068569
Applicant(s): KURIN, INC.

Dear Jim:

1

We are pleased to report that the above identified Israel Patent Application has been accepted by the Israel Patent Office (ILPO), which issued the herein attached Notice of Acceptance dated **14 February 2023**.

The Applicant is now required to pay the Allowance Fee, by the due date of **14 May 2023**.

After the payment of the allowance fee the application shall be published for 3rd party opposition for a period of 3 months, after which if no opposition is filed the Certificate of patent will be issued.

This notice of acceptance is based on the following documents:

Drawings dated 26 June 2019
Claims dated 23 October 2022
Description dated 26 June 2019

The examiner has advised that the applicant must inform the ILPO should any opposition procedure or requests to cancel the parallel AU patent are filed before and up to the date of Grant of this application

Attached for your kind attention are:

- The allowed Description
- The allowed Claims
- The allowed Drawings

Please review the attached documents, namely the allowed description, claims and drawings before authorizing us to pay the allowance fee. Of course, we will review the documents as well.

We additionally remind you of the continuing responsibility of the Applicant to update the ILPO with information of cited art and/or opposition procedure and/or cancellation procedures in corresponding Applications under Section 18 of the Israel Patent Law - until the payment of the allowance fee. When the Applicant becomes aware of publications or other citations that may be relevant information/material to the examination of this application, such information/material must be forwarded to us for reporting to the ILPO. Failure to disclose such information to the ILPO may result in cancellation of an issued IL patent.

Publications filed after this notice will not be reviewed but will be on record. Should the applicant wish to receive continued examination based on new publications, a request to file for re-examination must be filed along with an update of the list of publications.

2

Divisional Applications

Please be advised that pursuant to Art. 24(a) of the Act, divisional applications may be filed after the payment of the Allowance fee but before the publication. We highly recommend filng divisional applications before the payment of the allowance fee.

We look forward to receiving your instructions in due course.

Yours sincerely,

Ronen Presenti

רח' אבא הלל סילבר 14, בית עוז, קומה 11, רמת-גן, 5250607 | info@patents-il.com | 03-9093614 | 03-9326393
+972-3-9326393 | +972-3-9093614 | info@patents-il.com | 14 Abba Hillel Rd. Beit OZ, 11th floor, Ramat Gan 5250607, Israel
www.patents-il.com

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דרך אבא הלל סילבר 14, בית עוז, קומה 11, רמת-גן, 5250607 | info@patents-il.com | 03-9093614 | 03-9326393
+972-3-9326393 | +972-3-9093614 | info@patents-il.com | 14 Abba Hillel Rd. Beit OZ, 11th floor, Ramat Gan 5250607, Israel

www.patents-il.com

BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

ABSTRACT

Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

BACKGROUND

[0001] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0002] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0003] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of

rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0004] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0005] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0006] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0007] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0008] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic

needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0009] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0010] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0011] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0012] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0013] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate

short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0014] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0015] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0016] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0017] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0018] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0019] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0020] The blood sequestration device, in one aspect can include an inlet port, an outlet port, a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further includes a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber, and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In certain related aspects, the sequestration chamber, the sampling channel and the junction are sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0021] In another aspect, the sampling channel and the junction is sized and configured such that a first portion of blood flows into and fills the sequestration chamber to displace air therein through the vent, and such that a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0022] The blood sequestration and sampling system sequestration device, in certain aspects can include a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and a blood sequestration device attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway. The blood sequestration device in one aspect can include an inlet port coupled with the blood sampling pathway toward the patient needle, an outlet port coupled with the blood sampling pathway toward the sample collection device, a sequestration chamber connected with the inlet port via a junction, which chamber has a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In a certain related aspect, the sequestration chamber, the sampling channel and the junction can be sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0023] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the

sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0024] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] These and other aspects will now be described in detail with reference to the following drawings.

[0026] FIG. 1 illustrates a blood sample optimization system.

[0027] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0028] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0030] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0031] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0032] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0033] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0034] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0035] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0036] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0037] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0038] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0039] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0040] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0041] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0042] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0043] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

[0044] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0045] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0046] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0047] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0048] FIGS. 23A – 23E illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0049] FIGS. 24A – 24D illustrate another implementation of a blood optimization system and blood sequestration device.

[0050] FIGS. 25A – 25D illustrate another implementation of a blood optimization system and blood sequestration device.

[0051] FIGS. 26A – 26E illustrate another implementation of a blood optimization system and blood sequestration device.

[0052] FIGS. 27A – 27D illustrate another implementation of a blood optimization system and blood sequestration device.

[0053] FIGS. 28A – 28F illustrate another implementation of a blood optimization system and blood sequestration device.

[0054] FIGS. 29A – 29C illustrate another implementation of a blood optimization system and blood sequestration device.

[0055] FIGS. 30A – 30G illustrate another implementation of a blood optimization system and blood sequestration device.

[0056] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0057] This document describes blood sample optimization systems and methods for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and

a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0058] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0059] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0060] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable

material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0061] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0062] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0063] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0064] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0065] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0066] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0067] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0068] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0069] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to

obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0070] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0071] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0072] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0073] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out

of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0074] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0075] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0076] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be

connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0077] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0078] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0079] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a

patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0080] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0081] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0082] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration

chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0083] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0084] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0085] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0086] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™,

associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0087] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0088] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0089] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0090] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define

housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0091] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0092] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a

blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0093] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0094] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0095] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air

permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0097] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0098] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0099] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00100] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[00101] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[00102] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[00103] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[00104] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00105] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration

device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[00106] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[00107] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[00108] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00109] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The

protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00110] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00111] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the inlet port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or

partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00112] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00113] In some instances, as shown in FIG. 15H, an inlet port 1532 can include a male luer connector for connecting to a removable patient needle, and an outlet port 11534 can include a female luer connector for connecting with a syringe. This implementation of the inlet port and outlet port can be used with any device described herein, for avoiding a propensity of a Vacutainer-type device collapsing a patient's vein. In this implementation, a clinician can use the syringe in a modulated fashion to obtain a blood sample. In operation, the syringe is attached to the outlet port 1004, and the needle is attached to the inlet port 1002. A venipuncture is performed with the needle, and without the clinician pulling on the syringe. An initial aliquot of blood fills a sequestration chamber, and then the syringe can be used to draw a sample of blood through the collection channel, bypassing the sequestered blood in the sequestration chamber.

[00114] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an inlet port, and outlet port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be

understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00115] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00116] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00117] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00118] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber

1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00119] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00120] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00121] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17E and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17E illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or

other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00122] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00123] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00124] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00125] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member

1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective member 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00126] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 1606 is directed to an outlet port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00127] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00128] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be

provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00129] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00130] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00131] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00132] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00133] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling

device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00134] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00135] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00136] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel 2308

before the initial aliquot of blood is sequestered in the sequestration chamber 2306. For instance, valve 2308 can also be formed as a flap, door or closable window or barrier within the sampling channel 2308.

[00137] FIGS. 23C – 23E illustrate an alternative implementation of the blood sequestration device 2300', in which a sequestration chamber 2320 branches off from a main collection channel 2322 between an inlet port 2316 to connect with a patient needle and an outlet port 2318 to connect with a blood sample collection device, such as a Vacutainer, a syringe, or the like. The sequestration chamber 2320 includes an air-permeable, blood impermeable blood barrier 2324, such as a hydrophobic plug of material, or a filter formed of one or more layers, for example. A valve 2324 closes off and opens the collection channel 2322, and the device 2300' can be used similarly as described above.

[00138] FIG. 24A – 24D illustrate a blood sample optimization system 2400 that includes a patient needle 2402 for vascular access to a patient's bloodstream, a blood sample collection device 2404 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2406 providing a fluid connection between the patient needle 2402 and the blood sample collection device 2404. In some implementations, the blood sample collection device 2404 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2402.

[00139] The blood sample optimization system 2400 further includes a blood sequestration device 2408, located at any point on the conduit 2406 between the patient needle 2402 and the blood sample collection device 2404. The location of the blood sequestration device 2408 can be based on a length of the conduit between the blood sequestration device 2408 and the patient needle 2402, and the associated volume that length provides.

[00140] The blood sequestration device 2408 includes an inlet port 2412 for being connected to the conduit 2406 toward the patient needle 2402, and an outlet port 2414 for being connected to the conduit 2406 toward the blood sample collection device 2404, and a housing 2416. The housing 2416 can be any shape, although it is shown in FIGS. 24A

– D as being substantially cylindrical, and includes the inlet port 2412 and outlet port 2414, which can be located anywhere on the housing although shown as being located on opposite ends of the housing 2416.

[00141] The blood sequestration device 2408 further includes a blood sequestration chamber 2418 connected with the inlet port 2412. The blood sequestration chamber 2418 is defined by an inner chamber housing 2419 that is movable from a first position to receive and sequester a first aliquot of blood, to a second position to expose one or more apertures 2424 at a proximal end of the inner chamber housing 2419 to allow blood to bypass and/or flow around the inner chamber housing 2419 and through a blood sample channel 2422 defined by the outer surface of the inner chamber housing 2419 and the inner surface of the housing 2416. The blood sequestration chamber 2418 includes an air permeable blood barrier 2420 at a distal end of the blood sequestration chamber 2418.

[00142] In operation, the inner chamber housing 2419 is in the first position toward the inlet port 2412, such that the one or more apertures 2424 are closed, and the blood sequestration chamber 2418 is in a direct path from the patient needle. Upon venipuncture of a patient, and drawing of blood by way of a syringe or Vacutainer, or other blood collection device 2404, the initial aliquot of blood flows into the blood sequestration chamber 2418. As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position. The inner chamber housing 2419 and/or housing 2416 can include a locking mechanism of one or more small tabs, grooves, detents, bumps, ridges, or the like, to maintain the inner chamber housing 2419 in the first position until the blood sequestration chamber 2418 is filled, providing force to overcome the locking mechanism to enable movement of the inner chamber housing 2419 to the second position. Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.

[00143] As described above, the housing 2416 and/or inner chamber housing 2419 can be formed as cylindrical and concentric, but can be any shape, such as squared, rectangular, elliptical, oval, or other cross-sectional shape. The outer surface of the distal

end of the inner chamber housing 2419 can have one or more outwardly projecting tangs 2421with gaps therebetween. The tangs 2421 contact the inner surface of the housing 2416 to help define the blood sampling channel 2422 therebetween, and to help stop the inner chamber housing 2419 in the second position. The gaps between the tangs 2421 enable blood to flow through the blood sampling channel 2422 and to the outlet port 2414. When the inner chamber housing 2419 is in the second position and the blood sequestration chamber 2418 is filled with the first aliquot of blood, further blood samples will automatically flow through the inlet port 2412, through the one or more apertures 2424, through the blood sampling channel 2422, through the gaps between the tangs 2421, and ultimately through the outlet port 2414 to be collected by a blood sampling device 2404.

[00144] FIGS. 25A – D show a blood optimization system 2500 and blood sequestration device 2502, formed substantially as described in FIGS. 15, 16, 17, 18 and 19, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2520. Air initially in the blood sequestration chamber 2520 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2520. The air venting mechanism includes an air permeable blood barrier 2506, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2520.

[00145] The air venting mechanism includes an inner wall 2516 that at least partially circumscribes or surrounds the air permeable blood barrier 2506, and an outer wall 2504 spaced apart from the inner wall 2516. The outer wall 2504 can have one or more air vents 2514 formed therein. The outer wall 2504 extends higher upward than the inner wall 2516, such that a lid 2510, such as a cap, plug, cover, etc., can be attached to the outer wall 2504 and be displaced by a small distance from the top of the inner wall 2516. A seal 2508 in the form of a silicone wafer, or other elastomeric material, fits within the outer wall 2504 to cover the air permeable blood barrier 2506 and abut the top of the inner wall 2516. The seal 2508 covers and seals the air permeable blood barrier 2506 and inhibits air from entering the blood sequestration chamber 2520 through the air permeable blood barrier 2506. A fulcrum 2512 on an underside of the lid 2510 allows the seal 2508 to flexibly disconnect from the top of the inner wall 2516 when pushed by air displaced from the blood sequestration chamber 2520, to allow air to vent from the air

permeable blood barrier 2506 and through the one or more air vents 2514 in the outer wall 2504.

[00146] FIG. 26A – E illustrate a blood sample optimization system 2600 that includes a patient needle 2602 for vascular access to a patient's bloodstream, a blood sample collection device 2604 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2606 providing a fluid connection between the patient needle 2602 and the blood sample collection device 2604. The conduit 2606 can include flexible tubing. In preferred implementations, the blood sample collection device 2604 includes a protective shield 2605 that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2602.

[00147] The blood sample optimization system 2600 further includes a blood sequestration device 2608, located at any point on the conduit 2606 between the patient needle 2602 and the blood sample collection device 2604. The location of the blood sequestration device 2608 can be based on a length of the conduit between the blood sequestration device 2608 and the patient needle 2602, and the associated volume that length provides.

[00148] The blood sequestration device 2608 includes an inlet port 2612 for being connected to the conduit 2606 toward the patient needle 2602, and an outlet port 2614 for being connected to the conduit 2606 toward the blood sample collection device 2604. The blood sequestration device 2608 includes an outer housing 2616 and an inner housing 2617, both having a cylindrical form, and being connected concentrically. The outer housing 2616 includes an outer wall 2618 and an inner conduit 2620 that defines a blood sampling channel 2622 to convey blood through the conduit 2606 to the blood sampling device 2604. The inner housing 2617 fits snugly between the inner conduit 2620 and the outer wall 2618 of the outer housing, and is rotatable in relation to the outer housing 2616. The fit between the outer housing 2616 and the inner housing 2617 can be a friction fit that maintains the housings in a particular position. The inner housing 2617 defines a blood sequestration chamber 2624, preferably a helical or corkscrew channel around the outer surface of inner conduit 2620 of the outer housing 2616, and which

terminates at an air vent 2628 having an air permeable blood barrier, as shown in FIG. 26E.

[00149] The blood sequestration chamber 2624 is connected with the blood sampling channel 2622 via diversion junction 2624 formed in the inner conduit 2620, when the blood sequestration device in a first state, illustrated in FIG. 26C. The protective shield 2606 on the collection needle 2604 provides a block for air or blood, enabling a diversion of an initial aliquot of blood into the blood sequestration chamber 2624 as the patient's blood pressure overcomes the ambient air pressure in the blood sequestration channel 2624 to displace air therefrom through air vent 2628.

[00150] When the inner housing 2617 is rotated relative to the outer housing 2616, or vice versa, to a second state, as illustrated in FIG. 26D, the blood sequestration chamber 2624 is shut off from diversion junction 2624, enabling a direct path from the patient needle through the conduit 2606 to the collection needle 2604, via blood sampling channel 2622. The outer housing 2616 and/or inner housing 2617 can include ridges or grooves formed within a portion of their surfaces, to facilitate relative rotation from the first state to the second state.

[00151] FIGS. 27A – D illustrate a blood optimization system 2700 and blood sequestration device 2702, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, and 25, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2720. Air initially in the blood sequestration chamber 2720 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2720. The air venting mechanism includes an air permeable blood barrier 2706, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2720.

[00152] The air venting mechanism includes an inner wall 2716 that at least partially circumscribes or surrounds the air permeable blood barrier 2706, and an outer wall 2704 spaced apart from the inner wall 2716. A cap 2722 is positioned on the air venting mechanism, preferably by having a lower cap wall 2728 that fits between the inner wall 2716 and the outer wall 2704 of the air venting mechanism, and frictionally abutting either the the inner wall 2716 or the outer wall 2704 or both. The cap 2722

further includes one or more vent holes 2724 or slits, apertures, openings, or the like, which extend through an upper surface of the cap 2722 around a downwardly extending plug 2726. The plug 2726 is sized and adapted to fit snugly within the space defined by inner wall 2716.

[00153] In a first position, as illustrated in FIG. 27C, the cap 2722 is extended from the air venting mechanism to allow air from the blood sequestration chamber 2720 to exit through the air permeable blood barrier 2706 and through the one or more vent holes 2724. Once the air from the blood sequestration chamber 2720 has been displaced, i.e., when the blood sequestration chamber 2720 is filled with the first aliquot of potentially tainted blood from the patient, then the cap 2722 can be pushed down on the air venting mechanism in a second position as shown in FIG. 27D, so that the plug 2726 fits within the inner wall 2716 over the air permeable blood barrier 2706 to seal the air venting mechanism. In either the first position or the second position, the cap 2722 protects the air permeable blood barrier 2706 from outside air or from being touched by a user.

[00154] FIGS. 28A – F illustrate a blood optimization system 2800 and blood sequestration device 2802, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but utilizing a multi-layered filter, and in some implementations, a filter with trapped reactive material, for an air permeable blood barrier. As shown in FIGS. 28C and D, an air permeable blood barrier 2803 includes a first layer 2804 of an air permeable but blood impermeable material, and a second layer 2806 that includes a reactive material, such as a hydrophobic material, for repelling blood while still allowing air to pass through both layers. As shown in FIGS. 28E and F, the air permeable blood barrier 2803 can include any number of layers, such as a third layer 2808 formed of the same air permeable but blood impermeable material as first layer 2804, while a second layer 2806 includes trapped or embedded blood reactive material.

[00155] FIGS. 29A – C illustrate a blood optimization system 2900 and blood sequestration device 2902, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but in which a blood sequestration chamber 2904 is at least partially filled with a blood-absorptive material 2906. The blood-absorptive material 2906 can act as a wicking material to further draw in blood to be sequestered upon venipuncture of the patient, and prior to use of a blood drawing device such as a Vacutainer™ or a syringe, or the like.

[00156] FIGS. 30A – G illustrate a blood optimization system 3000 and blood sequestration device 3002, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26. The blood sequestration device 3000 includes an inlet port 3002 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 3002 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 3002 defines an opening into the blood sequestration device 3000, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00157] The inlet port 3002 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 3002, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 3000 at the time of blood draw or sampling.

[00158] The blood sequestration device 3000 further includes an outlet port 3004, which defines an opening out of the blood sequestration device 3000 and to the blood sample collection device. The outlet port 3004 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 3000 at the time of blood draw or sampling.

[00159] The blood sequestration device 3000 further includes a sampling channel 3006 between the inlet port 3002 and the outlet port 3004, and a sequestration chamber 3008 that is connected to and split off or diverted from the sampling channel 3006 at any

point between the inlet port 3002 and the outlet port 3004. The sampling channel 3006 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 3008. The sampling channel 3006 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 3006 has a substantially similar cross sectional area as the opening of the inlet port 3002. In other implementations, the sampling channel 3006 can gradually widen from the inlet port 3002 to the outlet port 3004. The sequestration chamber 3008 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 3006.

[00160] In some exemplary implementations, the diversion between the sampling channel 3006 and the sequestration chamber 3008 is by diverter junction 3007. Diverter junction 3007 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008. The sequestration chamber 3008 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 3008.

[00161] The sequestration chamber 3008 is preferably maintained at atmospheric pressure, and includes a vent 3010 at or near a distal end of the sequestration chamber 3008. The vent 3010 may include an air permeable blood barrier 3012 as described above.

[00162] The blood sequestration device 3000 can include a housing 3001 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated FIG. 30F, the housing 3001 includes a top member 3020 and a bottom member 3022 that are mated together. The blood sequestration device 3000 can also include a gasket or other sealing member (not shown) so that when the top member 3020 is mechanically attached with the bottom member 3022, the interface between the two is sealed by the gasket or sealing member. The bottom member 3022 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 3006, the sequestration chamber 3008, and diverter junction 3007.

[00163] The sequestration chamber 3008 may have a larger cross section than the sampling channel 3006 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 3006.

[00164] In some implementations, the sampling channel 3006 and the sequestration chamber 3008 are formed by grooves, channels, locks or other pathways formed in housing 3001. The housing 3001 can be made of rubber, plastic, metal or any other suitable material. The housing 3001 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 3001 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 3006 and/or the sequestration chamber 3008 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 3008 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 3006. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 3012 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00165] The air permeable blood barrier 3012 can be covered with, or surrounded by, a cap 3032. The cap 3032 can be sized and configured to inhibit a user from touching the air permeable blood barrier 3012 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 3012 as the air is displaced from the sequestration chamber 3008. The cap 3032 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00166] The air venting mechanism includes a wall 3030 that at least partially circumscribes or surrounds the air permeable blood barrier 3012. The wall 3030 can have one or more air vents formed therein. The cap 3032 covers wall 3030 and can be snapped, glued, or otherwise attached in place. A seal 3017 in the form of a silicone wafer, or other elastomeric material, fits within the wall 3030 to cover the air permeable blood barrier 3012 and abut the top of the wall 3030. The seal 3017 covers and seals the

air permeable blood barrier 3012 and inhibits air from entering the blood sequestration chamber 3008 through the air permeable blood barrier 3012. A fulcrum 3012 on an underside of the cap 3032 allows the seal 3008 to flexibly disconnect from the top of the inner wall 3016 when pushed by air displaced from the blood sequestration chamber 3008, to allow air to vent from the air permeable blood barrier 3012 and through the one or more air vents in the wall 3030 and/or cap 3032.

[00167] In use, the blood sequestration device 3000 includes a sampling channel 3006 and a sequestration chamber 3008. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 3006 is directed to an outlet port 3004 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 3008 terminates at a vent 3010 to atmosphere that includes an air permeable blood barrier 3012.

[00168] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 3002 of blood sequestration device 3000. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 3008 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 3008 to displace air therein through the air permeable blood barrier 3012, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 3006. In various exemplary embodiments, the sequestration chamber 3008 and sampling channel 3006 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00169] Eventually, the sequestration chamber 3008 fills with blood that displaces air through the air permeable blood barrier 3012. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 3012 material to completely or partially seal the vent 3010. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00170] Upon filling the blood sequestration pathway 3008 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 3006, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 3006, queuing up the uncontaminated blood to be drawn through the sampling channel 3006.

[00171] In yet another aspect, the blood sequestration chamber and/or blood sampling channel, or other component, of any of the implementations described herein, can provide a visually discernable warning or result in a component adapted for operative fluid communication with the flash chamber of an introducer for an intravenous catheter into a blood vessel of a patient. The device and method provides a visually discernable alert when blood from the patient communicates with a test component reactive to communicated blood plasma, to visually change. The reaction with the blood or the plasma occurs depending on one or a plurality of reagents positioned therein configured to test for blood contents, substances or threshold high or low levels thereof, to visually change in appearance upon a result.

[00172] In yet other aspects, the blood sequestration chamber and/or blood sampling channel can be sized and adapted to provide a particular volumetric flow of blood, either during the sequestration process and/or the sampling process.

[00173] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

CLAIMS

1. A blood control device comprising; an inlet port; an outlet port;

a chamber connected with the inlet port via a junction, the chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and that includes one or more air vents, the vent further including a cap that at least partially covers the outer wall and including a one-way seal abutting the air permeable blood barrier that inhibits air from entering the chamber; and

a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;

the chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the chamber toward the air permeable blood barrier for being held therein, and a second portion of blood bypasses the chamber and the first portion of blood held therein and is directed into the sampling channel toward the outlet port.

2. The blood control device in accordance with claim 1, further comprising a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

3. The blood control device in accordance with claim 1, wherein the vent further includes an inner wall within the outer wall and that contains the air permeable blood barrier.

4. The blood control device in accordance with claim 1, wherein the one-way seal is positioned over the inner wall and within the outer wall of the vent.

5. The blood control device in accordance with claim 4, wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the chamber.

6. The blood control device in accordance with claim 1,
wherein the air permeable blood barrier includes a sealing material that seals the vent upon contact with blood.

7. The blood control device in accordance with claim 1,
wherein the air permeable blood barrier includes a filter having a first layer and a second layer, the second layer of the filter having a hydrophobic material to repel blood.

8. A blood control and sampling system comprising;
a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and
a blood control device attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway, the blood control device comprising:
an inlet port coupled with the blood sampling pathway toward the patient needle;
an outlet port coupled with the blood sampling pathway toward the sample collection device;
a chamber connected with the inlet port via a junction, the chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and that includes one or more air vents, the vent further including a cap that at least partially covers the outer wall and including a one-way seal abutting the air permeable blood barrier that inhibits air from entering the chamber; and
a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;
the chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for being held therein, and a second portion of blood bypasses the chamber and the first portion of blood held therein and is directed into the sampling channel toward the outlet port.

9. The blood control system in accordance with claim 8,
wherein the blood control device further comprises a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

10. The blood control system in accordance with claim 8,
wherein the vent of the blood control device further includes an inner wall within the outer wall and that contains the air permeable blood barrier.

11. The blood control system in accordance with claim 8,
wherein the one-way seal of the vent is positioned over an inner wall and within the outer wall of the vent.

12. The blood control system in accordance with claim 11,
wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the chamber.

13. The blood control system in accordance with claim 8,
wherein the air permeable blood barrier of the blood control device includes a sealing material that seals the vent upon contact with blood.

14. The blood control system in accordance with claim 8,
wherein the air permeable blood barrier of the blood control device includes a filter having a first layer and a second layer, the second layer of the filter having a hydrophobic material to repel blood.

15. A blood control device comprising;
an inlet port;

an outlet port;

a chamber connected with the inlet port via a junction, the chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall

that at least partially circumscribes the air permeable blood barrier and that includes one or more air vents, the vent further including a cap that at least partially covers the outer wall and including a one-way seal abutting the air permeable blood barrier that inhibits air from entering the chamber; and

a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;

the chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into and fills the chamber to displace air therein through the vent, and such that a second portion of blood bypasses the chamber and the first portion of blood held therein and is directed into the sampling channel toward the outlet port.

16. The blood control device in accordance with claim 15, further comprising a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

17. The blood control device in accordance with claim 15, wherein the vent further includes an inner wall within the outer wall and that contains the air permeable blood barrier.

18. The blood control device in accordance with claim 15, wherein the one-way seal is positioned over the inner wall and within the outer wall of the vent.

19. The blood control device in accordance with claim 18, wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the control chamber.

20. The blood control device in accordance with claim 15, wherein the air permeable blood barrier includes a sealing material that seals the vent upon contact with blood.

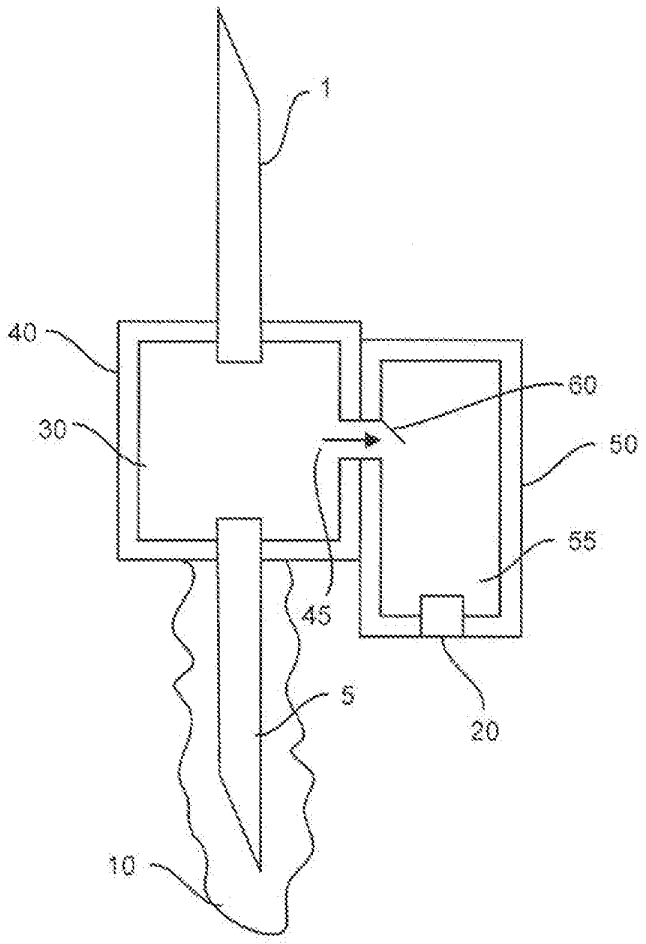


FIG. 1

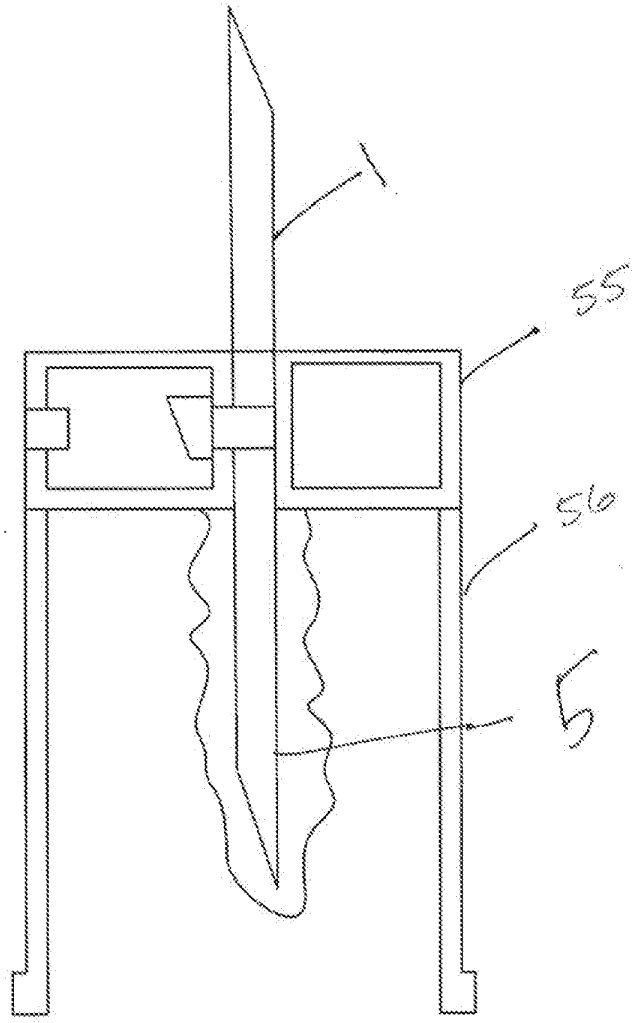


FIG. 2

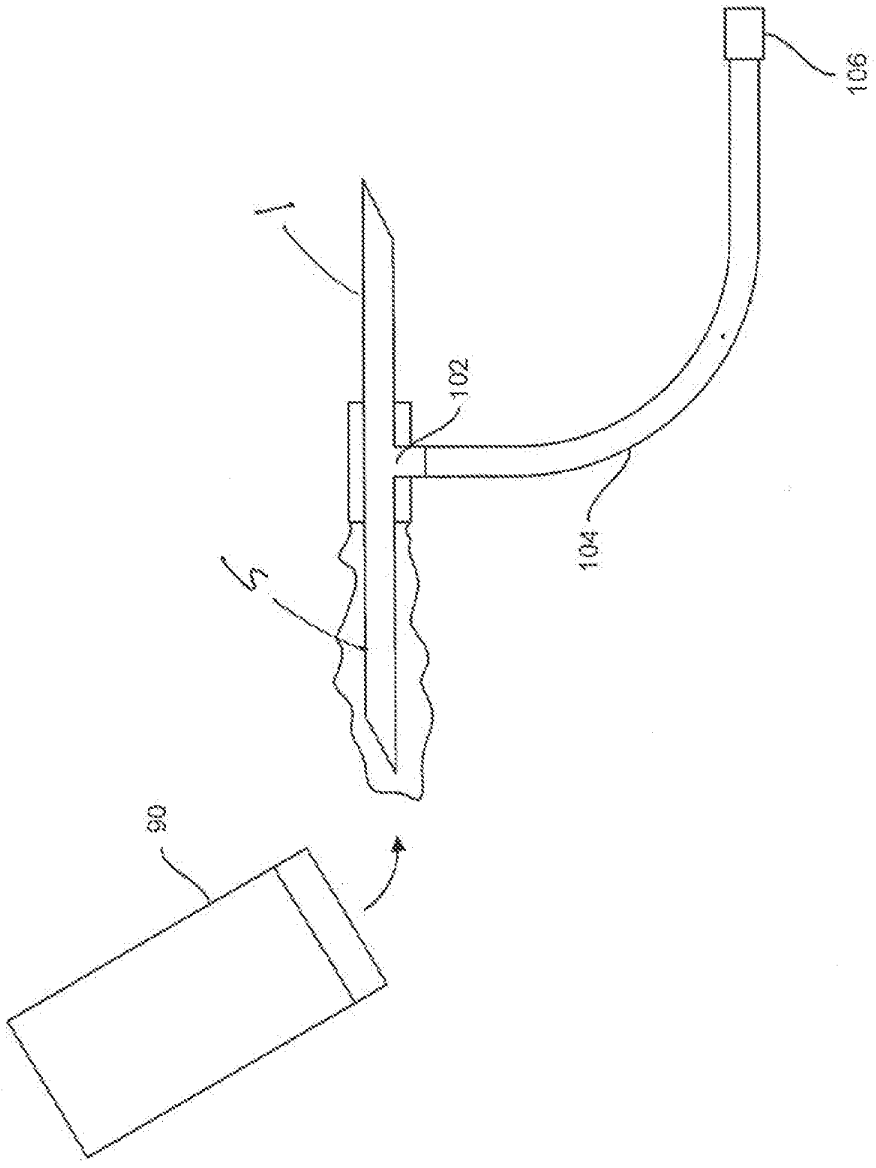


FIG. 3

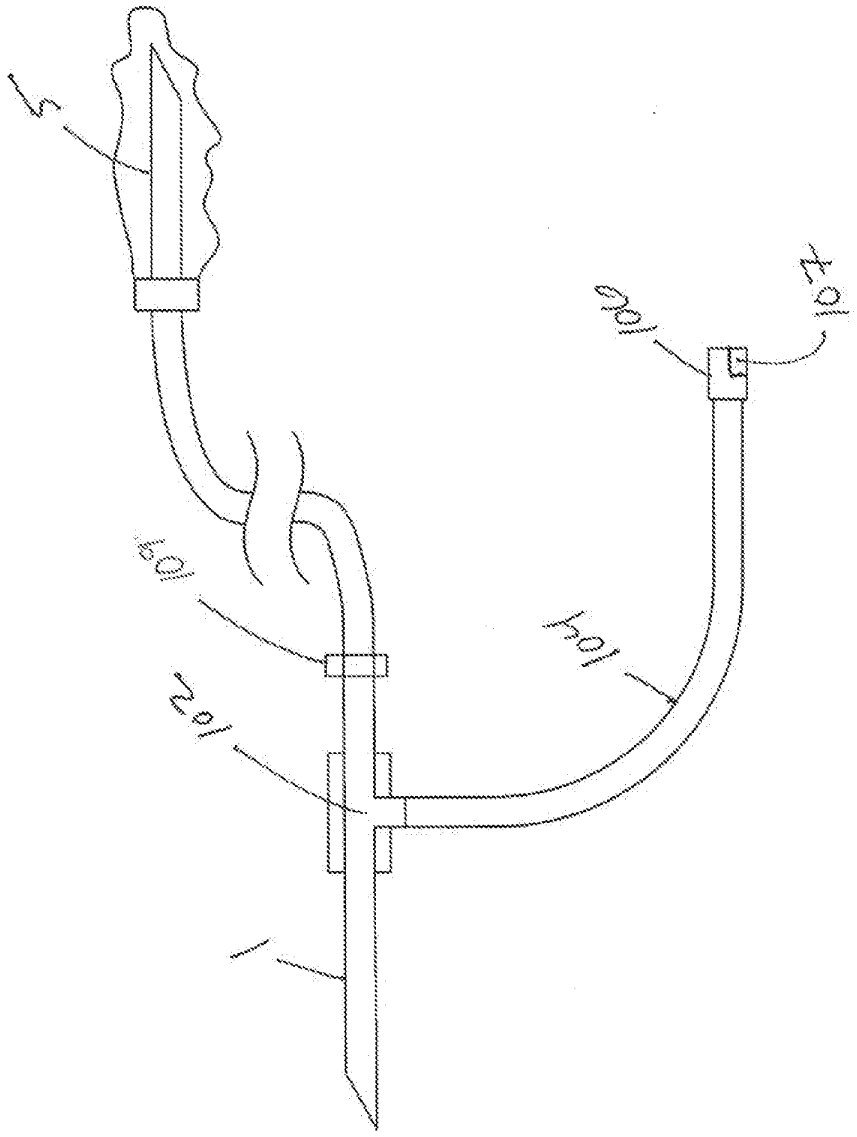


FIG. 4

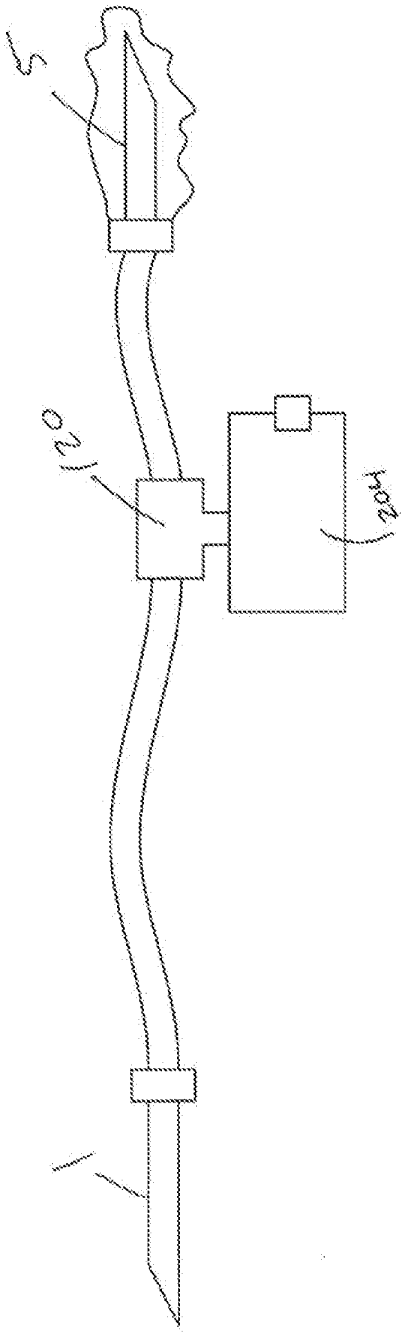


FIG. 5

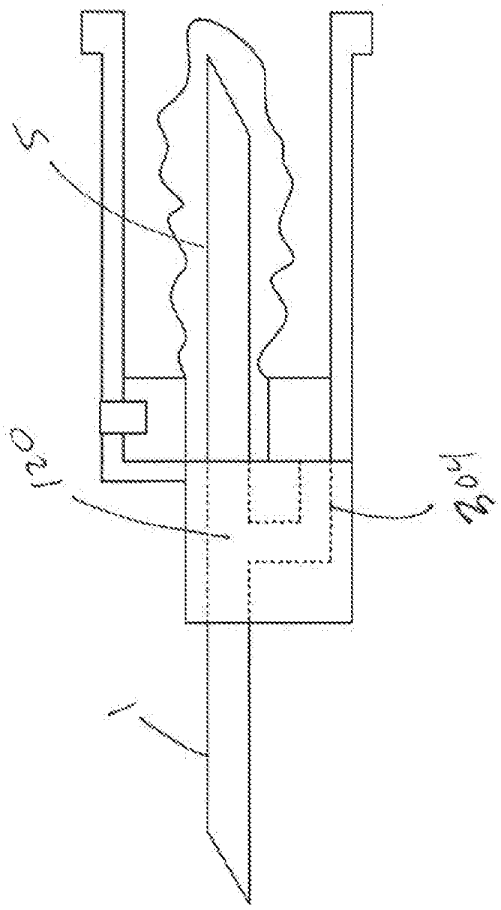


FIG. 6

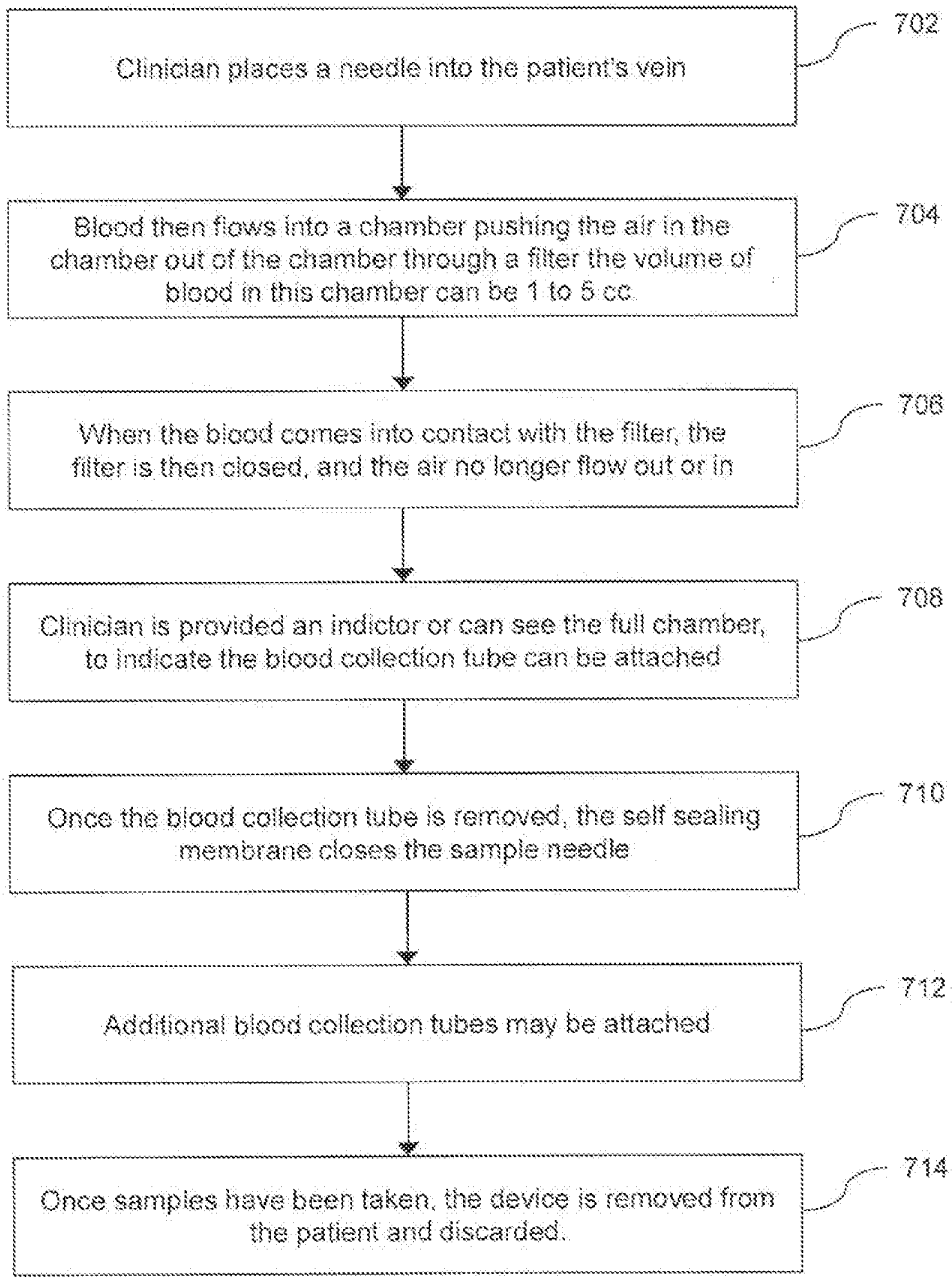
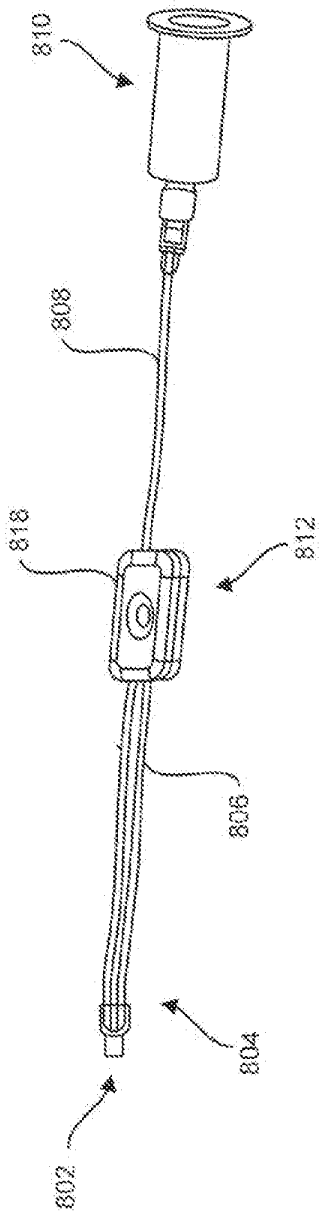

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7



800

FIG. 8A

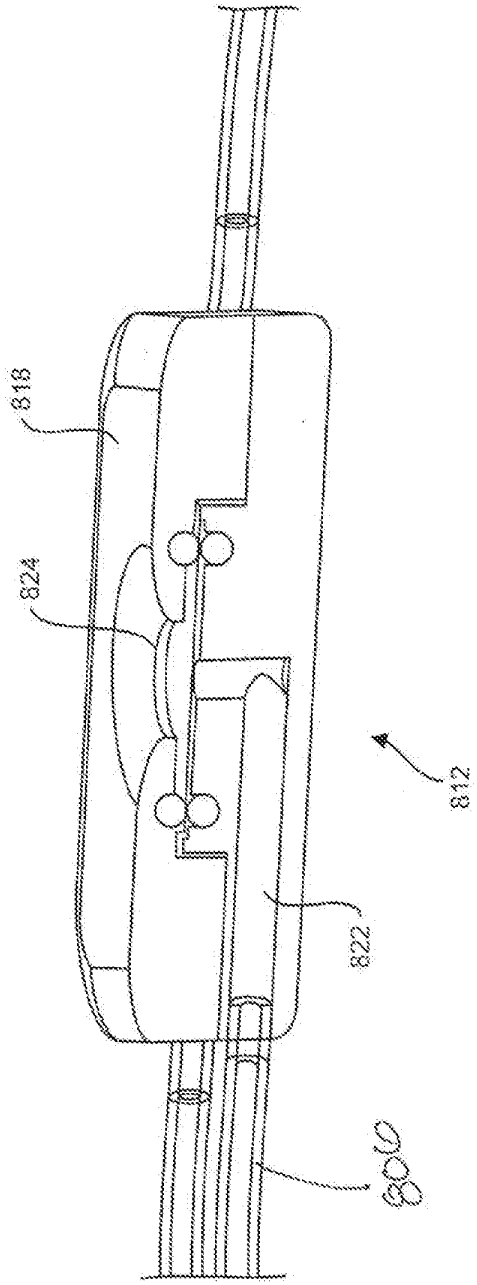


FIG. 8B

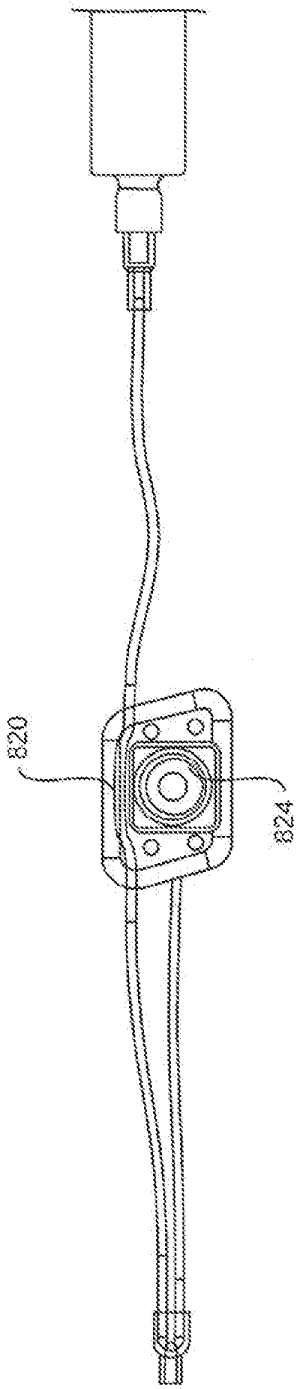


FIG. 8C

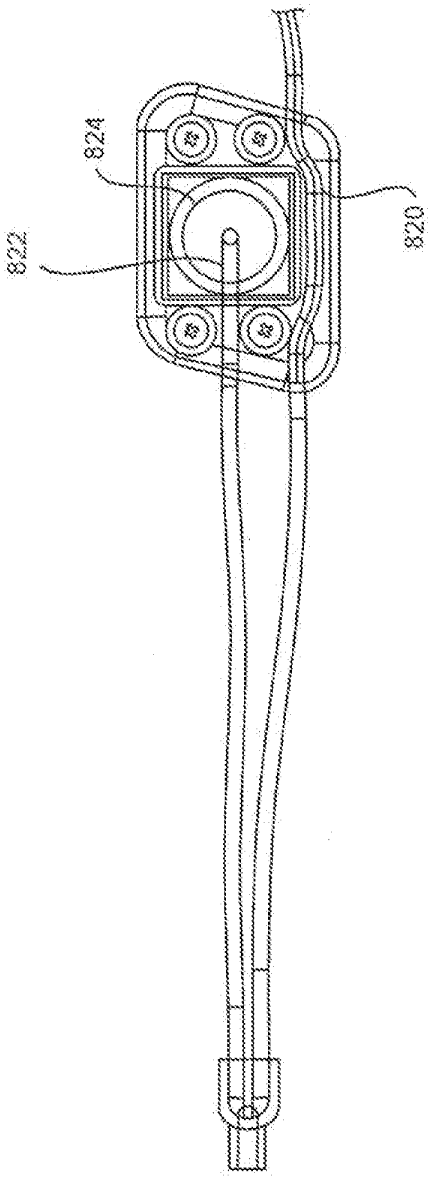


FIG. 8D

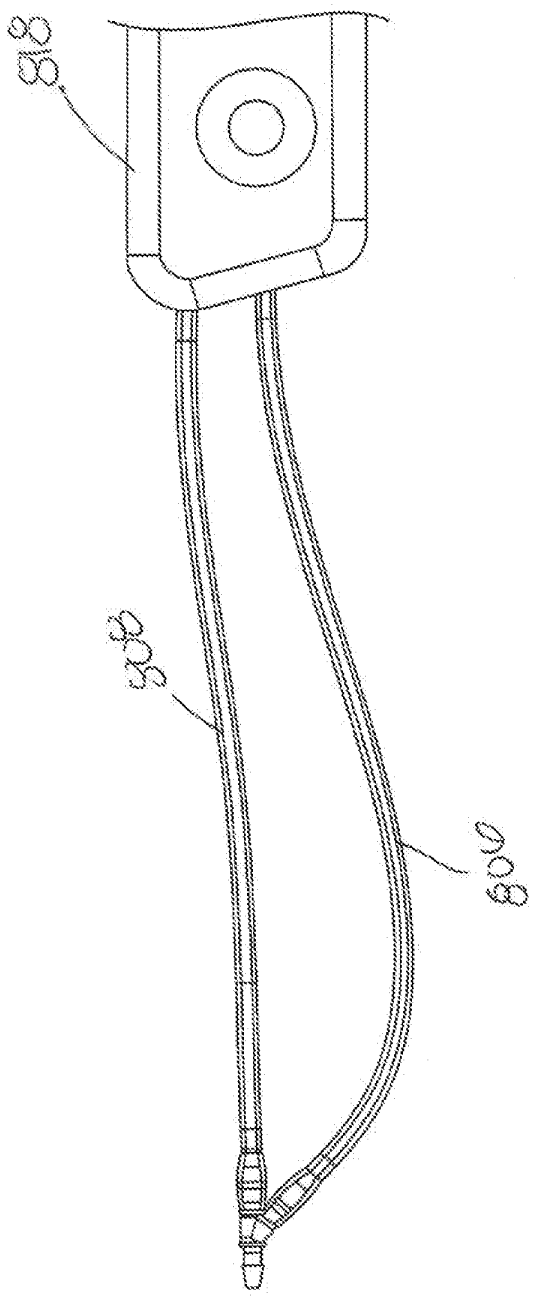


FIG. 8E

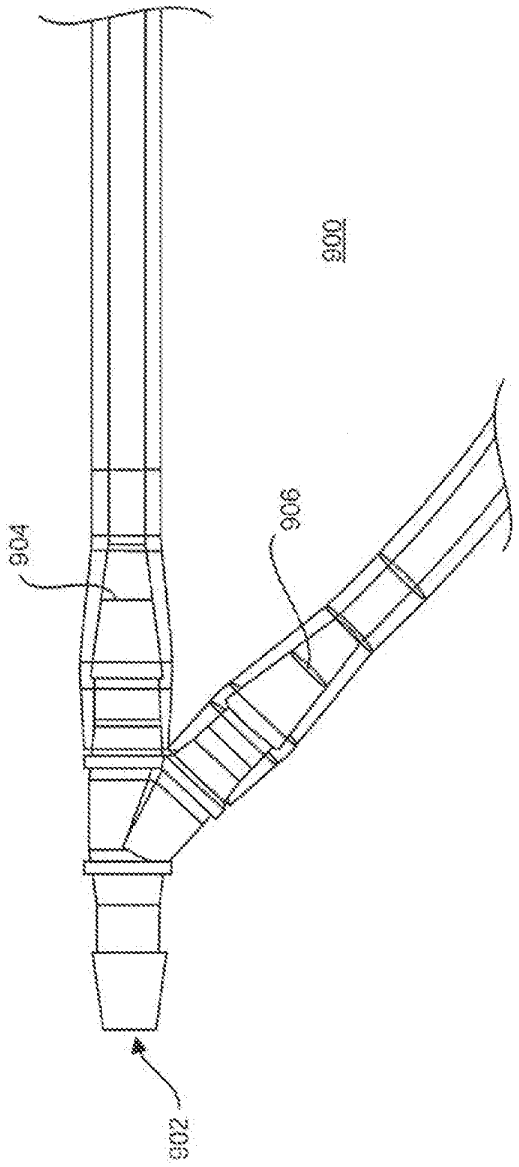


FIG. 9

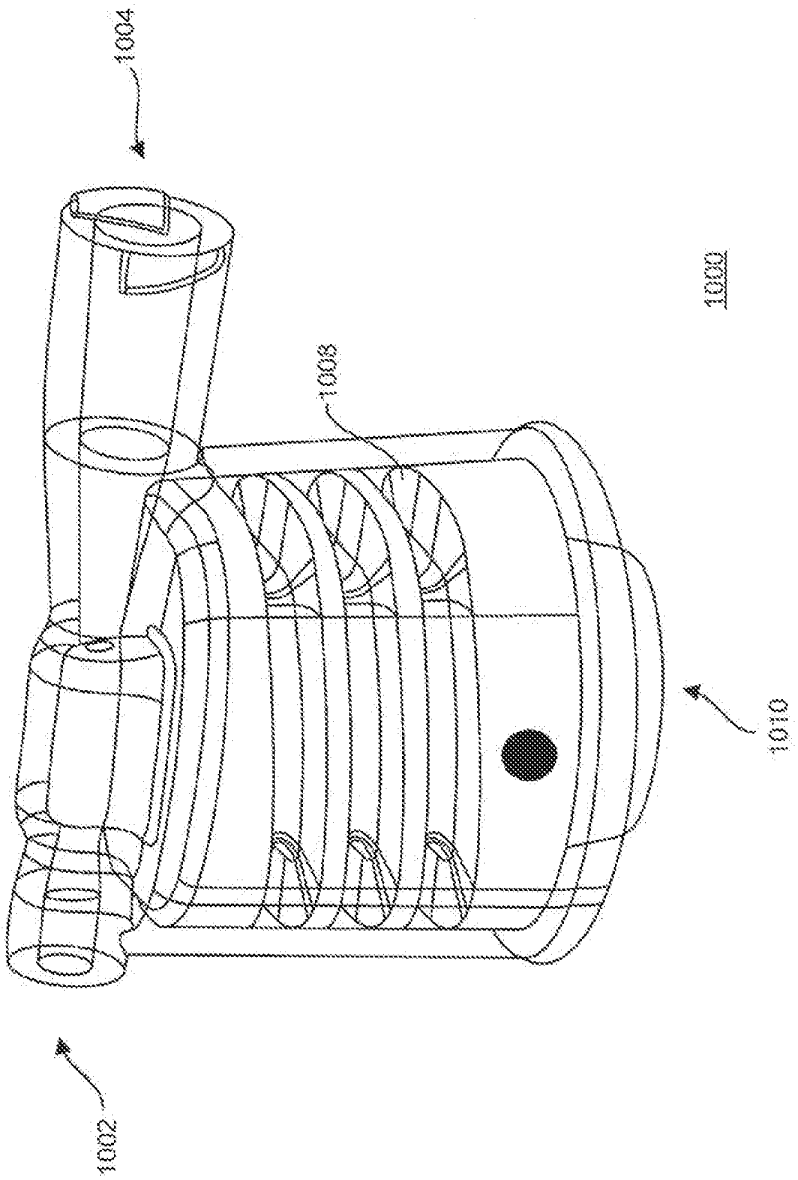


FIG. 10A

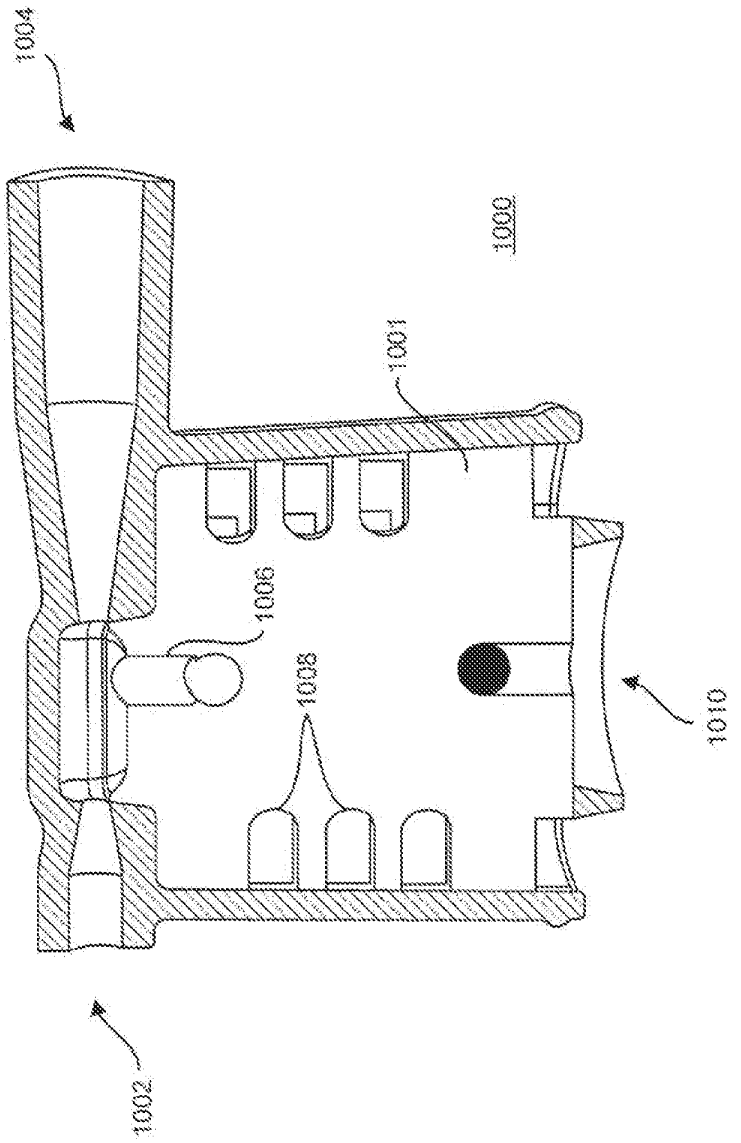


FIG. 10B

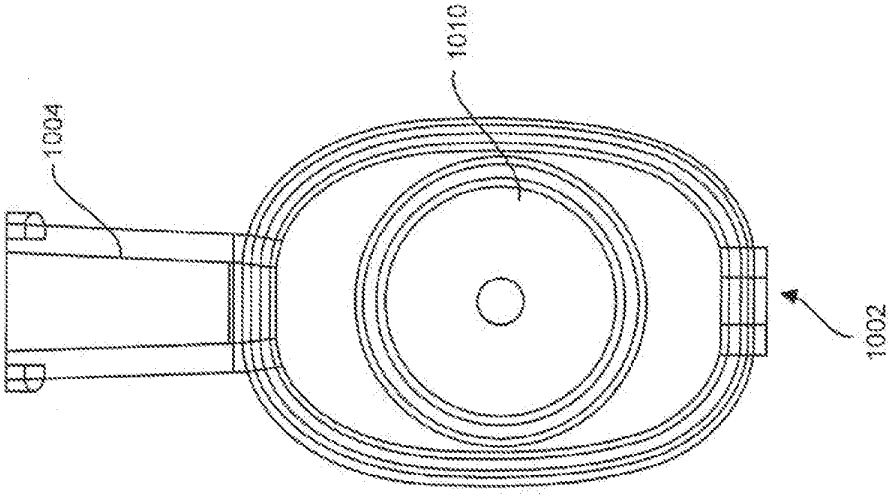


FIG. 10C

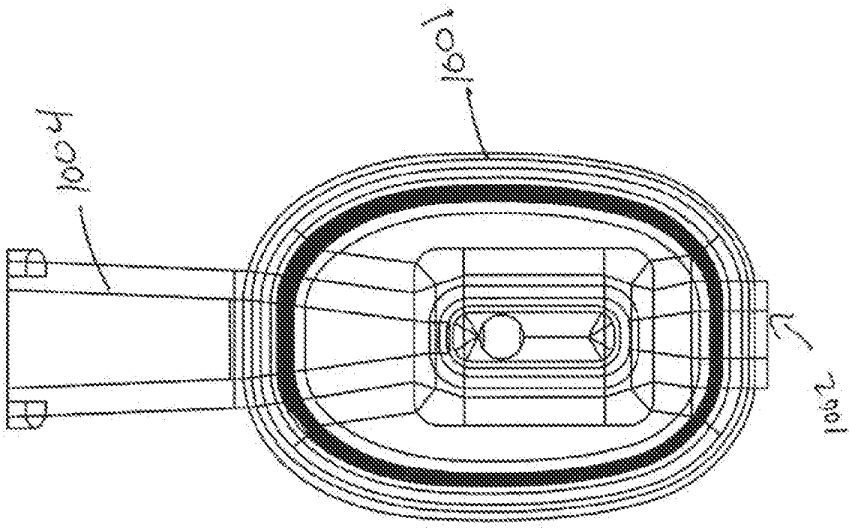


FIG. 10D

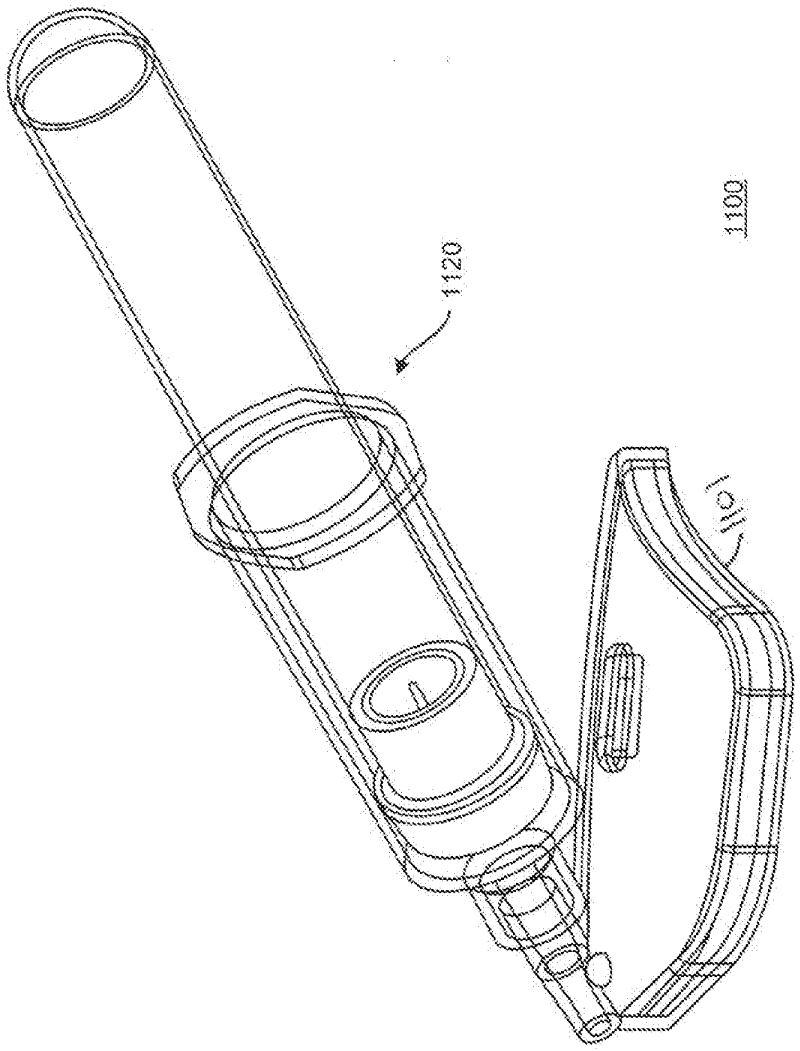


FIG. 11A

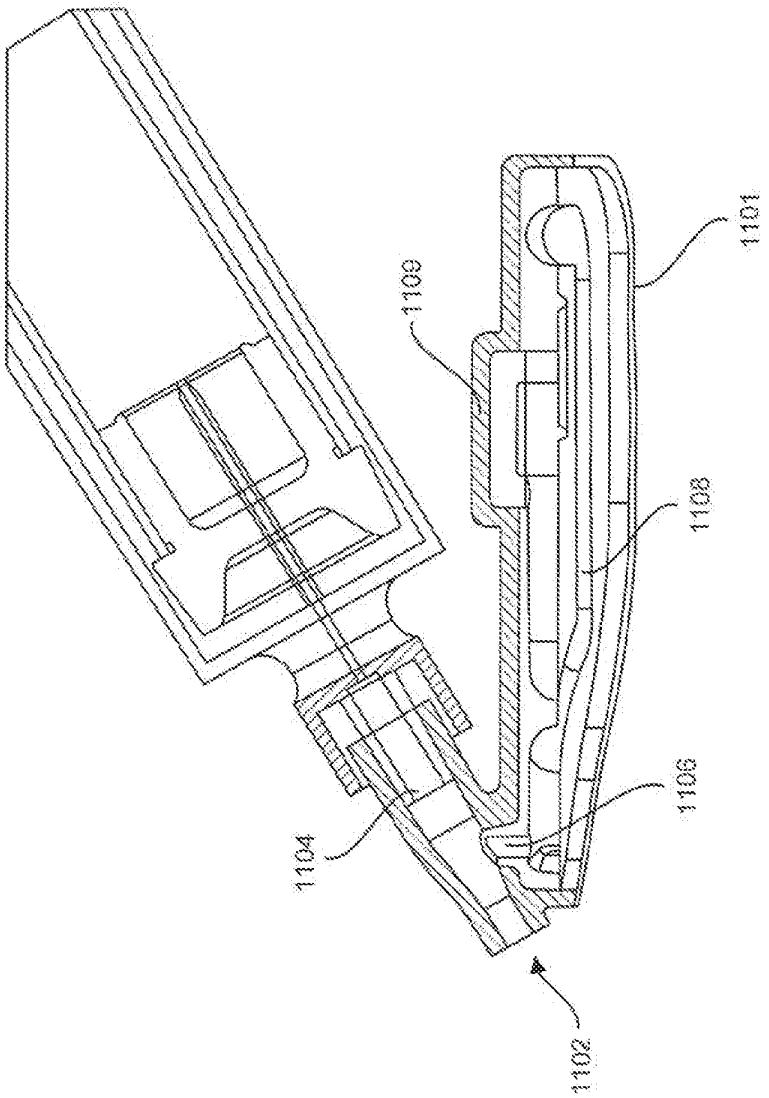


FIG. 11B

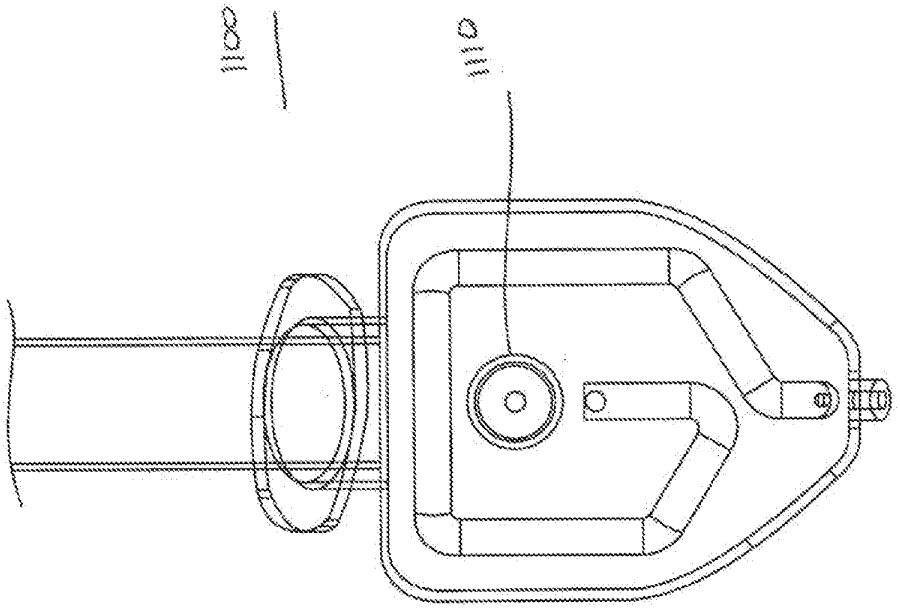


FIG. 11C

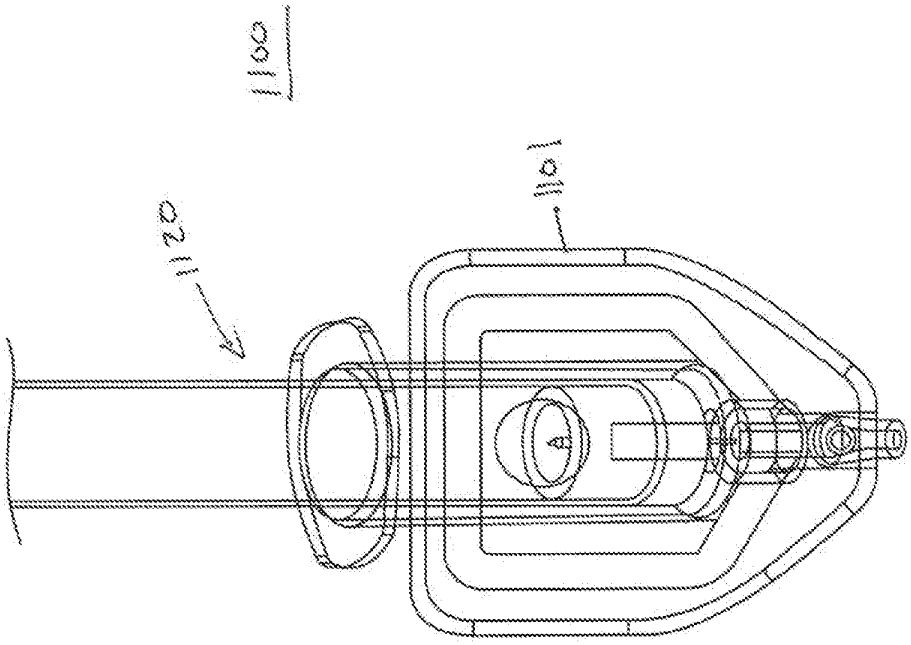


FIG. 11D

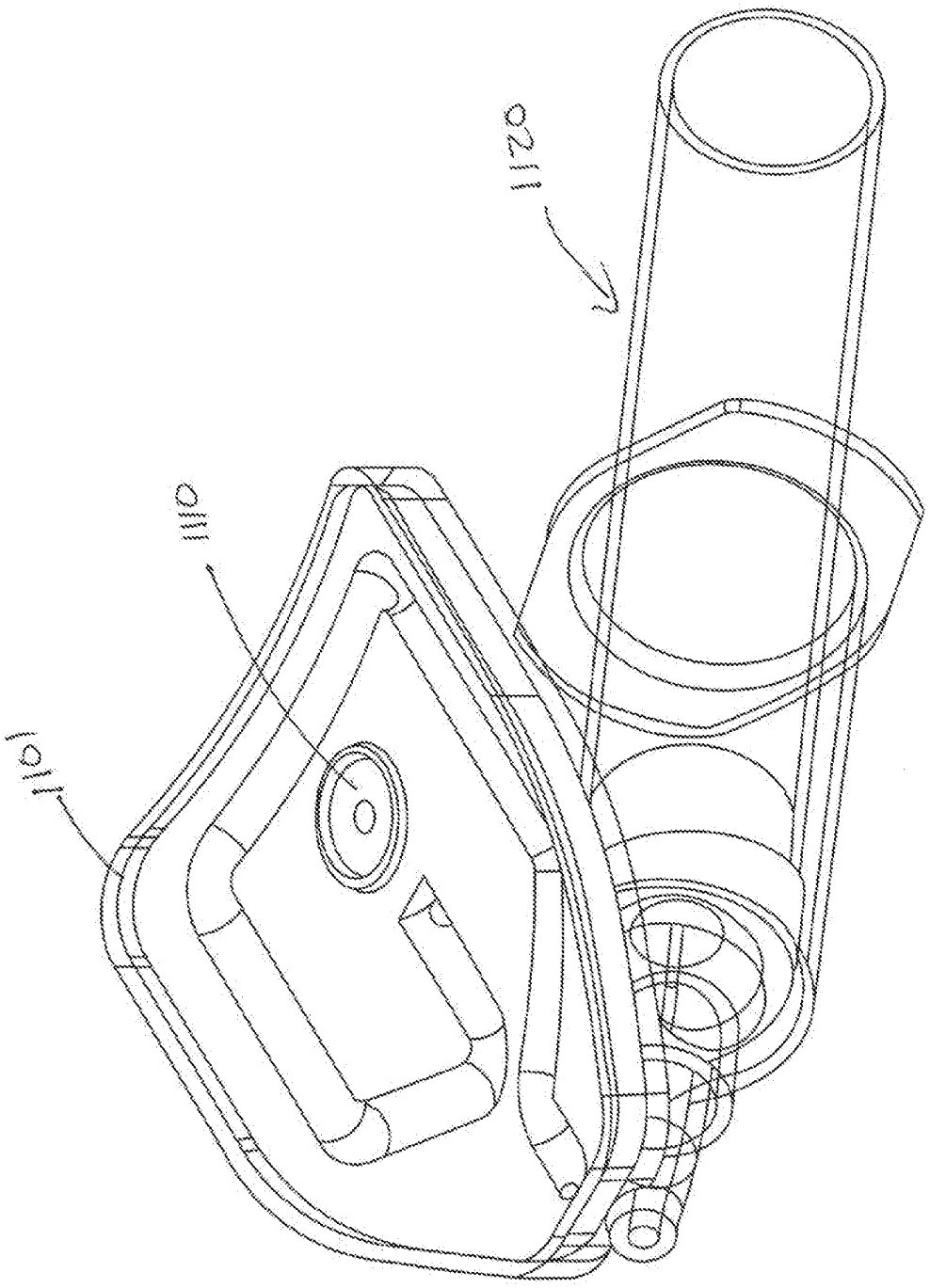


FIG. 11E

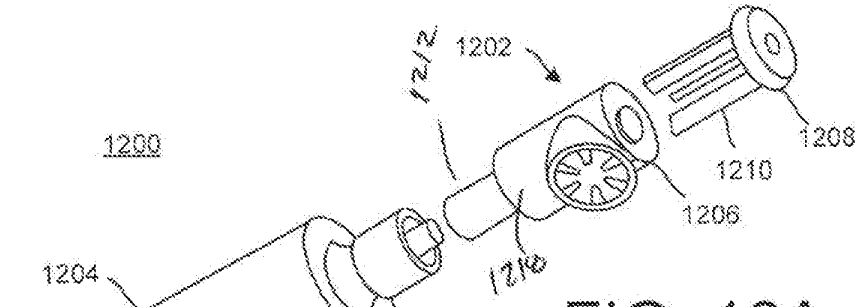


FIG. 12A

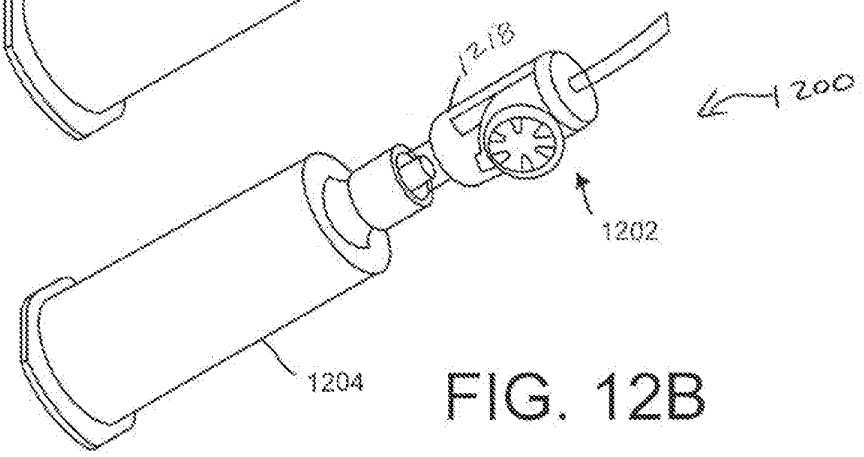


FIG. 12B

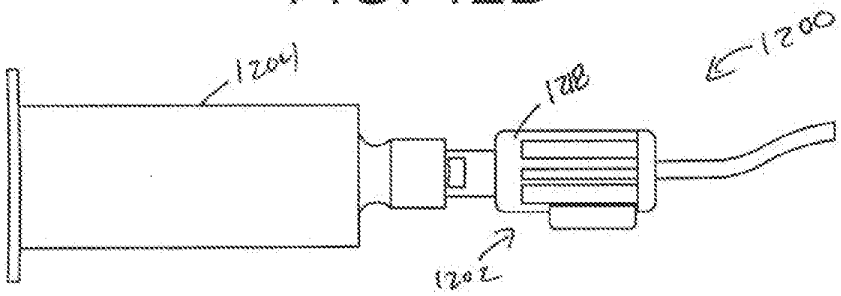


FIG. 12C

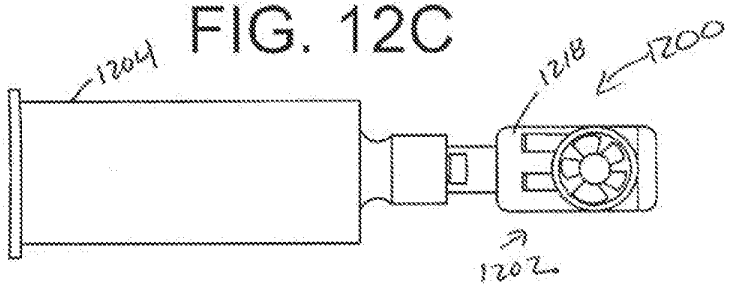


FIG. 12D

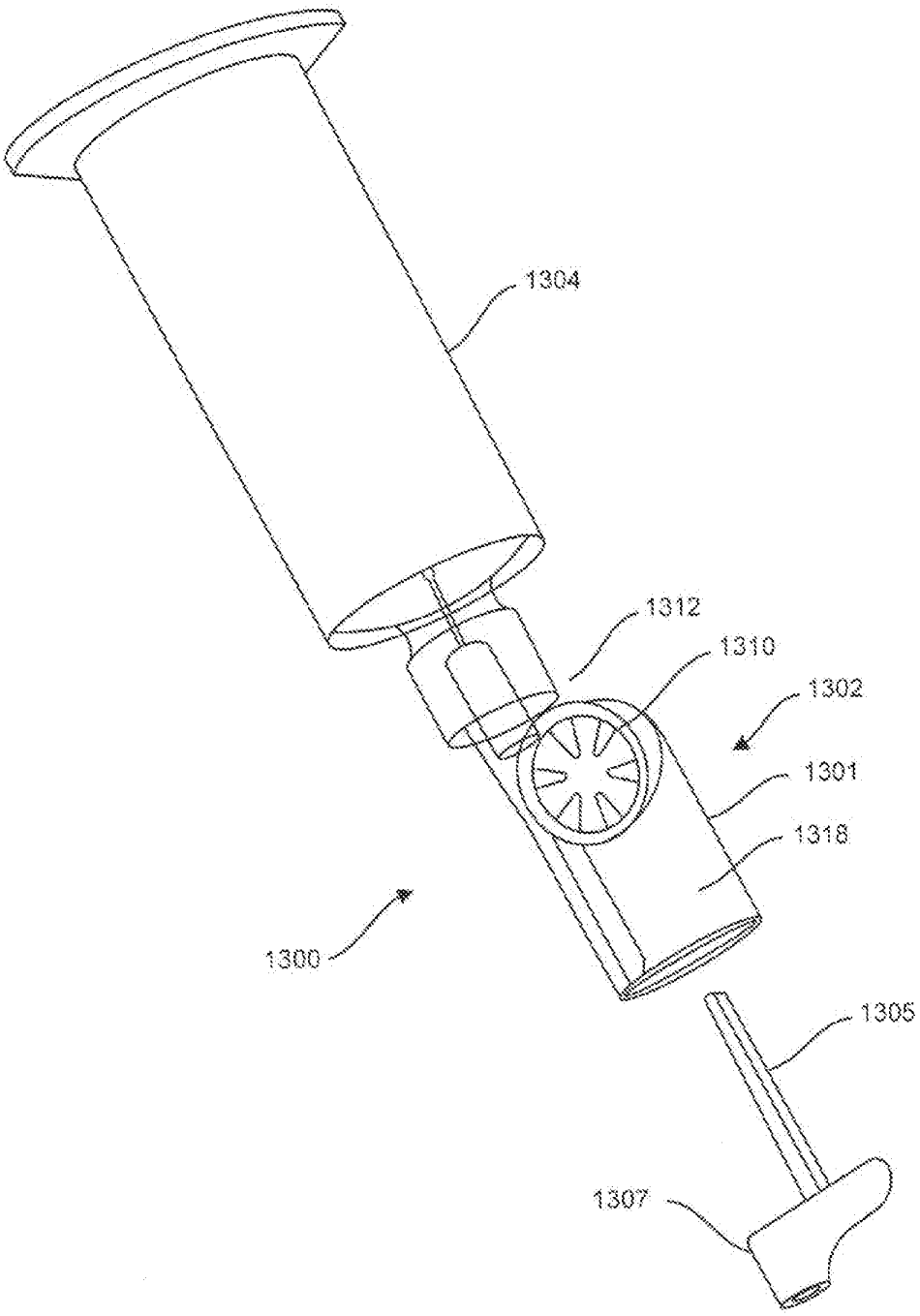


FIG. 13A

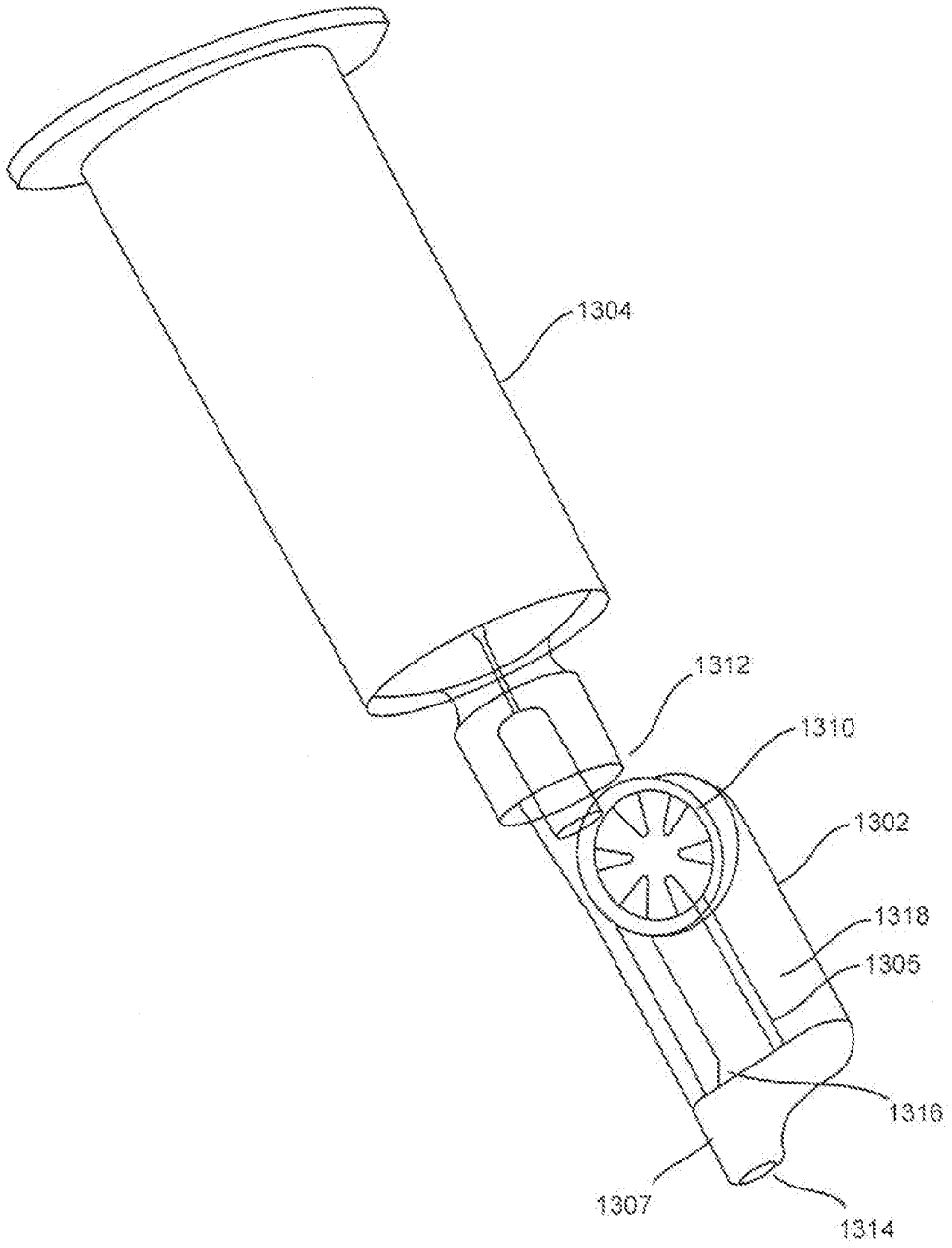


FIG. 13B

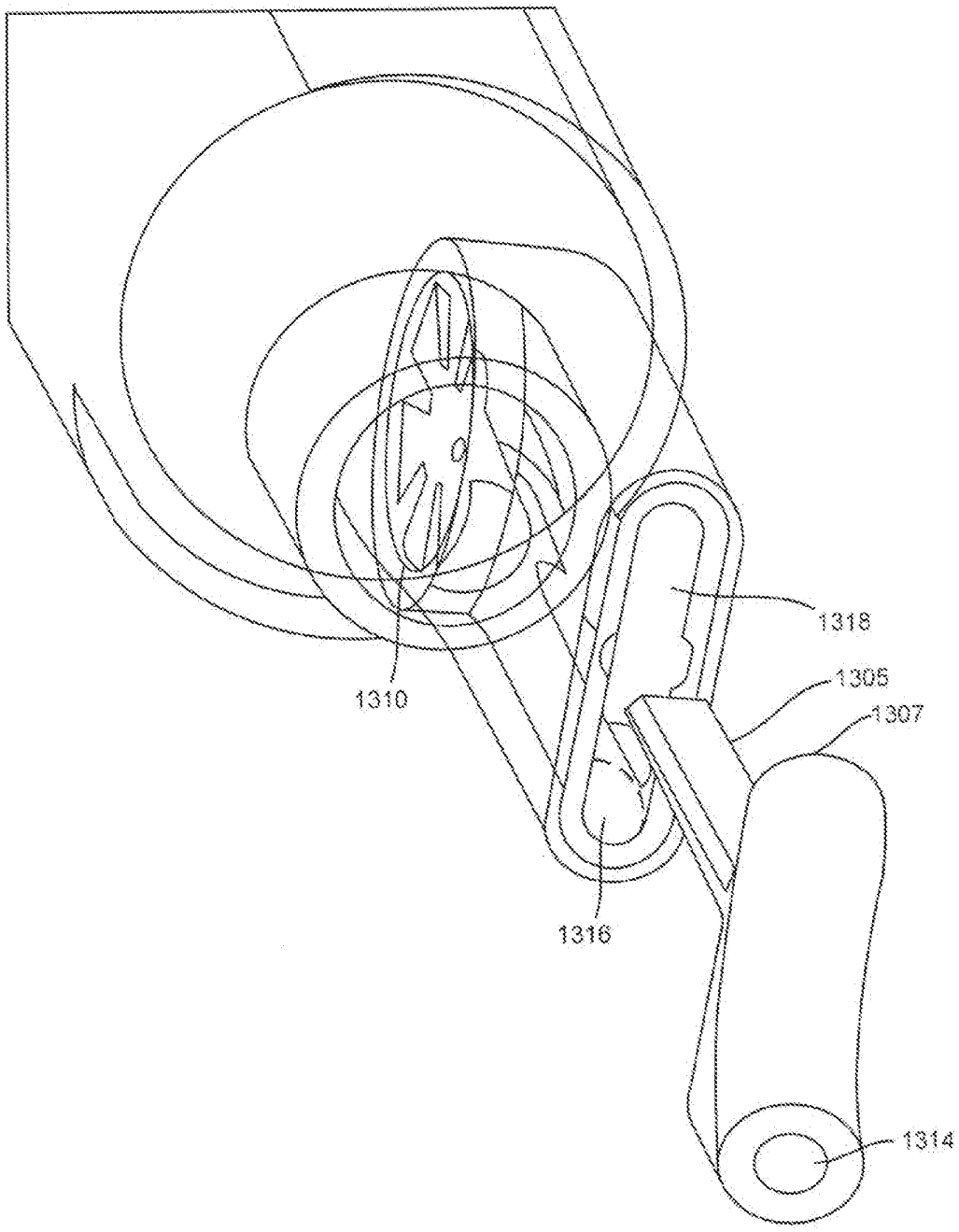


FIG. 13C

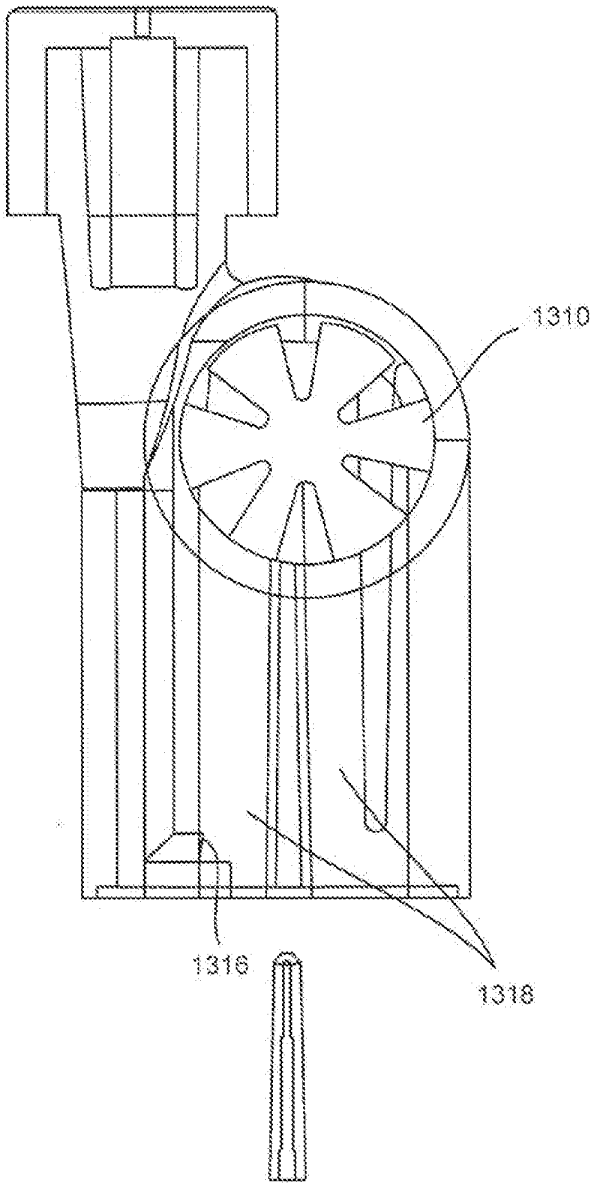


FIG. 13D

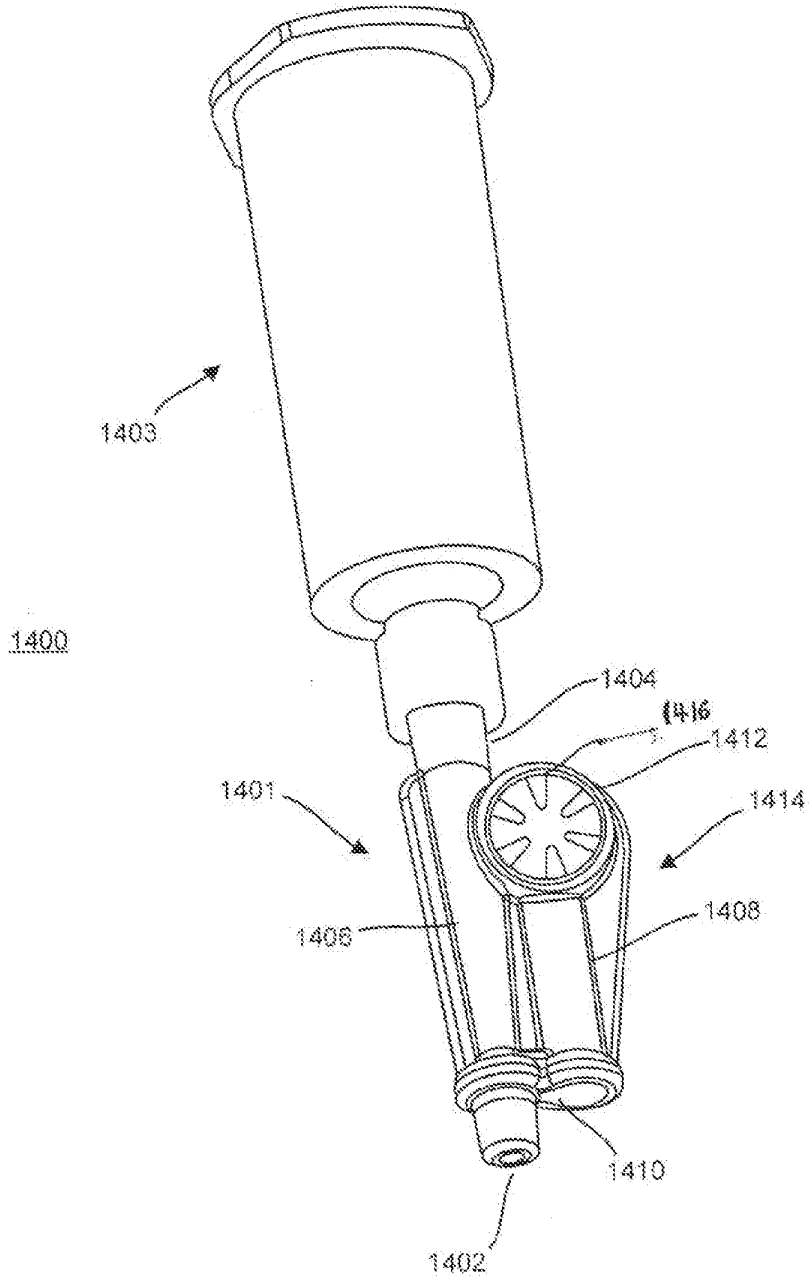


FIG. 14A

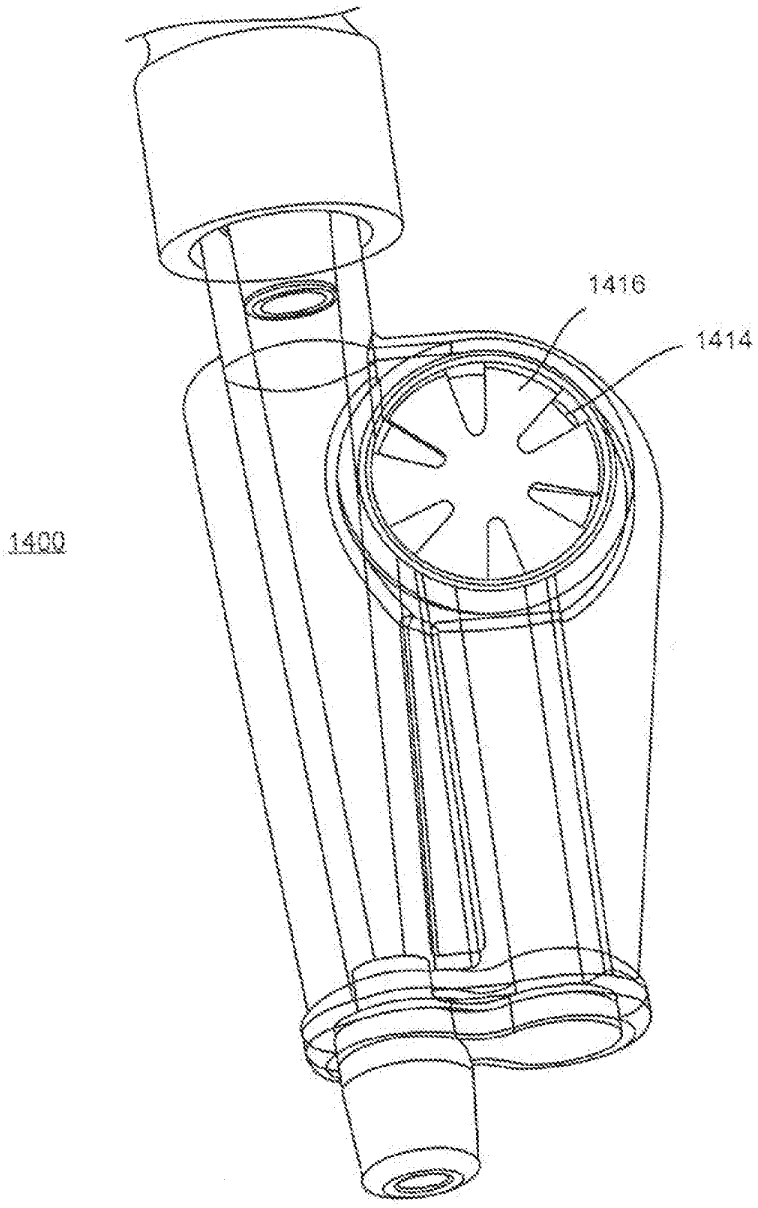


FIG. 14B

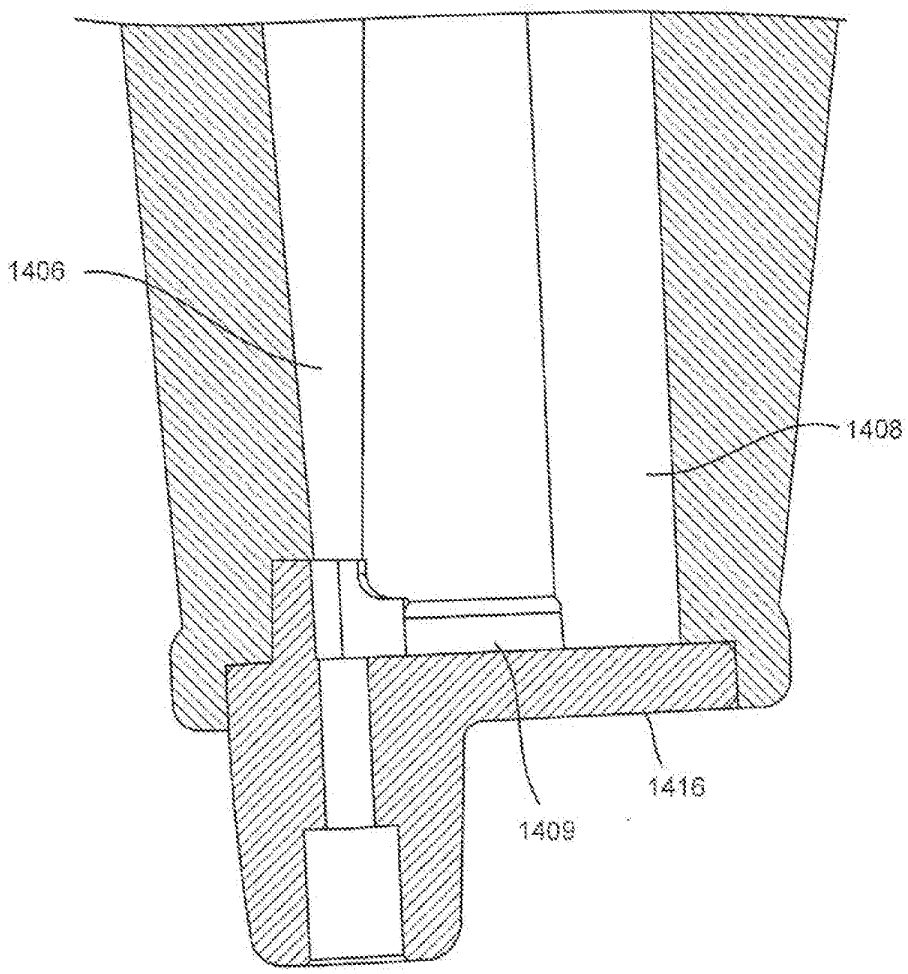


FIG. 14C

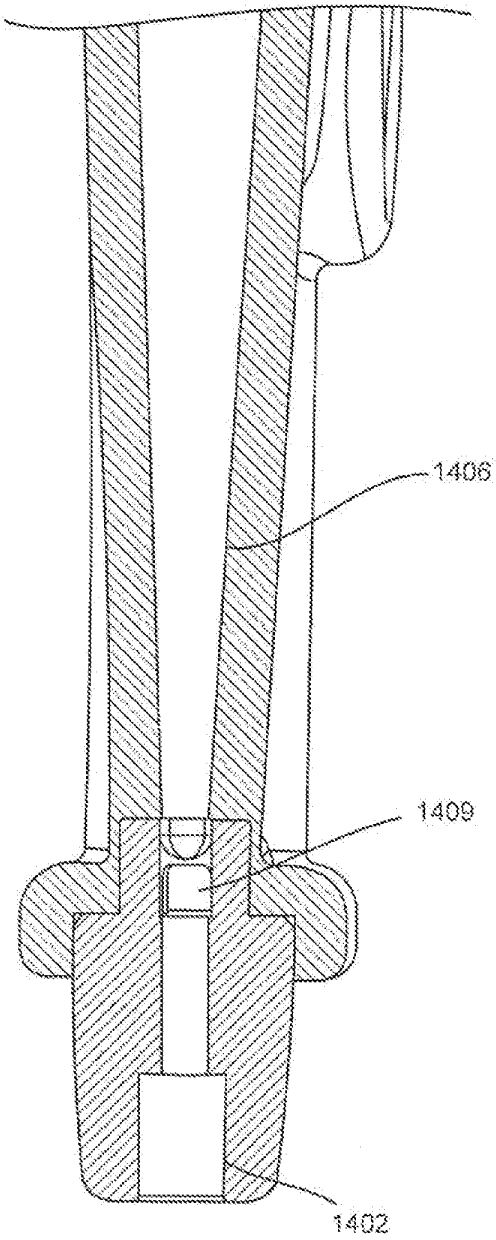


FIG. 14D

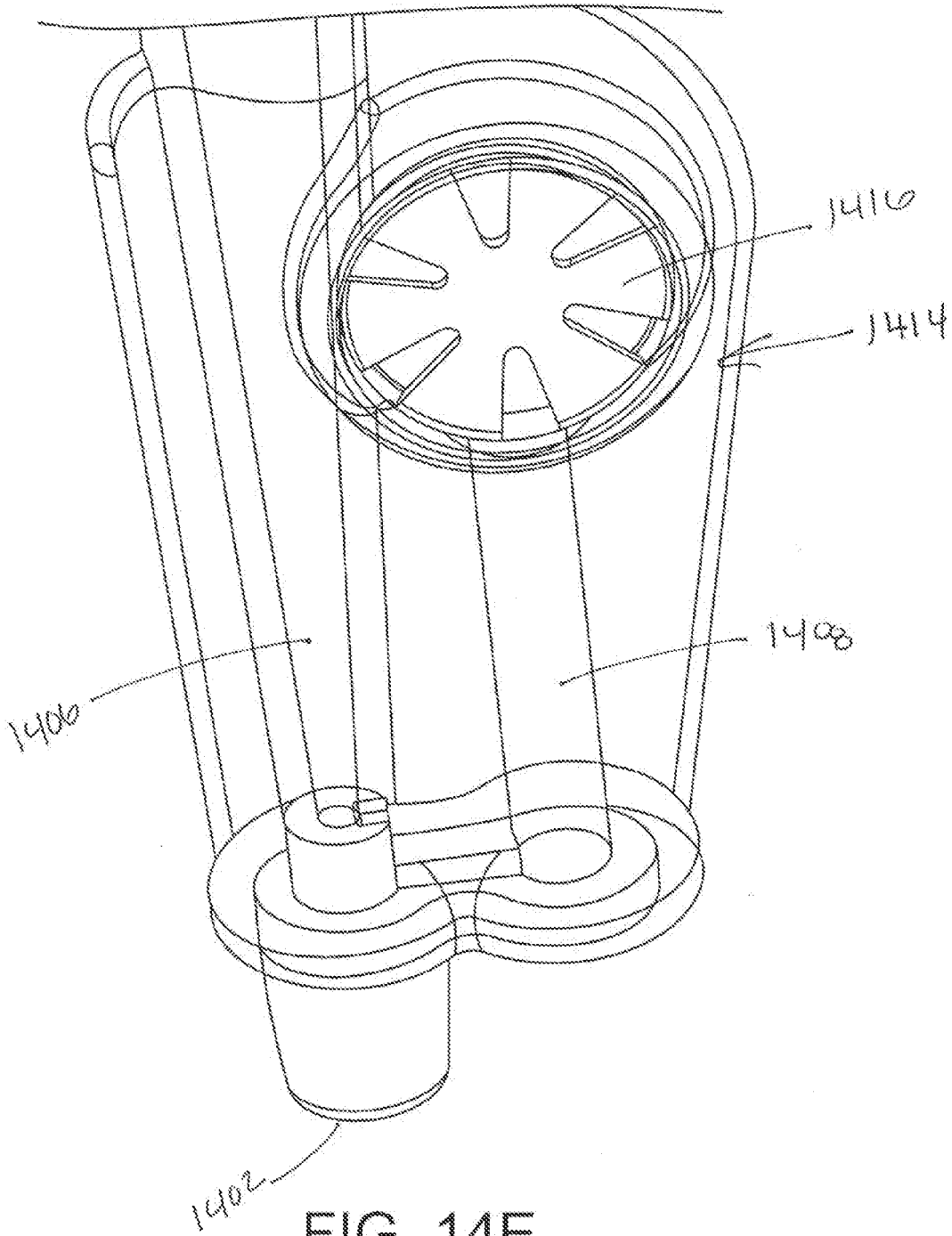


FIG. 14E

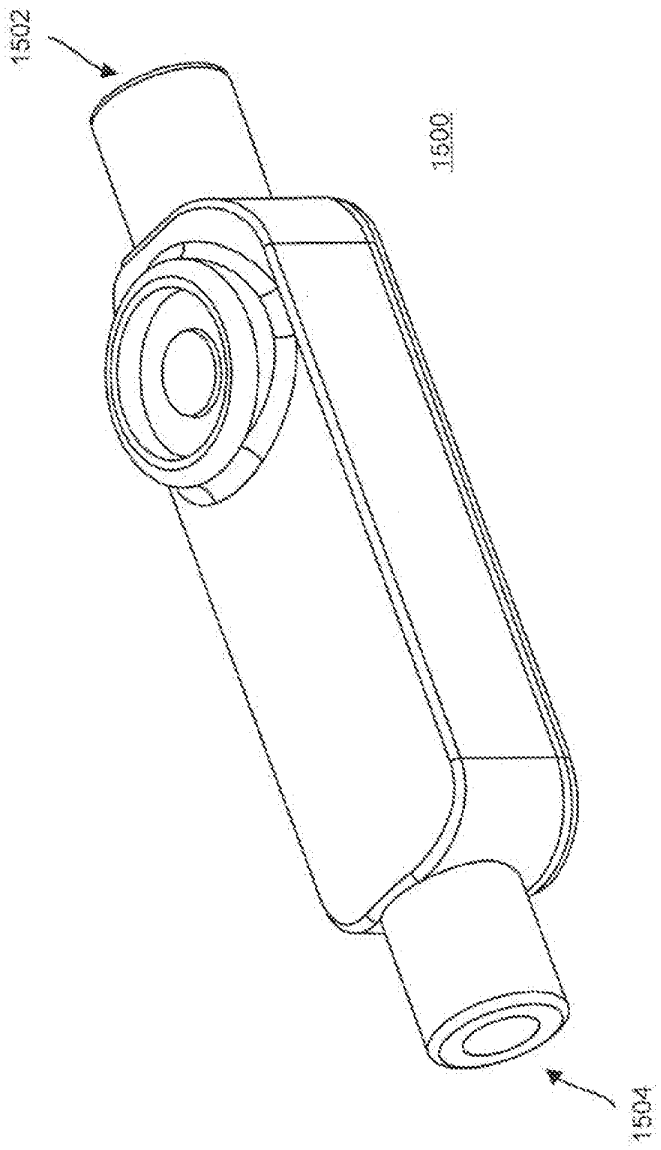


FIG. 15A

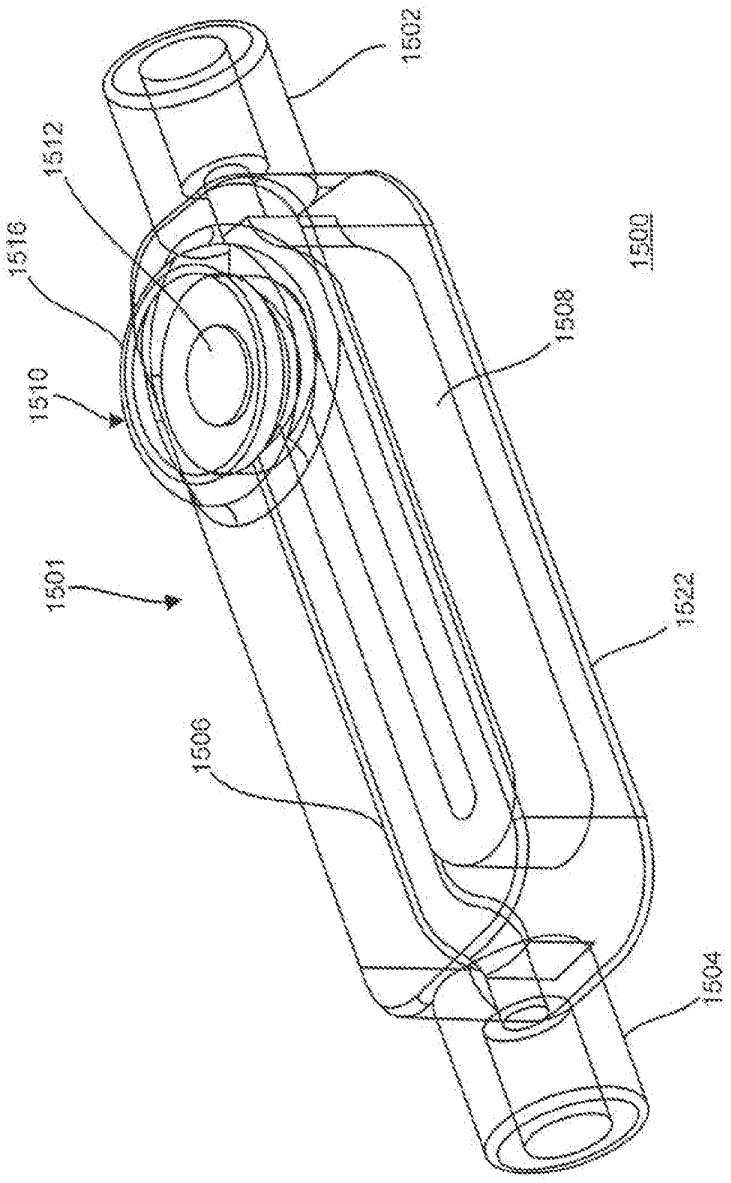


FIG. 15B

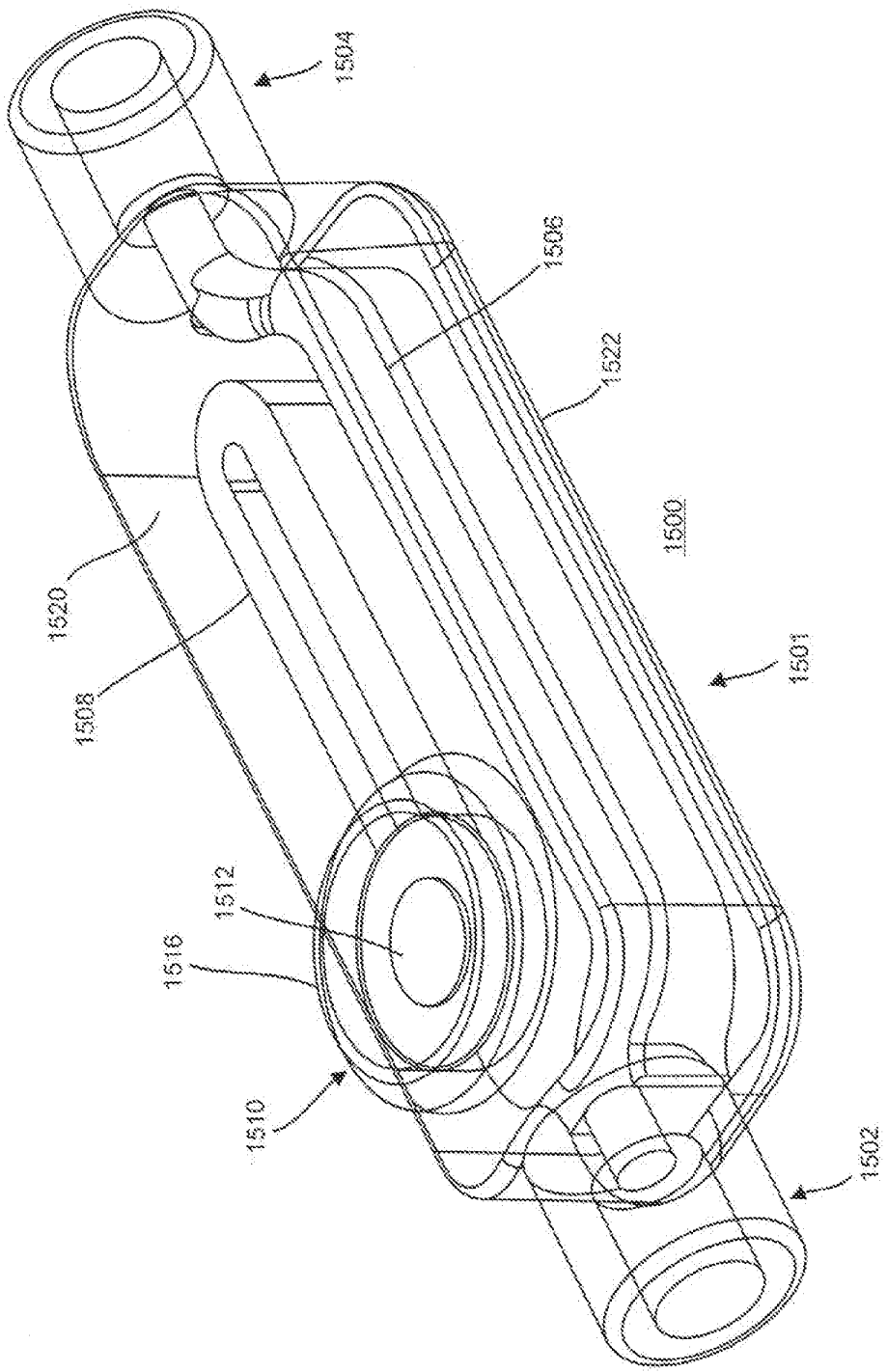


FIG. 15C

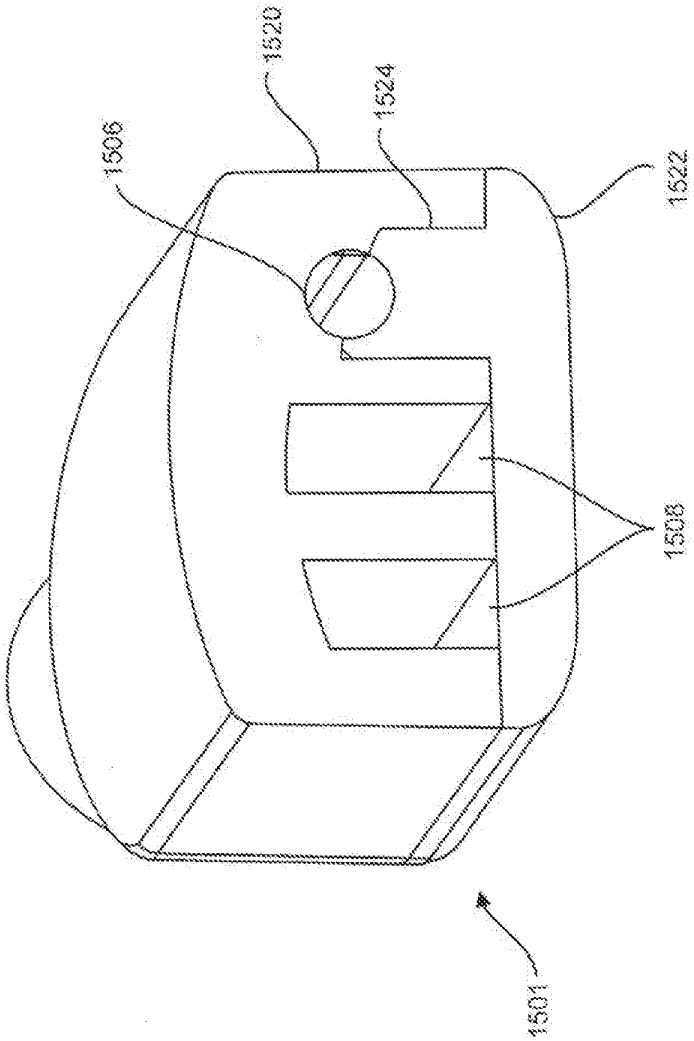


FIG. 15D

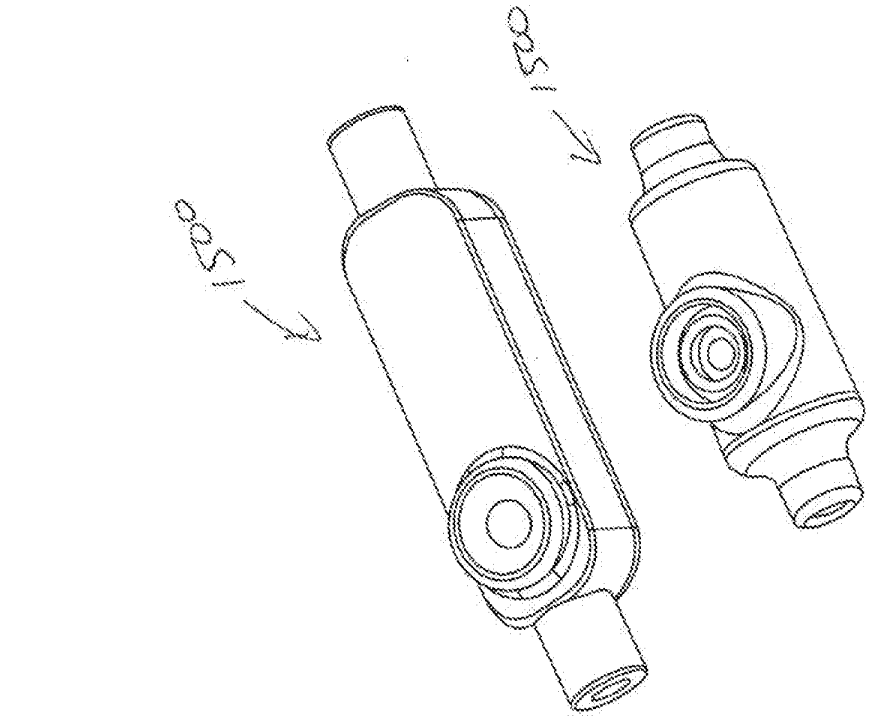


FIG. 15F

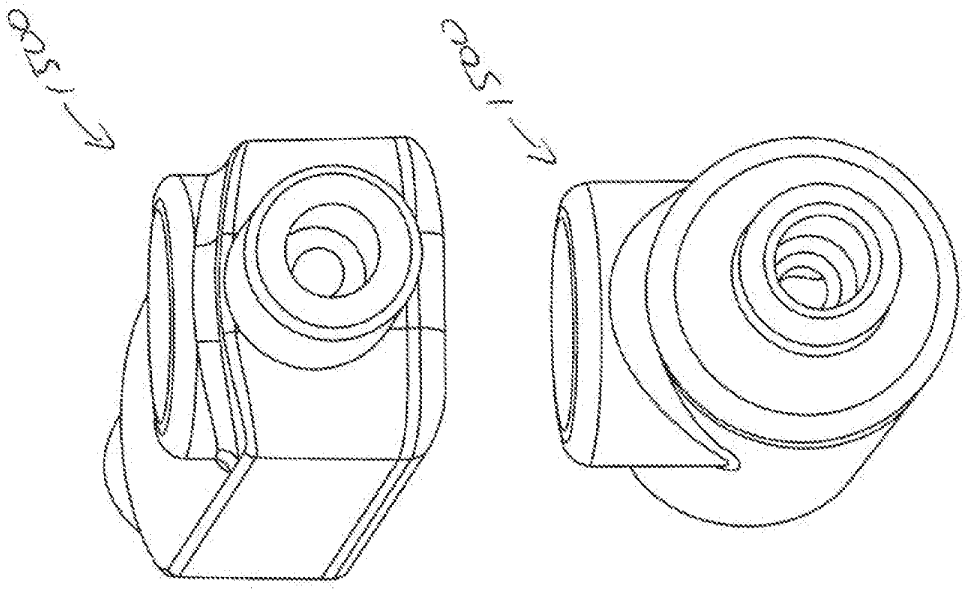


FIG. 15E

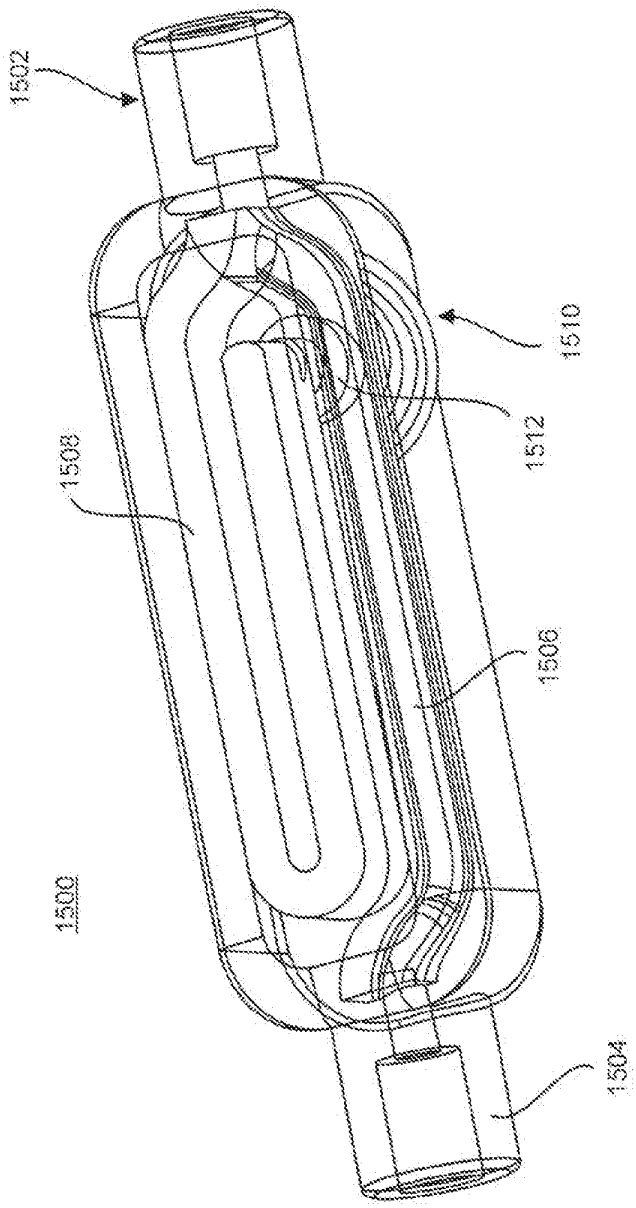


FIG. 15G

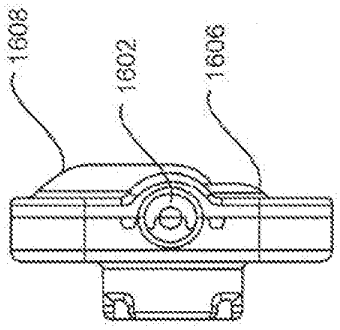


FIG. 16C

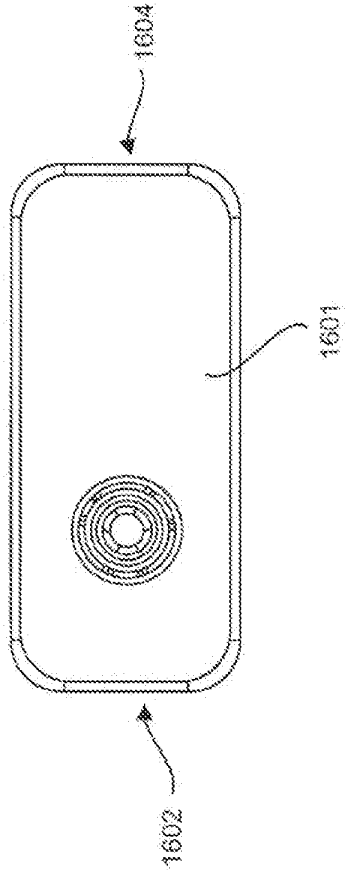


FIG. 16A

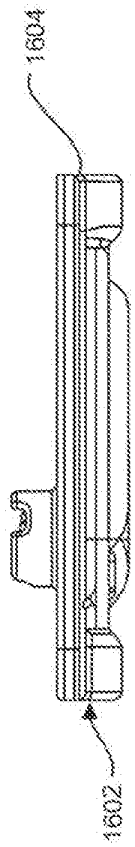


FIG. 16B

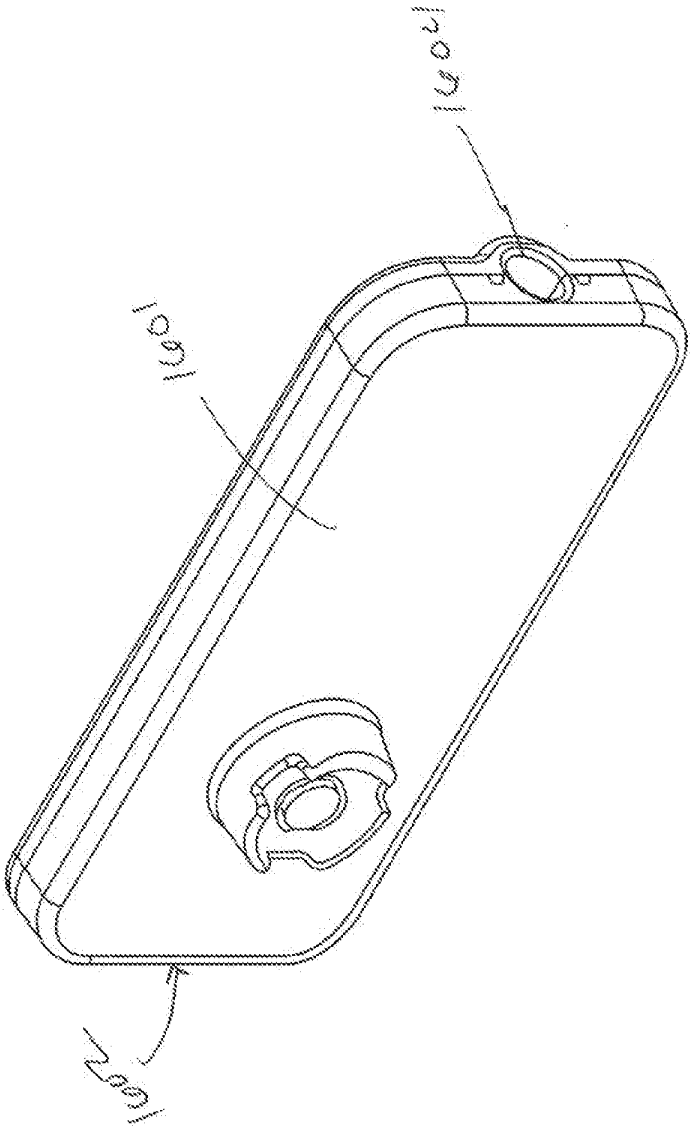


FIG. 16D

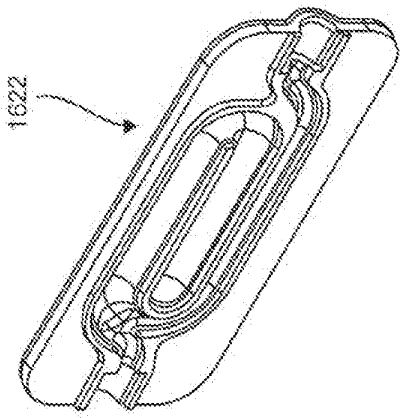


FIG. 17B

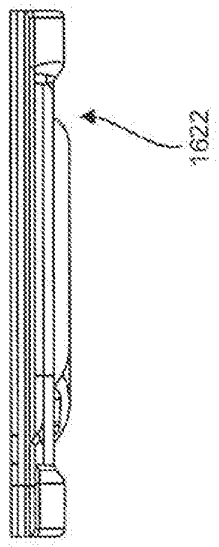


FIG. 17E

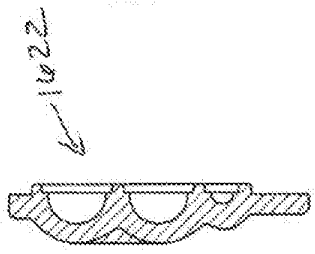


FIG. 17D

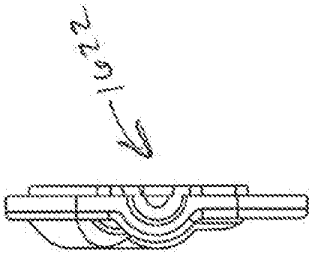


FIG. 17C

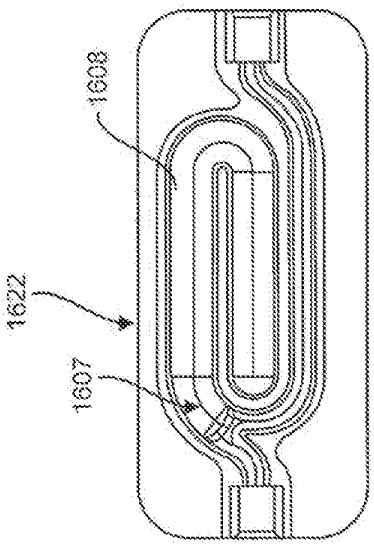


FIG. 17A

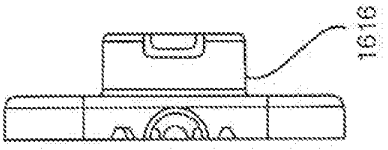


FIG. 18C

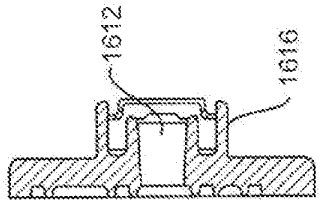


FIG. 18F

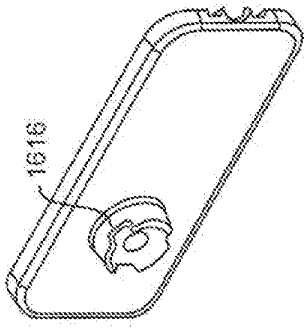


FIG. 18B

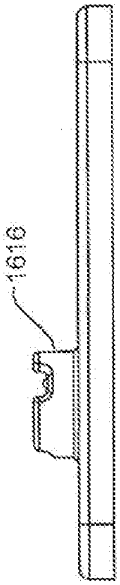


FIG. 18E

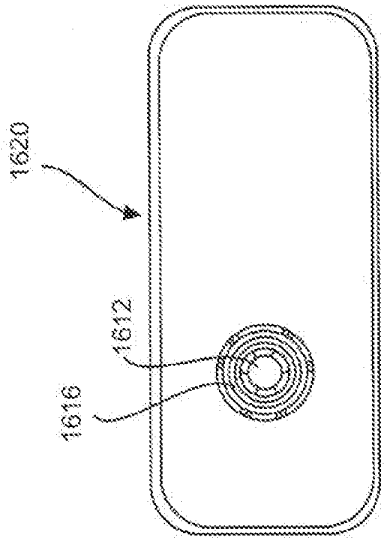
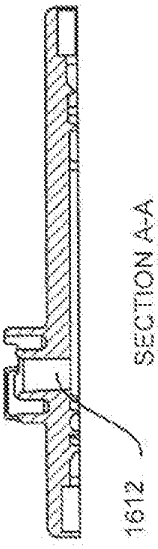


FIG. 18A



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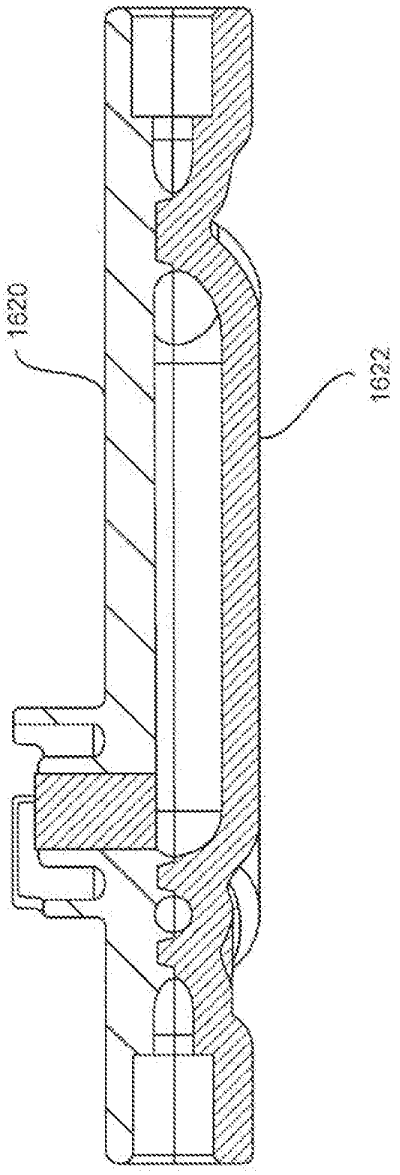
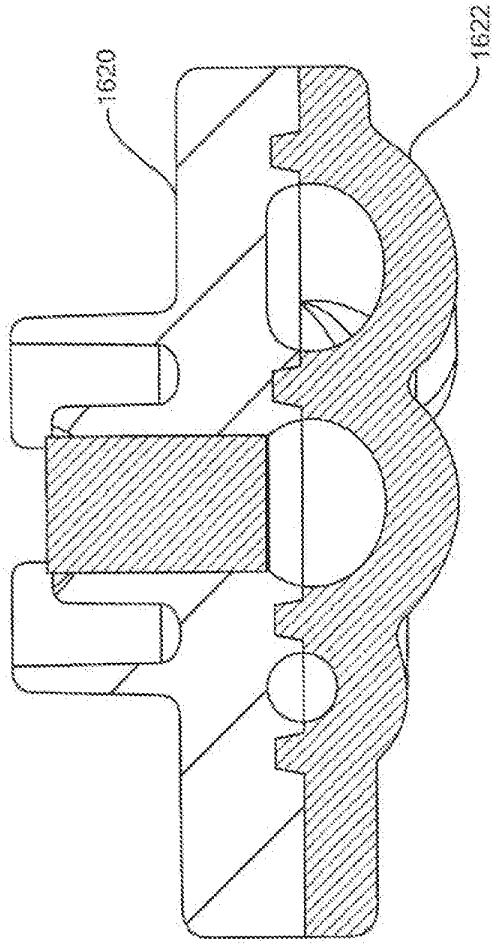


FIG. 19A



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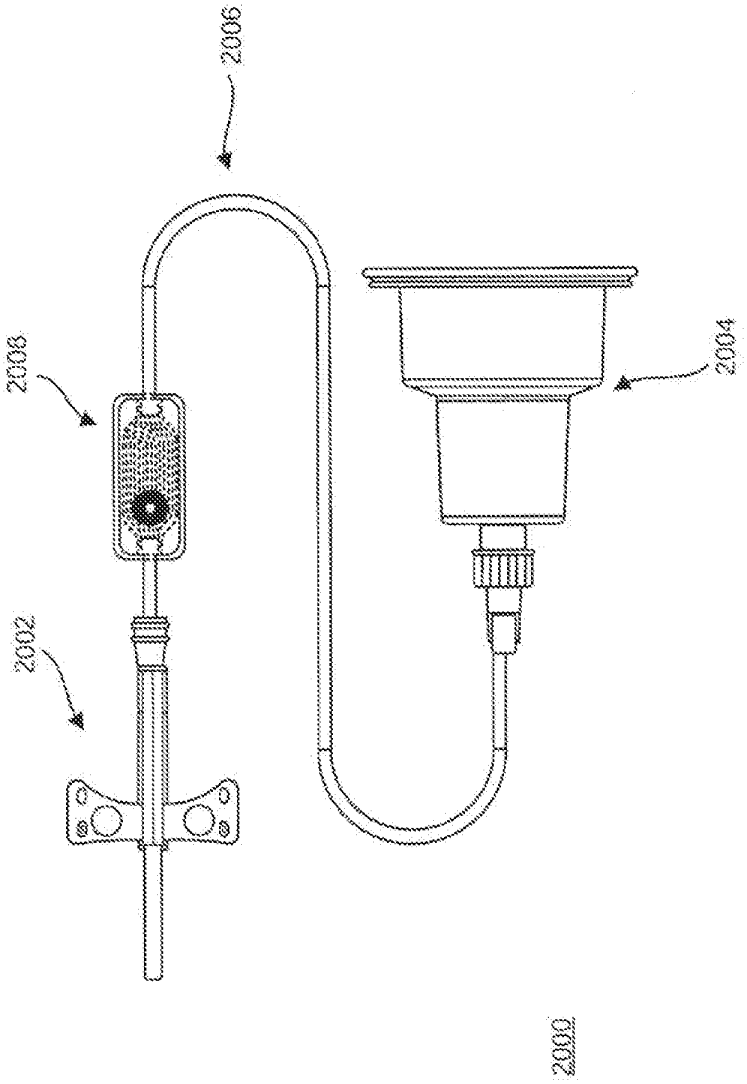


FIG. 20

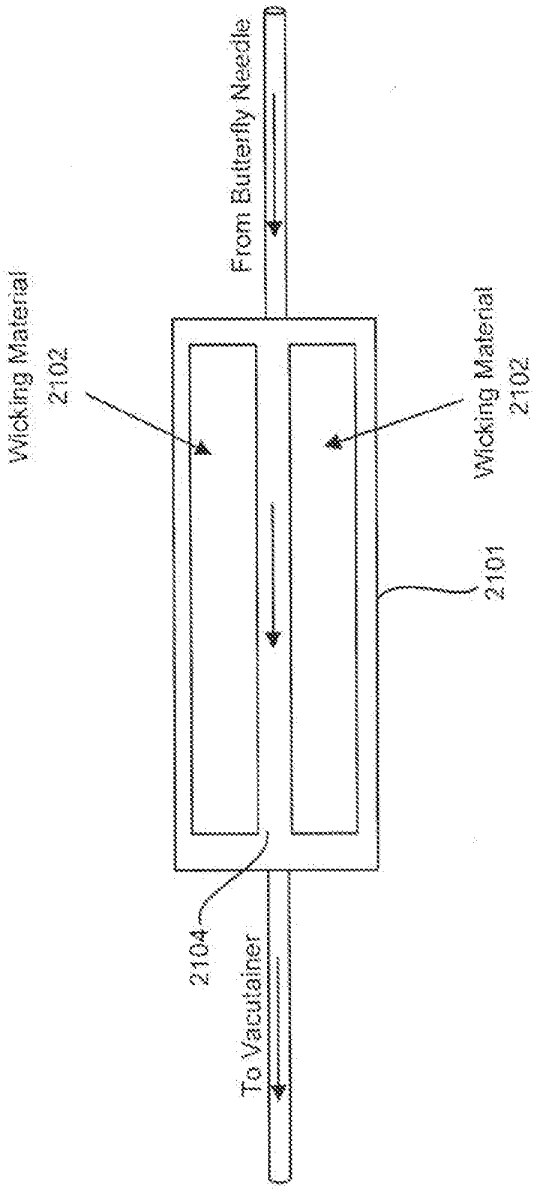

From Butterfly Needle
Wicking Material
2102
Wicking Material
2102
2101
2104
To Vacutainer
2100

FIG. 21

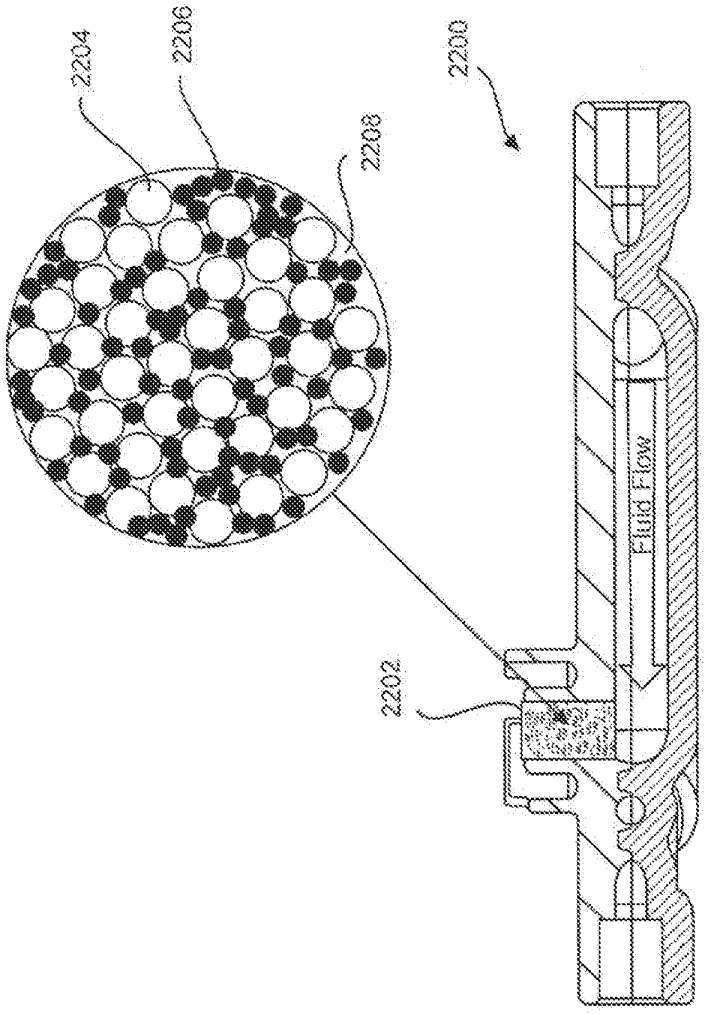


FIG. 22A

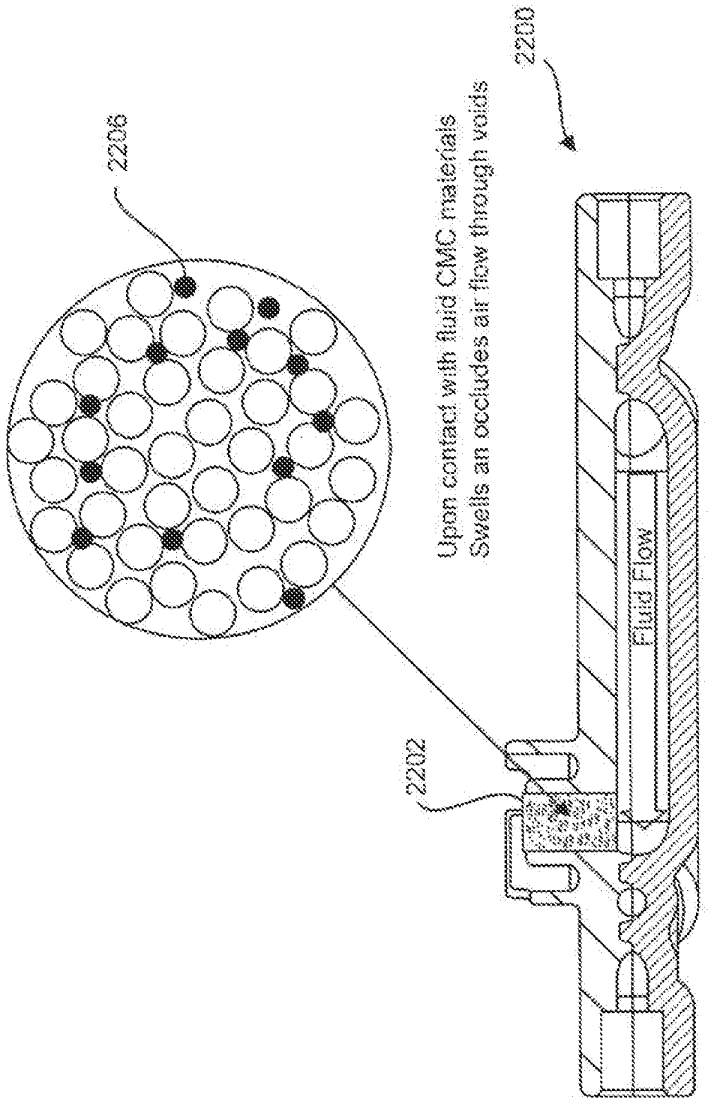

2206
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
2200
Fluid Flow
2202

FIG. 22B

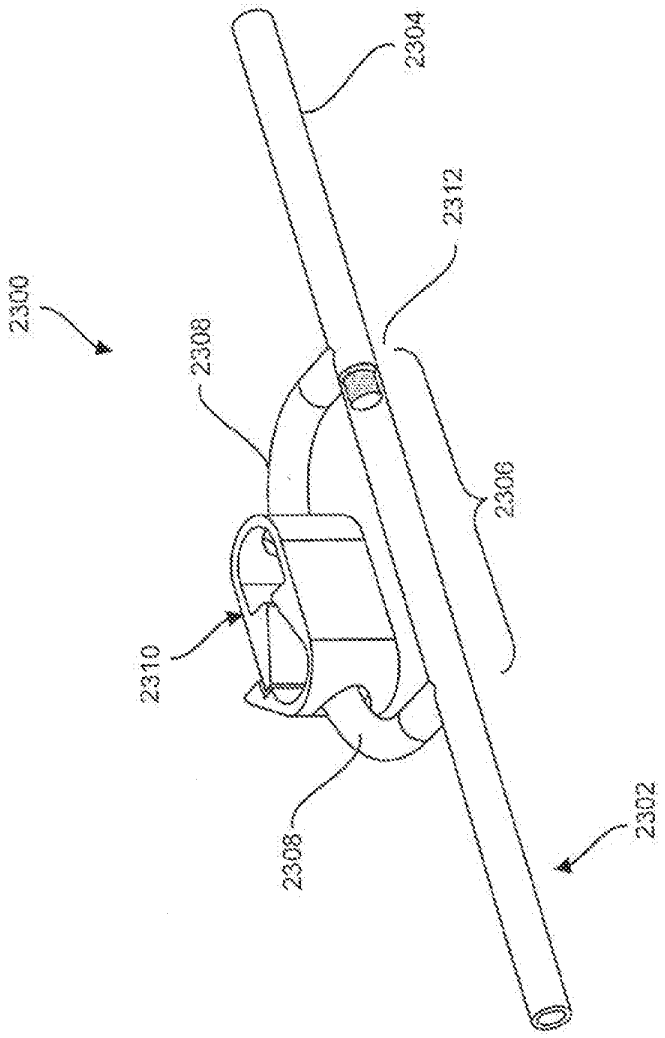


FIG. 23A

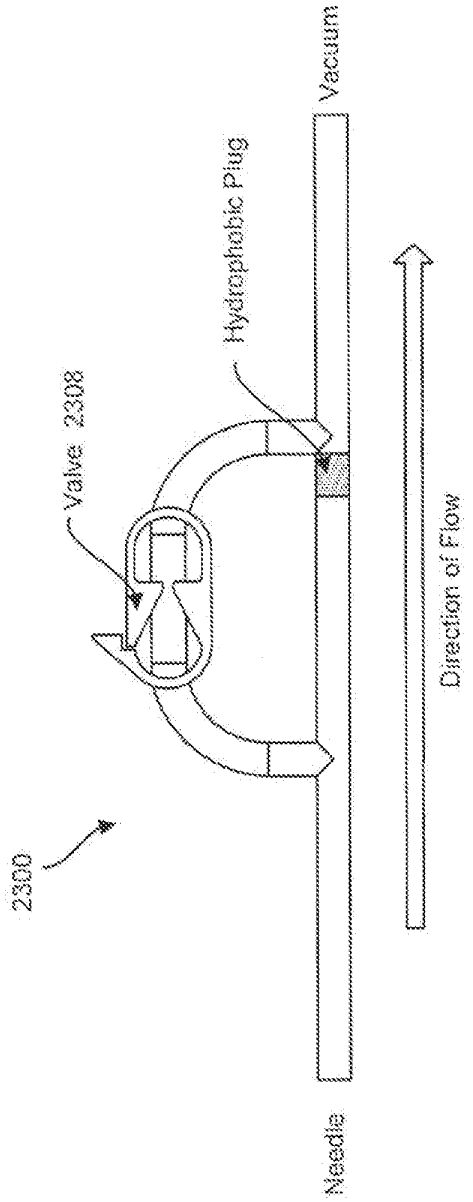

2300
Valve 2308
Hydrophobic Plug
Vacuum
Needle
Direction of Flow

FIG. 23B

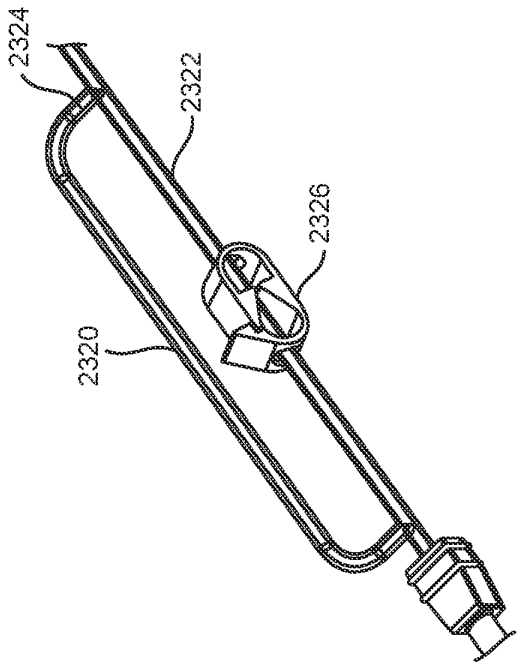


FIG. 23D

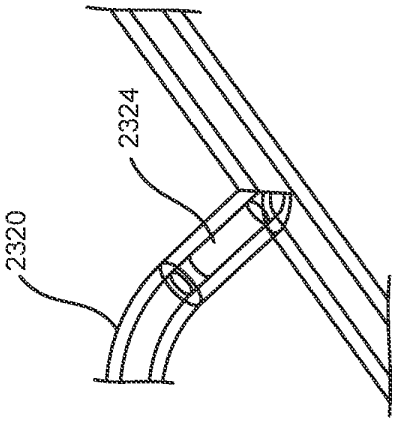


FIG. 23E

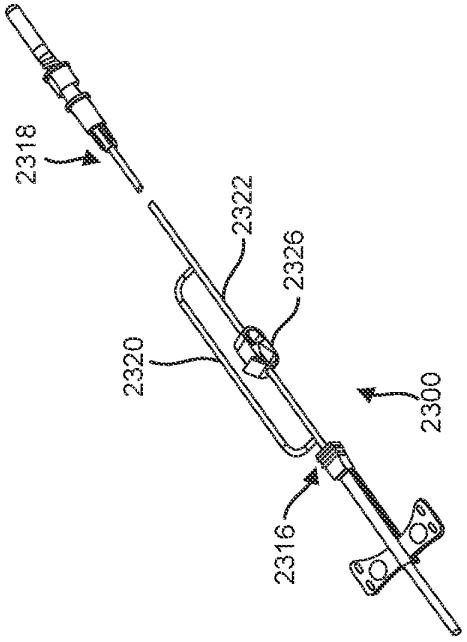


FIG. 23C

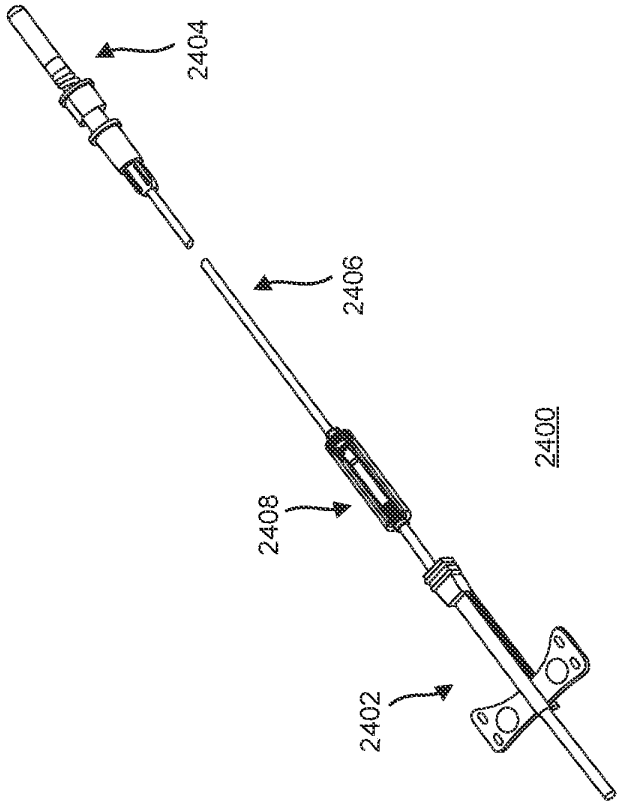


FIG. 24A

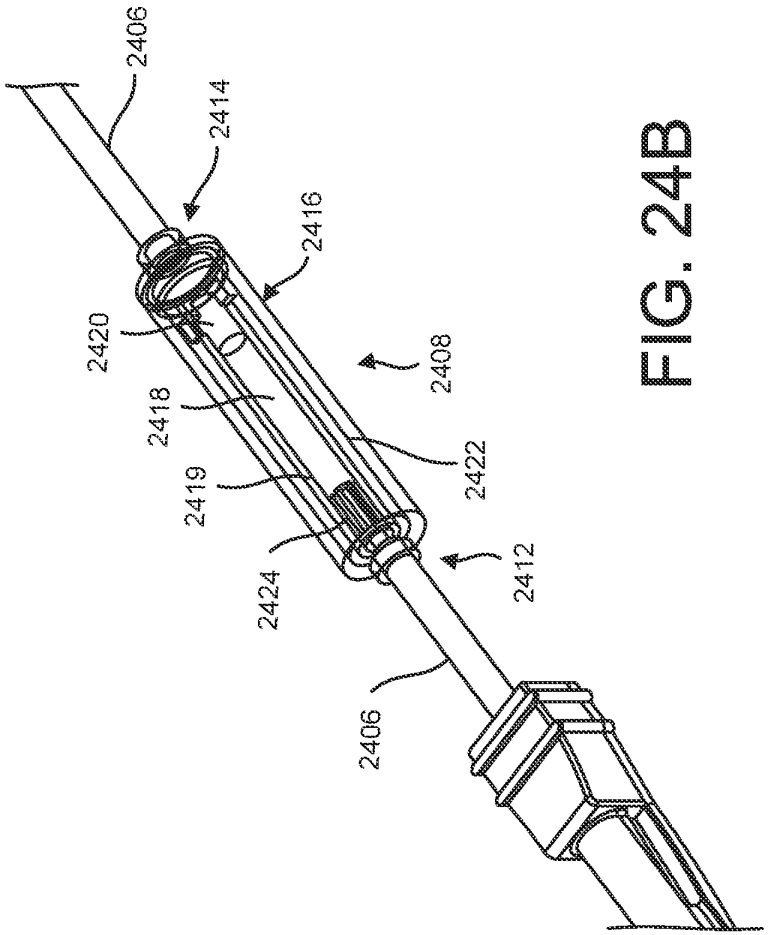


FIG. 24B

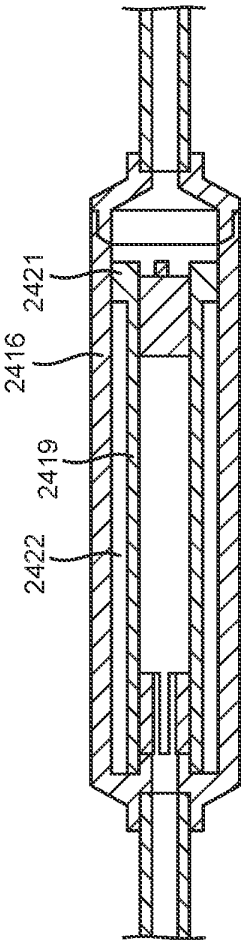


FIG. 24C

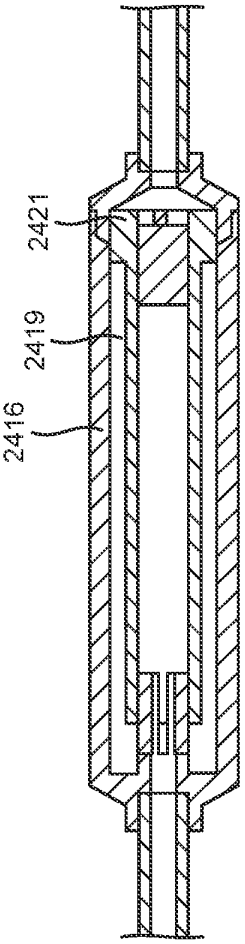


FIG. 24D

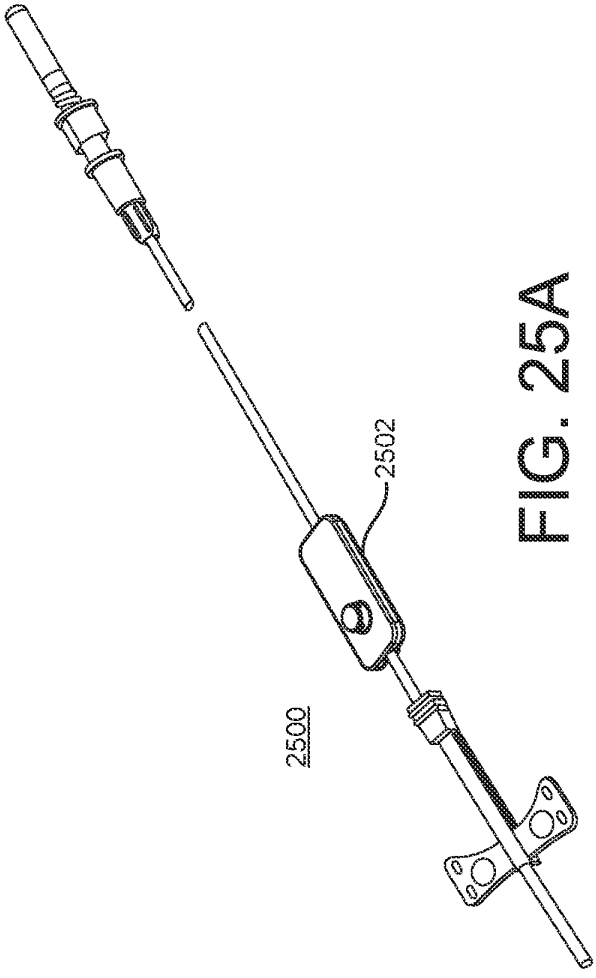


FIG. 25A

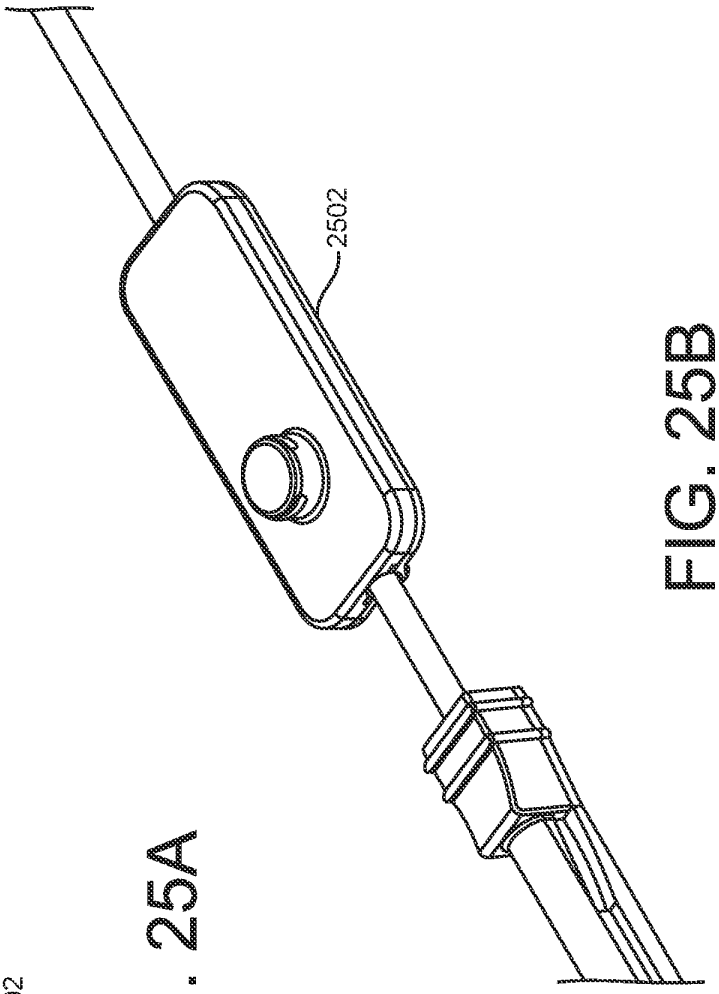


FIG. 25B

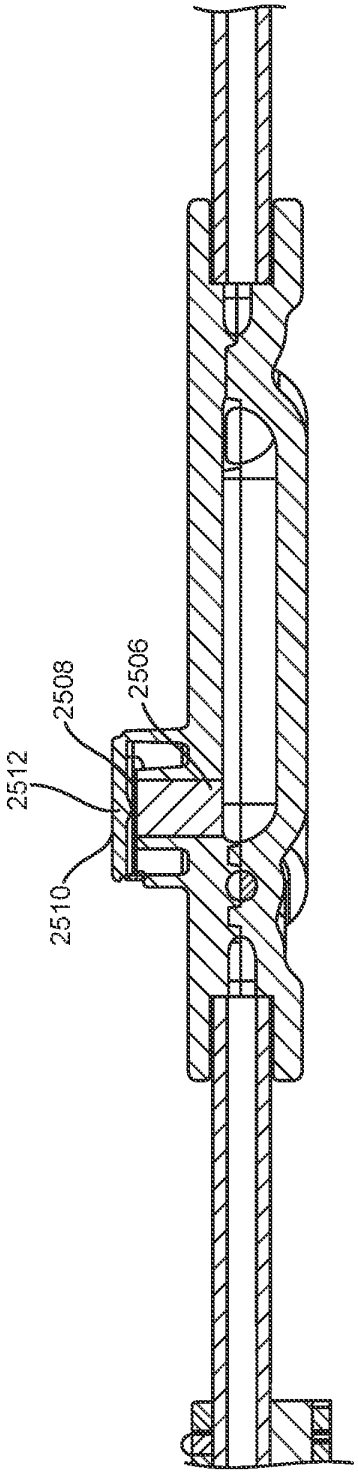


FIG. 25C

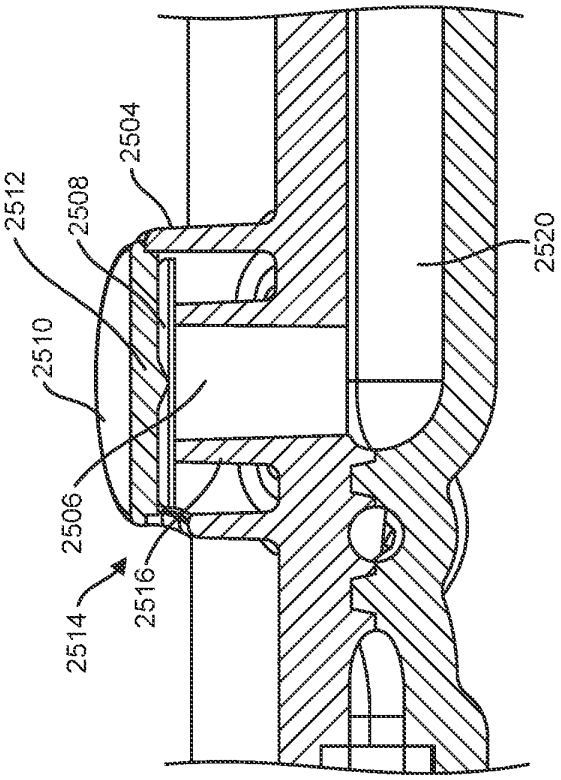


FIG. 25D

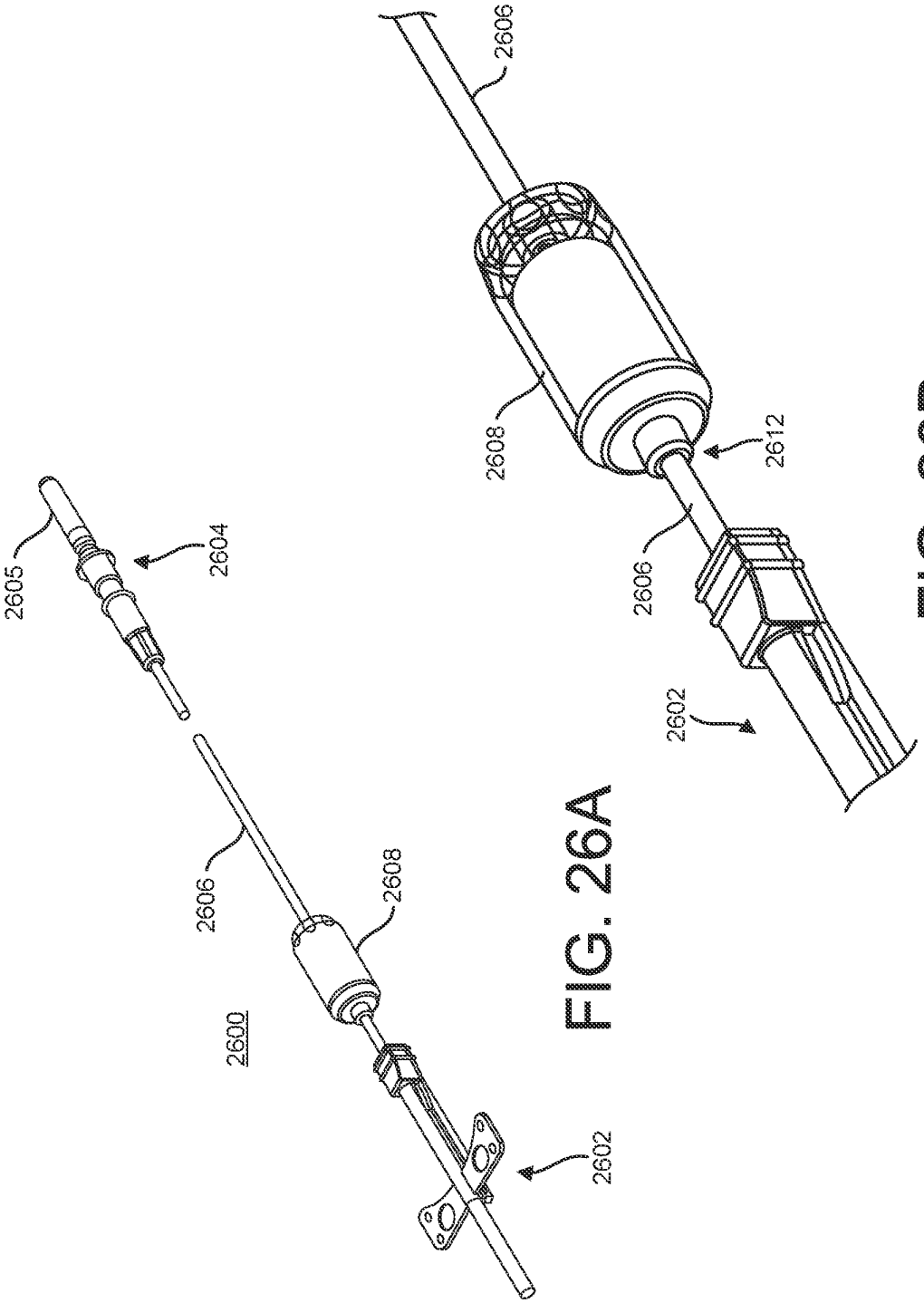


FIG. 26A

FIG. 26B

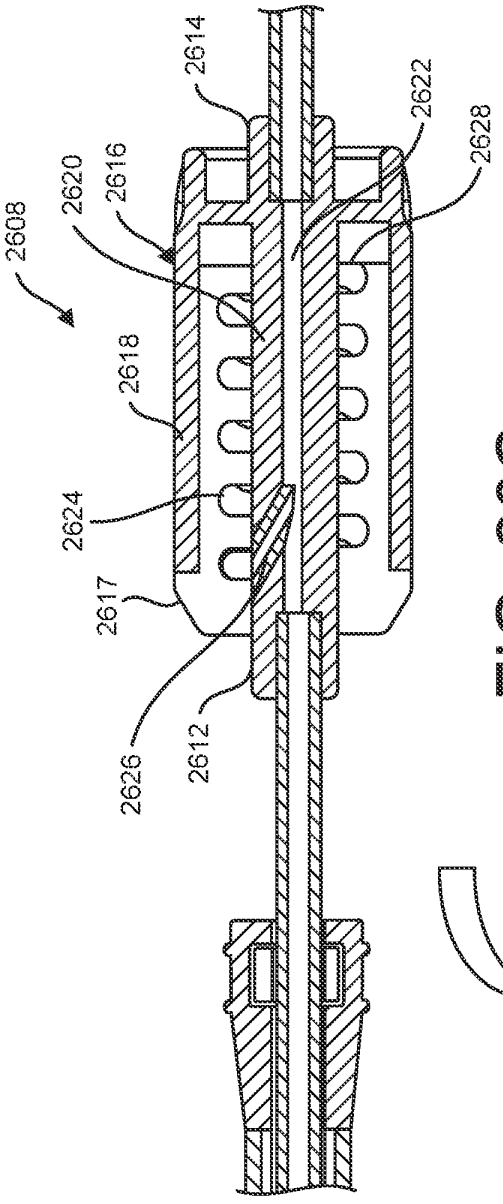


FIG. 26C

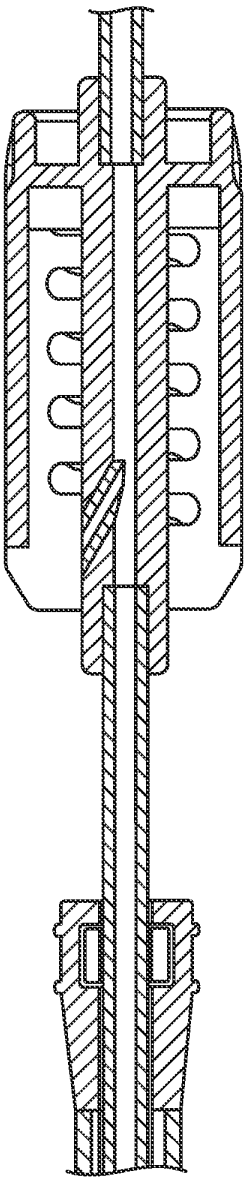


FIG. 26D

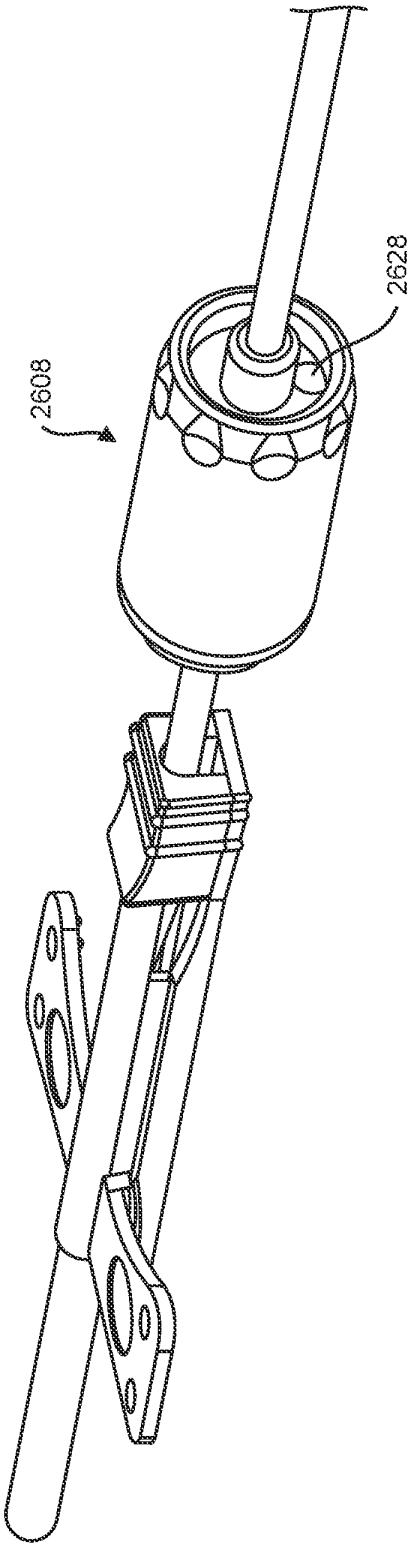


FIG. 26E

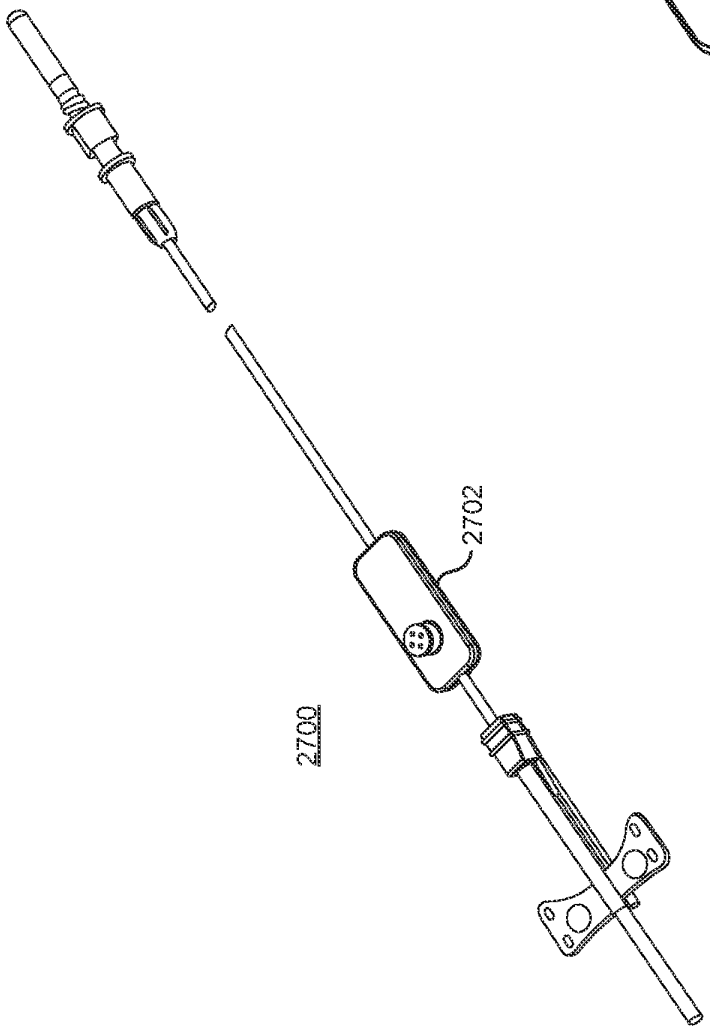
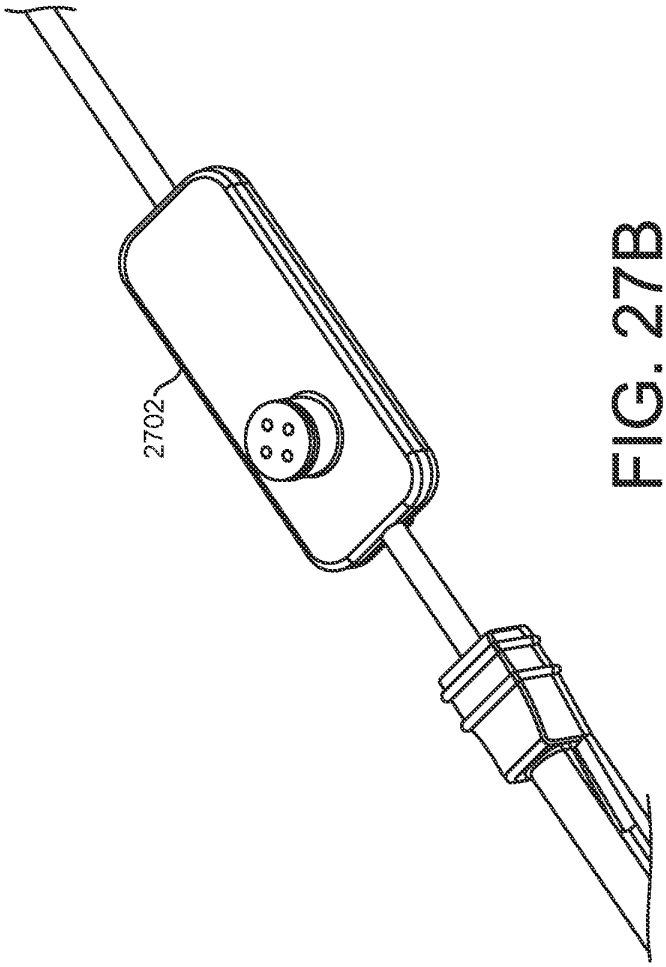


FIG. 27A



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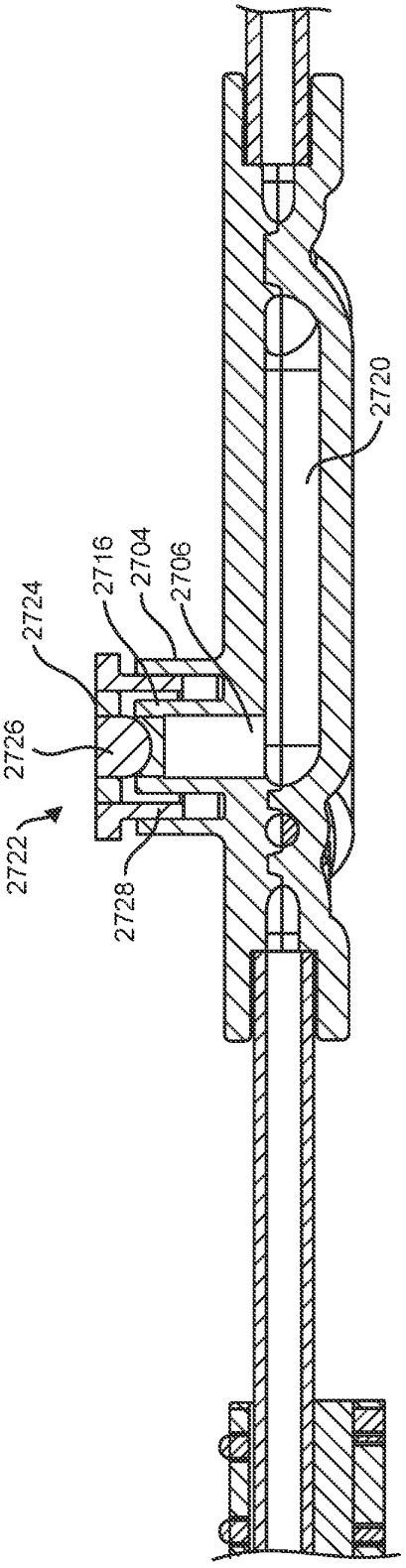

FIG. 27C

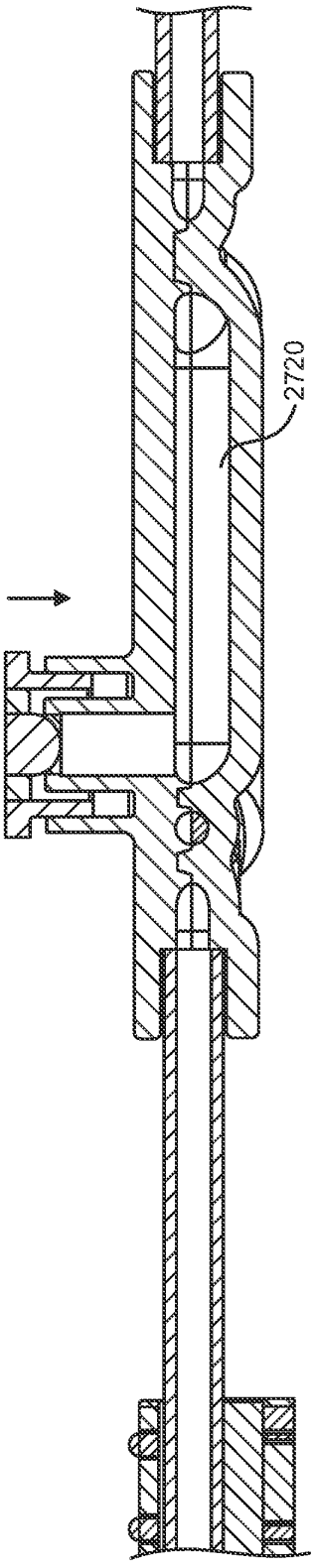

FIG. 27D

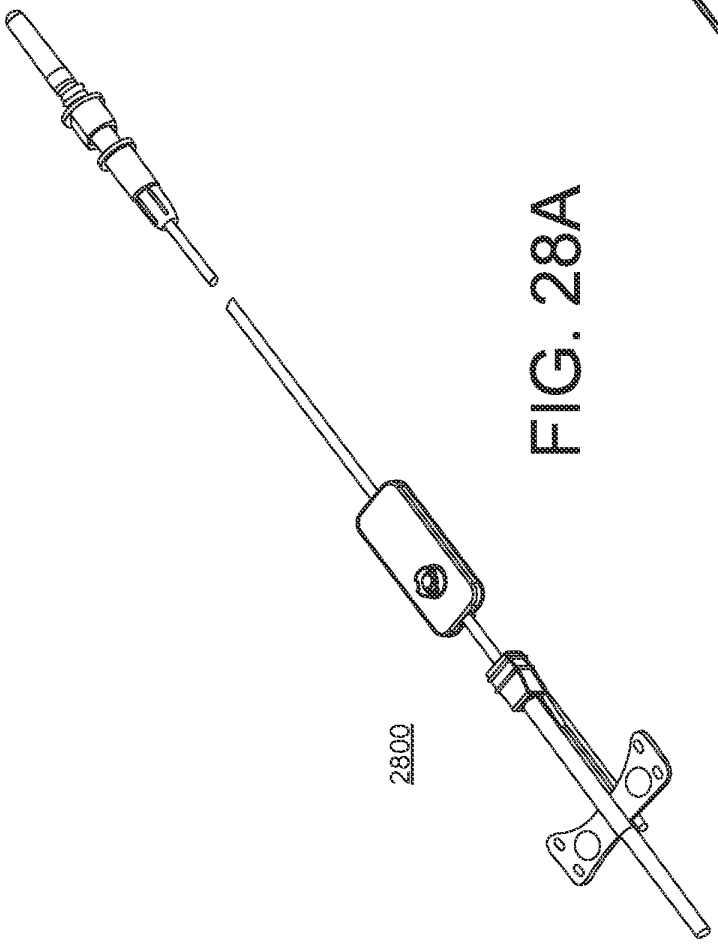

FIG. 28A

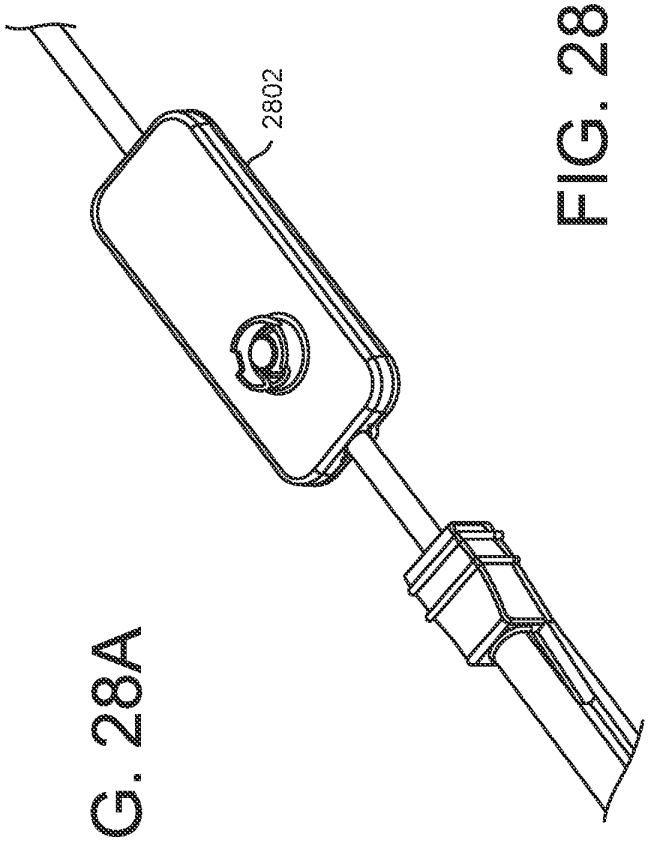

FIG. 28B

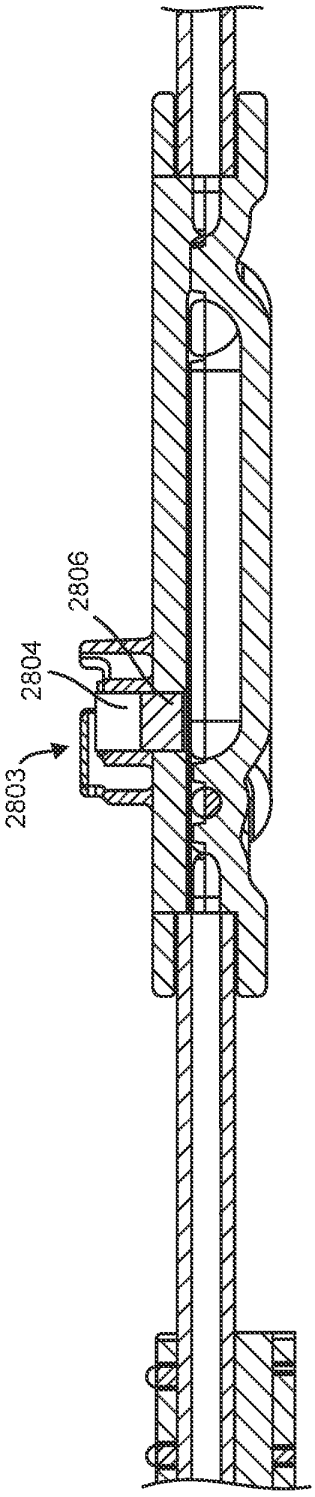

FIG. 28C

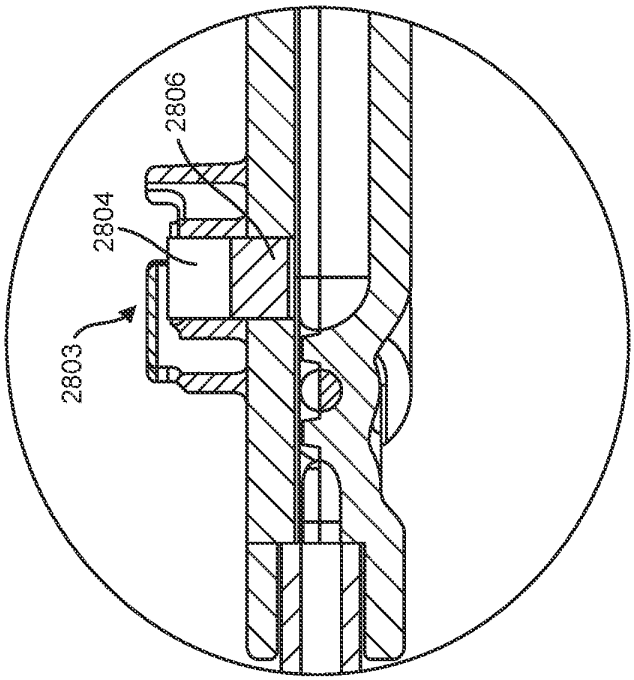

FIG. 28D

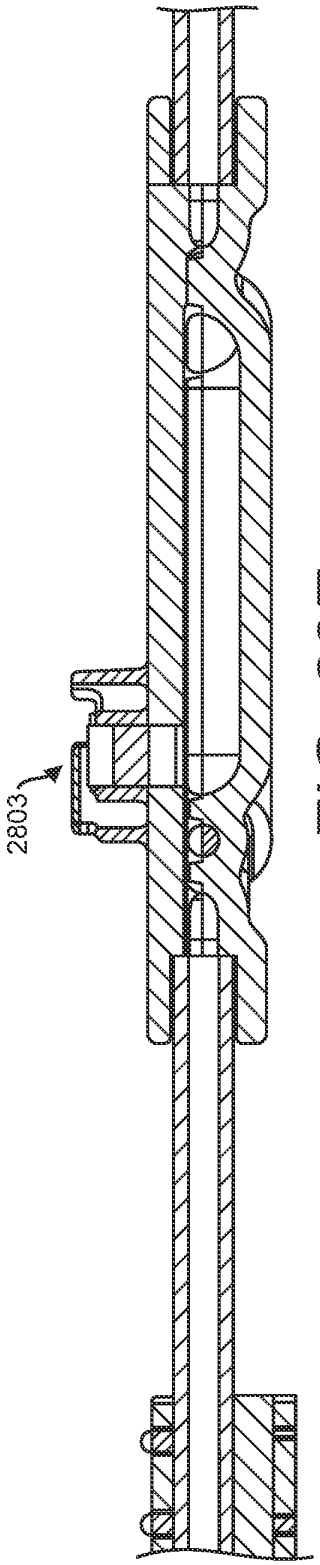

FIG. 28E

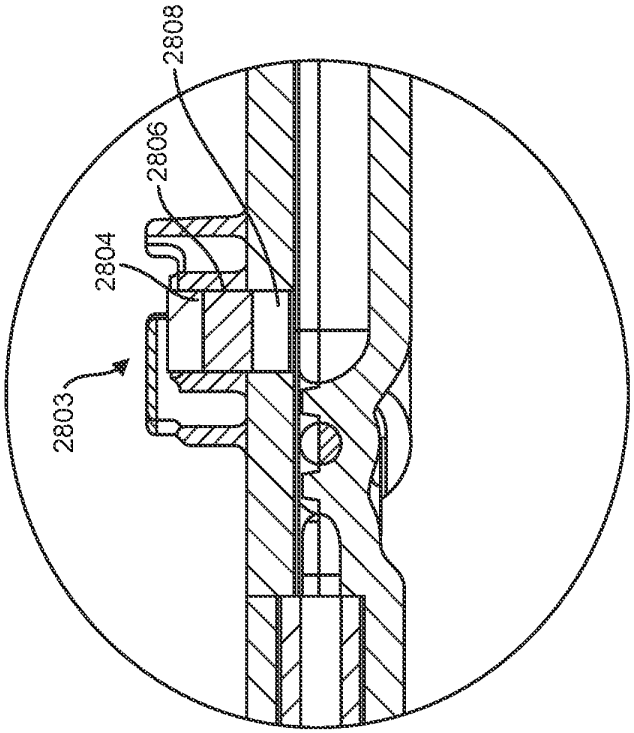

FIG. 28F

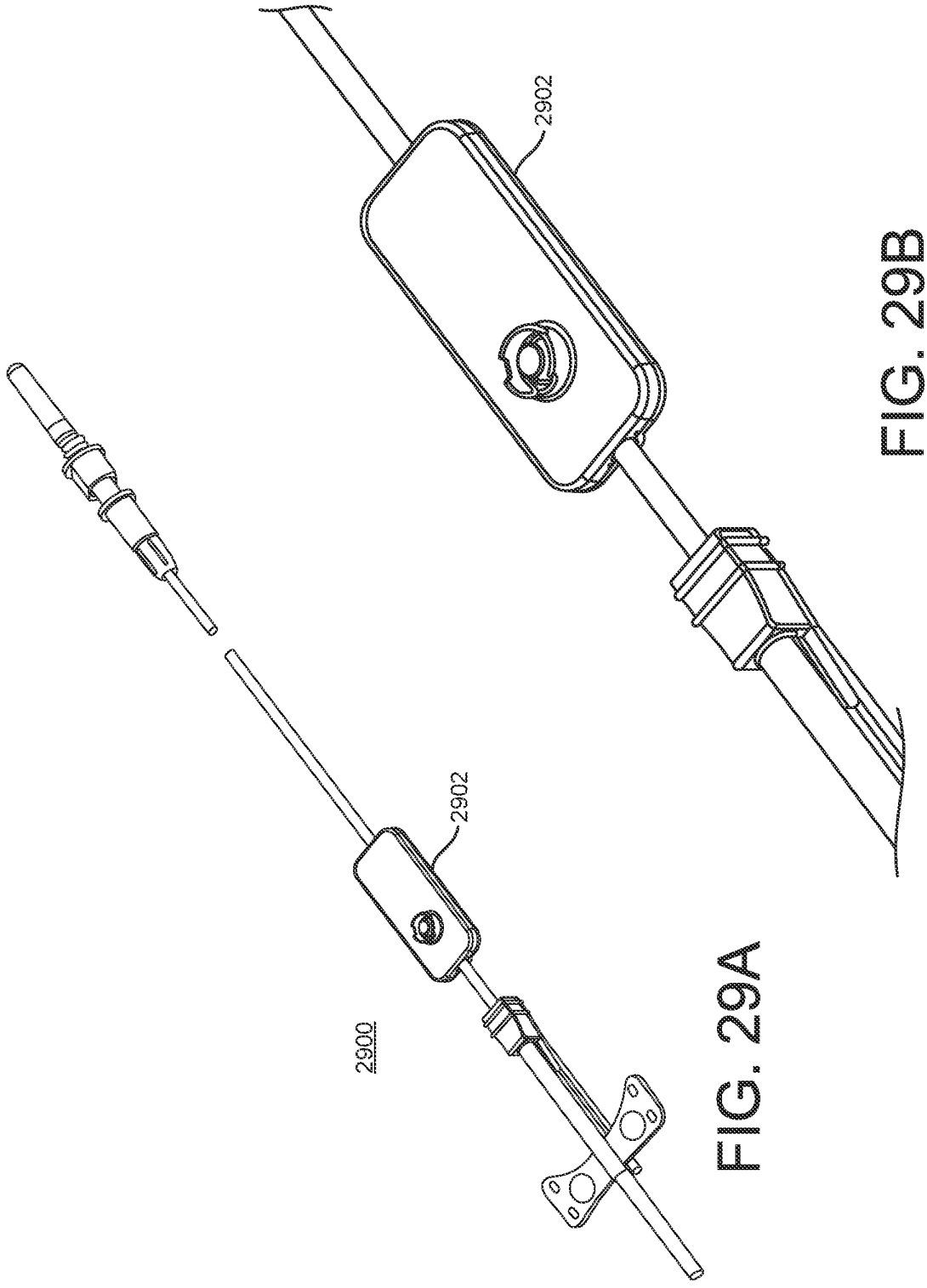

FIG. 29B

FIG. 29A

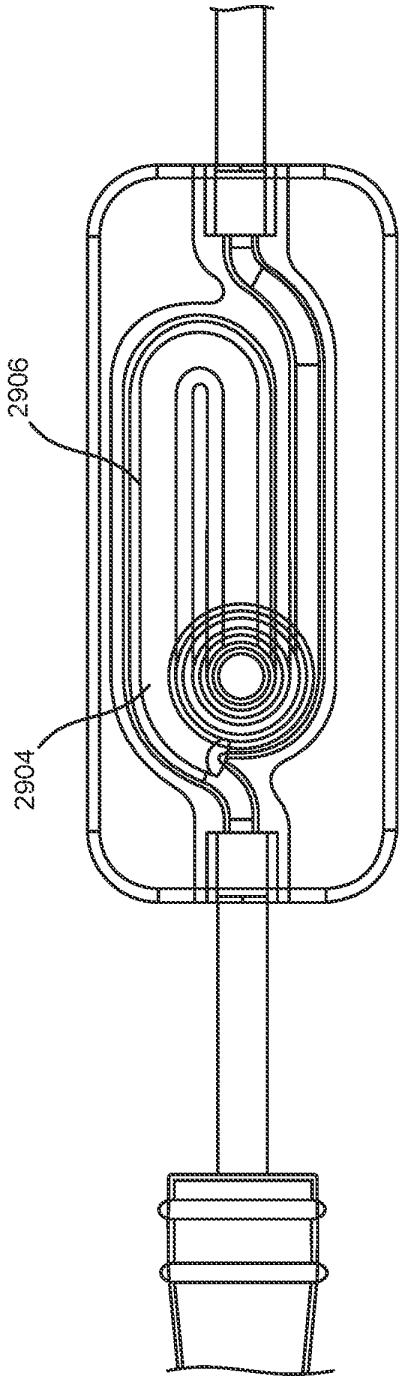

FIG. 29C

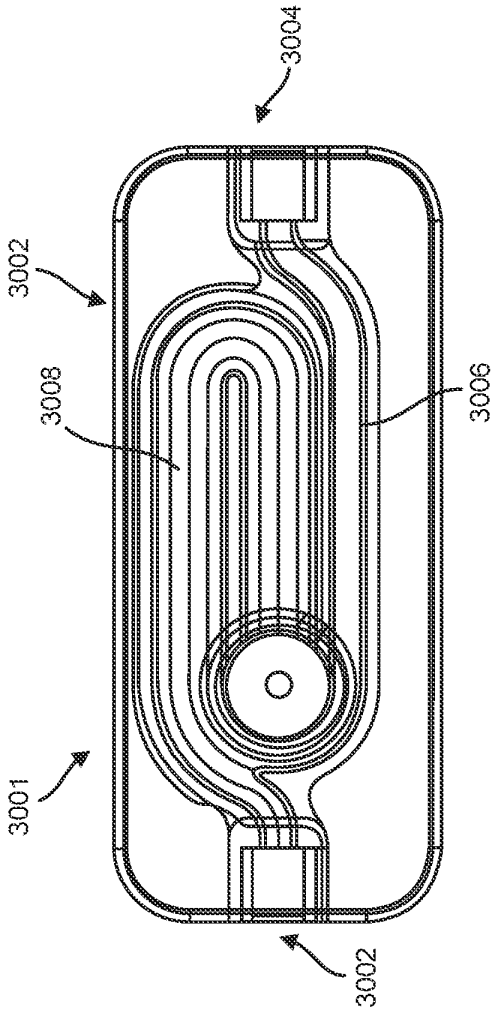

FIG. 30A

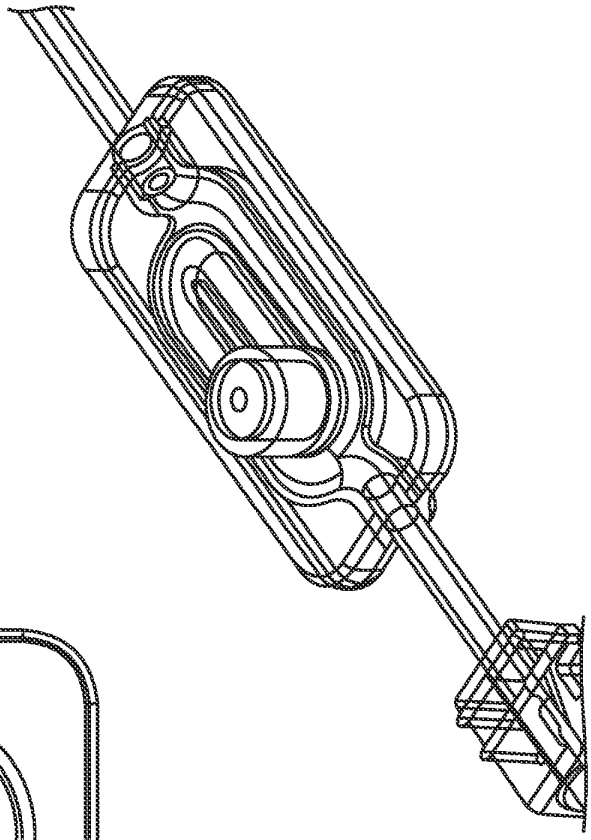

FIG. 30B

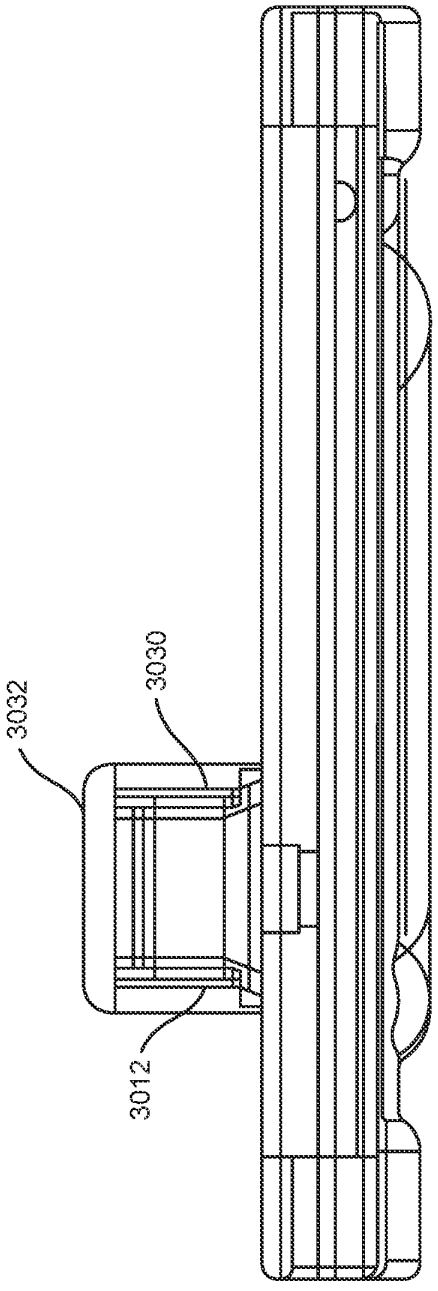

FIG. 30C

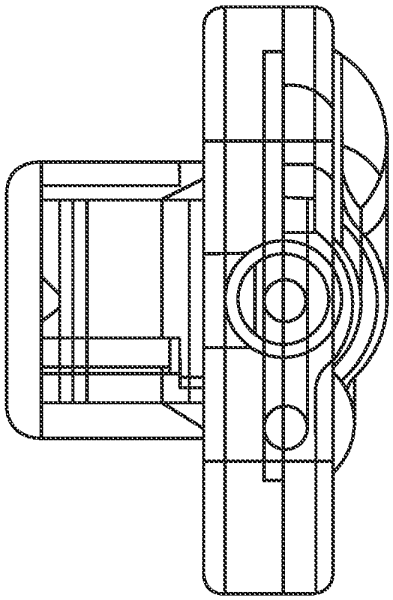

FIG. 30D

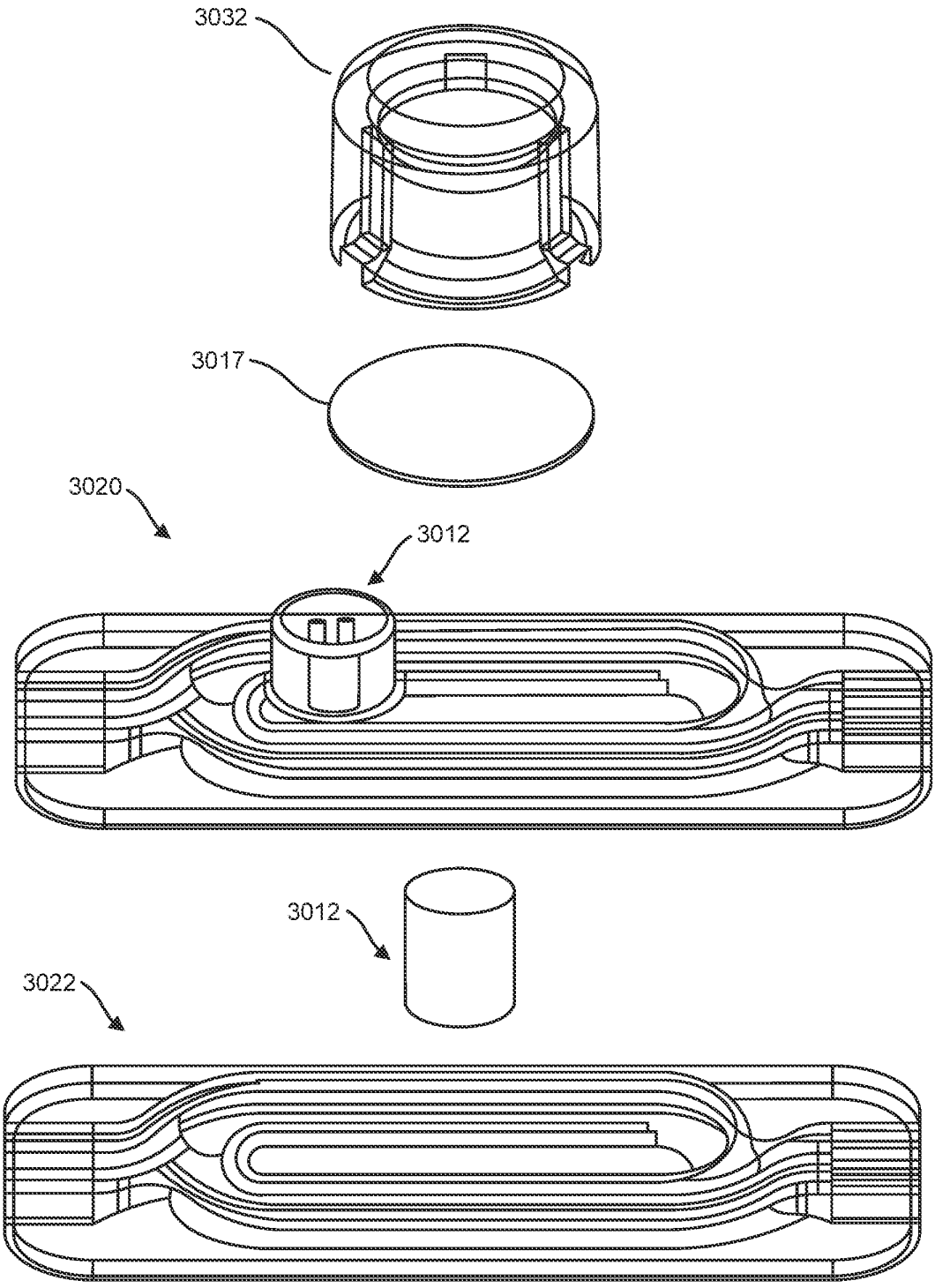

FIG. 30E

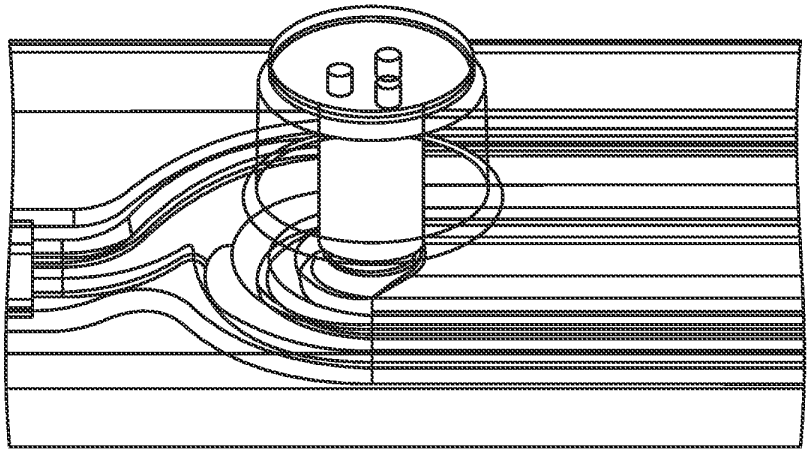

FIG. 30F

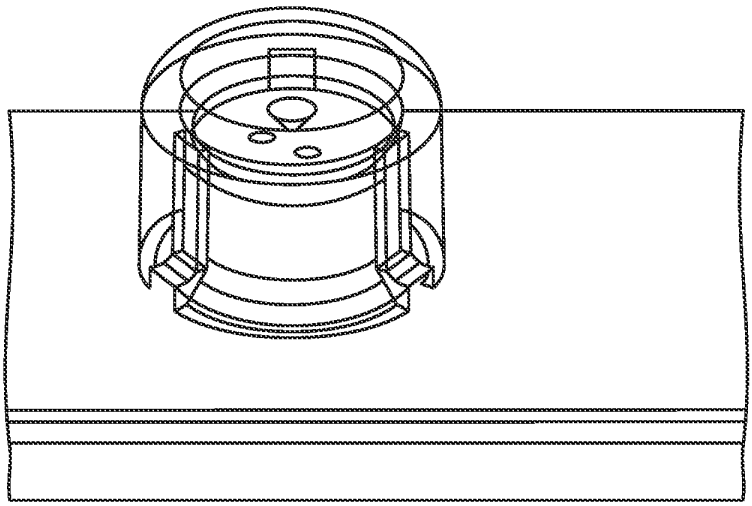

FIG. 30G

(1) Notify the designated first-aid trained personnel.

(2) Where practical, lay the patient flat or lower his/her head and arms, if the patient is sitting.

(3) Loosen tight clothing.

(4) The use of ammonia inhalants may be associated with untoward effects and is not recommended.

11.8.2 Nausea

The procedure for dealing with a patient who is experiencing nausea is to:

(1) Make the patient as comfortable as possible.

(2) Instruct the patient to breathe deeply and slowly.

(3) Apply cold compresses to the patient's forehead.

(4) Notify the designated first-aid trained personnel.

11.8.3 Vomiting

The procedure for dealing with a patient who vomits is to:

(1) Give the patient an emesis basin or carton, and have tissues ready.

(2) Give the patient water to rinse out his/her mouth.

(3) Notify the designated first-aid trained personnel.

11.8.4 Convulsions

The procedure for dealing with a patient who is having convulsions is to:

(1) Prevent the patient from injuring himself/herself. Do not restrain the movements of the patient's extremities completely, but try to prevent him/her from being injured.

(2) Notify the designated first-aid trained personnel.

11.8.5 Incident Reports

Incident reports should be filed according to institutional policy.

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Summary of Comments and Subcommittee Responses

H3-A4: *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fourth Edition*

General

1. NCCLS has inconsistencies in their own publications (H3 and H21) when it comes to the order of draw for coagulation testing relative to tissue thromboplastin contamination and procurement of a "discard tube." In performing intra-laboratory studies at our institution and sister institutions, results showed no significant clinical or statistical significance on any of the assays between each of the specimen tubes performed at each individual laboratory. Also, our results indicated that NCCLS guidelines for obtaining a second tube when performing coagulation testing should be eliminated when the revised document is published.

- **The text has been revised (see Section 8.10.2), including the order of draw, and several notes have been added to address the use of discard tubes for coagulation test collection. The next version of H21—*Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays* is due to be released by the end of 2003. The documents are now consistent.**

Section 7.9.3.4, Intravenous Therapy (Now Section 8.6.7.4)

2. The text of this section states, "Optimally, specimens should not be collected from an arm with an intravenous site. If this is impossible the attending physician should be consulted (see Section 10.3). Blood should never be collected from above any active intravenous site (see Section 10.6). We would like a clearer definition of what is considered to be "active." What defining factors are present that would classify an "active" intravenous site?

- **The term "active" has been removed from the text. The text in Sections 8.6.7.4 and 11.6 has been revised to describe the procedure for specimen collection in relation to intravenous fluids.**

Section 7.13.3.3, Coagulation Testing (Now Section 8.10.3)

3. The text of this section states, "if only a coagulation tube is drawn for routine coagulation testing (APTT and PT tests) the first tube drawn may be used for testing." This statement has raised some discussion regarding the definition of the phrase "routine coagulation testing." Does this include coumadin patient samples?

- **Specimens collected from patients on warfarin sodium (Coumadin™) are considered for routine coagulation testing.**

Section 10, Special Situations (Now Section 11)

4. H3-A4 does not list recommendations for obtaining venipuncture specimens during blood transfusions. Information on this topic would be greatly appreciated.

- **The directions outlined in Section 11.6 should be followed during transfusions as it is described for intravenous fluids.**

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Summary of Delegate Comments and Working Group Responses

H3-A5: *Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition*

General

1. Nothing was included about pain management (EMLA, coldspray, etc.) or age-specific consideration on developmental stages of children. I can send you what we have if you like.

- **The working group recognizes the availability of pain reducing techniques. Topical sprays and treatments are available and are used at the discretion of each institution.**

  Age-specific considerations are outside the scope of this document. Please refer to the current edition of NCCLS document H4—*Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture.*

2. Add a Section 11.2.6, RNA Specimen. Since RNA is unstable, the whole blood should be transported to the laboratory at 2 to 25 °C within six hours of collection.

   References: de Gerbehaye A-I, et al. Stable hepatitis C virus RNA detection by RT-PCR during four days storage. *BMC Infectious Diseases.* 2002;2:22, and Halfon P, et al. Impact of various handling and storage conditions on quantitative defection of hepatitis C virus RNA. *J Hepatol.* 1996;25:307-311.

- **This comment is more related to specimen handling than collection and is beyond the scope of this document. This comment will be considered during the revision of NCCLS document H18-A2—*Procedures for the Handling and Processing of Blood Specimens; Approved Guideline.***

Foreword

3. Page vii should include hemolysis and clotting of samples, as these are common problems with hematology or coagulation samples. "The errors that can occur during the collection and handling of blood specimens are potentially numerous (e.g., inaccurate identification of specimens, the use of incorrect anticoagulant, the formation of hematomas, hemoconcentration)."

- **The text has been revised to include specimen hemolysis and improper handling of anticoagulants.**

Section 8, Venipuncture Procedure

4. Consider switching steps 14 and 15 so that bandaging occurs after specimens are labeled, not before. This helps assure that specimen labeling will occur before leaving the patient's side. It also accommodates situations in which the patient assists in applying pressure while the phlebotomist labels tubes.

- **The working group appreciates the comment; we believe, however, that the order is correct as written. The text in Section 8.15 emphasizes the need to label the tube before leaving the side of the patient.**

5. Between steps 5 and 6, add the following: "Inquire as to patient's sensitivity to latex products." Step 7, change as follows: "Put on appropriate gloves based on patient's response to Step 6."

- **The working group agrees with the comment. The text of step 3 has been revised as follows: "Verify patient's diet restrictions, as appropriate, and inquire if the patient has a latex sensitivity. Select appropriate gloves and tourniquet."**

6. Modify step 6 to new "step 6: Inquire on patient's allergy to latex products." Also add: "Due to the prevalence of latex sensitivity, the phlebotomist should inquire as the patient's sensitivity to latex products (tourniquet and gloves.)"

- **The text of Step 3 and Section 8.3 has been revised to include asking the patient if he/she has a latex sensitivity. The text in Section 8.6 has been revised to refer the reader to Section 7.7.**

7. The patient should be asked to open his/her hand just when entering the vein, therefore eliminating some of the pain a tense closed fist may cause. Also, recommend performing venipuncture using the correct order of draw.

- **In response to this comment, the text of step 9 has been revised as follows: "Perform venipuncture; once blood flow begins, request patient to open hand." Step 10 has been revised to recommend the use of the correct order of draw.**

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8. Following the removal of the needle, pressure should be applied to the venipuncture site (either by the patient or phlebotomist).

- **In response to this comment, the text of step 14 has been revised as follows: "Apply pressure to the site, making sure bleeding has stopped, and then bandage the arm."**

Section 8.1.1, Information for Test Request Form

9. "May include" should be utilized.

- **The working group believes that the test request form information listed should be included.**

Section 8.1.2, Accessioning Blood Bank Specimens

10. Neither AABB nor CAP requires "time of collection" on the specimen tube label.

- **Time of collection is important for some specimens (e.g., therapeutic drug monitoring). The subcommittee confirmed that AABB does not require "time of collection" on the specimen tube label. The text, "Blood bank specimens must be labeled according to the standards set by the American Association of Blood Banks (AABB)," has been incorporated into Section 8.15, Label Blood Collection Tubes and Record Time of Collection. The remainder of Section 8.1.2 has been deleted.**

11. This passage is more about patient identification and labeling specimens than accessioning. Passages are important, but seem out of place. Consider moving the passage on identifying blood bank patients to Section 8.2 ("Step 2: Approach and Identify the Patient.") and the passage about labeling to Section 8.15 ("Step 15: Label Blood Collection Tubes and Record Time of Collection").

- **See response to comment 10.**

Section 8.2.3, Patient Who Is Semiconscious, Comatose, or Sleeping

12. This passage does not address identification and is out of place. Consider moving to Section 8.5.4.

- **The location of this text is appropriate. Section 8.2 addresses both approaching and identifying the patient. The following has been added to the end of the paragraph: "If unable to identify the patient, then contact the nurse or physician."**

Section 8.2.4, Patient Who Is Unconscious, Too Young, Mentally Incompetent, or Does Not Speak the Language of the Phlebotomist

13. The first bullet states, "Ask the nurse, a relative, or a friend to identify the patient by name, address, and identification number and/or birth date." This is inconsistent with Section 8.2.2, re: asking for patient's address and identification number. Suggest changing "and" to "or" for consistency with step 1 of 8.2.2.

- **The text in Section 8.2.4 has been revised for consistency with Section 8.2.2.**

Section 8.4.1, Supplies

14. "Inspect all supplies for possible defects" should include inspection of expiration dates on blood collection tubes.

- **The text has been revised to include applicable expiration dates during inspection of supplies.**

15. Supplies, sharps, or other disposal container is missing from the list (as discussed in Section 8.13). This should be available at the bedside for safe disposal.

- **The following bullet point has been added to the list: "Sharps container, consistent with OSHA regulations."**

16. Supplies such as tubes and needles should be checked before use to ensure they are not outdated. Sterile conditions or tube vacuum could be lost in old supplies. NCCLS document H4-A discusses tube stability and dating; H1-A4 discusses expiration date. Therefore, this step should be added to the collection procedure.

- **See response to comment 13.**

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Section 8.6.3, Blood Pressure Cuff

17. In Section 7.7 the blood pressure cuff is said to be inflated to 40 mmHg. However, in Section 8.6.3 it is said that a blood pressure is taken first (an activity performed by NO phlebotomists I know) and maintained below the diastolic pressure of the patient. I would recommend using the specific 40 mm Hg found in Section 7.7 and replace the language in Section 8.6.3 with the same.

- **The text has been revised as recommended. The following text has been added to replace the previous text: "If a blood pressure cuff is used as a tourniquet, inflate it to 40 mm Hg."**

Section 8.6.5, Select Vein

18. "Brachial" is misspelled in Figure 1.

- **The spelling error in Figure 1 has been corrected.**

Section 8.7, Step 7: Put on Gloves

19. Step 7: Add the following after the existing sentence: "…is performed. The type of gloves (latex, vinyl or nitrile) used for venipuncture will depend on the patient's and/or phlebotomist's sensitivity to latex products." General note—As both a patient and laboratorian, I know the importance of covering the issue of latex sensitivity with both patients and the phlebotomists. I highly recommend that you incorporate the information presented here into the document.

- **The text has been revised as follows: "The phlebotomist must put gloves on before the venipuncture is performed, for each patient, with consideration for latex sensitivity as discussed in Section 7.3."**

Section 8.9.1, Venipuncture Procedure When Venous Blood Collection Tubes Are Used

20. The illustration on page 14 is very primitive and would be improved if the proper angle included a view of the needle bevel up just as the needle enters the skin.

- **The illustrations (Figures 2 and 3) have been replaced with comparable photographs.**

Section 8.9.3, Fill the Tubes If Syringe and Needle Are Used

21. The third bullet suggests a straight needle be applied to the syringe after removing the winged collection set. Consider substituting "attach a 19- to 21-gauge sterile needle" with "attach a safety transfer device."

- **The text of the third bullet has been revised as follows: "To transfer the blood from the syringe to a venous blood collection tube, activate the safety feature of the needle or winged blood collection set used to withdraw the specimen, remove and discard the needle or winged collection set, and apply a safety transfer device."**

22. The fourth bullet seems to define the third bullet. Consider combining the two.

- **The working group agrees with the comment and has deleted the fourth bullet.**

23. The fifth bullet is not necessary in light of the third bullet. If standards are being followed, a transfer device protects the user, and holding the tubes should be safe.

- **The fifth bullet has been deleted as suggested.**

Section 8.9.4, Blood Specimen That Cannot Be Obtained

24. Consider making the passage about trying another tube into a bullet. Consider differentiating between probing and a calculated needle relocation in an additional bullet so that the section is rewritten as follows:

    ► Try another tube to ensure the tube selected is not defective.
    ► Change the position of the needle. If the needle has penetrated too far into the vein, pull it back a bit. If it has not penetrated far enough, advance it farther into the vein. Rotate the needle half a turn.
    ► Lateral needle relocation should be attempted only if the phlebotomist has a high degree of confidence that so doing will access the vein successfully without risking injury to the patient. Lateral needle relocation should never be attempted in an effort to access the basilic vein, since nerves and the brachial artery are in close proximity.

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- ► Manipulation other than that recommended above is considered probing. Probing is not recommended. Probing is painful to the patient. In most cases, another puncture in a site below the first site (or use of another vein on the other arm) is advisable.
- ► It is not advisable to attempt a venipuncture more than twice. If possible, have another person attempt to draw the specimen or notify the physician.

- **The following text has been added to the first bullet point: "Lateral needle relocation should never be attempted in an effort to access the basilic vein, since nerves and the brachial artery are in close proximity."**

Section 8.10.2, Glass and Plastic Venous Blood Collection Tubes

25. Consider deleting tube 4: gel serum separator tube. Since gel does not carryover, its presence or absence should not affect the order of draw. It seems more fitting for the second italicized paragraph to immediately follow the order of draw than the first paragraph.

- **Gel serum separator tube has been deleted from the fourth position on the order of draw. The third position has been revised as follows: "Serum tube with or without clot activator, with or without gel (e.g., red closure)."**

  The italicized paragraphs have been reorganized as suggested; the note regarding the revised order of draw appears immediately following the order of draw.

Section 8.13, Step 13: Remove and Dispose of the Needle

26. Removal of a needle (after the safety feature is activated) is necessary and acceptable to OSHA if applying a safety transfer device. Consider modifying to read: "Needles should not be resheathed, bent, broken, or cut, nor should they be removed from disposable syringes unless attaching a safety transfer device…"

- **The text of the third sentence has been revised as follows: "Needles should not be resheathed, bent, broken, or cut, nor should they be removed from disposable syringes unless attaching a safety transfer device prior to disposal."**

Section 8.14.2, Continued Bleeding

27. "When a patient continues to bleed," indicates that it is inevitable. Consider revising to "If a patient continues to bleed or a hematoma develops, …"

- **The text has been revised as recommended. The first paragraph now reads as follows: "If a hematoma develops or bleeding persists longer than five minutes, a nurse should be alerted so that the attending physician can be notified."**

Section 8.15, Step 15: Label Blood Collection Tubes and Record Time of Collection

28. Step 15: Consider revising the paragraph after the bullet list to accommodate handwritten identification of tubes. Suggested revision: "The label must be attached to the tube or the tube inscribed with complete information before leaving the side of the patient …."

- **The text has been revised as recommended. The following text has been added to the second paragraph: "Alternatively, the manufacturer's tube label can be inscribed with the patient's complete information."**

29. Tubes should be labeled in accordance with the laboratory requirements. These may not meet all requirements for all laboratories.

- **The text in this section has been revised in response to comment 9.**

Section 9, Venipuncture in Children and Difficult Collections

30. Passage states, "If a venipuncture is done on a child younger than one year of age, the site should be limited to superficial veins." As opposed to what? This statement is unclear.

- **The first sentence has been revised for clarity. The revision is as follows: "If a venipuncture is requested on a child younger than one year of age, the phlebotomist should consult with the physician or follow institutional policy."**

Section 9.2, Equipment

31. Consider modifying the range of needles to be used on pediatrics from 20-23 to 22-23 for patient comfort unless platelet aggregation studies are required.

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- **The needle gauge range has been revised as suggested. The following text has also been added: "For pediatric patients, through the age of 16, larger gauge needles may be appropriate."**

Section 11.6, Intravenous Fluids

32. Add the following reference: Savage R, ed. Q&A column. *CAP Today*. 2002:16(4):102-103.

- **The recommended reference, regarding performance of venipunctures above intravenous sites, has been added as suggested.**

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The Quality System Approach

NCCLS subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1—*A Quality System Model for Health Care.* The quality system approach applies a core set of "quality system essentials (QSEs)," basic to any organization, to all operations in any healthcare service's path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

H3-A5 addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the next page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
				X H1	X T/DM6						X M29

Adapted from NCCLS document HS1— *A Quality System Model for Health Care.*

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, GP26-A2 defines a clinical laboratory path of workflow which consists of three sequential processes: preanalytical, analytical, and postanalytical. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

H3-A5 addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the next page.

Preanalytic					**Analytic**		**Postanalytic**	
Patient Assessment	Test Request	Specimen Collection	Specimen Transport	Specimen Receipt	Testing Review	Laboratory Interpretation	Results Report	Post-test Specimen Management
X	X	X C38 H4 H11 H21	X C38 H4 H11 H21	X H18	X T/DM6			

Adapted from NCCLS document HS1— *A Quality System Model for Health Care.*

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Related NCCLS Publications*

C38-A **Control of Analytic Variation in Trace Element Analysis; Approved Guideline (1997).** This document provides guidelines for patient preparation, specimen collection, transport, and processing for the analysis of trace metals in a variety of biological matrices.

H1-A4 **Evacuated Tubes and Additives for Blood Specimen Collection—Fourth Edition; Approved Standard (1996).** This document provides requirements for blood collection tubes and additives.

H4-A4 **Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard—Fourth Edition (1999).** A consolidation of H4-A3 and H14-A2, this standard provides detailed descriptions and explanations of proper collection techniques, as well as hazards to patients from inappropriate specimen collection by skin puncture procedures.

H11-A3 **Procedure for the Collection of Arterial Blood Specimens; Approved Standard—Third Edition (1999).** *American National Standard.* This standard describes principles of collecting, handling, and transporting arterial blood specimens. The document is aimed at reducing collection hazards and ensuring integrity of the arterial specimen.

H18-A2 **Procedures for the Handling and Processing of Blood Specimens; Second Edition—Approved Guideline (1999).** This guideline addresses multiple factors associated with handling and processing specimens, as well as factors that can introduce imprecision of systematic bias into results.

H21-A3 **Collection, Transport, and Processing of Blood Specimen for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline—Third Edition (1998).** This guideline contains procedures for collecting, transporting, and storing blood; processing blood specimens; storing plasma for coagulation testing; and provides general recommendations for performing the tests.

M29-A2 **Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition (2001).** This document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure.

T/DM6-A **Blood Alcohol Testing in the Clinical Laboratory; Approved Guideline (1997).** This document gives technical and administrative guidance on laboratory procedures related to blood alcohol testing.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent edition.

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NCCLS ▾ 940 West Valley Road ▾ Suite 1400 ▾ Wayne, PA 19087 ▾ USA ▾ PHONE 610.688.0100
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/838,017	04/01/2020	Bobby E. ROGERS	069366-0572158_KUR7001US	1044

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PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
PORTILLO, JAIRO H	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
01/29/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 16/838,017	Applicant(s) ROGERS et al.	
	Examiner JAIRO H PORTILLO	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 7/19/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-9,14,16-18 and 21-26 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-9,14,16-18 and 21-26 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 1-4, 6-9, 14, 16-18, and 21-23 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Rogers et al (US 2017/0020428) ("Rogers")** in view of **Davis et al (US 2007/0031283) ("Davis").**

Regarding Claim 1, while Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0124] Figs. 23A and 23B), the device comprising:

an inlet configured to connect with the fluid source ([0124] inlet port 2302);

an outlet configured to connect with the fluid collection device ([0124] outlet port 2304);

a sample path connected between the inlet and the outlet ([0124] sample path/sampling channel 2308), the sample further having a resistive plug ([0124] valve 2308); and

a chamber connected between the inlet and the outlet (Figs. 23A and 23B, [0124] sequestration chamber 2306), the chamber having an air permeable fluid resistor proximate the outlet (Figs. 23A and 23B, hydrophobic plug 2312), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid

sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.),

Rogers fails to teach

The resistive plug including a membrane that is pierceable; and

A piercing member configured to pierce the membrane.

However Davis teaches a medical sampling device (Abstract) comprising a valve composition of a film that is pierceable and a piercing element to allow fluid flow ([0278], [0280]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to substitute the pinching valve of Rogers for a needle-pierceable membrane valve of Davis as a simple substitution of one form of controlling fluid flow for another to obtain predictable results of sample optimization by denying the initial aliquot of blood.

Regarding Claim 2, Rogers and Davis teach the device in accordance with claim 1, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 1 Rejection,* the tubing of the blood sequestration device 2300 acts as a housing).

Regarding Claim 3, Rogers and Davis teach the device in accordance with claim 1, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (*See Claim 1 Rejection)*.

Regarding Claim 4, Rogers and Davis teach the device in accordance with claim 1, and Rogers teaches in a separate embodiment that a chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to configure the contaminant containment reservoir of Rogers with a tortuous path as Rogers teaches that a tortuous path has a sealing function ([0065]) which would be useful for containing contaminants.

Regarding Claim 21, Rogers and Davis teach the device in accordance with claim 1, wherein the membrane is spaced apart from the piercing member in an initial state (*See Claim 1 Rejection*, for needle pierceable membrane to act as a valve, the membrane must be initially spaced apart from a piercing member).

Regarding Claim 6, Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0124] Figs. 23A and 23B), the device comprising:

an inlet configured to connect with the fluid source ([0124] inlet port 2302);

an outlet configured to connect with the fluid collection device ([0124] outlet port 2304 connected to a blood sample collection device);

a sample path connected between the inlet and the outlet ([0124] sample path/sampling channel 2308), the sample path further having a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample from entering the sample path ([0124] valve 2310. Examiner notes that the patent publication has the valve written as 2308, but the language of paragraph [0124] and the Figures heavily imply the valve should be understood as corresponding to reference character 2310); and

a chamber connected between the inlet and the outlet (Figs. 23A and 23B, [0124] sequestration chamber 2306), the chamber further having an air permeable fluid resistor proximate the outlet (Figs. 23A and 23B, hydrophobic plug 2312), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet ([0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.),

Rogers fails to teach

The resistive plug including a membrane that is pierceable; and

A piercing member configured to pierce the membrane.

However Davis teaches a medical sampling device (Abstract) comprising a valve composition of a film that is pierceable and a piercing element to allow fluid flow ([0278], [0280]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to substitute the pinching valve of Rogers for a needle-pierceable membrane valve of Davis as a simple substitution of one form of controlling fluid flow for another to obtain predictable results of sample optimization by denying the initial aliquot of blood.

Regarding Claim 7, Rogers and Davis teach the device in accordance with claim 6, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 6 Rejection*, the tubing of the blood sequestration device 2300 acts as a housing).

Regarding Claim 8, Rogers and Davis teach the device in accordance with claim 6, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (*See Claim 6 Rejection*).

Regarding Claim 9, Rogers and Davis teach the device in accordance with claim 6, and Rogers teaches in a separate embodiment that a chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to configure the contaminant containment reservoir of Rogers with a tortuous path as Rogers teaches that a tortuous path has a sealing function ([0065]) which would be useful for containing contaminants.

Regarding Claim 22, Rogers and Davis teach the device in accordance with claim 6, wherein the membrane is spaced apart from the piercing member in an initial state (*See Claim 6 Rejection*, for needle pierceable membrane to act as a valve, the membrane must be initially spaced apart from a piercing member).

Regarding Claim 14, Rogers teaches a device for optimizing a fluid sample (Abstract, Figs. 23A and 23B), the device comprising:

an inlet ([0124] inlet port 2302);

an outlet ([0124] outlet port 2304);

a sample path connected between the inlet and the outlet ([0124] sample path/sampling channel 2308); and

a chamber connected between the inlet and the outlet (Figs. 23A and 23B, [0124] sequestration chamber 2306), the chamber having an air permeable fluid resistor proximate the

outlet (Figs. 23A and 23B, hydrophobic plug 2312), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.),

wherein the sample path further includes a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample from entering the sample path during receipt of the first portion of the fluid sample in the chamber ([0124] valve 2310. Examiner notes that the patent publication has the valve written as 2308, but the language of paragraph [0124] and the Figures heavily imply the valve should be understood as corresponding to reference character 2310),

Rogers fails to teach the resistive plug including a membrane that is pierceable; and

a piercing member configured to pierce the membrane,

However Davis teaches a medical sampling device (Abstract) comprising a valve composition of a film that is pierceable and a piercing element to allow fluid flow ([0278], [0280]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to substitute the pinching valve of Rogers for a needle-pierceable

membrane valve of Davis as a simple substitution of one form of controlling fluid flow for another to obtain predictable results of sample optimization by denying the initial aliquot of blood.

Regarding Claim 16, Rogers and Davis teach the device in accordance with claim 14, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 14 Rejection*, the tubing of the blood sequestration device 2300 acts as a housing).

Regarding Claim 17, Rogers and Davis teach the device in accordance with claim 14, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (*See Claim 14 Rejection*).

Regarding Claim 18, Rogers and Davis teach the device in accordance with claim 14, and Rogers teaches in a separate embodiment that a chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to configure the contaminant containment reservoir of Rogers with a tortuous path as Rogers teaches that a tortuous path has a sealing function ([0065]) which would be useful for containing contaminants.

Regarding Claim 23, Rogers and Davis teach the device in accordance with claim 14, wherein the membrane is spaced apart from the piercing member in an initial state (*See Claim 14 Rejection*, for needle pierceable membrane to act as a valve, the membrane must be initially spaced apart from a piercing member).

Claim(s) 24-26 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Rogers** in view of **Davis** as evidenced by **"Membrane Definition & Meaning."**

Regarding Claim 24, Rogers and Davis teach the device in accordance with claim 21, wherein the membrane is configured to stretch and contact the piercing member after the first portion of the fluid sample is received by the chamber (*See Claim 21 Rejection*, a membrane is

defined as "a thin soft *pliable* sheet or layer especially of animal or plant origin" by the "Membrane Definition & Meaning." And is thus configured to stretch. Further, as a needle-pierceable membrane, it is configured contact the piercing member after the first portion of the fluid sample is received by the chamber as it is by nature configured to contact the piercing member).

Regarding Claim 25, Rogers and Davis teach the device in accordance with claim 22, wherein the membrane is configured to stretch and contact the piercing member after the first portion of the fluid sample is received by the chamber (*See Claim 22 Rejection*, a membrane is defined as "a thin soft *pliable* sheet or layer especially of animal or plant origin" by the "Membrane Definition & Meaning." And is thus configured to stretch. Further, as a needle-pierceable membrane, it is configured contact the piercing member after the first portion of the fluid sample is received by the chamber as it is by nature configured to contact the piercing member).

Regarding Claim 26, Rogers and Davis teach the device in accordance with claim 23, wherein the membrane is configured to stretch and contact the piercing member after the first portion of the fluid sample is received by the chamber (*See Claim 23 Rejection*, a membrane is defined as "a thin soft *pliable* sheet or layer especially of animal or plant origin" by the "Membrane Definition & Meaning." And is thus configured to stretch. Further, as a needle-pierceable membrane, it is configured contact the piercing member after the first portion of the fluid sample is received by the chamber as it is by nature configured to contact the piercing member).

Response to Arguments

Applicant's amendments and arguments filed 7/19/2023 with respect to the 35 USC 112(f) interpretation have been fully considered and are persuasive. The interpretation is obviated.

Applicant's amendments and arguments filed 7/19/2023 with respect to the 35 USC 103 rejection have been fully considered, but are not persuasive.

Applicant argues that Davis does not teach or motivate a fluid sample being forced through a membrane when a pressure differential is applied. Examiner respectfully notes that the independent claims as written do not state a pressure differential is applied to actuate the use of the membrane. Thus, even a user actuated needle piercing of the membrane would fulfill the current claim set.

Applicant's next argument is that the piercing member of Davis is an external instrument and is therefore not part of the device. Examiner respectfully disagrees. As a necessary sub-unit for the piercing of the membrane, Examiner consider the needle to be part of the device.

The rejection(s) stands.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAIRO H PORTILLO whose telephone number is (571)272-1073. The examiner can normally be reached M-F 9:00 am - 5:15 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAIRO H. PORTILLO/
Examiner
Art Unit 3791

/KAYLEE R WILSON/
Primary Examiner, Art Unit 3791

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	Examiner JAIRO H PORTILLO	Art Unit 3791	Page 1 of 1

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membrane

Entries 1 to 10 of 15. Next 5

On Off

membrane
basement membrane
basilar membrane
cell membrane

Main Entry: **mem·brane**
Pronunciation: \'mem-ˌbrān\
Function: *noun*
Etymology: Middle English, from Latin *membrana* skin, parchment, from *membrum*
Date: 15th century

1 : a thin soft pliable sheet or layer especially of animal or plant origin
2 : a piece of parchment forming part of a roll
— mem·braned \'mem-ˌbrānd\ *adjective*

Learn more about "membrane" and related topics at Britannica.com

See a map of "membrane" in the Visual Thesaurus

Pronunciation Symbols

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Examiner Name	PORTILLO, JAIRO H
Attorney Docket Number	069366-0572158_KUR7001US

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	Examiner Name	PORTILLO, JAIRO H
	Attorney Docket Number	069366-0572158_KUR7001US

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	2	Bullington, et al., Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in U.S. Appl. No. 62/517,681, dated Jun. 9, 2017, 131 pages.	☐
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☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-07-19
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Direct labeling and visualization of blood vessels with lipophilic carbocyanine dye DiI

Yiwen Li[1], **Ying Song**[2], **Lian Zhao**[2], **Gabriel Gaidosh**[1], **Alan M Laties**[2], and **Rong Wen**[1]

[1]Bascom Palmer Eye Institute, Miller School of Medicine, University of Miami, 506 McKnight Building, 1638 NW 10th Avenue, Miami, Florida 33136, USA

[2]Scheie Eye Institute, School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania 19104, USA

Abstract

We describe a protocol to rapidly and reliably visualize blood vessels in experimental animals. Blood vessels are directly labeled by cardiac perfusion using a specially formulated aqueous solution containing 1,1′-dioctadecyl-3,3,3′,3′-tetramethylindocarbocyanine perchlorate (DiI), a lipophilic carbocyanine dye, which incorporates into endothelial cell membranes upon contact. By lateral diffusion, DiI also stains membrane structures, including angiogenic sprouts and pseudopodial processes that are not in direct contact. Tissues can be immediately examined by conventional and confocal fluorescence microscopy. High-quality serial optical sections using confocal microscopy are obtainable from thick tissue sections, especially at low magnification, for three-dimensional reconstruction. It takes less than 1 h to stain the vasculature in a whole animal. Compared with alternative techniques to visualize blood vessels, including space-occupying materials such as India ink or fluorescent dye-conjugated dextran, the corrosion casting technique, endothelial cell-specific markers and lectins, the present method simplifies the visualization of blood vessels and data analysis.

INTRODUCTION

We describe here a direct labeling protocol[1,2] to visualize blood vessels in small experimental animals rapidly and reliably using a lipophilic carbocyanine dye, DiI ($DiIC_{18}(3)$). Lipophilic carbocyanine dyes, including DiI, have been widely used to label cell membranes[3–8] and to trace neuronal connections in live and fixed tissues[7–14]. In the cell membrane, a DiI molecule has its two hydrocarbon chains buried in the lipid bilayer parallel to the phospholipid acyl chains, and the chromophores are on the surface of the bilayer[15].

The direct labeling technique takes advantage of the lipophilic property of DiI. A special aqueous DiI solution is formulated to have the maximum sodium chloride concentration without causing precipitation of DiI. Glucose is added to maintain the physiological osmolarity. Labeling is achieved by bringing DiI solution in direct contact with endothelial cells through cardiac perfusion. A simple perfusion device is assembled with two three-way stopcocks, a butterfly needle and three 10-ml disposable syringes for phosphate-buffered saline (PBS), DiI solution and fixative, respectively (Fig. 1).

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Correspondence should be addressed to R.W. (rwen@med.miami.edu)..

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During perfusion, DiI partitions quickly into the cell membrane (lipid) phase, the endothelial cell membrane lining the blood vessels, resulting in instantaneous labeling of blood vessels (Fig. 2). Once in the membrane, DiI molecules diffuse laterally within the lipid bilayer[3]. The lateral diffusion helps to stain membrane structures that are not in direct contact with the DiI solution, including angiogenic sprouts and psuedopodial processes of angiogenic endothelial cells (Fig. 3c,d).

As DiI is directly delivered to the endothelial cell membrane, it is possible to achieve high concentration in cell membrane and thus high signal intensities, which dramatically increases the signal-to-noise ratio. In addition, the dye itself is intensely fluorescent with slow fading when exposed to the excitation light[7,8]. The strong intensity and slow fading feature are ideal for serial optical sections using laser scanning confocal microscopy, especially at low magnification. Images can be obtained throughout the entire thickness of a tissue sample of 100 μm without noticeable deterioration of image quality. The vasculature in the inner surface of a hollow organ like the eye can be scanned as a single stack of confocal images at very low magnification (×5 objective lens). Digitized data of thick tissue sections can be used to reconstruct 3-dimemsional (3-D) images of vascular network in the samples of interest and/or to perform other analyses with suitable software. The 3-D images have the advantage of viewing the vascular network in its entirety (Fig. 3; Supplementary Movies 1–3 online). In addition, the use of thick tissue sections would save time and effort, as fewer tissue sections need to be prepared to cover the entire tissue sample. This is especially important when many samples are to be examined.

Many alternative techniques are available to visualize blood vessels. Space-occupying high-contrast materials, including India ink[16] and fluorescent dye-conjugated dextran (e.g., fluorescein isothiocyanate or FITC)[17], are used to fill blood vessels to render them visible. However, the dye molecules are not bound to blood vessels but move freely in the filling solution. When a tissue sample is compressed, especially during sample preparation, the filling solution can be squeezed out of blood vessels, resulting in interrupted or 'broken' vascular patterns. This method, however, directly stains the endothelial cell membranes.

The corrosion casting technique using low-viscosity plastics, another type of space-occupying material, to make casts of blood vessel network has been employed to study the three dimensionality of vasculature[18,19] in combination with scanning electron microscopy (SEM) [20,21]. The casts are viewed with SEM to obtain 3-D images of the vasculature. It is technically demanding to make casts and requires access to SEM[20,21]. It is also difficult to visualize angiogenic sprouts and pseudopodial processes. In comparison, the method described here is technically much simpler in sample preparation and data collection.

Blood vessels can also be visualized by endothelial cell-specific markers, including factor VIII (see ref. [22]) or CD34 (see ref. [23]). Lectins have been used as surrogate markers for endothelial cells. For example, *Ulex europaeus* I lectin recognizes human endothelial cells[24], and *Griffonia simplicifolia* isolectin B_4 specifically labels endothelial cells in mouse, rat and other laboratory animals[25,26]. Use of these markers usually requires multistep procedures. In addition, it is difficult for these techniques to achieve the high signal intensities that can be achieved by direct labeling methods described here.

The direct labeling technique with DiI provides an efficient, reliable and low-cost (the amount of DiI used per rat is less than 1 mg that costs less than USD $2) alternative to obtain high intensity, high signal-to-noise ratio labeling of blood vessels in the entire body for both low- and high-power microscopic observation. It can also be used to study angiogenic sprouts and pseudopodial processes. Although described here for use in rodents, this procedure can be adapted easily to the study of vasculature in other vertebrate animals including rabbits, either

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for the vasculature of the entire body or for *ex vivo* perfusion of a particular organ, such as rabbit kidneys.

In this method, DiI molecules are directly incorporated into the membrane of endothelial cells. As it is a lipophilic dye, the molecules in the membrane could be washed away by lipophilic solvents. It is therefore not easy to combine DiI staining with other techniques, such as immunohistochemical analysis, if the subsequent procedures involve those lipophilic solvents. This issue could be overcome by using a fixable DiI derivative, CM-DiI (C-7001, Invitrogen/Molecular Probes). CM-DiI is particularly useful in experiments that combine membrane labeling with subsequent immunohistochemical analysis, fluorescence *in situ* hybridization or electron microscopy. DiI staining is, however, compatible with the nuclear dye DAPI (4′-6-diamidino-2-phenylindole).

MATERIALS

REAGENTS

- DiI (D-282, Invitrogen/Molecular Probes; 42364, Sigma-Aldrich)
- Ethanol (100% vol/vol)
- NaCl (S7653, Sigma-Aldrich)
- KCl (P9333, Sigma-Aldrich)
- Na_2HPO_4 (S8282, Sigma-Aldrich)
- NaH_2PO_4 (S7907, Sigma-Aldrich)
- Glucose (G7568, Sigma-Aldrich)
- HCl (1 M) (13-1700, Sigma-Aldrich)
- NaOH (5 M) (S8263, Sigma-Aldrich)
- Glycerol (G6279, Sigma-Aldrich)
- Paraformaldehyde (158127, Sigma-Aldrich)
- Agarose (A5939, Sigma-Aldrich)
- Superglue (can be obtained from regular hardware stores)
- Experimental animals (rats and mice, Charles River)

▲ CRITICAL All animal experiments must comply with national laws and institutional regulations.

EQUIPMENT

- 25 gauge butterfly needles
- Microscope slides
- Standard BK7 glass coverslip (no. 1.5, 170 μm thickness)
- Three-way stopcocks
- 10-ml disposable syringes
- Aluminum boats
- Vibratome (VT1000S, Leica Microsystems)

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REAGENT SETUP

DiI stock solution—Dissolve 100 mg of DiI crystal in 16.7 ml of 100% ethanol on a rocker overnight (covered with aluminum foil when rocking) and store in the dark at room temperature (RT, 20–25 °C) for up to 1 year. ⁑ CAUTION DiI solution stains easily on skin and other surfaces. If accidental staining occurs, it can be wiped off easily by 70% ethanol.

PBS (pH 7.4)—Dissolve 8 g of NaCl, 0.2 g of KCl, 1.44 g of Na_2HPO_4 and 0.23 g of NaH_2PO_4 in 800 ml of distilled water. Adjust pH to 7.4 with HCl. Add water to 1,000 ml, filter through a 0.22-μm bottle-top filter. Store at RT for up to 1 year.

5% (wt/vol) glucose—Dissolve 50 g of glucose in 1,000 ml of distilled water. Filter through a 0.22-μm bottle-top filter. Store at RT for up to 1 year.

Diluent—Mix PBS and 5% glucose at a ratio of 1:4. Store at RT for up to 1 year.

DiI work solution—Immediately before use, add 200 μl of DiI stock solution into 10 ml of diluent, mix by quick shaking. DiI work solution should be freshly made under room lighting.

Phosphate buffer (pH 7.4)—Prepare separately a solution of 0.2 M NaH_2PO_4 and another one of 0.2 M Na_2HPO_4. Mix the two solutions at a ratio of 19:81. Check the pH with a pH meter. Adjust pH with either HCl or NaOH. Store at RT for up to 1 year.

8% (wt/vol) paraformaldehyde—Under a chemical hood, add 8 g of paraformaldehyde to 90 ml of distilled water in a beaker with a magnetic stirrer. Heat to 65 °C and adjust the pH to 7.4 (using pH paper) with 5 M NaOH. Add distilled water to adjust the final volume to 100 ml. Cool the solution and filter. Store at 4 °C for up to 1 month.

4% (wt/vol) paraformaldehyde solution—Mix 8% paraformaldehyde with 0.2 M phosphate buffer at a ratio of 1:1 before use. Store at 4 °C for up to 1 month.

80% (vol/vol) glycerol—Add 1 ml of distilled water into 4 ml of glycerol and mix well. Store at RT for up to 1 year.

5% (wt/vol) agarose—Add 20 ml of distilled water to a beaker, and add 1 g of agarose. Heat on a heat place until agarose melts. Keep 5% agarose to 60 °C. Agarose (5%) can be stored at 4 °C for up to 1 month. To use the agarose again, heat until it melts and keep it at 60 °C.

EQUIPMENT SETUP

Perfusion device—The perfusion device is assembled with two three-way stopcocks, a 25 gauge butterfly needle and three 10-ml syringes (Fig. 1). First, connect the two three-way stopcocks in series (Fig. 1, inset) and then the 25-gauge butterfly needle to the outflow port of the stopcocks (Fig. 1). Load the three syringes with 2 ml of PBS, DiI solution (5 ml for a mouse, 10 ml for a rat) and 10 ml of fixative (4% paraformaldehyde), respectively. Connect the syringe with fixative to the first inflow port and inject solution until there is no air in the line; turn the stopcock to block the port. Then, connect the DiI syringe to the second inflow port, inject solution until there is no air in the line, and turn the stopcock to block the port. Finally, connect the PBS syringe to the last inflow port and inject solution until there is no air in the line. Assembly is under room lighting. ⁂ CRITICAL Make sure that no air is trapped in the line or the syringes before proceeding to perfusion. Once in the circulation system, air will block blood vessels, resulting in poor perfusion.

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Aluminum boats—Cut a piece of Styrofoam into the shape and size of the samples of interest. Wrap the Styrofoam with a piece of aluminum foil, leaving one side open. Remove the Styrofoam and store the aluminum boats appropriately at RT.

PROCEDURE

Perfusion ● TIMING **~45 min**

▲ CRITICAL All steps are carried out under ambient lighting unless specified.

1¦ Assemble the perfusion device as described in EQUIPMENT SETUP.

? TROUBLESHOOTING

2¦ Kill a mouse or rat by CO_2 overdose in a CO_2 chamber, or by sodium phenobarbital overdose (120 mg kg^{-1}, i.p).

▲ CRITICAL STEP All animal experiments must comply with national laws and institutional regulations.

3¦ In a glass tray with an absorbing blue pat or several paper towels, position the animal on its back. Make a transverse incision to open the abdominal cavity. Expose and cut the diaphragm. Cut the chest wall on both sides up to the first or the second rib.

4¦ Take a small hemostat to hold the lower tip of the sternum and the turn the anterior chest wall toward the head of the animal to expose the chest cavity.

5¦ (Optional) If the tissues of interest are in the upper body, such as the brain or the eye, there is no need to perfuse the lower body. If this is the case, load half amount of the regular perfusion solutions in Step 1 and clamp the descending aorta to block the flow to the lower body before perfusion. This is not necessary for mice.

6¦ Insert the butterfly needle of the perfusion device into the left ventricle and then puncture the right atrium with a 16-gauge needle.

▲ CRITICAL STEP Make sure that the needle is in the left ventricle, which appears lighter than the right ventricle. Do not penetrate the opposite side of the ventricular wall. Such penetration will result in a leak in the left ventricle, making perfusion difficult.

? TROUBLESHOOTING

7¦ Inject 2 ml of PBS from the perfusion device at the rate of 1–2 ml min^{-1} (total 1–2 min). A sign of good perfusion is bleeding from the right atrium. After injection, turn the switch to block the port of PBS syringe and open the port to the DiI syringe.

? TROUBLESHOOTING

8¦ Inject 5–10 ml of the DiI solution at the rate of 1–2 ml min^{-1} (total 5–10 min). Monitor color change in the ears, nose and palms. DiI appears purple in visible light. During perfusion with DiI solution, the ears, nose and palms will turn slightly purple. After injection, turn the switch to block the port of DiI syringe and open the port to the fixative syringe.

9¦ Inject 5–10 ml of the fixative at the rate of 1–2 ml min^{-1} (total 5–10 min).

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10| Harvest tissues of interest. To make eyecup preparation, eyes are enucleated and the anterior segments are removed. The retinas are further dissected from eyecups[1]. Other tissues of interest can be harvested by directly removing them from the body.

PAUSE POINT Samples can be left in the fixative or PBS in the dark for up to 1 month at 4 °C.

CRITICAL STEP Be sure to place the used needles into a sharp container and to dispose of the animal and waste appropriately.

TROUBLESHOOTING

Tissue sectioning TIMING ~1–2 h, depending on the size of the tissue to be sectioned

11| Rinse samples in PBS 2× 15 min.

12| Embed tissue sample in 5% agarose: heat agarose in a 100-ml beaker to 60 °C and pour it (about one-third of the volume required to submerge the sample) into an aluminum boat that fits the sample. Submerge the tissue sample into the agarose and adjust the orientation. Add more agarose into the boat to keep the sample totally submerged. Samples can be kept at 4 °C in the dark up to 1 month when wrapped in plastic wrap to prevent dehydration. Remove the sample block from the aluminum boat before sectioning. Embedding is not necessary for solid tissue such as the brain and the liver.

TROUBLESHOOTING

13| Trim off excess agarose. Glue the sample to the section stage of the Vibratome using Superglue. Secure the section stage in the section chamber and adjust the sample to the appropriate orientation. Fill the sectioning chamber with PBS to submerge the sample.

TROUBLESHOOTING

14| Set the start and the end point of sectioning (for additional information regarding operating the Leica VT1000S Vibratome, please read the manufacturer's manual).

TROUBLESHOOTING

15| Set the thickness of the section to 100 μm (for additional information regarding operating the Leica VT1000S Vibratome, please read the manufacturer's manual).

TROUBLESHOOTING

16| Section the tissue and collect a section with a small (no. 6 or 8) round watercolor brush; put it on a glass slide. One slide may hold several sections.

TROUBLESHOOTING

17| Use a larger watercolor brush to remove excess PBS, add a small amount of 80% glycerol to the sections and cover with no. 1.5 cover slip. Seal it with nail polish.

PAUSE POINT Sections are better viewed as soon as possible but can be kept for several days at 4 °C in the dark.

TROUBLESHOOTING

View sections TIMING Depending largely on the number of the sections and the area of interest to be examined, ~1 h to 1 d

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18| View tissue sections under a fluorescence microscope or a confocal microscope using the filter set for rhodamine.

19| Collect a stack of confocal images. Reconstruction of 3-D images can be achieved using any image analysis software that has such a function. We used AutoVisualize 3-D (version 5.5, AutoQuant Image Inc.) and Leica Application Suite Advanced Fluorescence (LAS AF, TCS-SP5) (Leica).

● TIMING

Steps 1–10: ~45 min

Steps 11–17: ~1–2 h, depending on the size of the tissue to be sectioned

Steps 18 and 19: depending largely on the number of the sections and the area of interest to be examined, ~1 h to 1 d

? TROUBLESHOOTING

Troubleshooting advice can be found in Table 1.

ANTICIPATED RESULTS

Perfusion with DiI solution delivers dye molecules to endothelial cells lining blood vessels in the entire circulation system, thus blood vessels in the whole body are stained. DiI appears purple in color under visible light, so tissues that are well stained should appear slightly purple. Large blood vessels on the surface should be visible. Blood vessels appear intensely red under a fluorescence microscope using a rhodamine filter set (Fig. 2). Stacks of confocal images could be obtained and used to reconstruct 3-D images in hollow organs like the eye (Fig. 3a) and thick tissue samples (Fig. 3b). Because of lateral diffusion, DiI also stains membrane structures that are not in direct contact with the dye solution, including angiogenic sprouts and pseudopodial processes. Images of angiogenic sprouts with their extruding processes (3-D reconstruction) are shown in Figure 3c,d. Thick tissue sections allow efficient screening of the entire tissue of interest at low magnifications for relatively rare events, which can then be studied in detail at high magnifications and/or using an electronic zoom. For example, to study choroidal neovascularization, it is important to find the site where new blood vessels from the choriocapillaris penetrate the Bruch's membrane. In our study on choroidal neovascularization in a subretinal Matrigel model of choroidal neovascularization in the rat[1], we routinely screen the entire Matrigel-injected area (20–25 sections of 100 μm thick) to identify the penetration sites and then to carefully study them. One such site is shown in Figure 4. The combined DiI staining and DIC (differential interference contrast) image shows the site at which a new blood vessel originated in the choriocapillaris penetrated the Bruch's membrane and entered the space between the retinal pigment epithelium and the Bruch's membrane.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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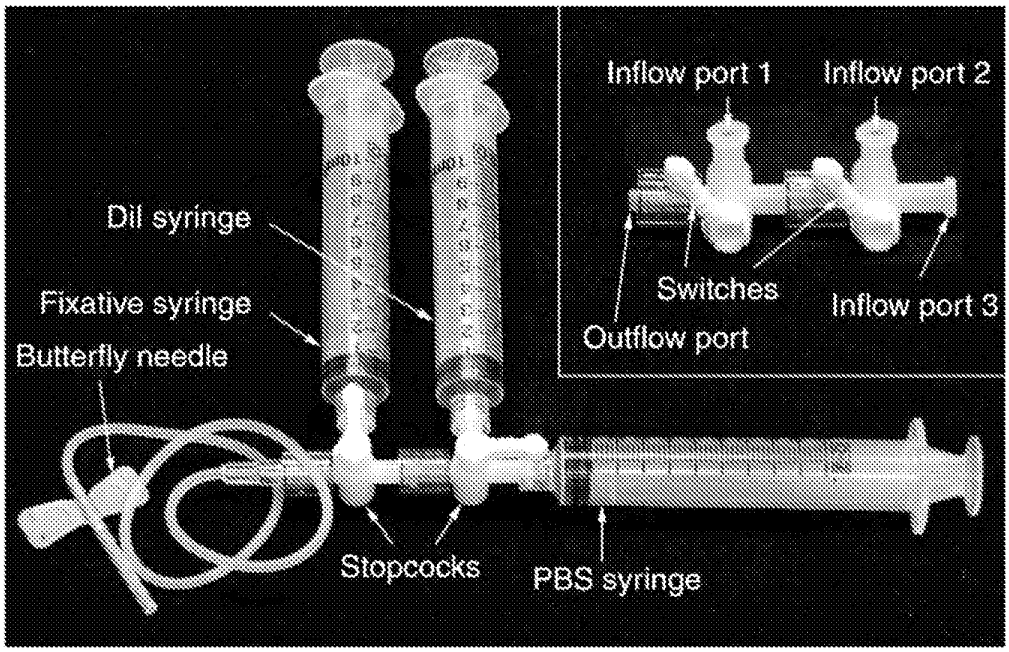

Figure 1.
Perfusion device. The main body of the perfusion device is two three-way stopcocks connected in series (inset). The output port of the stopcocks is connected to a butterfly needle. The inflow ports are connected to three 10-ml disposable syringes for PBS, DiI solution and fixative, respectively. The positions of the three syringes depend on the specific stopcock used, as stopcocks of different brands may have different configurations. It is also possible to use a single stopcock for the device. In that case, it will require change of syringes after perfusion with DiI solution. During syringe change, it is important to avoid air from entering the perfusion line.

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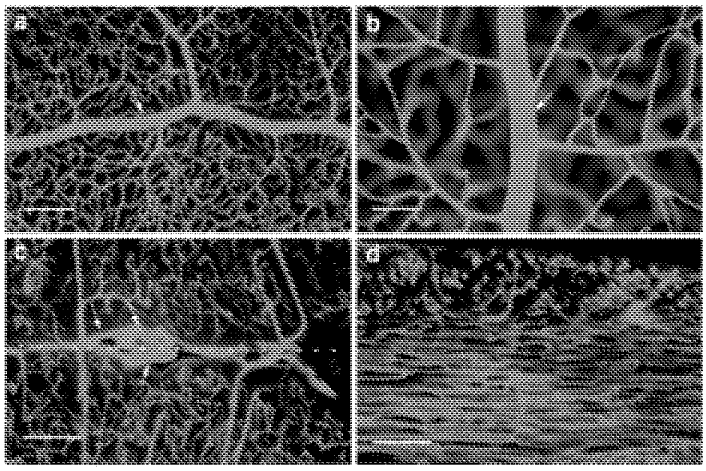

Figure 2.

Vasculature visualized by DiI labeling. (**a**) Retinal whole-mount showing an artery (arrow) on the retinal inner surface along with its branches connecting to the deep capillaries, which are also visible, although out of focus (10 objective lens). (**b**) Retinal whole-mount-showing another artery (arrow) at a higher magnification (×20 objective lens). The nuclei of endothelial cells are identifiable as oval spots in both **a** and **b**. (**c**) A brain section (100 μm thick, ×10 objective lens) showing three large blood vessels (arrows) located in the midline (dashed line) between the two hemispheres and the vascular network in the tissue. (**d**) A heart section (left ventricle, 100 μm thick, ×10 objective lens) showing capillaries in the left ventricle wall. In the outer layer (upper part), they are perpendicular to the section plane and appear as bright dots, whereas in the inner layer (lower part), they are parallel to the section plane. Tissues were viewed by fluorescence microscopy (Nikon Eclipse E800 fluorescence microscope with plan fluo ×10/0.3 numerical aperture (**NA**) or plan fluo ×20/0.5 NA objective lens and Chroma 34,000 rhodamine filter set, with the excitation wavelength of 570 nm and the emission of 590). Scale bars, 200 μm for **a**, **c** and **d**, and 100 μm for **b**.

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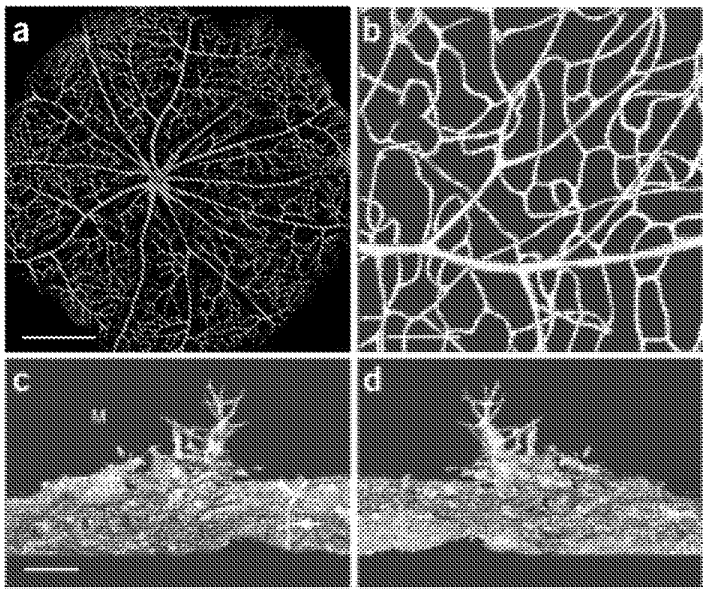

Figure 3.

Three-dimensional reconstructed images of retinal vasculature and angiogenic sprouts and pseudopodial processes. (**a**) A 3-D reconstructed image of the eyecup as a 'bird's eye' view of the vasculature of the posterior retina. The eyecup was placed in a holder and submerged in PBS for direct imaging. A ×5/0.15 NA objective lens was used to take a stack of confocal images, which were used for the reconstruction. DiI signal was detected using Leica DM6000B microscope with the ×5 objective (HC PL Fluotar/0.15) (Leica). Images were acquired by a Leica Application Suite Advanced Fluorescence (LAS AF), 1.7.0, Build 1240 software TCS-SP5 (Leica). The same software was used to create 3-D reconstruction of images and a movie clip, which shows the retinal vasculature rotated around the *x* axis (Supplementary Movie 1). (**b**) A 3-D image showing an artery on the retinal surface connected to the deep capillaries. A movie clip shows the artery and its network rotated around the *y* axis (Supplementary Movie 2). (**c**) A 3-D image of angiogenic sprouts and pseudopodial processes in a subretinal Matrigel of choroidal neovascularization[1] at a viewing angle of 0° (from the coverslip side downward). The vertical line (arrow) indicates the cross section of the choroid. Another line (arrowhead) indicates the surface of the choroicapillaris. Several sprouts from the choriocapillaris invaded the Matrigel layer (M) in the subretinal space. Their pseudopodial processes protruded into the Matrigel deposit (M) in different directions. (**d**) 3-D image of angiogenic sprouts and pseudopodial processes at a viewing angle of 180°. A movie clip shows the sprouts rotated around the *y* axis (Supplementary Movie 3). Scale bar, 400 μm for **a**, 100 μm for **b** and 20 μm for **c** and **d**.

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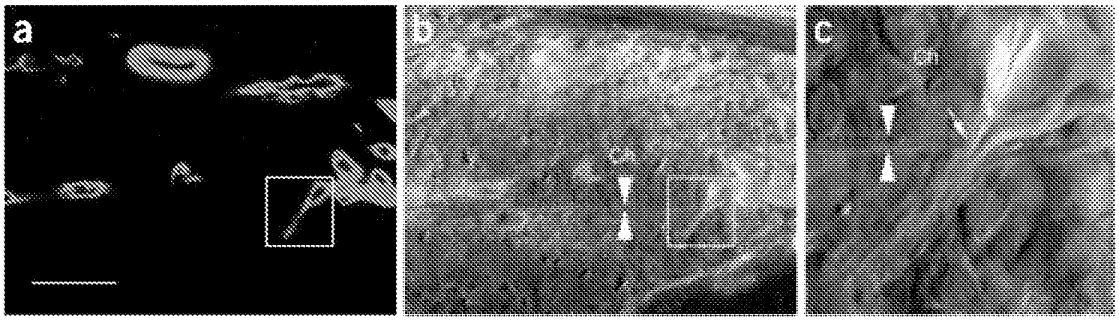

Figure 4.

Penetration of Bruch's membrane by choroidal neovascularization. Choroidal neovascularization was induced by subretinal injection of Matrigel[1]. To locate the penetration sites of choroidal neovascularization, serial tissue sections (100 μm thick each) were cut through the entire Matrigel injected area (about 2 mm in diameter). Tissue sections were screened at low power (×10 objective) under a fluorescence microscope. Potential penetration sites were further examined by confocal microscopy. (**a**) A confocal image of a new blood vessel that had penetrated the Bruch's membrane (square). (**b**) A superimposed image of DIC (differential interference contrast) and fluorescence (red) shows the penetrating blood vessel (square) relative to Bruch's membrane (between two arrowheads). (**c**) The penetration site (arrow) at higher magnification to show Bruch's membrane (between two arrowheads). Ch, choroid. Scale bar, 50 μm for **a** and **b**; 7 μm for **c** .

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TABLE 1

Troubleshooting table

Problem	Possible reason	Possible solution
Weak signal	Poor perfusion due to air trapped in the system (Steps 1 and 6)	Make sure no air is trapped in the perfusion line before perfusion. When inserting the needle into the left ventricle, slightly press the PBS syringe to allow a fluid drop to appear at the needle tip
	Poor perfusion because of a leak in the left ventricle (Step 6)	Do not penetrate the opposite side of the ventricle when inserting the butterfly needle. Using a small hemostat to clamp the leaking point sometimes works
	Poor staining because of too much PBS perfusion (Step 7)	Make sure not more than 2 ml of PBS is used before DiI perfusion
'Leak' staining	The inner lining of blood vessels are broken because of rough handling of tissue preparation and sectioning (Steps 10, 12–17)	DiI will not 'leak' to the surrounding tissues if blood vessels are intact. Be gentle during tissue harvesting. View tissue sections as soon as possible

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Thum, Bernhard
Thum & Partner
Thum Mötsch Weickert
Patentanwälte PartG mbB
Siebertstr. 6
81675 München
ALLEMAGNE

Date
28.10.2022

Reference	Application No./Patent No.
KUR-18996-P-EP	20781928.5 - 1122 / 3948211 PCT/US2020026276
Applicant/Proprietor	
Kurin, Inc.	

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the supplementary European search report (Art. 153(7) EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☒ 0 additional set(s) of copies of such documents is (are) enclosed as well.

Refund of the search fee
If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued shortly (R. 70(2) EPC).

Europäisches Patentamt • European Patent Office • Office européen des brevets

The examination is being carried out on the **following application documents**

Description, Pages

1-28 as published

Claims, Numbers

1-20 as published

Drawings, Sheets

1/16-16/16 as published

Reference is made to the following documents; the numbering will be adhered to in the rest of the procedure.

D1 US 2018/271425 A1 (ROGERS BOBBY E [US] ET AL) 27 September 2018 (2018-09-27)

D2 EP 3 324 845 A1 (KURIN INC [US]) 30 May 2018 (2018-05-30)

D3 WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05)

D4 WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21)

1. The application does not meet the requirements of Article 84 EPC, because claims 1, 6 and 14 are not clear.

Claims 1, 6 and 14 have been drafted as separate independent claims.

Under Article 84 in combination with Rule 43(2) EPC, an application may contain more than one independent claim in a particular category only if the subject-matter claimed falls within one or more of the exceptional situations set out in paragraph (a), (b) or (c) of Rule 43(2) EPC. However, this is not the case in the present application.

2. The present application does not meet the requirements of Article 52(1) EPC because the subject-matter of claims 1, 6 and 14 is not new within the meaning of Article 54(1) and (2) EPC.

2.1 D1 discloses **a fluid sample optimization device** (see fig.23,24, par. [0141]-[0149]:"blood sample optimization system 2400") **for optimizing a fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants** (see par. [0141]:" a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered"), **the fluid sample optimization device comprising:**

an inlet ("inlet port 2412") **configured to connect with the fluid source;**

an outlet ("outlet port 2414") **configured to connect with the fluid collection device;**

a sample path ("blood sample channel 2422") **connected between the inlet and the outlet; and**

a contaminant containment reservoir ("blood sequestration chamber 2418 ") **connected between the inlet and the outlet, the contaminant containment reservoir having an air permeable fluid resistor** ("air permeable blood barrier 2420") **proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet** (see par. [0148]:"As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position.","Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.".

The subject-matter of claim 1 is therefore not new (Article 54(1) and (2) EPC).

2.2 D1 discloses a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source (see fig.23,24, par. [0141]-[0149]:"blood sample optimization system 2400"), a first portion of the fluid sample potentially having contaminants (see par. [0141]:" a sampling channel 2308 that

bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered"), the fluid sample optimization device comprising:

an inlet ("inlet port 2412") configured to connect with the fluid source;

an outlet ("outlet port 2414") configured to connect with the fluid collection device;

a sample path ("blood sample channel 2422") connected between the inlet and the outlet, the sample path further having a resistive plug ("apertures 2424") that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path (see par.[0141]:"the inner chamber housing 2419 is in the first position toward the inlet port 2412, such that the one or more apertures 2424 are closed, and the blood sequestration chamber 2418 is in a direct path from the patient needle."); and

a contaminant containment reservoir ("blood sequestration chamber 2418 ") connected between the inlet and the outlet, the contaminant containment reservoir further having an air permeable fluid resistor ("air permeable blood barrier 2420") proximate the outlet, the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet (see par.[0148]:"As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position.","Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.").

The subject-matter of claim 6 is therefore not new (Article 54(1) and (2) EPC).

2.3 The subject-matter of claim 14, which comprises for essentially the same features as the subject matter of claim 1, is for essentially the same reasons as those given above (see point 2.1) also not new (Article 54(1) and (2) EPC).

2.4 Furthermore, the documents D2-D3 also disclose all the features of claim 1, 6 and 14. For further details, see the relevant parts thereof as cited in the Search Report.

3. The dependent claims 2 to 5, 7 to 13 and 15 to 20 and seem not to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC in respect of novelty and/or inventive step, defining either features already known from any of D1-D3 or straightforward possibilities from which the person skilled in the art would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

4. Independent claims are not in the two-part form in accordance with Rule 43(1) EPC, which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 43(1)(a) EPC) and the remaining features being included in the characterising part (Rule 43(1)(b) EPC).

5. The features of the claims should be provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 43(7) EPC). This applies to both the preamble and characterising portion (see Guidelines F-IV, 4.18).

6. The applicant is invited to file new claims which take account of the above comments.

In order to comply with the requirements of Rule 137(4) EPC, the applicant should clearly identify the amendments made, irrespective of whether they concern amendments by addition, replacement or deletion, and indicate the passages of the application as filed on which these amendments are based (see Guidelines H III, 2.1).

If the applicant considers it appropriate, these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed or in documents with tracked changes.

When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and of any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

Information on Search Strategy - Pilot phase (see OJ 2015, A86)
The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number
EP 20 78 1928

TITLE: NON-VENTING BODILY FLUID SAMPLE OPTIMIZATION DEVICE AND SYSTEM

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: G01N1/10, G01N1/02, A61B5/15, A61B5/154

EXAMINER: Coja, Michael

CONSULTED DATABASES: EPODOC, WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150221, A61B5/150251

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

EPO FORM P04A42

Europäisches Patentamt
European Patent Office
Office européen des brevets

SUPPLEMENTARY EUROPEAN SEARCH REPORT

Application Number
EP 20 78 1928

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2018/271425 A1 (ROGERS BOBBY E [US] ET AL) 27 September 2018 (2018-09-27) * the whole document *	1-20	INV. G01N1/10 G01N1/02 A61B5/15
X	EP 3 324 845 A1 (KURIN INC [US]) 30 May 2018 (2018-05-30) * paragraph [0104]; figure 23 *	1-20	A61B5/154
X,P	WO 2019/232196 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 5 December 2019 (2019-12-05) * paragraphs [0074], [0099], [0120], [0141]; figures 1-14 *	1,6,14	
A	WO 2019/055487 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]) 21 March 2019 (2019-03-21) * paragraph [1179]; figures 35-37 *	1-20	

TECHNICAL FIELDS SEARCHED (IPC)

A61B

The supplementary search report has been based on the last set of claims valid and available at the start of the search.

Place of search	Date of completion of the search	Examiner
The Hague	20 October 2022	Coja, Michael

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

1

EPO FORM 1503 03.82 (P04C04)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 20 78 1928

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

20-10-2022

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 2021145336 A1	20-05-2021
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		JP 2020533045 A	19-11-2020
		US 2019076074 A1	14-03-2019
		US 2022175284 A1	09-06-2022
		WO 2019055487 A1	21-03-2019

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

Europäisches Patentamt
European Patent Office
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Application No.: 20781928.5

The search has started on 19.10.22 (see Notice from the European Patent Office dated 03/2013, OJ EPO 2013, 153).

Receiving Section

פ.ק 26

תאריך : י״ח כסלו תשפ״ב
22/11/2021
מספרכם : 1000-016-01

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14, ת.ד.
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה על ליקויים בבקשת פטנט מספר 286030</u>**
סימוכין : מכתבכם מיום 15/11/2021

לתשומת לבכם : מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 203.00 ש״ח בעד כל חודש או חלק ממנו. **לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים** בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

<u>הודעה זו מבוססת על המסמכים הבאים :</u>
שרטוטים מתאריך : 01/09/2021
פרטי הבקשה מתאריך : 01/09/2021
תביעות מתאריך : 01/09/2021

<u>ההפניות בהודעה זו מתייחסות לפרסומים הבאים :</u>

D1: WO 2011162772 A1 [CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]] - 29/12/2011

<u>הסתייעות הבוחן בדוח בינלאומי</u>

מערכת התביעות שבבקשה שבפניי זהה / זהה בחלקה למערכת התביעות בבקשה הבין-לאומית PCT/US/2016/043709 שנבחנה על ידי רשות חיפוש ובחינה בין-לאומית. לאחר עיון בדוח הבין-לאומי ולאור הזהות בתביעות כאמור, החלטתי כי הליקויים שפורטו בדוח הבין-לאומי חלים על הבקשה שבפניי כמפורט בהמשך הודעה זו.

<u>בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדתי לעניין כשירות התביעות לפטנט :</u>

בתביעה/ות מס׳ 1-4 נמצאו ליקויים.
ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות **תקנה 41** הנני להודיעכם כי נמצאו בבקשה הנ״ל הליקויים המפורטים להלן :

1. <u>בחינת הבקשה מבוססת על ההודעות הבאות:</u>

1.1 הריני להודיעכם כי:

(א) תאריך הבקשה הנוכחית, שהינה בקשת חלוקה מן הבקשה מס' 257137, הוקדם לתאריך 22/07/2016, שהוא תאריך הבקשה ההורה, וזאת בהתאם ל**סעיף 24(ג) לחוק**;

(ב) הבקשה הנוכחית זכאית לאותו(ם) תאריך(כי) בכורה אשר עליו(הם) הושתתה הבקשה ההורה.

2. <u>חידוש והתקדמות המצאתית</u>

2.1 תביעה 1 אינה מגדירה אמצאה חדשה כהגדרתה ב**סעיף 4 לחוק**, לאור פרסום: D1.

תביעה 1 שבבקשה שבפניי תואמת לתביעה 17 בבקשה AU2016297849 שנבחנה על ידי IP Australia והופק עבורה דוח בחינה בתאריך 29/04/2020. לאחר עיון בדוח הבחינה האמור ולאור תאימות התביעות, מצאתי כי הליקוי שפורט בנוגע לחוסר חידוש חל גם על התביעות שבפניי לפי חוק הפטנטים הישראלי.

2.2 תביעות 2-4 אינן מגדירות אמצאה שיש בה התקדמות המצאתית כהגדרתה ב**סעיף 5 לחוק**, לאור פרסום: D1.

תביעות 2-4 שבבקשה שבפניי תואמות לתביעות 18-20 בבקשה AU2016297849 שנבחנה על ידי IP Australia והופק עבורה דוח בחינה בתאריך 29/04/2020. לאחר עיון בדוח הבחינה האמור ולאור תאימות התביעות, מצאתי כי הליקוי שפורט בנוגע לחוסר התקדמות המצאתית חל גם על התביעות שבפניי לפי חוק הפטנטים הישראלי.

3. <u>התביעות</u>

3.1 תביעה מס' 1 (התואמת לתביעה 17 בבקשה הבין-לאומית) אינה עונה לדרישות **סעיף 13 לחוק** ו**תקנה 20(א)(3)** מאחר והיא לא בהירה ו/או תמציתית, כמפורט בדוח הבחינה הבין-לאומי.

<u>חובת המבקש לעדכן את הרשות</u>

תשומת לבכם ל**סעיף 18א לחוק** לעניין חובת המבקשת לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור ב**סעיף 18(א) לחוק** ול**סעיף 18ג לחוק** בדבר אמצעי האכיפה.

<u>הגשת תיקונים לפירוט במהלך בחינת הבקשה</u>

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית **לתקנה 22(א)**. יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך: <u>דוגמה</u>) והשמטות בקו חוצה (כך: ~~דוגמה~~). **אין להגיש מחדש קבצים שלא תוקנו.**

לתשומת לבכם:

א) בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהודעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלקם, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון בתביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק.

ב) בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון

פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת הודעה לפני סירוב.

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

https://israelpatents.justice.gov.il/#/en/patent-file/details/286030

<u>ראיון עם בוחן</u>

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחן באמצעות פגישה במשרדי הרשות או בשיחה טלפונית.

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחן למבקש או בא-כוחו באמצעות שירות זה.

קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט.

במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה.

תיאום הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם.

לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

<u>השגה בפני הרשם</u>

על פי **סעיף 161 לחוק**, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
טלפון: 073-3927233
דואר אלקטרוני: albertak@justice.gov.il
ראש צוות: מוריה שלמה לוי

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 1

Notice of Allowance

(Divisional)

Application Serial No.:	2021-214177
Drafting Date:	June 16, 2023
Examiner:	Naoya TAKAGI 3611 2Q00
Title of the Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
Number of Claims:	20
Applicant(s):	KURIN, INC.
Agent:	MURAKOSHI, Satoshi

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.
Certificated: June 19, 2023
Administrative Official of Ministry of Economy, Trade and Industry, Takashi SATO

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

- Type of Application: Divisional Application
- Cited References: Yes
- Grace Period under Patent Act Article 30: No
- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 3/E

Reference Information

Application Serial No.: 2021-214177

- FI

  A61B 5/15 200

- Search Fields (IPC, DB Name):

  A61B 5/15-5/157

- References Cited :

  Japanese Patent Application Publication No.2013-240628 (JP,A)
  Japanese Patent Application Publication No.2016-504075 (JP,A)
  International Patent Application Publication No.2014/058945 (WO,A1)
  US Patent Application Publication No.2005/0245885 (US,A1)

- Non-patent literatures:

特許査定

（分割）

特許出願の番号	特願２０２１－２１４１７７
起案日	令和　５年　６月１６日
特許庁審査官	▲高▼木　尚哉　３６１１　２Ｑ００
発明の名称	流体分流デバイス、及び流体分流サンプリングシステム
請求項の数	２０
特許出願人	クリン　インコーポレイテッド
代理人	村越　智史（ほか　４名）

この出願については、拒絶の理由を発見しないから、特許査定をします。

上記はファイルに記録されている事項と相違ないことを認証する。
認証日　令和 5年 6月19日　経済産業事務官　佐藤　隆

注意：この書面を受け取った日から３０日以内に特許料の納付が必要です。

・出願種別　分割
・参考文献　有
・特許法第３０条適用　無
・発明の名称の変更　無

・菌寄託

参考情報

特許出願の番号　特願２０２１－２１４１７７

・ＦＩ

Ａ６１Ｂ　５／１５　２００

・調査した分野（ＩＰＣ，ＤＢ名）

Ａ６１Ｂ　５／１５－５／１５７

・参考特許文献

特開２０１３－２４０６２８　（ＪＰ，Ａ）
特表２０１６－５０４０７５　（ＪＰ，Ａ）
国際公開第２０１４／０５８９４５　（WO，Ａ１）
米国特許出願公開第２００５／０２４５８８５　（ＵＳ，Ａ１）

・参考図書雑誌

21 May 2024

PILLSBURY WINTHROP SHAW PITTMAN, LLP
P.O. BOX 10500
McLean, VA 22102
USA

By Email Only:
james.conley@pillsburylaw.com
benjamin.hudson@pillsburylaw.com
suzanne.simpson@pillsburylaw.com
Docket_ip@pillsburylaw.com

To the attention of Jim Conley

P.K. 26 – First Office Action of:

IL Patent Application No.: 286812
Title: NON-VENTING BODILY FLUID SAMPLE OPTIMIZATION DEVICE AND SYSTEM
Filing Date: 29 September 2021
App. date: 1 April 2020
IL NP of PCT Patent Application No.: PCT/US2020/26276
Applicant(s): KURIN, INC.

Your ref.: 069366-0572161_KUR7N01IL Our ref.: 1000-020-01

1

Dear Jim:

The Israel Patent Office (ILPO) has issued its first Office Action (substantive examination report) dated 20 May 2024, notifying the Applicant of the beginning of the examination process of the above identified IL Patent Application.

A response to the Office Action should be filed within four months and before **20 September 2024**. Monthly extensions (up to four months) are available upon payment of government fees of about $60 per month. Kindly note that the maximum extension period which can be obtained during substantive examination cannot exceed 12 months.

The examination is based on the following documents:

Description dated 29 September 2021

Claims dated 29 September 2021

Drawings dated 29 September 2021

The references hereunder relate to the following publications:

D1: US2018271425A1 [KURIN INC [US]] - 27/09/2018
D2: GB1378602A [BECTON DICKINSON CO] - 27/12/1974
D3:US2014112841A1 [BOEHRINGER INGELHEIM MICROPART [DE]] - 24/04/2014

In accordance with details below the following are the examiner's remarks regarding the allowability of the claims:

Defects were found in claims 1-20:

1. **Novelty and Inventive Step**

   1.1. Claims 1-3,5-7,10,14-17 do not define a novel invention as per section 4 of the law, in light of D1, as detailed in the International Search Report.

   1.2. Claims 1-20 do not define an invention with an inventive step as per section 5 of the law, in light of D1, D2, D3, as detailed in the International Search Report.

2 **Duty of Disclosure**

The applicant is hereby reminded that any change in the list of prior art or status of corresponding application (section 18c of the law) regarding oppositions, procedures to cancel corresponding applications / registrations must be reported to the ILPO up to the payment of the allowance fee.

We look forward to receiving your instructions in due course.

Yours sincerely,

Dr. Sarah Presenti, Adv
Katz, Presenti & Co

דרך אבא הלל סילבר 14, בית עוז, קומה 11, רמת-גן, 5250607 | info@patents-il.com | 03-9093614 | 03-9326393
+972-3-9326393 | +972-3-9093614 | info@patents-il.com | 14 Abba Hillel Rd. Beit OZ, 11th floor, Ramat Gan 5250607, Israel
www.patents-il.com

Submitted herewith

> The original OA (p.k. 26) in Hebrew.

> D1, D2, D3

> Our invoice number 3465

3

פ.ק 26

תאריך : י״ב אייר תשפ״ד
20/05/2024
מספרכם : 1000-020-01

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה על ליקויים בבקשת פטנט מספר 286812</u>**
סימוכין : מכתבכם מיום 26/12/2022, 19/10/2023

לתשומת לבכם : מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 226.00 ש״ח בעד כל חודש או חלק ממנו. **לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים** בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

<u>הודעה זו מבוססת על המסמכים הבאים :</u>
תביעות מתאריך : 29/09/2021
שרטוטים מתאריך : 29/09/2021
פרטי הבקשה מתאריך : 29/09/2021

<u>ההפניות בהודעה זו מתייחסות לפרסומים הבאים :</u>

D1: US2018271425A1 [KURIN INC [US]] - 27/09/2018
D2: GB1378602A [BECTON DICKINSON CO] - 27/12/1974
D3: US2014112841A1 [BOEHRINGER INGELHEIM MICROPART [DE]] - 24/04/2014

<u>בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדתי לעניין כשירות התביעות לפטנט :</u>

בתביעה/ות מס׳ 1-20 נמצאו ליקויים.
ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות **תקנה 41** הנני להודיעכם כי נמצאו בבקשה הנ״ל הליקויים המפורטים להלן :

1. <u>חידוש והתקדמות המצאתית</u>

1.1 תביעות מס׳ 1-3,5-7,10,14-17 אינן מגדירות אמצאה חדשה כהגדרתה ב**סעיף 4 לחוק**, לאור פרסום/ים : D1, כמפורט בדוח הבחינה הבין-לאומי.

1.2 תביעות 1-20 אינן מגדירות אמצאה שיש בה התקדמות המצאתית כהגדרתה ב**סעיף 5 לחוק**, לאור פרסום/ים : D1 ,D2 ,D3, כמפורט בדוח הבחינה הבין-לאומי.

<u>חובת המבקש לעדכן את הרשות</u>

תשומת לבכם ל**סעיף 18א לחוק** לעניין חובת המבקשת לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור ב**סעיף 18(א) לחוק** ול**סעיף 18ג לחוק** בדבר אמצעי האכיפה.

<u>הגשת תיקונים לפירוט במהלך בחינת הבקשה</u>

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית **לתקנה 22(א)**. יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך : <u>דוגמה</u>) והשמטות בקו חוצה (כך :~~דוגמה~~). **אין להגיש מחדש קבצים שלא תוקנו**.

לתשומת לבכם :

א) בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהודעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלקם, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון בתביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק .

ב) בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת הודעה לפני סירוב.

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור :

https://israelpatents.justice.gov.il/#/en/patent-file/details/286812

<u>ראיון עם בוחן</u>

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחן באמצעות פגישה במשרדי הרשות, בשיחה טלפונית או בהיוועדות חזותית.

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחן למבקש או בא-כוחו באמצעות שירות זה.

קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט.

במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה.

תיאום הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם.

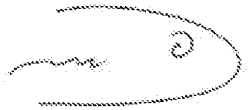
לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

<u>השגה בפני הרשם</u>

על פי **סעיף 161 לחוק**, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בתקווה לימים שקטים ובטוחים יותר.

בכבוד רב



מתן כוחיי
סגן הממונה על הבוחנים
טלפון : 073-3927255
דואר אלקטרוני : matanc@justice.gov.il

Bibliographic data: EP0448795 (A2) — 1991-10-02

Compartmental body fluid collection tube.

Inventor(s): DUFRESNE CHRISTOPHER M [US] ± (DUFRESNE, CHRISTOPHER M)

Applicant(s): BECTON DICKINSON CO [US] ± (BECTON DICKINSON AND COMPANY)

Classification: - **international:** ***A61B5/15; A61B5/154; B01L3/14;*** (IPC1-7): B01L3/14
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Abstract of EP0448795 (A2)

A compartmented body fluid specimen collection tube (10) is provided which allows the user to select a size compartment (14,16) depending upon the quantity of specimen required. Thus, the tube of the invention may be of the standard size which is much easier for the user to handle than very small tubes when taking a blood sample, but a selected size compartment (14,16) is available. The manufacturer of the tube itself may use a single moid for making tubes accommodating differing required specimen quantities, and, thereafter the vendor may select either size compartment (14,16) for imparting a vacuum and the other processing required into a final product. The invention allows the use of a single standard size laboratory equipment array for processing collected specimens of varying quantities, as well as a single standard stopper (28). Finally, reduced vacuum application or "partial draw" tubes are avoided, thus eliminating the problem of unpredictable specimen draw response because of varying atmospheric pressures at different locations of use.

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(71) Applicant: **Becton Dickinson and Company**
One Becton Drive
Franklin Lakes New Jersey 07417-1880(US)

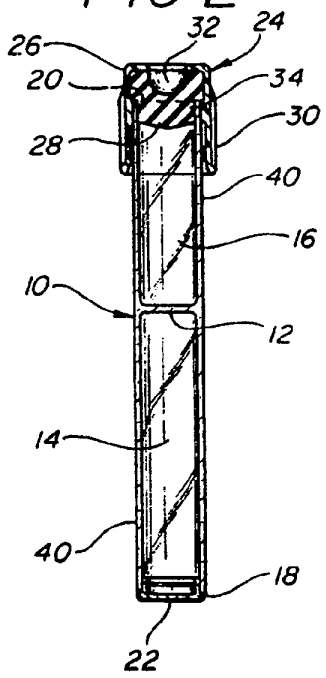
(72) Inventor: **Dufresne, Christopher M.**
27 Millington Avenue
Hewitt, New Jersey(US)

(74) Representative: **Selting, Günther, Dipl.-Ing. et al**
Patentanwälte von Kreisler, Selting, Werner
Deichmannhaus am Hauptbahnhof
W-5000 Köln 1(DE)

(54) Compartmental body fluid collection tube.

(57) A compartmented body fluid specimen collection tube is provided which allows the user to select a size compartment depending upon the quantity of specimen required. Thus, the tube of the invention may be of the standard size which is much easier for the user to handle than very small tubes when taking a blood sample, but a selected size compartment is available. The manufacturer of the tube itself may use a single mold for making tubes accommodating differing required specimen quantities, and, thereafter the vendor may select either size compartment for imparting a vacuum and the other processing required into a final product. The invention allows the use of a single standard size laboratory equipment array for processing collected specimens of varying quantities, as well as a single standard stopper. Finally, reduced vacuum application or "partial draw" tubes are avoided, thus eliminating the problem of unpredictable specimen draw response because of varying atmospheric pressures at different locations of use.

FIG-2



EP 0 448 795 A2

BACKGROUND AND STATEMENT OF THE INVENTION

This invention relates to body fluid collection tubes for collecting a body fluid specimen from a patient for subsequent examination in a laboratory. More particularly, this invention relates to a blood collection tube for taking such specimens in which the tube has imparted thereto an internal vacuum with the vacuum being utilized for drawing the blood specimen from the vein of a patient.

Attempts have been made to overcome the problem of proliferation of a number of tubes for taking a plurality of specimens from a single venous entry into a patient. For example, Japanese Patent Application No. 62-51238, filed March 6, 1987 teaches a device in which a tube is divided axially into two chambers for taking two blood specimens simultaneously. However, there is no recognition for arranging different size compartments for taking different separate specimens of different size to accommodate subsequent laboratory testing of those specimens.

Other prior art arrangements, such as that taught in U.S. Patent 3,894,951, for example, provide for compartmentalized blood collection tubes in which the compartments have fluid connections for subsequent separation of a single blood sample into separate components.

In taking such specimens, differing quantities or volumes of specimens are required for certain applications. For this reason, larger and smaller tubes are manufactured for this purpose. As an alternative to making larger and smaller tubes, so-called "partial draw" tubes are provided in which the vacuum imparted to the tube is varied in order to accommodate differing quantities of specimen as required. All of these variations increase the cost of collecting blood specimens, and when it is understood that literally billions of such tubes are used and discarded after a single use each year the costs become substantial for medical applications.

This invention overcomes this problem by using a conventionally sized tube of, for example, 6cc in volume and incorporates an integral divider substantially centrally of the length of the tube to provide two compartments of differing size. Such compartments may be, for example, 2cc and 3cc. Thus, the manufacturer, rather than having to use two separate molds and two separate production lines, may manufacture a single tube having a selection of a 2cc and a 3cc compartment or chamber. Thereafter, the user or vendor may utilize or select one of the sizes of compartment and impart a vacuum thereto and place a stopper in the open end of the compartment size selected. The remaining compartment or chamber not being utilized for this particular series of tubes has a plug for closing the open end of the non-utilized chamber or compartment.

Conventional blood collection tubes have only one chamber, and volume in those conventional tubes is varied by using either larger or smaller diameter tubes, taller or shorter length tubes or varying the degree of vacuum imparted. As will be understood by practitioners-in-the-art, larger and smaller diameter tubes require specific dimensioned stoppers for accommodating those various sizes. Moreover, taller and shorter tubes require different packaging to accommodate tube length. If an accommodation is made to utilizing only a single size tube and imparting a partial vacuum for subsequent use in which only a small quantity of specimen is required in relatively large tubes, there is inconsistent draw over different areas of use because of differing atmospheric pressure gradients.

Finally, the users of tubes of different length and diameter must have varying size equipment, such as centrifuges, tube racks and like supporting arrangements to accommodate the varying sizes of tubes being utilized for collecting differing quantities of body fluid specimens for different applications.

With this invention, by contrast, a single size tube, as noted above is utilized. For this reason, the user, in the sometimes tense environment of taking a blood specimen from an individual, has a relatively large tube for handling during the collection activity Nevertheless the tube has a smaller compartment; for accommodating the actual size specimen required. Moreover, because only a single size tube relative to diameter is being utilized with the invention here, a single stopper size is required rather than a plurality of stopper sizes of differing diameters to accommodate differing diametered tubes. This reduces manufacturing requirements as well as storage requirements for such a variety of stopper sizes.

Moreover, because of the large size tubes having small compartmentalized areas, no "partial draw" vacuum applications are required. This eliminates the problem of inconsistency depending upon the atmospheric pressure gradients over many areas of use of such tubes. Finally, because of the uniformity of size of the tube, the hospital or clinical laboratory only needs to have one size equipment necessary for handling the tubes of a standard size.

A further feature of the invention may be the use of both compartments of a single tube by the phlebotomist. That is, the vendor or manufacturer of the tubes may, for example, impart vacuum to both a 3cc and a 2cc compartment or chamber in a single tube and place stoppers for sealing and

maintaining the vacuum. Thereafter, the phlebotomist, in requiring two separate blood sample volumes for different tests subsequently can first draw blood into one chamber followed by inversion of the tube and collection of blood into the second chamber. Two blood samples would then be contained in a single tube for subsequent examination in the clinical laboratory, and with only one venous entry.

Other objects and advantages of this invention will be apparent from the following description, the accompanying drawings and the appended claims.

DESCRIPTION OF THE DRAWINGS

Fig. 1 is longitudinal sectional view of the compartmentalized blood collection tube of the invention;

Fig. 2 is a longitudinal sectional view of one embodiment of the invention wherein a vacuum has been imparted to the smaller chamber or compartment of the tube of the invention and showing the sealing stopper arrangement for such a tube, together with a plug for the unused chamber;

Fig. 3 is a longitudinal sectional view of the tube of the invention reversed in its application from that shown in Fig. 2;

Fig. 4 is an enlarged partial cross-sectional view of one open end of the tube of the invention showing the mating configuration of a sealing plug applied to the open end for closing off the non-utilized chamber or compartment of the tube of the invention;

Fig. 5 is a longitudinal sectional view of a blood sample tube holder for taking a blood sample from a vein of a patient with the tube of the invention inserted therein; and

Fig. 6 is a longitudinal sectional view of a tube similar to that shown in Fig. 1, but both chambers being closed with a stopper closure for use in evacuating two chambers for collecting two specimens sequentially.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, Fig. 1 illustrates the invention in the form of a conventionally sized blood collection tube compartmentalized in its formation to provide two chambers or compartments of differing size to accommodate differing blood sample requirements.

In Fig. 1, the device 10 is an elongated tube with walls 40 and having open ends 18, 20 at each end thereof. As can be seen in Fig. 1, tube 10 is divided by a wall 12 into compartments or chambers 14 and 16. Also, as will be seen in Fig. 1, chamber 14 is larger than chamber 16. For example, in a 6cc tube, chamber 14 may be, for example, 3cc in volume while chamber 16 may be 2cc in volume.

It will be understood that the volume amounts may be varied as use requirements dictate. Tube 10 may be comprised of a thermoplastic resin material, for example, formed in a mold to provide wall 12 integrally joined to wall 40 of tube 10.

Referring now to Fig. 2, tube 10 is shown in a prepared form for use by a vendor. In this case, the smaller dimensioned chamber 16 has had, for example, a vacuum applied thereto with a subsequent insertion of a stopper assembly 24 for maintaining the vacuum in chamber 16. The assembly 24 includes a rubber stopper for closing the open end, 20 of the tube, assembly 10. That is, the outer surface of lower portion of stopper 28 seals against the internal surface of walls 40 of the upper end of tube 10. The assembly 24 includes a plastic cap 26 connected to and surrounding elastomer stopper 28. This serves to accommodate removal of stopper 28 in a simple fashion, when required, to obtain access to the collected sample in chamber 16.

Stopper 28 includes a well 32 formed in the top surface thereof which has the purpose of reducing the vertical extent of stopper 28 in the center portion thereof to provide a diaphragm 34 of vertically smaller dimension through stopper 28 for receiving a needle such as needle 52 and the point 54 thereof, as shown in Fig. 5. The plastic portion 26 of stopper 24 assembly includes outer ridges 34 to provide an easier grip of the assembly 24 for removal thereof from the evacuated chamber 16, when required.

Referring to Fig. 4, the open end 18 of chamber 14, which in this case is not being utilized for fluid collection includes a plug 22 for stabilizing the open end 18 of the tube assembly 10 for subsequent use of the tube or for storing the tube prior to use.

In Fig. 4, an enlarged view of the open end 18 or 20 is shown to accommodate the snap-fit arrangement of plug 22 in the open end 18 or 20 of chamber 14 or 16, as the case may be, when they are not being utilized in a particular tube 10 assembly. That is, the lower end of wall 40 may include an annular indentation 36 for receiving in snap-fit engagement an annular abutment, 38 on plug 22.

Referring now to Fig. 3, a tube 10 is shown reversed from the Fig. 2 showing for accommodating use of the 3cc and/or larger compartment 14 as desired by the user. In this case, stopper assembly 24 closes the open end 18 rather than 20, while the open end 20 is closed with a plug 22. It will be understood by practitioners-in-the-art that both compartments or chambers 14, 16 may be utilized in a single tube 10 by imparting a vacuum to both chambers and using a stopper closure assembly

24 for closing both open ends 18 and 20. In such cases, a plug 22 is not utilized.

Such an arrangement is shown in Fig. 6 wherein a tube 60 similar to tube 10 is shown with chambers 64, 66 divided by wall 62. Tube 60 includes two open ends 68 and 70. In this case, a stopper assembly 24 is applied to both open ends after application of vacuum to chambers 64, 68, respectively. As discussed above, in such an application, the user collects two different volumes of specimen from a patient as required for subsequent testing purposes.

In use, the assembly 10 of the invention is inserted into a blood collection needle holder such as 42 shown in Fig. 5. Holders 42, for example, include at the closed end thereof a hub 46 with internal screw threads 48 for accommodating the screw threads of a needle holder hub 50. Thus, a plurality of needle holder hubs 50 may be, sequentially, screwed into hub 46 of needle holder 42 for repeated use. The needle 52 includes a sharpened end 56 which is inserted into the vein of a patient for collecting a blood Specimen.

Subsequent to insertion of the needle 56 into the vein of a patient, the laboratory technician, doctor or nurse inserts the tube assembly 10 into the blood collection holder 42 at the open end 43 thereof. In doing so, the technician holds onto the holder 42 utilizing the flange 44. Subsequently, the tube 10 is moved forward toward the closed end of the holder 42 until such time as the negative pressure needle point 54 passes through stopper 28. When this happens, access to the vacuum in chamber 16 takes place and the vacuum draws blood from the patient's vein through the needle 52 into chamber 16.

As will be understood by practitioners-in-the-art, the smaller chamber 16 may be, for example, of a volume of 2ccs which is all that is required for certain subsequent examinations of the specimen in the lab. A tube such as tube 60 shown in Fig. 6 may be used in holder 42 instead of tube 10. With such an arrangement, the double-ended needle assembly would include a sealing valve sleeve well known in the art so that the tube 60 may be pulled off needle point 54, and reversed for inserting the needle point 54 into the subsequent stopper 28 without blood loss, for collecting a second blood sample in chamber 66, for example.

Alternatively, the technician may use a standard size blood collection container and collect a subsequent larger blood sample, as required from the single insertion of point 56 of needle 52 in the patient's vein all as will be understood by the practitioner-in-the-art.

The blood collection tube of the invention may be comprised, preferably, from a clear molded thermoplastic material such as polyethylene, for example, or glass. Other materials which may be used, as will be appreciated by practitioners-in-the-art include various other thermoplastics such as polypropylene, polyethylene terephthalate, and polyvinyl chloride.

The evacuated chambers utilized for collection in the device of the invention here may have incorporated therein materials for reaction with the specimen being collected for providing a proper response to the collected specimen for subsequent examination in the clinical laboratory. The stopper may be comprised of an elastomer appropriate for providing the sealing required to maintain the imparted vacuum in the chamber selected for subsequent use by the laboratory technician. The plastic cover portion 26 of stopper assembly 24 may be comprised of polyethylene or other thermoplastic which may be molded into the proper shape for the assembly of the invention.

Whereas, as discussed above, specific embodiments of associated stoppers and caps have been shown, it should be understood that it is within the purview of this invention to provide other forms of closures for blood collection tubes of the kind discussed herein.

It will be understood that the invention here is most appropriate for medical applications because of the substantial reduced cost in accommodating a variety of different requirements for a body fluid specimen collection, and for reducing the number of molds required for providing an assembly which is nevertheless, much easier to handle than the miniaturized collection tubes presently being utilized for small volume specimen collection. Moreover, the arrangement herein eliminates the need for the application of "partial draw" tubes and the inconsistency apparent with the use of such partial draw tubes.

While the forms of apparatus herein described constitute preferred embodiments of the invention, it is to be understood that the invention is not limited to these precise forms of apparatus and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

Claims

1. A blood collection tube; comprising
   (a) a tube body;
   (b) said tube body comprised of walls formed as a cylinder to define a tube body chamber;
   (c) said tube body chamber having a first open end at one end of said tube body chamber and a second open end at the end of said tube body chamber opposite said first open end;

(d) a divider wall positioned between said first and second open ends;
(e) said divider wall dividing said tube body chamber into a first and a second compartment; and
(f) said divider wall being formed integrally as one piece with said cylindrical tube body walls.

2. The blood collection tube of Claim 1, further comprising
(a) said first and second compartments being of different volume capacity.

3. The blood collection tube of Claim 1 further comprising
(a) a stopper closing one of said first and second open ends; and
(b) a plug closing the other of said open ends not closed by said stopper.

4. The blood collection tube of Claim 3, further comprising
(a) said compartment with the open end closed by said stopper being evacuated.

5. The blood collection tube of Claim 3, further comprising said stopper being comprised of
(a) a first elastomeric portion inserted into said open end in sealing engagement therewith;
(b) a plastic portion fitted over and surrounding said elastomeric portion;
(c) said plastic portion encompassing said tubular walls adjacent said open end into which said stopper is inserted;
(d) the top of said plastic portion having an opening adjacent the axis thereof for providing needle access to said elastomeric portion; and
(e) cooperating abutment means on said elastomeric portion and said plastic portion for holding said elastomeric portion and said plastic portion together.

6. The blood collection tube of Claim 3, further comprising
(a) said tube walls and said divider wall are comprised of a material selected from the group consisting of polyethylene, polypropylene, polyethylene terephthalate, polyvinyl chloride and glass.

7. A blood collection tube; comprising
(a) a tube body;
(b) said tube body comprised of walls formed as a cylinder to define a tube body chamber;
(c) said tube body chamber having a first open end at one end of said tube body chamber and a second open end at the end of said tube body chamber opposite said first open end;
(d) a divider wall positioned between said first and second open ends;
(e) said divider wall dividing said tube body chamber into a first and a second compartment;
(f) said divider wall being formed integrally as one piece with said cylindrical tube body walls;
(g) said first and second compartments being of different volume capacity;
(h) a first stopper closing said first open end; and
(i) a second stopper closing said second open end.

8. The blood collection tube of Claim 7, further comprising
(a) both said first and said second compartments being evacuated.

9. The blood collection tube of Claim 7, further comprising each of said first and second stoppers comprised of
(a) a first elastomeric portion inserted into said open end in sealing engagement therewith;
(b) a plastic portion fitted over and surrounding said elastomeric portion;
(c) said plastic portion encompassing said tubular walls adjacent said open end into which said stopper is inserted;
(d) the top of said plastic portion having an opening adjacent the axis thereof for providing needle access to said elastomeric portion; and
(e) cooperating abutment means on said elastomeric portion and said plastic portion for holding said elastomeric portion and said plastic portion together.

10. The blood collection tube of Claim 7, further comprising
(a) said tube walls and said divider wall are comprised of a material selected from the group consisting of polyethylene, polypropylene, polyethylene terephthalate, polyvinyl chloride and glass..

FIG-1

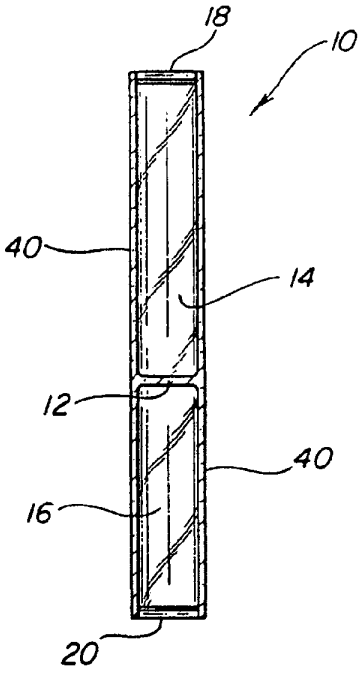


FIG-2

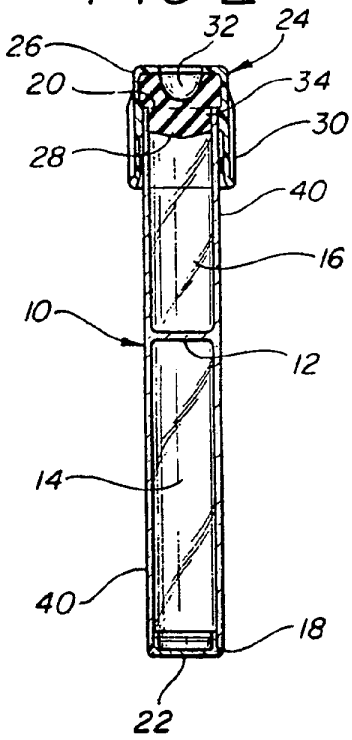


FIG-3

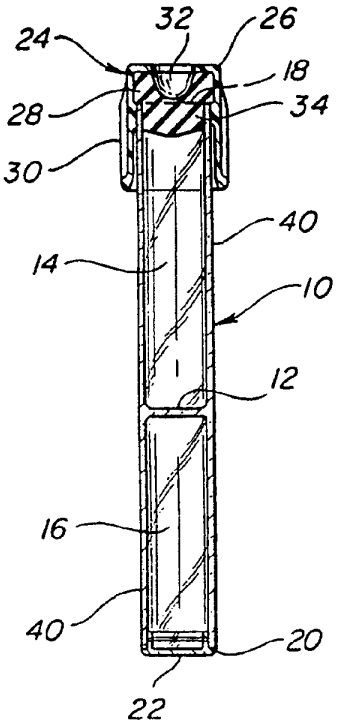


FIG-4

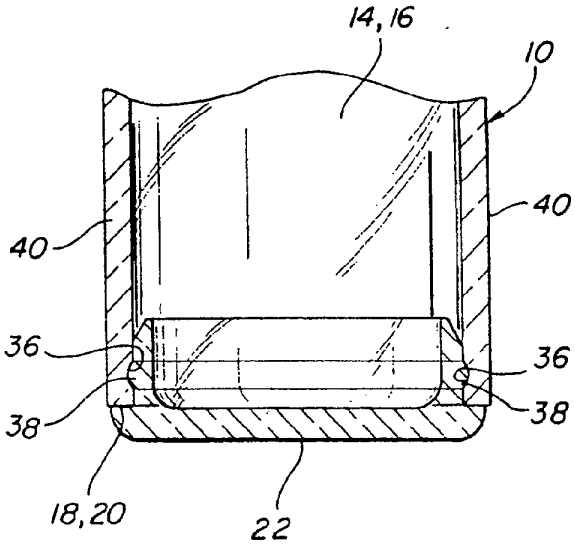


FIG-5

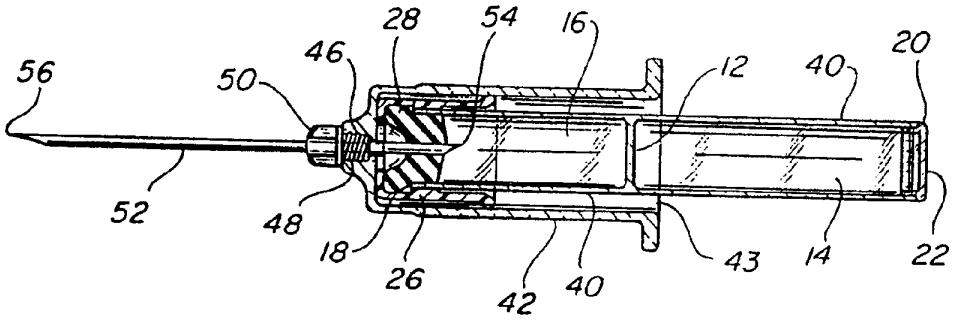

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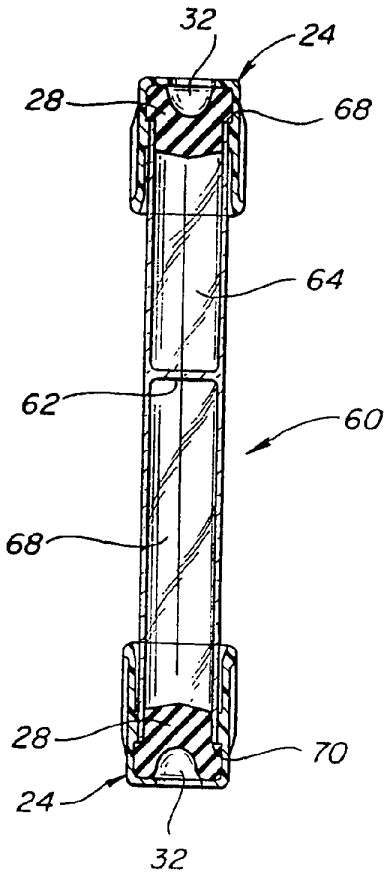
FIG-6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Espacenet

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Sterile bodily-fluid collection device and methods

Inventor(s): BULLINGTON GREGORY J; PATTON RICHARD G M D; GAW SHAN E ± (BULLINGTON GREGORY J, ; PATTON RICHARD G M D, ; GAW SHAN E, ; G·J·布林顿, ; R·G·M·D·巴顿, ; S·E·高)

Applicant(s): MAGNOLIA MEDICAL TECHNOLOGIES INC ± (MAGNOLIA MEDICAL TECHNOLOGIES INC, ; 木兰医药技术股份有限公司)

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Abstract of CN104981203 (A)

An apparatus includes a pre-sample reservoir, a diversion mechanism, and a flow metering mechanism. The diversion mechanism has an inlet port couplable to a lumen-defining device to receive bodily-fluids from a patient, a first outlet port fluidically couplable to the pre-sample reservoir, and a second outlet port fluidically couplable to a sample reservoir. The diversion mechanism defines a first fluid flow path and a second flow path that are configured to place the first outlet port and the second outlet port, respectively, in fluid communication with the inlet port. The flow metering mechanism is configured to meter a flow of a predetermined volume of bodily-fluid through the first fluid flow path into the pre-sample reservoir, to meter a flow of a second volume of bodily-fluid through the second fluid flow path into the sample reservoir, and to display a volumetric indicator associated with the predetermined volume and the second volume.

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(71)申请人 木兰医药技术股份有限公司
地址 美国华盛顿
(72)发明人 G·J·布林顿 R·G·M·D·巴顿 S·E·高
(74)专利代理机构 中国国际贸易促进委员会专利商标事务所 11038
代理人 朱海涛
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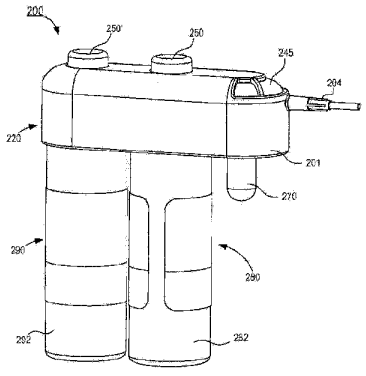
(54)发明名称

无菌体液采集装置和方法

(57)摘要

一种设备包括前样本储存器、转移机构和流计量机构。转移机构具有可耦接到内腔限定装置以从患者接收体液的入口端口、可流体耦接到前样本储存器的第一出口端口和可流体耦接到样本储存器的第二出口端口。转移机构限定被配置为使第一出口端口和第二出口端口分别与入口端口流体连通的第一流体流路径和第二流体流路径。流计量机构被配置为计量通过第一流体流路径流入前样本储存器的预定体积的体液流，计量通过第二流体流路径流入样本储存器的第二体积的体液流，并且显示与预定体积和第二体积相关的体积指示。



CN 104981203 A

1. 一种用于从患者获取体液样本的设备，所述设备包括：

前样本储存器，其被配置为接收从患者抽取的第一体积的体液；

转移机构，其包括入口端口、第一出口端口和第二出口端口，所述入口端口被配置为耦接到用于从患者接收体液的内腔限定装置，所述第一出口端口被配置为将所述前样本储存器流体耦接到所述转移机构，并且所述第二出口端口被配置为将样本储存器流体耦接到所述转移机构，所述转移机构限定被配置为使所述第一出口端口与所述入口端口流体连通的第一流体流路径和被配置为使所述第二出口端口与所述入口端口流体连通的第二流体流路径；以及

流计量机构，其与所述第一流体流路径和所述第二流体流路径流体连通，所述流计量机构被配置为计量通过所述第一流体流路径流入所述前样本储存器的第一体积的体液流并计量通过所述第二流体流路径流入所述样本储存器的第二体积的体液流，所述流计量机构被配置为显示与第一体积和第二体积相关的体积指示。

2. 如权利要求 1 所述的设备，其中，在第一时间段内所述第一体积的体液在所述第一流体流路径内流动，并且在第一时间段之后的第二时间段内所述第二体积的体液在所述第二流体流路径内流动。

3. 如权利要求 1 所述的设备，其中，所述第一体积的体液包括皮肤驻留的污染物，并且所述第二体积的体液基本不存在皮肤驻留的污染物。

4. 如权利要求 1 所述的设备，其中，所述前样本储存器至少部分地由所述转移机构的一部分限定。

5. 如权利要求 1 所述的设备，其中，所述体积指示是视觉指示。

6. 如权利要求 1 所述的设备，其中，所述转移机构包括被配置为移动通过所述第二出口端口以使所述样本储存器与所述第二流体流路径流体连通的可移动构件。

7. 如权利要求 6 所述的设备，其中，所述流计量机构至少部分地位于所述可移动构件的一部分内。

8. 如权利要求 1 所述的设备，其中，所述转移机构被配置为一旦第一体积的血液位于所述前样本储存器中就流体隔离所述前样本储存器和所述第一流体路径的至少一部分。

9. 如权利要求 1 所述的设备，其中，所述转移机构包括被配置为将第二样本储存器流体耦接到所述转移机构的第三出口端口，并且限定被配置为使所述第三出口端口与所述入口端口流体连通的第三流体流路径。

10. 如权利要求 1 所述的设备，还包括：

限定第一内腔和第二内腔的流控制器，所述流控制器被配置为在第一配置和第二配置之间移动，在所述第一配置，所述第一内腔使所述第一流体流路径与所述入口端口流体连通，在所述第二配置，所述第二内腔使所述第二流体流路径与所述入口端口流体连通。

11. 如权利要求 10 所述的设备，其中，所述流控制器被配置为在所述第一体积的体液位于所述前样本储存器中之后从所述第一配置移动到所述第二配置。

12. 一种用于从患者获取体液样本的设备，所述设备包括：

前样本储存器，其被配置为接收从患者抽取的第一体积的体液；

转移机构，其包括入口端口、第一出口端口和第二出口端口，所述入口端口被配置为耦接到用于从患者接收体液的内腔限定装置，所述第一出口端口被配置为将所述前样本储存

器流体耦接到所述转移机构，并且所述第二出口端口被配置为将样本储存器流体耦接到所述转移机构；

流控制器，其至少部分地位于所述转移机构内，并且被配置为在第一配置和第二配置之间移动，在所述第一配置，所述流控制器限定在所述入口端口和所述第一出口端口之间的流体流路径的至少一部分，在所述第二配置，所述流控制器限定在所述入口端口和所述第二出口端口之间的流体流路径的至少一部分；以及

可移动构件，其能够移动地耦接到所述转移机构，并且被配置为在其中所述样本储存器与在所述入口端口和所述第二出口端口之间的流体流路径流体隔离的第一配置和其中所述样本储存器与在所述入口端口和所述第二出口端口之间的流体流路径流体连通的第二配置之间移动通过所述第二出口端口，所述样本储存器被配置为当所述流控制器处于其第二配置并且所述可移动构件处于其第二配置时接收从患者抽取的第二体积的体液。

13. 如权利要求 12 所述的设备，其中，所述第一体积的体液包括皮肤驻留的污染物，并且所述第二体积的体液基本不存在皮肤驻留的污染物。

14. 如权利要求 12 所述的设备，其中，所述流控制器相对于所述转移机构在其第一配置和其第二配置之间旋转。

15. 如权利要求 12 所述的设备，其中，所述流控制器相对于所述转移机构以线性运动方式移动。

16. 如权利要求 12 所述的设备，其中，所述流控制器被配置为当所述流控制器处于其第二配置时流体隔离所述前样本储存器。

17. 如权利要求 12 所述的设备，其中，所述可移动构件包括被配置为当所述可移动构件处于其第二配置时刺穿所述样本储存器的一部分的刺穿构件。

18. 如权利要求 12 所述的设备，其中，所述可移动构件耦接到被配置为至少暂时地保持所述可移动构件处于其第一配置的偏置构件。

19. 如权利要求 12 所述的设备，其中，所述转移机构包括被配置为将第二样本储存器流体耦接到所述转移机构的第三出口端口。

20. 如权利要求 19 所述的设备，其中，所述可移动构件是第一可移动构件，所述设备还包括：

第二可移动构件，其被配置为在所述第二样本储存器与被限定在所述入口端口和所述第三出口端口之间的流体流路径流体隔离的第一配置和所述第二样本储存器与被限定在所述入口端口和所述第三出口端口之间的流体流路径流体连通的第二配置之间移动通过所述第三出口端口，所述第二样本储存器被配置为当所述流控制器处于其第二配置并且所述第二可移动构件处于其第二配置时接收从患者抽取的第三体积的体液。

21. 一种用于从患者获取体液样本的设备，所述设备包括：

前样本储存器，其被配置为接收从患者抽取的第一体积的体液；

转移机构，其包括外壳和分配构件，所述外壳限定第一孔口和第二孔口，所述第一孔口与所述前样本储存器流体连通，所述分配构件至少部分地位于所述外壳内并限定与所述第二孔口流体连通的流体流通道，所述分配构件包括与所述流通道流体连通的耦接部分并且被配置为物理地和流体地耦接到样本储存器；以及

流控制器，其包括被配置为耦接到用于从患者接收体液的内腔限定装置的入口端口，

所述流控制器能够旋转地耦接到所述转移机构并且被配置为在其中所述入口端口与所述第一孔口流体连通的第一配置和其中所述入口端口与所述第二孔口流体连通的第二配置之间移动。

22. 如权利要求 21 所述的设备，其中，所述第一体积的体液包括皮肤驻留的污染物，并且所述第二体积的体液基本不存在皮肤驻留的污染物。

23. 如权利要求 21 所述的设备，其中，所述前样本储存器至少部分地由所述分配构件的一部分限定。

24. 如权利要求 21 所述的设备，其中，所述耦接部分包括被配置为刺穿所述样本储存器的一部分以使所述样本储存器与所述流体流通道流体连通的刺穿构件。

25. 如权利要求 24 所述的设备，其中，当所述流控制器处于其第二配置时，利用所述刺穿构件刺穿所述样本储存器的所述部分使体液开始从患者流过所述入口端口和所述流通道并流入所述样本储存器中。

26. 如权利要求 21 所述的设备，其中，所述第一体积的体液是第一预定体积的体液，所述流体流通道被配置为接收第二预定体积的体液，所述第二预定体积的体液与样本体积相关。

27. 如权利要求 26 所述的设备，其中，所述样本体积在约 10 毫升和约 50 毫升之间。

28. 如权利要求 26 所述的设备，其中，所述样本体积为约 30 毫升。

29. 如权利要求 21 所述的设备，其中，所述转移机构包括密封构件，当所述流控制器耦接到所述转移机构时，所述密封构件位于所述外壳和所述流控制器之间，从而使得所述密封构件与所述流控制器的表面和所述外壳的表面形成基本流体密封的密封结构，所述密封构件限定第一孔口和第二孔口，所述密封构件的第一孔口与所述外壳的第一孔口基本同心，并且所述密封构件的第二孔口与所述外壳的第二孔口基本同心。

30. 一种利用流计量传送装置从患者获取预定样本体积的体液的方法，所述流计量传送装置包括转移机构，所述转移机构包括被配置为选择性地与前样本储存器和样本储存器流体连通的入口端口，并且所述流计量传送装置包括被配置为计量从患者流至所述前样本储存器和所述样本储存器的体液流的流计量机构，所述方法包括：

在患者和所述流计量传送装置的端口之间建立流体连通；

在所述端口和所述前样本储存器之间建立流体连通；

计量从患者传送到所述前样本储存器的体液流；

经由所述流计量传送装置的所述流计量机构验证位于所述前样本储存器中的前样本体积的体液是预定前样本体积的体液；

使所述前样本储存器与所述端口流体隔离，以将所述前样本体积的体液隔绝在所述前样本储存器中；

在所述端口和所述样本储存器之间建立流体连通；

计量从患者传送到所述样本储存器的体液流；

经由所述流计量传送装置的所述流计量机构验证位于所述样本储存器中的样本体积的体液是预定样本体积的体液。

31. 如权利要求 30 所述的方法，其中，所述流计量传送装置包括被配置为在建立患者和所述前样本储存器之间的流体连通的第一配置和建立患者和所述样本储存器之间的流

体连通的第二配置之间移动的流控制器。

32. 如权利要求 30 所述的方法，其中，所述体液是血液。

33. 如权利要求 32 所述的方法，其中，所述样本储存器包括需氧培养介质或厌氧培养介质中的至少一种。

34. 如权利要求 30 所述的方法，其中，所述预定前样本体积在约 1 毫升和约 10 毫升之间。

35. 如权利要求 30 所述的方法，其中，所述预定样本体积在约 20 毫升和约 60 毫升之间。

36. 如权利要求 30 所述的方法，其中，所述预定样本体积为约 60 毫升。

37. 如权利要求 30 所述的方法，其中，所述样本储存器是第一样本储存器，并且所述样本体积是第一样本体积，所述方法还包括：

在验证所述第一样本储存器中的所述第一样本体积是所述预定样本体积之后，在所述端口和所述第二样本储存器之间建立流体连通；

计量从患者传送到所述第二样本储存器的体液流；以及

经由所述流计量传送装置的所述流计量机构验证位于所述第二样本储存器中的第二样本体积的体液是所述预定样本体积的体液。

38. 如权利要求 37 所述的方法，其中，所述第一样本体积和所述第二样本体积相等并都处于约 20 毫升和约 60 毫升之间。

39. 如权利要求 37 所述的方法，还包括：

在验证所述第二样本储存器中的所述第二样本体积是所述预定样本体积之后，在所述端口和所述第三样本储存器之间建立流体连通；

计量从患者传送到所述第三样本储存器的体液流；以及

经由所述流计量传送装置的所述流计量机构验证位于所述第三样本储存器中的第三样本体积的体液是所述预定样本体积的体液。

40. 如权利要求 39 所述的方法，其中，所述第一样本体积、所述第二样本体积和所述第三样本体积相等并都处于约 30 毫升和约 60 毫升之间。

41. 如权利要求 39 所述的方法，其中，所述第一样本体积、所述第二样本体积和所述第三样本体积都等于约 60 毫升。

无菌体液采集装置和方法

[0001] 相关申请的交叉引用

[0002] 本申请要求2012年12月4日提交的名称为“无菌体液采集装置和方法”的美国临时专利申请序列号61/733,199的优先权和利益，其全部公开内容通过引用合并于此。

背景技术

[0003] 本文描述的实施例总体涉及不经肠道获得体液样本，更具体地，涉及在减少微生物污染或体液源外部的其他污染物（诸如皮肤驻留的微生物）的情况下不经肠道获得体液样本的装置和方法。

[0004] 医疗保健行业从业者例行利用非经肠道获得的体液对患者进行各种类型的微生物测试。在一些情形中，测试患者样本（例如，体液）是否存在一种或多种潜在有害的微生物，诸如细菌、真菌或酵母属（例如，假丝酵母属）。微生物测试可包括在包含有助于微生物生长、实时诊断和/或基于PCR的方法的培养介质的一个或多个无菌器皿中培养患者样本。一般来说，当患者样本中存在这类微生物时，培养介质中的微生物随时间迅速增多。在可变的时间（例如，几小时至几天）之后，可通过自动的持续监控检测有机体的生长。这种自动监控可检测有机体生长所产生的二氧化碳。于是可测试培养介质中是否存在微生物。培养介质中微生物的存在表示从其获得样品的患者的体液中存在相同的微生物。因此，当确定培养介质中存在微生物时，患者的处方可以是一种或多种抗生素或者专门用于治疗或以其他方式去除患者体内的有害微生物的其他治疗方式。

[0005] 但是，患者样本可能在获得期间被污染和/或易于以其他方式导致错误的阳性结果。患者样本污染可能发生的一种方式是传送体表的微生物（例如，皮肤驻留的微生物），该微生物在针头插入患者期间被带走，随后被传送到具有患者样本的培养介质。体表和/或其他有害外部微生物可直接被带走，或经由组织碎片、毛囊、汗腺和其他附器结构被带走。另一种可能的污染源来自提取患者样本的人。例如，医生、采血师、护士等可将污染物从他们的身体（例如，手指、手臂等）传送到患者样本和/或传送到包含患者样本的仪器。进一步详述，在患者样本获得过程中（例如，患者至针头、针头/管至样本器皿等）使用的仪器和/或装置通常包括都可引入潜在的污染部位的多个流体分界面。这类仪器和/或装置的使用通常包括用以连接和/或流体耦接各个分界面的人工干预。由于这些分界面未被预组装和消毒为单个流体耦接系统，因此外部污染物可经由使用者（例如，医生、采血师等）和/或其他源（例如，环境空气、患者房间中的桌子和案台表面上的污染物、传送自亚麻织物或衣服的微生物等）被引入患者样本中。在一些情形中，这类污染物可在培养介质中存活并最终导致阳性微生物测试结果，由此错误地表明活体中存在这类微生物。

[0006] 在一些情形中，错误的阳性结果和/或错误的阴性结果可归因于患者样本的特定体积。例如，过度填充容积敏感的血液培养瓶可导致错误的阳性结果，如这类培养瓶的制造商提供的使用说明和/或警告标签以及相关的自动连续监控微生物检测系统提示的。在另一方面，作为另一例子，培养介质内不足的患者样本体积可导致错误的阴性结果。例如，在Mayo Clinic 2011年12月在Journal of Clinical Microbiology发表的名称为

"Optimized Pathogen Detection with 30-Compared to20-Milliliter Blood Culture Draws"的研究中,20 毫升 (mL) 的患者样本体积的结果是检测到患者样本中存在约 80%的细菌,40 毫升 (mL) 的患者样本体积的结果是检测到约 88%的细菌,60 毫升 (mL) 的患者样本体积的结果是检测到约 99%的细菌。

[0007] 在试图诊断或治疗可疑的疾病或情况时由污染、患者样本体积不足等导致的这种不准确的结果是一个顾虑。例如,微生物测试的错误阴性结果可导致误诊和 / 或延迟治疗患者的疾病,在一些情形中,这可能导致患者死亡。相反,微生物测试的错误阳性结果可导致患者不必要地经受一种或多种抗生素疗法,这会对患者产生严重的副作用,包括例如死亡,以及由于延长了患者住院时间和 / 或与错误治疗相关的其他并发症而给医疗保健系统带来不必要的负担和花费。错误,因这些错误的阳性结果而进行的诊断成像仪器的使用在成本方面以及患者安全方面 (因为不必要地暴露于与各种成像过程 (例如,CT 扫描) 相关的大剂量辐射对患者的长期健康具有许多已知的负面影响) 也是一个顾虑。

[0008] 因此,需要一种通过例如最小化患者样本和 / 或流体分界面暴露于周围的非无菌环境和 / 或其他外部污染源减少体液测试样本中的微生物污染的无菌"多合一"体液采集装置和方法。此外,这类体液采集装置需要包括准确计量、测量和 / 或其其他方式评估和确定从患者传送到样本储存器或培养介质的体液体积的装置,其可以是可视的、策略的或以其他方式与获得患者样本的医疗保健行业从业者基本实时地通信 (例如,在患者床边)。

发明内容

[0009] 本文描述了用于在减少体液源外部的微生物 (诸如皮肤驻留的微生物) 和 / 或其他有害外部污染物的情况下不经肠道获得体液样本的装置。在一些实施例中,用于从患者获取体液样本的设备包括前样本储存器、转移机构和流计量机构。前样本储存器被配置为接收从患者抽取的第一体积的体液。转移机构包括入口端口、第一出口端口和第二出口端口,并且限定第一流体流路径和第二流体流路径。所述入口端口可耦接到用于从患者接收体液的内腔限定装置。所述第一出口端口和第二出口端口被配置为将所述前样本储存器和样本储存器分别流体耦接到所述转移机构。第一流体流路径被配置为使所述第一出口端口与所述入口端口流体连通,并且第二流体流路径被配置为使所述第二出口端口与所述入口端口流体连通。流计量机构与所述第一流体流路径和所述第二流体流路径流体连通。所述流计量机构被配置为计量通过所述第一流体流路径流入所述前样本储存器的第一体积的体液流并计量通过所述第二流体流路径流入所述样本储存器的第二体积的体液流。所述流计量机构被配置为显示与第一体积和第二体积相关的体积指示。

附图说明

[0010] 图 1 是根据实施例的体液采集装置的示意图。

[0011] 图 2 是根据实施例的体液采集装置的立体图。

[0012] 图 3 是图 2 的体液采集装置的分解立体图。

[0013] 图 4 是沿图 3 的线 X_1-X_1截取的图 2 的体液采集装置中包括的外壳的剖视侧视图。

[0014] 图 5 是沿图 3 的线 X_2-X_2截取的图 2 的体液采集装置中包括的可移动构件的剖视图。

[0015] 图 6 和 7 分别是沿图 3 的线 X_3-X_3和 X_4-X_4截取的图 2 的体液采集装置中包括的流控制器的剖视图。

[0016] 图 8 是处于第一配置的图 2 的体液采集装置的顶视图。

[0017] 图 9 是沿图 8 的线 X_5-X_5截取的处于第一配置的图 2 的体液采集装置的剖视图。

[0018] 图 10 是处于第二配置的图 2 的体液采集装置的顶视图。

[0019] 图 11 是沿图 10 的线 X_6-X_6截取的处于第二配置的图 2 的体液采集装置的剖视图。

[0020] 图 12 和 13 分别是沿图 10 的线 X_6-X_6截取的处于第三配置和第四配置的图 2 的体液采集装置的剖视图。

[0021] 图 14 是根据实施例的体液采集装置的立体图。

[0022] 图 15 是沿图 14 的线 X_7-X_7截取的图 14 的体液采集装置的剖视侧视图。

[0023] 图 16 是根据实施例的体液采集装置的立体图。

[0024] 图 17 是图 16 的体液采集装置中包括的转移机构的分解立体图。

[0025] 图 18 是沿图 16 的线 X_8-X_8截取的图 16 的体液采集装置中包括的分配构件的剖视侧视图。

[0026] 图 19 是处于第一配置的图 16 的体液采集装置的顶视图。

[0027] 图 20 是沿图 19 的线 X_9-X_9截取的处于第一配置的图 16 的体液采集装置的一部分的剖视图。

[0028] 图 21 是处于第二配置的图 16 的体液采集装置的顶视图。

[0029] 图 22 是沿图 21 的线 X_{10}-X_{10}截取的处于第二配置的图 16 的体液采集装置的剖视图。

[0030] 图 23 是根据实施例的体液采集装置的立体图。

[0031] 图 24 是沿线 X_{11}-X_{11}截取的处于第一配置的图 23 的体液采集装置的一部分的剖视图。

[0032] 图 25 是沿线 X_{11}-X_{11}截取的处于第二配置的图 23 的体液采集装置的剖视图。

[0033] 图 26 是根据实施例的体液采集装置的立体图。

[0034] 图 27 的图 26 的体液采集装置中包括的转移机构的分解立体图。

[0035] 图 28 是沿图 27 的线 X_{13}-X_{13}截取的图 26 的体液采集装置中包括的分配构件的剖视图。

[0036] 图 29 是沿图 27 的线 X_{14}-X_{14}截取的图 26 的体液采集装置中包括的耦接构件的剖视图。

[0037] 图 30 是沿图 27 的线 X_{15}-X_{15}截取的图 26 的体液采集装置中包括的转盘的剖视图。

[0038] 图 31 是沿图 27 的线 X_{16}-X_{16}截取的图 26 的体液采集装置中包括的阀的剖视图。

[0039] 图 32 是沿线 X_{12}-X_{12}截取的处于第一配置的图 26 的体液采集装置的剖视图。

[0040] 图 33 是沿线 X_{12}-X_{12}截取的处于第二配置的图 26 的体液采集装置的剖视图。

[0041] 图 34 是根据实施例的体液采集装置的立体图。

[0042] 图 35 的图 34 的体液采集装置中包括的转移机构的分解立体图。

[0043] 图 36 是沿线 X_{17}-X_{17}截取的图 35 的转移机构中包括的分配构件的剖视图。

[0044] 图 37 是处于第一配置的图 34 的体液采集装置的一部分的顶视图。

[0045] 图 38 是沿线 X_{18}-X_{18}截取的处于第一配置的图 37 的体液采集装置的一部分的剖视

图。

[0046] 图 39 是处于第一配置的图 33 的体液采集装置的一部分的顶视图。

[0047] 图 40 是沿图 39 的线 X_{19}-X_{19}截取的处于第一配置的图 33 的体液采集装置的剖视图。

[0048] 图 41 是根据实施例的处于第一配置的体液采集装置的立体图。

[0049] 图 42 是图 41 的体液采集装置的一部分的分解立体图。

[0050] 图 43 是沿线 X_{20}-X_{20}截取的处于第一配置的图 41 的体液采集装置的剖视侧视图。

[0051] 图 44 是沿线 X_{20}-X_{20}截取的处于第二配置的图 41 的体液采集装置的剖视侧视图。

[0052] 图 45 是沿线 X_{20}-X_{20}截取的处于第三配置的图 41 的体液采集装置的剖视侧视图。

[0053] 图 46 是根据实施例的处于第一配置的体液采集装置的立体图。

[0054] 图 47 的图 45 的体液采集装置的一部分的分解立体图。

[0055] 图 48 是沿图 47 的线 X_{21}-X_{21}截取的图 46 的体液采集装置中包括的分配构件的剖视侧视图。

[0056] 图 49 是沿图 47 的线 X_{22}-X_{22}截取的图 46 的体液采集装置中包括的可移动构件的剖视图。

[0057] 图 50 是处于第一配置的图 46 的体液采集装置的顶视图。

[0058] 图 51 是沿图 50 的线 X_{23}-X_{23}截取的处于第一配置的图 46 的体液采集装置的一部分的剖视图。

[0059] 图 52 是处于第二配置的图 46 的体液采集装置的顶视图。

[0060] 图 53 是沿图 52 的线 X_{24}-X_{24}截取的处于第二配置的图 46 的体液采集装置的剖视图。

[0061] 图 54 是根据实施例的体液采集装置的立体图。

[0062] 图 55 是图 54 的体液采集装置的顶视图。

[0063] 图 56 是流程图，图示了利用根据实施例的采集装置获取减少污染的体液样本的方法。

具体实施方式

[0064] 本文描述了用于在减少体液源外部的微生物（诸如皮肤驻留的微生物）和/或其他有害外部污染物的情况下不经肠道获得体液样本的装置。在一些实施例中，用于从患者获取体液样本的设备包括前样本储存器、转移机构和流计量机构。前样本储存器被配置为接收从患者抽取的第一体积的体液。转移机构包括入口端口、第一出口端口和第二出口端口，并且限定第一流体流路径和第二流体流路径。所述入口端口可耦接到用于从患者接收体液的内腔限定装置。所述第一出口端口和第二出口端口被配置为将所述前样本储存器和样本储存器分别流体耦接到所述转移机构。第一流体流路径被配置为使所述第一出口端口与所述入口端口流体连通，并且第二流体流路径被配置为使所述第二出口端口与所述入口端口流体连通。流计量机构与所述第一流体流路径和所述第二流体流路径流体连通。所述流计量机构被配置为计量通过所述第一流体流路径流入所述前样本储存器的第一体积的体液流并计量通过所述第二流体流路径流入所述样本储存器的第二体积的体液流。所述流计量机构被配置为显示与第一体积和第二体积相关的体积指示。

[0065] 在一些实施例中，用于从患者获取体液样本的设备包括前样本储存器、转移机构、流控制器和可移动构件。前样本储存器被配置为接收从患者抽取的第一体积的体液。转移机构包括入口端口、第一出口端口和第二出口端口。所述入口端口可耦接到用于从患者接收体液的内腔限定装置。所述第一出口端口将所述前样本储存器流体耦接到所述转移机构，并且所述第二出口端口将样本储存器流体耦接到所述转移机构。流控制器至少部分地位于所述转移机构内，并且可在第一配置和第二配置之间移动，在所述第一配置，所述流控制器限定在所述入口端口和所述第一出口端口之间的流体流路径的至少一部分，在所述第二配置，所述流控制器限定在所述入口端口和所述第二出口端口之间的流体流路径的至少一部分。可移动构件可移动地耦接到所述转移机构，并且可在所述样本储存器与所述入口端口和所述第二出口端口之间的流体流路径流体隔离的第一配置和所述样本储存器与所述入口端口和所述第二出口端口之间的流体流路径流体连通的第二配置之间移动通过所述第二出口端口。所述样本储存器被配置为当所述流控制器处于其第二配置并且所述可移动构件处于其第二配置时接收从患者抽取的第二体积的体液。

[0066] 在一些实施例中，用于从患者获取体液样本的设备包括前样本储存器、转移机构和流控制器。前样本储存器被配置为接收从患者抽取的第一体积的体液。转移机构包括外壳和分配构件。所述外壳限定第一孔口和第二孔口，所述第一孔口与所述前样本储存器流体连通。所述分配构件至少部分地位于所述外壳内并限定与所述第二孔口流体连通的流体流通道。所述分配构件包括与所述流通道流体连通的耦接部分并且被配置为物理地和流体地耦接到样本储存器。流控制器包括可耦接到用于从患者接收体液的内腔限定装置的入口端口。所述流控制器可旋转地耦接到所述转移机构并且可在所述入口端口与所述第一孔口流体连通的第一配置和所述入口端口与所述第二孔口流体连通的第二配置之间移动。

[0067] 在一些实施例中，一种利用流计量传送装置的方法，所述流计量传送装置具有转移机构，所述转移机构具有被配置为选择性地与前样本储存器和样本储存器流体连通的入口端口，并且所述流计量传送装置包括被配置为计量从患者流至所述前样本储存器和所述样本储存器的体液流的流计量机构，所述方法包括在患者和所述流计量传送装置的端口之间建立流体连通。然后，在所述端口和所述前样本储存器之间建立流体连通。计量从患者传送到所述前样本储存器的体液流。所述方法包括经由所述流计量传送装置的所述流计量机构验证位于所述前样本储存器中的前样本体积的体液是预定前样本体积的体液。在前样本体积位于前样本储存器中时，使所述前样本储存器与所述端口流体隔离，以将所述前样本体积的体液隔绝在所述前样本储存器中。当前样本储存器被流体隔离时，所述方法包括在所述端口和所述样本储存器之间建立流体连通。计量从患者传送到所述样本储存器的体液流。所述方法包括经由所述流计量传送装置的所述流计量机构验证位于所述样本储存器中的样本体积的体液是预定样本体积的体液。

[0068] 在一些实施例中，所述设备包括转移机构和流控制器。转移机构可限定入口端口、第一出口端口、第二出口端口和第三出口端口。第一出口端口流体耦接到前样本储存器，第二出口端口流体耦接到第一样本储存器，并且第三出口端口流体耦接到第二样本储存器，等等。所有流体储存器可彼此流体隔离。流控制器包括可容许沿特定方向的流体移动的各种流体通道并可被配置为可操作地耦接到转移机构。在使用时，当转移机构处于第一配置时，流控制器可容许体液流进入前样本储存器。转移机构可移动到第二配置，在该配置中，

流控制器可容许体液流进入第一样本储存器。此外，之后可将转移机构移动到第三配置，由此流控制器可容许体液流进入第二样本储存器。

[0069] 在一些实施例中，体液采集装置可被配置为在允许第二体积的体液流入第一样本储存器和/或第三体积的体液流入第二样本储存器之前选择性地将第一预定体积的体液转移到前样本储存器中。以此方式，第二和/或第三体积的体液可用于诊断或其他测试，同时隔离可能包含来自（从其获得样本的）患者的体表或体外的其他源的微生物的第一体积的体液。在一些实施例中，根据将执行的分析和/或测试方案，体液采集装置可包括额外的样本储存器（例如，3、4、5、6个或更多个）。

[0070] 在一些实施例中，体液采集装置可包括流计量装置，以确保从患者采集合适体积的体液和/或将合适体积的体液传送到特定的前样本和/或样本储存器中。体液采集装置可被配置为在采集了经计量体积的体液之后自动地转移和/或控制流体流。例如，在采集了第一计量前样本体积之后，转移机构可被配置为将体液流转移到第一样本储存器，然后在采集了第一计量样本体积之后，转移机构可被配置为将体液流转移到第二样本储存器，等等。在一些实施例中，体液采集装置可包括计量体积显示器，诸如，例如，液晶显示器(LCD)，以为使用者提供关于多少体液已经被采集到每个特定的单个样本储存器中的视觉指示。在一些实施例中，可提供多个显示器，以容许定制的前样本和/或样本体积采集。

[0071] 如在本说明书和所附权利要求中使用的，单数形式的冠词可包括复数个指示对象，除非上下文清晰地指示相反。因此，例如，用语“一个构件”意在表示单个构件或多个构件的组合，“一种材料”意在表示一种或多种材料或其组合。

[0072] 如在此使用的，“体液”可包括从患者身体获取的任何流体，包括但不限于，血液、脑脊液、尿液、胆汁、淋巴液、唾液、滑液、血清、胸膜液、羊水等，或其任意组合。

[0073] 如在此使用的，用语“第一预定量”、“第一量”和“第一体积”描述被配置为由第一储存器或前样本储存器接收或容纳的体液的量。虽然用语“第一量”和“第一体积”未明确描述预定量，但应该理解，第一量是第一预定量，除非存在明确的不同描述。

[0074] 如在此使用的，用语“第二量”和“第二体积”描述被配置为由第二储存器或样本储存器接收或容纳的体液的量。第二量可以是任何合适的体液量，不必是预定的。相反，当明确地如此描述时，第二储存器或样本储存器接收或容纳的第二量可以是第二预定量。

[0075] 如在此使用的，用语“组”可涉及多个特征或具有多个部分的单个特征。例如，当涉及一组壁时，一组壁可被认为是具有不同部分的一个壁，或者一组壁可为认为是多个壁。另一种类似的表述是，整体构造的项可包括一组壁。所述一组壁可包括例如彼此不连续的多个部分。一组壁还可由单独生产、之后接合在一起（例如，经由焊接、粘合剂或任何合适的方法）的多个项制成。

[0076] 如在此使用的，词语“近端”和“远端”分别涉及靠近和远离使装置与患者接触的使用者的方向。因此，例如，首先接触患者身体的装置端部将是远端，而装置的相反端（例如，使用者操纵的装置端部）将是装置的近端。

[0077] 如在此使用的，在与数值一起使用时，用语“约”、“近似”和“大体上”意在传达的是如此限定的值名义上是表述值。换言之，在与数值一起使用时，用语约、近似和大体上通常包括表述值±给定公差。例如，在一些情形中，合适的公差可以是表述值的±10%；因此，约0.5将包括0.45和0.55，约10将包括9至11，约1000将包括900至1100。在其他

情形中，合适的公差可以表述值的最后一位有效数字的 ± 可接受百分比。例如，合适的公差可以是最后一位有效数字的 ±10％；因此，约 10.1 将包括 10.09 和 10.11，约 25 将包括 24.5 和 25.5。这些变化可由制造公差或其他实际考虑（诸如，例如，与测量工具或可接受的人为误差等相关的公差）决定。

[0078] 当描述体液的预定体积和体液的采集体积之间的关系时，应该理解所述值包括合适的公差，诸如上文描述的那些。例如，当表述体液的采集体积大体上等于体液的预定体积时，采集体积和预定体积在合适的公差内名义上相等。在一些情形中，公差可由采集体积的体液的目的用途决定。例如，在一些情形中，当血液的采集体积在制造商（或最佳循证实践）的建议量的 1.0％至 5.0％内时血液培养物的化验的准确率可约为 99％。例如，体液化验的制造商建议量可为每个样本采集瓶 10 毫升 (mL)，总计使用四至六个采集瓶（即，总体积 40ml 至 60ml），对于约 99％的可信度 ±5％。因此，10.5mL 的采集体积将提供超过约 99％可信度的结果，而 11mL 的采集体积将提供小于约 99％可信度的结果。在其他情形中，合适的公差可以为 0.1％、0.5％、1.0％、2.0％、3.0％、4.0％、5.0％、6.0％、7.0％、8.0％、9.0％、10.0％或其之间的百分比的任何分数。在其他情形中，公差可大于 10.0％。因此，本文描述的任何实施例可包括被配置为计量流和 / 或以其他方式测量合适公差内的体液体积的任何合适的流计量机构和 / 或装置，和 / 或与这样的机构和 / 或装置一起使用。此外。流计量机构和 / 或装置可被布置为用以最小化或消除可由不准确的测量和 / 或人为误差等的组合导致的公差叠加。

[0079] 图 1 是根据实施例的体液采集装置 100 的一部分的示意图。一般来说，体液采集装置 100（在此被称作“流体采集装置”或“采集装置”）被配置为允许从患者抽取体液，从而使得第一部分或体积的抽取流体被转移远离将用作生物样本（诸如，为医疗诊断和 / 或治疗而进行测试）的第二和 / 或第三部分或体积的抽取流体。换言之，采集装置 100 被配置为将第一预定体积的体液传送到前样本采集储存器，并将第二和第三体积（或者，在一些实施例中，第四、第五等等）的体液传送到与前样本采集储存器流体隔离的一个或多个样本采集储存器，如本文更详细地描述的。

[0080] 采集装置 100 包括转移机构 120、流控制器 140、前样本储存器 170、第一样本储存器 180 和不同于第一样本储存器 180 的第二样本储存器 190。转移机构 120 包括入口端口 121 和至少两个出口端口，诸如第一出口端口 125 和第二出口端口 126，如图 1 所示。在一些实施例中，转移机构 120 可包括与前样本储存器和样本储存器的总数相等的一组出口端口。例如，当采集装置 100 具有一个前样本储存器和四个样本储存器时，转移机构 120 可包括五个出口端口。在一些实施例中，转移机构 120 能够可操作地耦接到致动器（图 1 未示出），其可辅助转移机构 120 在多个配置之间的移动。入口端口 121 被配置为流体耦接到用于限定将体液从患者抽取和 / 或输送到采集装置 100 的路径 X 的医疗装置上。例如，入口端口 121 可流体耦接到针头或其他内腔限定装置（例如，柔性无菌管）。以此方式，转移装置 120 可经由针头或任何其他内腔限定装置从患者接收体液。

[0081] 转移机构 120 的第一出口端口 125 可流体耦接到前样本储存器 170。在一些实施例中，前样本储存器 170 与第一出口端口 125 和 / 或转移机构 120 的一部分一体形成。在其他实施例中，前样本储存器 170 可经由粘合剂、阻力配合、机械紧固件、任意数量的配合凹口、螺纹耦接和 / 或任何其他合适的耦接或其组合而机械地和 / 或流体地耦接到转移机

构 120。另一种类似的表述是，前样本储存器 170 可物理地（例如，机械地）耦接到转移机构 120，从而使得前样本储存器 170 所限定的内部容积与转移机构 120 的第一出口端口 125 流体连通。在其他实施例中，前样本储存器 170 可经由中间结构（图 1 未示出），诸如柔性无菌管，可操作地耦接到转移机构 120 的第一出口端口 125。更具体地，该中间结构可限定被配置为使前样本储存器 170 与第一出口端口 125 流体连通的内腔。

[0082] 前样本储存器 170 被配置为接收和容纳第一预定体积的体液。在一些实施例中，前样本储存器 170 被配置为容纳第一体积的体液，从而使得第一体积与随后从患者抽取的第二和 / 或第三体积的体液（其可与第一体积的体液相同或不同）流体隔离开。前样本储存器 170 可以是用于容纳体液的任何合适的储存器，诸如，2012 年 6 月 12 日公布的名称为“Systems and Methods for Parenterally Procuring Bodily-Fluid Samples with Reduced Contamination”的美国专利 No.8,197,420（在下文中称作“‘420 专利”）中详细描述的前样本储存器，该专利的全部公开内容通过引用合并于此。

[0083] 在一些实施例中，转移机构 120 的第二出口端口 126 被配置为流体耦接到内腔限定装置上，该内腔限定装置可耦接到第一样本储存器 180 和第二样本储存器 190。可选地，在其他实施例中，转移机构 120 的第二出口端口 126 可耦接到第一样本储存器 180，并且转移机构 120 可具有耦接到第二样本储存器 190 上的第三出口端口（未示出）。在一些实施例中，第一样本储存器 180 可与第二出口端口 126 和 / 或转移机构 120 的一部分一体形成。在其他实施例中，第一样本储存器 180 可机械耦接到第二出口端口 126 或经由中间结构（诸如，上文参照前样本储存器 170 描述的）可操作地耦接到第二出口端口 126。第一样本储存器 180 被配置为接收和容纳第二体积的体液。例如，第二体积的体液可以是在抽取第一前样本体积之后从患者抽取的量。在一些实施例中，第一样本储存器 180 被配置为以第二体积与第一体积的前样本体液流体隔离的方式容纳第二体积的体液。

[0084] 第一样本储存器 180 和第二样本储存器 190 可以是用于容纳体液的任何合适的无菌储存器，包括例如上文通过引用合并的‘420 专利中描述的样本储存器。在一些实施例中，第二体积可以是任何合适的体液体积并且不需要是预定的。在一些实施例中，将体液传送到第一样本储存器 180 和 / 或第二样本储存器 190 可被计量等，从而使得第二体积是第二预定体积。

[0085] 第二样本储存器 190 可以是任何合适的样本储存器。在一些实施例中，第二样本储存器 190 可大体上类似于上述第一样本储存器 180。第二样本储存器 190 可如上所述地流体耦接到第二出口端口 126。第二出口端口 126 与第二样本储存器 190 的流体耦接可大体上类似于第二出口端口 126 与第一样本储存器 180 的流体耦接。因此，在此不进一步详细描述这些部分，并且应该认为大体上类似，除非存在明确的不同描述。此外，转移机构 120 的其他出口端口和样本储存器（图 1 未示出）可大体上类似于第二出口端口 126 和第一样本储存器 180。

[0086] 在一些实施例中，前样本储存器 170、第一样本储存器 180 和第二样本储存器 190 可以类似方式耦接到转移机构 120（或与其形成在一起）。在其他实施例中，前样本储存器 170、第一样本储存器 180 和第二样本储存器 190 不必以类似方式耦接到转移机构 120。例如，在一些实施例中，前样本储存器 170 可与转移机构 120（例如，第一出口端口 124）一体形成，并且第一样本储存器 180 和 / 或第二样本储存器 190 可经由诸如柔性无菌管或其任

意组合的中间结构可操作地耦接到转移机构 120（例如，第二出口端口 126）。

[0087] 在一些实施例中，采集装置 100 可还包括致动器（图 1 未示出）和限定第一流体流路径 142、第二流体流路径 144 和可选的其他流体流路径（图 1 未示出）的流控制器 140。在一些实施例中，致动器可包括在转移机构 120 中或以其他方式可操作地耦接到转移机构 120。以此方式，致动器可被配置为控制流控制器 140 内的流体移动（例如，在不同配置之间）。例如，致动器可在对应于流控制器 140 的第一配置的第一位置、与第一位置不同的对应于流控制器 140 的第二配置的第二位置等等之间移动。在一些实施例中，致动器可被配置为单向移动。例如，致动器可从其第一位置移动到其第二位置，但不能从其第二位置移动到其第一位置。类似地，致动器可从其第二位置移动到第三位置，但不能从其第三位置移动返回其第二位置。以此方式，防止流控制器 140 在移动到其第一配置之前移动到其第二或第三配置，因此需要将第一量体液引导到前样本储存器 170 中，而非被设计为容纳将用作生物样本（诸如，为医疗诊断和 / 或治疗而进行测试）的第二和 / 或第三部体积的抽取流体的样本储存器 180 和 / 或 190 中。

[0088] 流控制器 140 被配置为使得，当处于第一配置时，第一流体流路径 142 将入口端口 121 流体耦接到第一出口端口 125，并且当处于第二配置时，第二流体流路径 144 将入口端口 121 流体耦接到第二出口端口 126。在一些实施例中，如上所述的致动器可被配置为在第一配置和第二配置以及可选的第三或第四配置之间以平移方式移动流控制器 140。例如，在一些实施例中，当流控制器 140 相对于采集装置 100 处于远端位置时，流控制器 140 可处于第一配置。在这类实施例中，致动器可被致动，以相对于采集装置 100 沿近端方向将流控制器 140 移动到近端位置，由此使流控制器 130 处于第二配置。在其他实施例中，致动器也可被致动，以在第一配置和第二配置或可选的第三或第四配置之间以旋转运动方式移动流控制器 140。

[0089] 因此，当流控制器 140 处于第一配置时，第二出口端口 126（以及耦接到相同储存器的可选的其他出口端口）与入口端口 121 流体隔离。类似地，当流控制器 140 处于第二配置时，第一出口端口 125 与入口端口 121 流体隔离。并且可选地，如果流控制器 140 处于第三配置（图 1 未示出），则第一出口端口 125 和第二出口端口 126 与入口端口 121 流体隔离。以此方式，当流控制器 140 处于第一配置时，流控制器 140 可经由第一出口端口 125 将第一量的体液引导或转移到前样本储存器 170，并且当流控制器 140 处于第二配置时，流控制器 140 可经由第二出口端口 126 将第二量的体液引导或转移到第一样本储存器 180。

[0090] 在一些实施例中，致动器的至少一部分可以可操作地耦接到前样本储存器 170。以此方式，致动器（或至少致动器的所述部分）可被配置为在“前样本”流体储存器 170 内引入真空或以其他方式促进真空的产生，由此，当转移机构 120 处于其第一配置时，使体液开始通过采集装置 100 流入前样本流体储存器 170 中。致动器可包括用于促使液体流入采集装置 100 的任何合适的机构，诸如，例如，旋转盘、活塞、滑块、转盘、按钮、手柄、杠杆和 / 或任何其他合适的机构或其组合。在此参照特定实施例更详细地描述合适的致动器的例子。

[0091] 在一些实施例中，转移机构 120 可被配置为需要在转移机构 120 允许第二量的体液流通过转移机构 120 被输送到第一样本流体储存器 180 和 / 或第二样本流体储存器 190 之前将第一量体液输送到前样本流体储存器 170。以此方式，转移机构 120 的特征可被描绘为需要医疗保健行业从业者服从在采集第二和 / 或第三量（例如，样本）体液之前采集第

一预定量（例如，前样本）。另一种类似的表述是，转移机构 120 可被配置为防止医疗保健行业从业者在未首先将第一量或前样本体液转移到前样本储存器 170 的情况下将第二量或样本体液采集到第一样本储存器 180 中。以此方式，防止医疗保健行业从业者将第一量体液包括（无论是有意的还是无意的）在用于分析的体液样本中，该第一量体液更可能含有体表微生物和 / 或其他有害外部污染物。在其他实施例中，流体采集装置 100 不需要包括强制服从特征或部件。

[0092] 在一些实施例中，转移机构 120 可具有与第一、第二和第三配置不同的第四配置（图 1 未示出）。当处于第四配置时，转移机构 120 可同时将入口端口 121 与第一出口端口 125、第二出口端口 126 和可选的第三出口端口流体隔离。因此，当转移机构 120 处于其第四配置时，防止体液从入口端口 121 流到前样本储存器 170、第一样本储存器 180 和第二样本储存器 190。在使用时，例如，可致动（例如，手动地或自动地）转移机构 120，以使转移机构 120 处于第一配置，从而使得体液从入口端口 121 流到前样本储存器 170，然后移动到第二配置，从而使得体液可从入口端口 121 流到第一样本储存器 180，并可选地移动到第三配置，从而使得体液可从入口端口 121 流到第二样本储存器 190，然后移动到第四配置，以使体液停止流入和 / 或流过转移机构 120。以此方式，装置被有效地“锁定”并独立地处于第四配置，从而防止装置 100 中任何残留的体液被污染和 / 或以其他方式使医疗保健行业从业者和 / 或患者暴露于潜在的危险流体。此可选的安全特征可防止暴露于可能感染诸如 HIV、丙型肝炎等病原体的体液样本。

[0093] 在一些实施例中，采集装置 100 的一个或多个部分可位于外壳（图 1 未示出）内。例如，在一些实施例中，转移机构 120、第一前样本储存器 170 及样本储存器 180 和 190 中的一个或多个的至少一部分可位于外壳内。在这种实施例中，转移机构 120 的至少一部分可通过外壳，以容许使用者致动流控制器 140，从而控制体液从患者（例如，血管）流到采集装置 100。在此参照特定实施例更详细地描述合适的外壳的例子。

[0094] 在一些实施例中，采集装置 100 可以可选地包括可计量通过采集装置的体液流的一个或多个流计量装置。例如，流计量装置可与第一流体流路径 142 和 / 或第二流体流路径 144 流体连通，以计量通过它们的体液流。在其他实施例中，流计量装置可与第一端口 125 和 / 或第二端口 126 流体连通和 / 或位于其中。流计量装置可包括指示器等（例如，转盘、显示器、颜色、触觉输出装置、电信号输出装置，诸如无线电信号、蓝牙无线电信号等），其可被配置为向使用者提供与传送到前样本储存器 170、第一样本储存器 180 和 / 或第二样本储存器 190 相关的指示。在一些实施例中，流计量装置可以可操作地耦接到例如致动器等，诸如上文描述的那些。在这类实施例中，流计量装置可致动致动器，以基于已流过流计量装置的期望量体液使流控制器 140 在其第一配置和其第二配置之间移动。因此，流计量装置可用于确保期望量的体液被传送到前样本储存器 170、第一样本储存器 180 和 / 或第二样本储存器 190，这继而可防止在例如患者样本等的微生物测试中产生不足的、不准确的和 / 或错误的结果。

[0095] 现在参照图 2-13，采集装置 200 包括转移机构 220、流控制器 240、前样本储存器 270、第一样本储存器 280 和与第一样本储存器 280 不同的第二样本储存器 290。如在此进一步描述的，采集装置 200 可在第一、第二和第三配置之间移动，以传递大体上不存在体外微生物（诸如，例如，皮肤驻留的微生物和 / 或其他有害外部污染物）的体液流。采集装置

200 可具有任何合适的形状、尺寸或配置。例如，尽管图 2-13 示出了样本储存器 280 和 / 或 290 相对于外壳 201 垂直地定向，但采集装置 200 的样本储存器 280 和 / 或 290 可定向在外壳 201 的平面中或相对于外壳 201 成圆锥形地放置，等等。

[0096] 转移机构 220 包括外壳 201 和可移动构件 250 和 250'。如图 2-4 所示，外壳 201 耦接到前样本储存器 270、第一样本储存器 280 和第二样本储存器 290。外壳 201 包括入口端口 221、第一出口端口 230、第二出口端口 231、第三出口端口 232，并限定内部流通道 235，流通道 235 可限定从患者采集体液的流体流路径。入口端口 221 可选择性地与内部流通道 235 流体连通。更具体地，入口通道 221 可限定可与内部流通道 235 流体连通的入口内腔 202。以此方式，入口端口 221 从外壳 201 的一部分延伸出，从而使得内部流通道 235 可经由入口内腔 202 与大体在外壳 201 外的空间流体连通。入口端口 221 可流体耦接到限定将体液从患者抽取和 / 或输送到采集装置 200 的流体流路径的医疗装置（未示出）。例如，入口端口 221 可直接地或经由适配器 204 间接地流体耦接到针头或其他内腔限定装置（例如，柔性无菌管）。另一种类似的表述是，当内腔限定装置耦接到入口端口 221 时，入口端口 221 限定的入口内腔 202 与内腔限定装置限定的内腔流体连通。进一步详述，当内腔限定装置位于患者身体的一部分内（例如，在患者的血管或脊柱腔内）时，外壳 201 的内部流通道 235 可与患者身体的该部分流体连通。

[0097] 外壳 201 限定的内部流通道 235 是中心内腔，其沿外壳 201 的长度延伸并且可在静脉穿刺（用于获取体液的其他方法）之后与患者的体液流体连通，如在此描述的。内部流通道 235 形成用于在入口端口 221 和第一出口端口 230、第二出口端口 231 及第三出口端口 232 之间传送体液的流体流路径。更具体地，当内部流通道 235 与患者（经由耦接到入口端口 221 的医疗装置）流体连通时，第一出口端口 230、第二出口端口 231 和第三出口端口 232 可选择性地与内部流通道 235 流体连通，以容许体液流入前样本储存器 270、第一样本储存器 280 或第二样本储存器 290 中的至少一个。在一些实施例中，在预定体积的体液被采集在前样本储存器 270 中之前，阻止体液流到第二出口端口 231 和第三出口端口 232。在一些实施例中，第二出口端口 231 和第三出口端口 232 可同时与内部流通道 235 流体连通。在一些实施例中，第二出口端口 231 和第三出口端口 232 可依次与内部流通道 235 流体连通。

[0098] 可移动构件 250、250' 被配置为被使用者从相对于外壳 201 的第一位置致动到第二位置，以将流体流引导到第一样本储存器 280 和第二样本储存器 290 中。可移动构件 250、250' 大体相同，并因此参照单个可移动构件 250 进行描述。如图 5 所示，可移动构件 250 包括限定内部腔 252 的凸台 251、入口端口 253、第一出口端口 254 和限定流体耦接到内部腔 252 的内腔 256 的刺穿构件 255。入口端口 253 和出口端口 254 延伸通过限定可移动构件 250 的内部腔 252 的凸台 251 的壁。可移动构件 250 被配置为被安装在外壳 201 的支撑件 257（见图 4）上，从而使得凸台 251 位于孔眼 258（见图 4）内并且可移动构件 250 的至少一部分被容纳在环形腔 260 中。可选地，偏置构件 259（例如，弹簧）可位于环形腔 260 中，以使可移动构件 250 在被使用者致动之后返回其第一位置。在一些实施例中，可移动构件 250、环形腔 260、孔眼 258 或凸台 251 可包括被配置为在被使用者致动之后将可移动构件 250 承托在第二位置（例如，下压位置）的机械锁定特征。

[0099] 如在此描述的，在第一配置，以使得可移动构件 250 与内部流通道 235 分隔开的

方式放置可移动构件 250。在这种配置中，不会在患者身体的一部分（例如，血管、脊柱腔等）和样本储存器 280 和 / 或 290 之间建立流体流路径。换言之，当可移动构件 250 处于其第一配置时，第一样本储存器 280 和第二样本储存器 290 与外壳 201 所限定的内部流通道 235 流体隔离开。使用者可致动可移动构件 250，以将可移动构件 250 从第一配置移动到第二配置并与内部流通道 235 对齐。使用者施加的力可足以使偏置构件 259 变形（例如，压缩），由此容许刺穿构件 255 插入样本储存器 280 和 / 或 290 中。在第二配置，入口端口 253 和出口端口 254 与内部流通道 235 大体对齐，使得内部腔 252 与内部流通道 235 流体连通。因此，当可移动构件 250 处于第二配置时，在内部流通道 235、内部腔 252、刺穿构件 255 的内腔 256 和样本储存器 280 之间建立流体流路径。换言之，在这种配置中，体液可从患者（例如，血管、脊柱腔等）通过转移机构 220 流入第一样本储存器 280 和 / 或第二样本储存器 290 中，如在此更详细地描述的。

[0100] 前样本储存器 270 可以是用于容纳体液的任何合适的储存器，诸如，例如，一次性可丢弃式采集管和 / 或基于真空的采集管等。前样本储存器 270 被配置为以任何合适的方式流体耦接到采集装置 200 的第一出口端口 230（直接地或经由中间结构，诸如无菌柔性管）。例如，在一些实施例中，前样本储存器 270 的一部分可在第一出口端口 230 的一部分内形成摩擦配合。在其他实施例中，前样本储存器 270 可经由螺纹耦接、粘合剂、卡扣配合、机械紧固件和 / 或任何其他合适的耦接方法耦接到第一出口端口 230。在一些实施例中，前样本储存器 270 可与万科 201 一体形成。前样本储存器 270 可被配置为保持（前样本储存器 270）内部处于负压状态（真空状态），这可容许经由真空吸力通过出口端口 230 将体液从入口端口 221 抽入前样本储存器 270。前样本储存器 270 被配置为包含第一量体液，其中，第一量体液可以是预定或未定量，使得第一量体液与随后从患者抽取的第二和 / 或第三量体液流体隔离。

[0101] 样本储存器 280 和 / 或 290 可以是用于容纳体液的任何合适的储存器，诸如，例如，一次性可丢弃式采集管、基于真空的采集管和 / 或通过引用合并的 '420 专利中描述的样本储存器等。在一些实施例中，样本储存器 280 和 / 或 290 可以大体类似于或等同于已知的样本容器，诸如，例如，**Vacutainer®** 等。样本储存器 280 和 / 或 290 分别包括样本容器 282 和 292，并分别包括真空密封件 284 和 294。真空密封件 284 或 294 分别保持样本容器 282 或 292 内的负压状态（真空状态），这可容许经由真空吸力将体液分别从内部流通道 235 抽入本容器 282 或 292。样本储存器 280 和 / 或 290 可被配置为以任何合适的方式分别流体耦接到采集装置 200 的第二出口端口 231 和第三出口端口 232（直接地或经由中间结构，诸如无菌柔性管）。可相对于出口端口 231 和 / 或 232 移动样本储存器 280 和 / 或 290，以使样本储存器 280 和 / 或 290 与出口端口 231 和 / 或 232 流体连通。样本储存器 280 和 290 可被配置为包含第二或第三量的体液。第二或第三量的体液可以是预定或未定量，使得第二或第三量的体液与从患者抽取的第一量体液流体隔离。在一些配置中，样本储存器 280 和 / 或 290 可通过以与前样本储存器 270 类似的方式与外壳 201 一体形成而耦接到采集装置 200，因此在此不详细描述。在一些情形中，样本储存器 280 和 / 或 290 可以是透明的，从而使得使用者可具有视觉反馈，以确认流入样本储存器 280 和 / 或 290 的体液流。

[0102] 在一些实施例中，样本储存器 280 和 290 及转移机构 220（和 / 或采集装置 200 的

除样本储存器 280 和 290 之外的部分）单独形成（例如，非一体形成）并在例如制造期间耦接在一起。在一些情形中，可在大体上无菌或密封环境（例如，填充乙撑氧等的环境）中，将样本储存器 280 和 290 耦接到转移机构 220。因此，样本储存器 280 和 290 与转移机构 220 之间的接触面在使用之前大体是无菌的。此外，可以以预组装方式运输和 / 或存储采集装置 200，从而保持样本储存器 280 和 290 与转移机构 220 之间的接触面大体无菌。

[0103] 如图 6 和 7 所示，流控制器 240 包括第一构件 241 和第二构件 245。第一构件 241 被配置为位于外壳 201 的凹口 266（例如，见图 4）中，并且可由生物兼容的任意数量的材料制成，诸如，例如，钛、石墨、热解碳、聚酯、聚碳酸酯、聚亚安酯和 / 或弹性体材料等。在一些实施例中，第二构件 245 用作将第一构件 241 从第一配置移动到第二配置的致动器。更具体地，当第一构件 241 位于凹口 266 中时，第二构件 245 可在第一位置和第二位置之间移动，以在第一和第二配置之间移动流控制器 240。在一些实施例中，外壳 201 可选择性地限制第二构件 245 从其第一位置到其第二位置的移动。在一些实施例中，外壳 201 可被配置为一旦第二构件 245 已经移动到第二位置就阻止其移动。换言之，外壳 201 可包括阻止第二构件 245 从第二位置移动返回第一位置的锁定构件。第二构件 245 和 / 或外壳 201 还可包括机械棘爪和 / 或提供视觉或触觉反馈以确保精确地定位第二构件 245 的其他指示器。

[0104] 第一构件 241 可包括用于在静脉穿刺（和 / 或其他获得患者体液的方法）之后引导流体流的多个通道。例如，如图 6 和 7 所示，第一构件 241 包括第一流通道 242 和第二流通道 244。当第二构件 245 处于第一位置时（例如，见图 8 和 9），流控制器 240 处于第一配置，并且第一流通道 242 在入口端口 221 和第一出口端口 230 之间建立流体连通，同时使入口端口 221 和内部流通道 235 流体隔离。当第二构件 245 处于第二位置时（例如，见图 10-13），流控制器 240 处于第二配置，并且第二流通道 244 在入口端口 221 和内部流通道 235 之间建立流体连通，同时使入口端口 221 和第一出口端口 230 流体隔离。可包括与额外的第一构件 241 的流通道和 / 或流控制器 240 配置相对应的额外第二构件 245 位置，以在患者和采集装置 200 之间进一步引导 / 隔离流体。例如，第二构件 245 可具有与流控制器 240 的第三配置相对应的第三位置，其大体上完全阻止患者和采集装置 200 之间的流体流。换言之，在一些实施例中，在从患者获取了全部体液样本之后，可将转盘移动到第三位置，以相对于外部环境大体上密封采集装置 200 中的样本。

[0105] 在操作时，采集装置 200 可用于从患者采集减少污染（来自皮肤驻留的微生物和 / 或其他有害外部污染物）的体液（例如，血液）。例如，采集装置 200 的入口端口 221 经由适配器 204 流体耦接到针头或其他内腔限定装置（例如，柔性无菌管）。在静脉穿刺（或其他体液获得方法）之后，旋转第二构件 245，直到它达到如图 8 和 9 所示的第一位置。替代性地，第二构件 245 可被预设在第一位置，并且采集装置 200 可以其他方式被密封，以保持前样本储存器 270 中的真空和采集装置 200 的无菌性。例如，入口端口 221 和 / 或适配器 204 可包括当采集装置 200 耦接到针头或其他内腔限定装置时打开的阀。

[0106] 如上所述，当第二构件 245 处于第一位置时，流控制器 240 处于第一配置，并且第一构件 241 的第一流通道 242 在入口端口 221 和第一出口端口 230 之间建立流体连通，同时使入口端口 221 和内部流通道 235 流体隔离。此外，在第一配置中，第一和第二样本储存器 280 和 290 与入口端口 221 流体隔离，并且在患者身体的一部分（例如，血管）和前样本储存器 270 之间限定流体流路径，如图 9 的箭头 AA 所示。如上所述，采集装置 200 中使用

的流体储存器，诸如，前样本储存器 270 及样本储存器 280 和 290，可被配置为限定负压（例如，小于采集装置 200 正在从其抽取体液的身体部分的流体压力的压力），从而使得一旦在患者身体的一部分（例如，血管）和前样本储存器 270 之间建立流体连通，前样本储存器 270 内的负压就会使前样本储存器 270 和患者身体的所述部分之间的压力差将体液抽入样样本储存器 270。在此第一配置，流控制器 240 还使前样本储存器 270 与内部流通道 235 流体隔离。因此，第一量（预定的或未定的）体液可在静脉穿刺（例如）之后立即被容纳到前样本储存器 270 中并与随后的样本隔离。以此方式，采集装置 200 可用于防止第一量体液（其最可能含有体表微生物和 / 或其他有害的外部污染物）污染随后量的体液样本，这些体液样本被采集并用于可受污染物影响的诊断或其他测试。

[0107] 在前样本储存器 270 中采集了所述体积的体液前样本之后，可旋转第二构件 245 直到它达到其第二位置，如图 10 和 11 所示。当第二构件 245 处于第二位置时，流控制器 240 处于第二配置，并且第一构件 241 的第二流通道 244 在入口端口 221 和内部流通道 235 之间建立流体连通，同时使第一出口端口 230（即，前样本储存器 270）与入口端口 221 流体隔离。换言之，在第二配置，流控制器 240 经由第二流通道 244 在患者身体的一部分（例如，血管）和内部流通道 235 之间建立流体流路径，如图 11 的箭头 BB 所示。

[0108] 当流控制器 240 处于第二配置时，使用者可将可移动构件 250 和 / 或 250’从第一位置致动（即，按压）到第二位置，以在患者身体的一部分（例如，血管）与第一样本储存器 280 和 / 或第二样本储存器 290 之间建立流体连通。更具体地，将可移动构件 250 从其第一位置移动到其第二配置，从而使刺穿构件 255 以刺穿构件 255 可穿透位于样本容器 282 内的第一样本储存器 280 的真空密封件 284 的方式穿过出口端口 231，如图 12 的箭头 CC 所示。当处于第二位置时，可移动构件 250 的入口端口 253 和出口端口 254 与内部流通道 235 大体对齐并流体连通，这容许体液从内部流通道 235 流入可移动构件 250 的内部腔 252 并离开刺穿构件 255 的内腔 256 进入第一样本储存器 280。样本储存器 280 和内部流通道 235 之间的压力差（例如，真空或负压）将体液抽入样本储存器 280。换言之，在第二配置，可移动构件 250 在内部流通道 235 和第一样本储存器 280 之间建立流体流路径，如图 12 的箭头 DD 所示。一旦期望量的体液（例如，第二量）被采集在第一样本储存器 280 中，使用者就可释放可移动构件 250，容许偏置构件 259 将按钮 250 移动回其第一位置。当可移动构件 250 返回其第一位置时，刺穿构件 255 被移离第一样本储存器 280，并且密封件 284（例如，独立密封隔膜）使第一样本储存器 280 与内部流通道 235 流体隔离。

[0109] 以类似方式，当流控制器 240 处于第二配置时，使用者可将可移动构件 250’从其第一位置致动（即，按压）到其第二位置，如图 13 的箭头 EE 所示。以此方式，以与上述可移动构件 250 和第一样本储存器 280 类似的方式，在患者身体的一部分（例如，血管）和第二样本储存器 290 之间（经由出口端口 232）建立流体连通。换言之，在第二配置，可移动构件 250’在内部流通道 235 和第二样本储存器 290 之间建立流体流路径，如图 13 的箭头 FF 所示。一旦期望量的体液（例如，第三量）被采集在第二样本储存器 290 中，使用者就可释放可移动构件 250’，容许偏置构件 259’将按钮 250’移动回其第一位置。尽管被示出和描述为按顺序的过程，但不必要求填充顺序和 / 或排序（即，不必必须在样本储存器 290 之前填充样本储存器 280，等等）。换言之，一旦流控制器 240 被移动到第二配置，就可按任何顺序、在同一时刻（例如，同时）和 / 或以重叠的时间间隔填充第一样本储存器 280 和第

二样本储存器 290（和任何额外的样本储存器）。例如，使用者可开始填充第一样本储存器 280，然后在部分地填充第一样本储存器 280 之后，使用者可按压可移动构件 250'，以填充第二样本储存器 290，而第一样本储存器 280 填充完成。此外，通过反复致动（插入）可移动构件 250 和 / 或 250' 可调整样本储存器 280 和 / 或 290 中采集的体液的体积。如上所述，第二构件 245 可具有与流控制器 240 的第三配置相对应的第三位置，其可大体上完全阻止患者和采集装置 200 之间的流体流，以相对于外部环境大体上密封采集装置 200 中的样本。

[0110] 尽管图 2-13 未示出，但采集装置 200 可包括可被配置为计量被传送到前样本储存器 270、第一样本储存器 280 和 / 或第二样本储存器 290 的体液体积的流计量装置等。例如，在一些实施例中，流控制器 240 的第一构件 241 可包括与第一流通道 242 和第二流通道 244 流体连通的流计量装置。在其他实施例中，流计量装置可位于可移动构件 250 和 / 或 250' 的内部腔 252 内。因此，可计量和 / 或控制被传送到和位于第一样本储存器 280 和第二样本储存器 290 中的体液样本的体积，从而使得位于每个样本储存器 280 和 290 中的体液的体积是预定体积，诸如，例如，10mL、20mL、30mL 等。

[0111] 尽管采集装置 200 被示出和描述为包括第一样本储存器 280 和第二样本储存器 290，但在其他实施例中，采集装置可包括任意数量的前样本和 / 或样本储存器。例如，图 14 和 15 图示了根据实施例的采集装置 300。如图所示，采集装置 300 的某些方面可与以上参照图 2-13 描述的采集装置 200 的相应方面大体类似。因此，在此不进一步详细描述类似的方面。

[0112] 如图 14 和 15 所示，采集装置 300 包括转移机构 320、流控制器 340、前样本储存器 370、第一样本储存器 380、第二样本储存器 380'、第三样本储存器 390 和第四样本储存器 390'。前样本储存器 370 可大体类似于上文详细描述的前样本储存器 270。在一些实施例中，样本储存器 380、380'、390 和 390' 可大体类似于上文详细描述的样本储存器 280 和 290。在一些实施例中，样本储存器 380、380'、390 和 390' 可具有大体相同的形状和尺寸并包括例如大体相同的培养介质。在其他实施例中，样本储存器 380、380'、390 和 390' 可具有大体相同的形状和尺寸并包括需氧培养介质或厌氧培养介质中的一种。例如，在一些实施例中，第一样本储存器 380 和第三样本储存器 390 可包括需氧培养介质，而第二样本储存器 380' 和第四样本储存器 390' 可包括厌氧培养介质。在其他实施例中，样本储存器 380、380'、390 和 390' 可各自包括处于任何布置或组合的需氧或厌氧培养介质。

[0113] 转移机构 320 包括外壳 301 和一组可移动构件 350、350'、350"、350"'。可移动构件 350、350'、350"、350"' 例如大体类似于上文参照图 5 描述的可移动构件 250。因此，可移动构件 350、350'、350"、350"' 可相对于外壳 301 在第一位置和第二位置之间移动，以分别与样本储存器 380、380'、390 和 390' 流体连通。外壳 301 包括和 / 或限定入口端口 321、被配置为与前样本储存器 370 流体连通的第一出口端口 330、被配置为与第一样本储存器 380 流体连通的第二出口端口 331、被配置为与第二样本储存器 380' 流体连通的第三出口端口 332、被配置为与第三样本储存器 390 流体连通的第四出口端口 333 和被配置为与第四样本储存器 390' 流体连通的第五出口端口 334。此外，外壳 301 限定内部流通道 335，流通道 335 可以与上文参照外壳 201 的内部流通道 235 描述的类似方式选择性地与入口端口 321 和出口端口 331、332、333 和 334 流体连通。

[0114] 例如，流控制器 340 大体类似于上文参照图 6-13 描述的流控制器 240。因此，流控制器 340 可在第一配置和第二配置之间旋转，以选择性地限定患者和前样本储存器 370 或样本储存器 380、380'、390 和 390' 之间的流体流路径的一部分。以此方式，使用者可用与上文参照图 8-13 中的采集装置 200 描述的类似方式操纵采集装置 300。因此，第一体积的体液可被传送到并位于前样本储存器 370 中，并且随后体积的体液可被传送到并位于样本储存器 380、380'、390 和 390' 中。

[0115] 图 16-22 图示根据实施例的采集装置 400。采集装置 400 包括转移机构 420、流控制器 440 和样本储存器 480、480'、490 和 490'。如在此进一步描述的，采集装置 400 可在第一、第二、第三、第四和第五配置之间移动，以传递大体上不存在体外微生物（诸如，例如，皮肤驻留的微生物和 / 或其他有害外部污染物）的体液流。采集装置 400 可具有任何合适的形状、尺寸或配置。例如，尽管图 16-22 示出了样本储存器 480、480'、490 和 490' 相对于外壳 401 垂直地定向，但采集装置 400 的样本储存器 480、480'、490 和 490' 可相对于外壳 401 定向在任何合适的平面中或相对于外壳 401 成圆锥形地放置，等等。

[0116] 样本储存器 480、480'、490 和 490' 在形式和功能上大体类似于或等同于采集装置 200 的样本储存器 280 和 / 或 290，因此这里不详细描述。如上所述，样本储存器 480、480'、490 和 490' 保持负压状态（真空状态），这可容许经由吸力将体液从患者抽入样本储存器 480、480'、490 和 490'。在一些实施例中，样本储存器 480 和 480' 可以是需氧培养瓶，样本储存器 490 和 490' 可以是厌氧培养瓶，并且采集装置 400 可用于通过单次静脉穿刺采集多个需氧和多个厌氧血液培养样本。如在此进一步详细描述的，样本储存器 480、480'、490 和 490' 可各自与转移机构 420 的至少一部分流体连通，以接收一定体积的体液样本。体液样本的体积可以是预定或未定的量。此外，一旦期望量的体液位于样本储存器 480、480'、490 和 490' 中，每个样本储存器 480、480'、490 和 490' 就可与转移机构 420 的至少一部分流体隔离，如在此进一步详细描述的。

[0117] 转移机构 420 包括外壳 401 和分配构件 429。转移机构 420 的外壳 401 物理地和流体地耦接到分配构件 429，并提供和 / 或限定用于从患者采集体液的一组流体流路径。外壳 401 限定凹口 466 和一组出口孔口 403。凹口 466 被配置为容纳包括在流控制器 440 中的密封构件 441，如在此进一步详细描述的。该组出口孔口 403 包括第一出口孔口 403a、第二出口孔口 403b、第三出口孔口 403c、第四出口孔口 403d 和第五出口孔口 403e，它们各自被配置为限定与分配构件 429 的不同部分流体连通的不同流体流路径。更具体地，分配构件 429 限定和 / 或形成与第一出口孔口 403a 流体连通的前样本储存器 470 的至少一部分以及与第二出口孔口 403b 流体连通的第一流通道 435a、与第三出口孔口 403c 流体连通的第二流通道 435b、与第四出口孔口 403d 流体连通的第三流通道 435c 和第五出口孔口 403e 流体连通的第四流通道 435。

[0118] 如图 17 和 18 所示，分配构件 429 限定腔或空间，所述腔或空间限定前样本储存器 470 的至少一部分。前样本储存器 470 被配置为容纳体液，诸如，例如，血液、血浆和 / 或尿液等。外壳 401 的第一出口孔口 403a 可与前样本储存器 470 的开口部分大体对齐，以容许前样本储存器 470 接收来自患者的体液流。例如，前样本储存器 470 可接收和容纳第一量或体积的体液，其中，体液的第一量可以是预定的或未定的量。此外，转移机构 420 的布置可使得前样本储存器 470 保持与流通道 435a、435b、435c 和 435d 和 / 或随后从患者抽取的

多部分体液流体隔离，如在此进一步详细描述的。尽管上文将前样本储存器 270 和 370 描述为保持负压，但前样本储存器 470 不保持负压状态（真空状态），因而其他机制，诸如，例如，重力可用于将体液抽入前样本储存器 470 中。

[0119] 流通道 435a-435d 从分配构件 429 的中心沿径向延伸并被布置为使得每个流通道 435a、435b、435c 和 435d 与前样本储存器 470 和其他流通道流体隔离。以此方式，流通道 435a、435b、435c 和 435d 可引导和 / 或以其他方式限定第一端部（分别与出口孔口 403b、403c、403d 和 403e 大体对齐）和第二端部之间的流体流路径。如图 17 和 18 所示，分配构件 429 限定位于第一流通道 435a 的第二端部处的第一出口端口 431、位于第二流通道 435b 的第二端部处的第二出口端口 432、位于第三流通道 435c 的第二端部处的第三出口端口 433 和位于第四流通道 435d 的第二端部处的第四出口端口 434。此外，分配构件 429 包括第一刺穿构件 455a、第二刺穿构件 455b、第三刺穿构件 455c、第四刺穿构件 455d，它们分别物理地和流体地耦接到第一出口端口 431、第二出口端口 432、第三出口端口 433、第四出口端口 434。因此，刺穿构件 455a-355d 可用于穿透样本储存器 480、480'、490 和 490'的真空密封件，这可使体液开始流动，如在此进一步详细描述的。尽管图 17 和 18 未示出，但样本储存器 480、480'、490 和 490'可以任何合适的方式物理地耦接到分配构件 429 的一部分上（直接地或经由中间结构，诸如无菌柔性管），这可容许样本储存器 480、480'、490 和 490' 分别与出口端口 431、432、433 和 434 流体连通。

[0120] 流控制器 440 包括转盘 445 和密封构件 441。密封构件 441 位于外壳 401 的凹口 466（例如，见图 20）中。更具体地，流控制器 440 可耦接到外壳 401，从而使得密封构件 441 位于限定凹口 466 的外壳 401 的表面和转盘 445 的表面之间并与两个表面接触。此外，密封构件 441 可具有这样的尺寸和形状，即，当流控制器 440 耦接到外壳 401 时，使得密封构件 441 与转盘 445 的表面和限定凹口 466（例如，见图 20）的外壳 401 的表面形成大体流体密封的密封结构，如在此进一步详细描述的。密封构件 441 可由任意数量的生物兼容材料制成，诸如，例如，硅酮、聚乳酸、聚乙交酯、聚乳酸 - 羟基乙酸共聚物 (PLGA)、聚酸酐、聚原酸酯、聚醚、聚已酸内酯、聚酰胺酯、聚丁酸、聚戊酸、聚氨酯、尼龙、聚酯、聚碳酸酯、聚丙烯酸酯、醋酸乙烯酯和其他酰基取代纤维素乙酸酯的聚合物、聚苯乙烯、聚氯乙烯、聚氟乙烯、聚乙烯咪唑、聚烯烃氯磺酸、聚环氧乙烷和 / 或其共混物和共聚物。

[0121] 如图 17 所示，密封构件 441 限定可在静脉穿刺（或其他获得体液的方法）之后引导体液流的一组孔口 444。例如，由密封构件 441 限定的该组孔口 444 包括第一孔口 444a、第二孔口 444b、第三孔口 444c、第四孔口 444d 和第五孔口 444e。密封构件 441 的布置使得，当密封构件 441 处于凹口 466 中时，第一孔口 444a、第二孔口 444b、第三孔口 444c、第四孔口 444d 和第五孔口 444e 分别与外壳 401 的第一出口孔口 403a、第二出口孔口 403b、第三出口孔口 403c、第四出口孔口 403d 和第五出口孔口 403e 大体对齐。

[0122] 流控制器 440 的转盘 445 可旋转地耦接到外壳 401 上并且可相对于外壳 401 在第一位置、第二位置、第三位置、第四位置和第五位置之间移动。转盘 445 包括限定内腔 402 的入口端口 421。入口端口 421 可流体耦接到限定用于将体液从患者抽取和 / 或输送到采集装置 400 的流体流路径的医疗装置（未示出）。例如，入口端口 421 可直接地或经由适配器 404 间接地流体耦接到针头或其他内腔限定装置（例如，柔性无菌管）。另一种类似的表述是，当内腔限定装置耦接到入口端口 421 时，入口端口 421 限定的入口内腔 402 与内腔限

定装置限定的内腔流体连通。以此方式，入口端口 421 可被配置为选择性地使前样本储存器 470、第一样本储存器 480、第二样本储存器 480'、第三样本储存器 490 和第四样本储存器 490' 与患者流体连通，如在此进一步详细描述的。

[0123] 如上所述，转盘 445 可在第一、第二、第三、第四和第五位置之间移动。当转盘 445 处于第一位置时，流控制器 440 处于第一配置，并且入口端口 421 可与密封构件 441 的第一孔口 444a 和外壳 401 的第一出口孔口 403a 大体对齐。以此方式，密封构件 441 的第一孔口 444a 在入口端口 421 和第一出口孔口 403a 之间建立流体连通，同时使入口端口 421 与出口端口 403b、403c、403d 和 403e 流体隔离，这继而使入口端口 421 与流通道 435a-335d 流体隔离。当第一出口端口 403a 与前样本储存器 470 的开口部分对齐时，第一孔口 444a 和第一出口孔口 403a 在入口端口 421 和前样本储存器 470 之间建立流体连通。当转盘 445 被旋转（或被致动）到第二位置时，流控制器 440 处于第二配置，并且第二出口孔口 444b 在入口端口 421 和第二出口孔口 403b 之间建立流体连通，同时使入口端口 421 与出口端口 403a、403c、403d 和 403e 流体隔离。当第二出口孔口 403b 与第一流通道 435a 的第一端部对齐时，第二孔口 444b 和第二出口孔口 403b 在入口端口 421 和第一流通道 435a 之间建立流体连通。

[0124] 当转盘 445 被旋转到第三、第四和第五位置时，采集装置 400 以类似方式工作。因此，当入口内腔 402 与患者（例如，经由耦接到入口端口 421 的医疗装置）流体连通时，第一出口端口 430、第二出口端口 431、第三出口端口 432、第四出口端口 433 和第五出口端口 434 可选择性地与入口内腔 402 流体连通，以容许全部体液流入样本储存器 480、480'、490 和 490' 中的一个或多个或前样本储存器 470 中的至少一者。在一些实施例中，可包括与额外的密封出口孔口和 / 或流控制器 440 的配置相对应的额外的转盘 445 的位置，以在患者和采集装置 400 之间进一步引导 / 隔离流体流。例如，转盘 445 可具有对应于流控制器 440 的第六配置的第六位置，其大体完全阻止患者和采集装置 400 之间的流体流。换言之，在一些实施例中，在从患者获取全部体液样本之后，转盘 445 可移动到第六位置，以相对于外部环境大体密封采集装置 400 中的样本。

[0125] 在一些实施例中，防止体液流到与样本储存器相连的出口端口（例如，出口端口 431-434），直到在前样本储存器 470 中采集了预定体积的体液。在一些实施例中，与样本储存器相连的出口端口（例如，出口端口 431-434）仅能依次与入口内腔 402 流体连通（例如，出口端口 431 必须在出口端口 432 之前与入口内腔 402 流体连通，等等）。在一些实施例中，与随后的样本储存器相连的出口端口（例如，出口端口 432-434）仅能在已经采集确定体积的体液之后与入口内腔 402 流体连通。在一些实施例中，与样本储存器相连的出口端口（例如，出口端口 431-434）可按任何随机方式、对顺序没有任何偏好地与入口内腔 402 流体连通（例如，出口端口 434 可在出口端口 431 之前与入口内腔 402 流体连通，出口端口 432 可在出口端口 433 之前与入口内腔 402 流体连通，等等）。

[0126] 在一些实施例中，外壳 401 可选择性地限制转盘 445 从其第一位置到其第二、第三、第四和第五位置的移动。在一些实施例中，外壳 401 可被配置为一旦转盘 445 已经移动到第五位置就阻止其移动。换言之，外壳 401 可包括阻止转盘 445 从第五位置移动返回第一位置的锁定机构。转盘 445 和 / 或外壳 401 还可包括机械棘爪和 / 或提供视觉或触觉反馈以确保相对于外壳 401 的出口孔口 403a-403e 精确地定位转盘 445 的其他指示器。

[0127] 在操作时，采集装置400可用于从患者采集减少污染的体液（例如，血液、血浆和/或尿液等）。例如，采集装置400的入口端口421流体耦接到针头或其他内腔限定装置（例如，柔性无菌管）。在静脉穿刺（或其他体液获得方法）之后，致动（或旋转）转盘445，直到它达到如图19和20所示的第一位置。替代性地，转盘445可被预设在第一位置，并且采集装置400可以其他方式被密封，以保持采集装置400的无菌性。例如，入口端口421可包括当采集装置400耦接到针头或其他内腔限定装置时打开的阀。

[0128] 如上所述，当转盘445处于第一位置时，流控制器440处于第一配置，并且密封构件441的第一孔口444a在入口端口421和第一出口端口430（包括在外壳401中）之间建立流体连通，同时使入口端口421和四个流通道435a-335d流体隔离。此外，在第一配置中，样本储存器480、480'、490和490'与入口端口421流体隔离，并且在患者身体的一部分（例如，血管）和前样本储存器470之间限定流体流路径，如图20的箭头GG所示。在此第一配置，体液（例如，通过重力、真空等）从患者身体的一部分通过入口端口421的入口内腔402、密封构件441的第一孔口444a、第一出口端口430流入前样本储存器470。在第一配置，流控制器440还使前样本储存器470与流通道435a-335d流体隔离。因此，第一量（预定的或未定的）体液可在静脉穿刺（例如）之后立即被容纳到前样本储存器470中并与随后的样本隔离。以此方式，采集装置400可用于防止第一量体液（其最可能含有体表微生物和/或其他有害的外部污染物）污染随后量的体液样本，这些体液样本被采集并用于可受污染物影响的诊断或其他测试。

[0129] 在前样本储存器470中采集了体液前样本之后，可致动（或旋转）转盘445直到它达到其第二位置，如图21和22所示。当转盘445处于第二位置时，流控制器440处于第二配置，并且密封构件441的第二孔口444b在入口端口421和流通道435a之间建立流体连通，同时使前样本储存器470与入口端口421流体隔离。换言之，在第二配置，流控制器440在患者身体的一部分（例如，血管）和流通道435a之间建立流体流路径，如图22的箭头HH所示。当流控制器440处于第二配置时，使用者可将样本储存器480从第一配置致动到第二配置（例如，推动刺穿构件455a），以在患者身体的一部分（例如，血管）与第一样本储存器480之间建立流体连通。

[0130] 如上所述，将样本储存器480移动到第二配置会致使刺穿构件455a穿透样本储存器480的真空密封件，位于样本储存器480内的。在此第二配置，患者身体的所述部分（例如，血管）暴露于来自样本储存器480的由其中的负压状态（真空）产生的真空吸力下。样本储存器480和患者身体的所述部分之间的压力差（例如，真空或负压）将体液抽入样本储存器480。体液从患者身体的所述部分通过入口端口421的入口内腔402、密封构件441的第二孔口444b、外壳401的第二出口孔口403b流入第一流通道435a。真空吸力经由第二出口端口431和刺穿构件455a通过第一流通道435a将体液流抽入样本储存器480。换言之，在第二配置，流控制器440在入口端口421和样本储存器480之间建立流体流路径。一旦期望量的体液（例如，第二量）被采集在样本储存器480中，使用者就可将流控制器440致动（旋转）到第三位置和/或将样本储存器480移回其第一配置，以使样本储存器480与流通道435a隔离。当样本储存器480返回其第一配置时，刺穿构件455a被移离样本储存器480，并且样本储存器480的密封件（例如，独立密封隔膜）使第一样本储存器480与流通道435a流体隔离。当流控制器440分别位于第三、第四和第五配置时，以类似方式填

充其他样本储存器。

[0131] 应该注意，不必要求填充顺序和/或排序（即，不必必须在样本储存器490之前填充样本储存器480，等等）。换言之，可按任何顺序填充第一样本储存器480和第二样本储存器490（和任何额外的样本储存器）。例如，使用者可开始填充第一样本储存器480，然后在部分地填充第一样本储存器480之后，使用者可填充第二样本储存器490。此外，通过反复填充样本储存器480和/或490可调整样本储存器480和/或490中采集的体液的体积。但是，在其他实施例中，可机械地操纵填充顺序，从而使得在确定特定量的体液已经位于第一储存器之前不能进入第二样本储存器，等等。如上所述，转盘445可具有与流控制器440的第六配置相对应的第六位置，其可大体上完全阻止患者和采集装置400之间的流体流，以相对于外部环境大体上密封采集装置400中的样本。

[0132] 尽管采集装置400被示出和描述为包括和/或耦接到一组四个样本储存器（例如，第一样本储存器480、第二样本储存器480'、第三样本储存器490和第四样本储存器490'），但在其他实施例中，采集装置可包括和/或耦接到任意合适数量的样本储存器。例如，图23-25图示了根据实施例的采集装置500。如图所示，采集装置500的某些方面可与以上参照图16-22描述的采集装置500的相应方面大体类似。因此，在此不进一步详细描述类似的方面。

[0133] 采集装置500包括转移机构520、流控制器540和第一样本储存器580和第二样本储存器590。样本储存器580和590可与上文详细描述的样本储存器大体类似。在一些实施例中，样本储存器580和590可具有大体相同的形状和尺寸并可包括大体相同的培养介质。在其他实施例中，样本储存器580和590可具有大体相同的形状和尺寸并可包括需氧培养介质或厌氧培养介质中的一种。在其他实施例中，第一样本储存器580的第一尺寸可大体大于第二样本储存器590的尺寸。

[0134] 如图24和25所示，转移机构520包括外壳501和分配构件529。转移机构520的外壳501物理地和流体地耦接到分配构件529，并提供和/或限定用于从患者采集体液的一组流体流路径。如以上参照外壳401描述的，外壳501可限定凹口以及第一出口孔口503a、第二出口孔口503b和第三出口孔口503c。凹口被配置为容纳包括在流控制器540中的密封构件541，如上文详细描述的。第一出口孔口503a、第二出口孔口503b和第三出口孔口503c在形式和功能上可分别大体类似于外壳401限定的第一出口孔口403a、第二出口孔口403b和第三出口孔口403c。类似地，分配构件529限定与包括在转移机构429中的前样本储存器470、第一流通道435a和第二流通道435b大体类似的前样本储存器570、第一流通道535a和第二流通道535b。因此，前样本储存器570与第一出口孔口503a流体连通，第一流通道535a与第二出口孔口503b流体连通，并且第二流体流通道535b与第三出口孔口503c流体连通，如上文参照转移机构420描述的。如图25所示，分配构件529限定与第一流通道535a和第一刺穿构件555a流体连通的第一出口端口531和与第二流通道535b和第二刺穿构件555b流体连通的第二出口端口532。如上所述，刺穿构件555a和555b可用于穿透样本储存器580和590的真空密封件，这可使体液开始流动，如在此进一步详细描述的。

[0135] 流控制器540包括转盘545和密封构件541。密封构件541位于外壳501的凹口中，如上所述。以此方式，当流控制器540耦接到外壳501时，密封构件541与转盘545的

表面和限定凹口的外壳 501 的表面形成大体流体密封的密封结构。如图 24 和 25 所示，密封构件 541 限定分别与第一出口孔口 503a、第二出口孔口 503b 和第三出口孔口 503c 大体对齐的第一孔口 544a、第二孔口 544b 和第三孔口 544c，如参照密封构件 441 详细描述的。

[0136] 流控制器 540 的转盘 545 在形式和功能上可大体类似于转盘 445，同时具有适于耦接到外壳 501 的尺寸。因此，转盘 545 可以可旋转地耦接到外壳 501 上并且可相对于外壳 501 在第一位置、第二位置和第三位置之间移动。转盘 545 包括限定内腔 502 的入口端口 521，并且入口端口 521 可流体耦接到限定用于将体液从患者抽取和 / 或输送到采集装置 500 的流体流路径的医疗装置（未示出）。以此方式，入口端口 521 可被配置为选择性地设置前样本储存器 570、第一样本储存器 580 和第二样本储存器 590。更具体地，当转盘 545 处于第一位置时，流控制器 540 处于第一配置，并且入口端口 521 可与密封构件 541 的第一孔口 544a 和外壳 501 的第一出口孔口 503a 大体对齐。以此方式，密封构件 541 的第一孔口 544a 在入口端口 521 和第一出口孔口 503a 之间建立流体连通，并因而使入口端口 521 与前样本储存器 570 流体连通，如上文参照采集装置 400 详细描述的。类似地，当转盘 545 被旋转（或被致动）到第二位置时，流控制器 540 处于第二配置，并且第二出口孔口 544b 在入口端口 521 和第二出口孔口 503b 之间建立流体连通，并因而在入口端口 521 和第一流通道 535a 之间建立流体连通；并且当转盘 545 被旋转到第三位置时，流控制器 540 处于第三配置，并且第三出口孔口 544c 在入口端口 521 和第三出口孔口 503c 之间建立流体连通，并因而在入口端口 521 和第二流通道 535a 之间建立流体连通。以此方式，采集装置 500 可用于将第一体积的体液传送到前样本储存器 570，随后用于分别将第二体积和第三体积的体液传送到第一样本储存器 580 和第二样本储存器 590，如上文参照采集装置 400 详细描述的。

[0137] 图 26-33 图示了根据实施例的采集装置 600。采集装置 600 包括转移机构 620、流控制器 640 和样本储存器 680、680’、690 和 690’。如在此进一步描述的，采集装置 600 可在第一、第二、第三、第四和第五配置之间移动，以传递大体上不存在体外微生物（诸如，例如，皮肤驻留的微生物和 / 或其他有害外部污染物）的体液流。采集装置 600 可具有任何合适的形状、尺寸或配置。例如，采集装置 600 的多个方面和 / 或部分在在形式和 / 或功能上大体类似于上述采集装置 100、200、300、400 和 / 或 500 中任何装置的相应方面和 / 或部分。因此，在此不进一步详细描述这类类似的方面和 / 或部分。例如，在一些实施例中，采集装置 600 的样本储存器 680、680’、690 和 690’在形式和 / 或功能上可分别大体类似于和 / 或等同于图 16-22 的采集装置 400 中包括的样本储存器 480、480’、490 和 490’。

[0138] 转移机构 620 包括分配构件 629 和一组耦接构件 637a、637b、637c 和 637d（例如，见图 27）。分配构件 629 与耦接构件 637a、637b、637c 和 637d 流体连通，并被配置为提供和 / 或限定用于从患者采集体液的一组流体流路径。如图 27 和 28 所示，分配构件 629 限定和 / 或形成与前样本储存器 670 流体连通的第一出口端口 630、与第一耦接构件 637a 流体连通的第二出口端口 631、与第二耦接构件 637b 流体连通的第三出口端口 632、与第三耦接构件 637c 流体连通的第四出口端口 633、与第四耦接构件 637d 流体连通的第五出口端口 634。

[0139] 如图 28 所示，分配构件 629 限定腔或空间，所述腔或空间限定前样本储存器 670 的至少一部分。前样本储存器 670 被配置为容纳体液，诸如，例如，血液、血浆和 / 或尿液等。例如，前样本储存器 670 可接收和容纳来自患者的第一量或体积的体液，其中，体液的第一

量可以是预定的或未定的量。此外，转移机构 620 和流控制器 640 的布置可使得前样本储存器 670 保持与耦接构件 637a、637b、637c 和 637d 和 / 或随后从患者抽取的多部分体液流体隔离，如在此进一步详细描述的。以此方式，出口端口 631、632、633 和 634 可在流控制器 640 与各个耦接构件 637a、637b、637c 和 637d 之间引导和 / 或限定流体流路径，如在此进一步详细描述的。在一些实施例中，第一出口端口 630 和前样本储存器 670 的布置在形式和功能上可大体类似于前样本储存器 470 和 / 或 570。因此，这里不进一步详细描述前样本储存器 670。

[0140] 如图 29 所示，第一耦接构件 637a 限定与刺穿构件 655a 流体耦接的流通道 638a。如上所述，耦接构件 637a 可物理地和流体地耦接到分配构件 629。例如，流通道 638a 可接纳分配构件的第二出口端口 631 的一部分，以将耦接构件 637a 物理地和流体地耦接到其上。在一些实施例中，第二出口端口 631 的表面可与限定流通道 638a 的耦接构件 637a 的内表面形成大体流体密封的密封结构（例如，可形成大体气密的密封结构的摩擦配合）。耦接部分 637a 的刺穿构件 655a 在形式和功能上可大体类似于图 16-22 的采集装置 400 中包括的刺穿构件 455a。因此，这里不进一步详细描述刺穿构件 655a。类似地布置第二耦接构件 637b、第三耦接构件 637c 和第四耦接构件 637d。因此，第二耦接构件 637b、第三耦接构件 637c 和第四耦接构件 637d 各自分别包括刺穿构件 655b、655c 和 655d，并各自分别限定流通道 638b、638c 和 638d。如在此进一步详细描述的，第一耦接构件 637a、第二耦接构件 637b、第三耦接构件 637c 和第四耦接构件 637d 可用于选择性地使转移机构 620 分别与第一样本储存器 680、第二样本储存器 680'、第三样本储存器 690 和第四样本储存器 690' 流体连通。

[0141] 如图 30 和 31 所示，流控制器 640 包括转盘 645 和密封构件 641。流控制器 640 的转盘 645 可旋转地位于分配构件 629 内（例如，见图 32 和 33）并且可在第一位置、第二位置、第三位置和第四位置之间移动。转盘 645 包括各自与内部容积 646（例如，见图 30）流体连通的入口端口 621、第一出口端口 647 和第二出口端口 648。内部容积 646 被配置为接纳密封构件 641 的一部分，如在此进一步详细描述的。入口端口 621 可流体耦接到限定用于将体液从患者抽取和 / 或输送到采集装置 600 的流体流路径的医疗装置（未示出）。例如，入口端口 621 可直接地或经由适配器 604（例如，见图 26 和 27）间接地流体耦接到针头或其他内腔限定装置（例如，柔性无菌管）。第一出口端口 647 与前样本储存器 670 流体连通。例如，第一出口端口 647 可以可旋转地位于分配构件 629 的第一出口端口 630 中。当转盘 645 分别位于其第一位置、第二位置、第三位置和第四位置时，第二出口端口 648 可选择性地与第二出口端口 631、第三出口端口 632、第四出口端口 633 和第五出口端口 634 流体连通。以此方式，转盘 645 的内部容积 646 可选择性地与前样本储存器 670、第一样本储存器 680、第二样本储存器 680'、第三样本储存器 690 和第四样本储存器 690' 与流体连通，如在此进一步详细描述的。

[0142] 流控制器 640 的密封构件 641 的至少一部分可旋转地位于转盘 645 的内部容积 646 中并可在第一位置和第二位置之间移动。此外，密封构件 641 可具有这样的尺寸和形状，即，使得密封构件 641 的外表面与限定内部容积 646 的至少一部分的转盘 645 的内表面形成大体流体密封的密封结构。如图 31 所示，密封构件 641 限定第一流通道 642 和第二流通道 644。当密封构件 641 处于其在内部容积 646 内的第一位置时，第一流通道 642 在入

口端口 621 和第一出口端口 647 之间建立流体连通，同时使入口端口 621 与第二出口端口 648 流体隔离。类似地，当密封构件 641 处于其在内部容积 646 内的第二位置时，第二流通道 644 在入口端口 621 和第二出口端口 648 之间建立流体连通，同时使入口端口 621 与第一出口端口 647 流体隔离。当转盘 645 旋转到分配构件 629 内的第二、第三和第四位置时，采集装置 600 以类似方式工作。因此，当入口端口 621 与患者（例如，经由耦接到入口端口 621 和 / 或适配器 604 的医疗装置）流体连通时，分配构件 629 的第一出口端口 630、第二出口端口 631、第三出口端口 632、第四出口端口 633 和第五出口端口 634 可选择性地与入口端口 621 流体连通，以容许体液分别流入前样本储存器 670、第一样本储存器 680、第二样本储存器 680'、第三样本储存器 690 和第四样本储存器 690'。

[0143] 在操作时，采集装置 600 可用于从患者采集减少污染的体液（例如，血液、血浆和 / 或尿液等）。例如，采集装置 600 的入口端口 621 流体耦接到针头或其他内腔限定装置（例如，柔性无菌管）。在静脉穿刺（或其他体液获得方法）之后，可致动（或旋转）密封构件 641，直到它处于如图 32 所示的第一位置。替代性地，密封构件 641 可被预设在第一位置，并且采集装置 600 可以其他方式被密封，以保持采集装置 600 的无菌性。当密封构件 641 处于其第一位置时，流控制器 640 在入口端口 621 和分配构件 629 的第一出口端口 630 之间建立流体连通，同时使入口端口 621 与耦接构件 637a、637b、637c 和 637d 流体隔离。因此，如图 32 的箭头 II 所示，可按上文参照采集装置 400 描述的类似方式将体液从患者通过入口端口 621、第一流通道 642、转盘 645 的第一出口端口 647 和分配构件 629 的第一出口端口 630 流入前样本储存器 670。

[0144] 在前样本储存器 670 中采集了体液前样本之后，可相对于转盘 645 将密封构件 641 从其第一位置致动（或旋转）到其第二位置。类似地，可相对于分配构件 629 致动（或旋转）转盘 645，直到它达到第二位置，如图 33 所示。当密封构件 641 和转盘 645 处于第二位置时，流控制器 640 处于第二配置，并且密封构件 641 的第二流通道 644 在入口端口 621 和第一耦接构件 637a 的流通道 638a 之间建立流体连通，同时使前样本储存器 670 与入口端口 621 流体隔离。当流控制器 640 处于第二配置时，使用者可将样本储存器 680 从第一配置致动到第二配置（例如，推动刺穿构件 655a），以在患者身体的一部分（例如，血管）与第一样本储存器 680 之间建立流体连通。如上所述，将样本储存器 680 移动到第二配置会致使刺穿构件 655a 穿透样本储存器 680 的真空密封件，位于样本储存器 680 内的。在此第二配置，患者身体的所述部分（例如，血管）暴露于来自样本储存器 680 的由其中的负压状态（真空）产生的真空吸力下。体液从患者身体的所述部分通过入口端口 621、第二流通道 641、第二出口端口 631、流通道 638a 和第一耦接构件 637a 的刺穿构件 655a 进入第一样本储存器 680，如图 33 的箭头 JJ 所示。

[0145] 一旦期望量的体液（例如，第二量）被采集在样本储存器 680 中，使用者就可将流控制器 640 致动（旋转）到第三位置和 / 或将样本储存器 680 移回其第一配置，以使第一样本储存器 680 与第二流通道 644 隔离。当样本储存器 680 返回其第一配置时，刺穿构件 655a 被移离样本储存器 680，并且样本储存器 680 的密封件（例如，独立密封隔膜）使第一样本储存器 680 与流通道 635a 流体隔离。当流控制器 640 分别位于第三、第四和第五配置时，以类似方式填充其他样本储存器。

[0146] 图 34-40 描绘根据实施例的采集装置 700。采集装置 700 包括转移机构 720、流控

制器 740 以及样本储存器 780 和 790（尽管描绘了用于四个样本储存器的托架，但为了清楚起见图中仅包括两个样本储存器，并且额外的样本储存器（例如，第五、第六等）可被包括作为采集装置 700 的一部分）。如在此进一步描述的，采集装置 700 可在第一、第二、第三、第四和第五配置之间移动，以传递大体上不存在体外微生物（诸如，例如，皮肤驻留的微生物和 / 或其他有害外部污染物）的体液流。采集装置 700 可具有任何合适的形状、尺寸或配置。例如，采集装置 700 的一些方面和 / 或部分在形式和功能上可大体类似于采集装置 100、200、300、400、500 和 / 或 600 中任何装置的相应方面和 / 或部分。因此这里不进一步详细描述这些类似的方面和 / 或部分。例如，采集装置 700 的样本储存器 780 和 790 在形式和功能上可大体类似于图 16-22 的采集装置 400 中包括的样本储存器 480 和 490。

[0147] 转移机构 720 包括外壳 701、分配构件 729 和基板 771。如上文参照采集装置 400 描述的，外壳 701 限定第一出口孔口 703a、第二出口孔口 703b、第三出口孔口 703c、第四出口孔口 703d 和第五出口孔口 703e，它们各自被配置为与分配构件 729 的不同部分流体连通。更具体地，分配构件 729 限定和 / 或形成与第一出口孔口 703a 流体连通的前样本储存器 770 的至少一部分以及与第二出口孔口 703b 流体连通的第一流体腔 735a、与第三出口孔口 703c 流体连通的第二流体腔 735b、与第四出口孔口 703d 流体连通的第三流体腔 735c 和第五出口孔口 703e 流体连通的第四流体腔 735d。此外，外壳 701 限定被配置为可移动地接纳流控制器 740 的至少一部分的凹口 766，如在此进一步详细描述的。

[0148] 如图 36 所示，分配构件 729 限定腔或空间，所述腔或空间形成前样本储存器 770 的至少一部分。前样本储存器 770 被配置为容纳体液，诸如，例如，血液、血浆和 / 或尿液等。外壳 701 的第一出口孔口 703a 可与前样本储存器 770 的开口部分大体对齐，以容许前样本储存器 770 接收来自患者的体液流，如上文详细描述的。进一步详述，分配构件 729 包括一组壁 736，它们可例如将分配构件 729 的内部容积划分成彼此流体隔离的多个部分和 / 或空间。例如，如图 36 所示，该组壁 736 可将分配构件 729 的内部容积划分成前样本储存器 770、第一流体腔 735a、第二流体腔 735b、第三流体腔 735c 和第四流体腔 735d。在一些实施例中，壁 736 可均等地限定和 / 或形成前样本储存器 770 和流体腔 735a-735d。在其他实施例中，前样本储存器 770 限定的空间可不同于流体腔 735a-735d 限定的空间。

[0149] 分配构件 729 还包括第一刺穿构件 755a、第二刺穿构件 755b、第三刺穿构件 755c、第四刺穿构件 755d，它们分别与第一流体腔 735a、第二流体腔 735b、第三流体腔 735c 和第四流体腔 735d。因此，刺穿构件 755a-355d 可用于穿透样本储存器 780 和 790（以及图 34-40 中未示出的相应样本储存器）的真空密封件，这可使体液开始流动，如在此进一步详细描述的。

[0150] 采集装置 700 的流控制器 740 包括转盘 745 和密封构件 741。密封构件 741 位于外壳 701 的凹口 766（例如，见图 38 和 40）中。更具体地，流控制器 740 可耦接到外壳 701，从而使得密封构件 741 位于限定凹口 766 的外壳 701 的表面和转盘 745 的表面之间并与两个表面接触。密封构件 741 可被配置为与转盘 745 的表面和限定凹口 766 的外壳 701 的表面形成大体流体密封的密封结构，如上文详细描述的。如图 35 所示，密封构件 741 限定第一孔口 744a、第二孔口 744b、第三孔口 744c、第四孔口 744d 和第五孔口 744e。密封构件 741 的布置使得，当密封构件 741 处于凹口 766 中时，第一孔口 744a、第二孔口 744b、第三孔口 744c、第四孔口 744d 和第五孔口 744e 分别与外壳 701 的第一出口孔口 703a、第二出口孔口

703b、第三出口孔口 703c、第四出口孔口 703d 和第五出口孔口 703e 大体对齐。

[0151] 流控制器 740 的转盘 745 可旋转地耦接到外壳 701 上并且可相对于外壳 701 在第一位置、第二位置、第三位置、第四位置和第五位置之间移动。转盘 745 包括入口端口 721，入口端口 721 可（直接地或经由适配器 704 间接地）流体耦接到限定用于将体液从患者抽取和/或输送到采集装置 700 的流体流路径的医疗装置。以此方式，入口端口 721 可被配置为选择性地使前样本储存器 770、第一样本储存器 780、第二样本储存器 780'、第三样本储存器 790 和第四样本储存器 790' 与患者流体连通，如在此进一步详细描述的。当转盘 745 处于第一位置时，流控制器 740 处于第一配置，并且入口端口 721 可与密封构件 741 的第一孔口 744a 和外壳 701 的第一出口孔口 703a 大体对齐。以此方式，密封构件 741 的第一孔口 744a 在入口端口 721 和第一出口孔口 703a 之间建立流体连通，同时使入口端口 721 与出口端口 703b、703c、703d 和 703e 流体隔离，这继而使入口端口 721 与流体腔 735a-335d 流体隔离。当转盘 745 被旋转（或被致动）到第二位置时，流控制器 740 处于第二配置，并且第二出口孔口 744b 在入口端口 721 和第二出口孔口 703b 之间建立流体连通，同时使入口端口 721 与前样本储存器 770 和流体腔 735b-735d 流体隔离。当转盘 745 被旋转到第三、第四和第五位置时，采集装置 700 以类似方式工作。因此，当入口内腔 721 与患者（例如，经由耦接到入口端口 721 的医疗装置）流体连通时，第一出口孔口 703a、第二出口孔口 703b、第三出口孔口 703c、第四出口孔口 703d 和第五出口孔口 703e 可选择性地与入口端口 721 流体连通，以容许全部体液流入前样本储存器 770、第一样本储存器 780 或第二样本储存器 790（或与其耦接的任何其他流体储存器）中的至少一个。

[0152] 在一些实施例中，外壳 701 可选择性地限制转盘 745 从其第一位置到其第二、第三、第四和第五位置的移动。在一些实施例中，外壳 701 可被配置为一旦转盘已经移动到第五位置就阻止其移动。换言之，外壳 701 可包括阻止转盘 745 从第五位置移动返回第一位置的锁定机构。此特征可降低流体腔 735b-735d 和/或样本储存器 780 和 790 中采集的体液被前样本储存器 770 中容纳的体液（其具有包含表面束缚微生物和/或其他有害外部污染物的高风险）污染的风险。此锁定机构还可保护医疗保健行业从业者，防止其暴露于患者样本中的血源性病原体，其可包括 HIV、丙型肝炎等。转盘 745 和/或外壳 701 还可包括机械棘爪和/或提供视觉或触觉反馈以确保相对于出口端口 703b 和外壳 701 的出口孔口 703a-703d 精确地定位转盘 745 的其他指示器。

[0153] 与图 16-22 描绘的采集装置 400 的实施例类似，采集装置 700 包括前样本储存器 770，其是包含在分配构件 729 内的腔。前样本储存器 770 可包含体液，诸如，例如，血液、血浆和/或尿液等。前样本储存器 770 被配置为流体耦接到采集装置 700 的第一出口端口 703a（位于外壳 701 中）。在采集装置 700 的操作期间，当流控制器 740 处于第一位置时，体液从患者身体的一部分（例如，血管）经由入口端口 721 被抽入前样本储存器 770、用于前样本储存器的位于密封构件 741 中的孔口 744a 和第一出口端口 703a。前样本储存器 770 被配置为包含从患者抽取的第一量的体液，其中体液的第一量可以是预定或未定量，从而使得第一量体液与随后从患者抽取的第二和/或第三和/或第四和/或第五量体液流体隔离。

[0154] 在操作时，采集装置 700 可用于从患者采集减少污染的体液（例如，血液、血浆、尿液等）。例如，采集装置 700 的入口端口 721 流体耦接到针头或其他内腔限定装置（例如，

柔性无菌管）。在静脉穿刺之后，旋转转盘 745，直到它达到如图 37 和 38 所示的第一位置。替代性地，转盘 745 可被预设在第一位置，并且采集装置 700 可以其他方式被密封，以保持采集装置 700 的无菌性，如上所述。当转盘 745 处于第一位置时，流控制器 740 处于第一配置，并且密封构件 741 的第一出口孔口 744a 在入口端口 721 和第一出口端口 703a（包括在外壳 701 中）之间建立流体连通，同时使入口端口 721 和四个样品流通道 735a-735d 流体隔离。在此第一配置，体液从患者身体的一部分通过入口端口 721、密封构件 741 的第一出口孔口 744a、外壳 701 的第一出口端口 703a 流入分配构件 770 限定的前样本储存器 770，如图 38 的箭头 KK 所示。因此，第一量（预定的或未定的）体液可在静脉穿刺之后立即被接纳到前样本储存器 770 中并与随后的样本隔离，如上文详细描述的。

[0155] 在前样本储存器 770 中采集了体液前样本之后，可致动（或旋转）转盘 745 直到它达到第二位置，如图 39 和 40 所示。当转盘 745 处于第二位置时，流控制器 740 处于第二配置，并且密封构件 741 的第二出口孔口 744a 在入口端口 721 和第一流体腔 735a 之间建立流体连通，同时使前样本储存器 770 与入口端口 721 流体隔离。一旦第一流体腔 735a 被填充以体液，流控制器 740 就可移动到第三位置，以相对于外部环境隔离和密封第一流体通道 735a。此外，可将样本储存器 780 从第一配置致动到第二配置，以将体液从第一流体腔 735a 传送到样本储存器 780。例如，可通过使用者或自动地将样本储存器 780 从第一配置致动（推动刺穿构件 755a）到第二配置，以在患者身体的一部分（例如，血管）和样本储存器 780 之间建立流体连通。如上所述，将样本储存器 780 移动至第二配置会致使刺穿构件 755a 穿透样本储存器 780 的真空密封件并位于样本储存器 780 中。在第二配置，患者身体的所述部分（例如，血管）暴露于来自样本储存器 780 的由某些实施例中样本储存器 780 内存在的负压状态（真空）产生的真空吸力。因此，体液从患者身体的所述部分通过入口端口 721、密封构件 741 的第二出口孔口 744b、外壳 701 的第二出口孔口 703b、第二流体腔 735b 流入第一样本储存器 780，如图 40 的箭头 LL 所示。

[0156] 一旦期望量的体液（例如，第二量）被采集在样本储存器 780 中，使用者就可将流控制器 740 致动（旋转）到第三位置和 / 或将样本储存器 780 移回其第一配置，以使样本储存器 780 与入口端口 721 隔离。当样本储存器 780 返回第一配置时，刺穿构件 755a 被移离样本储存器 780，并且样本储存器 780 的密封件（例如，独立密封隔膜）使第一样本储存器 780 与第二流体腔 735b 及外部环境流体隔离。当流控制器 740 分别位于第三、第四和第五配置时，以相同方式填充其他样本储存器。

[0157] 在一些实施例中，采集装置 700 可被构造为不存在分隔分配构件 729 中的不同流体腔 735a-735d 的一组壁 736（见图 16 的详细剖视图）。在这类实施例中，分配构件 729 被划分在前样本储存器 770 和组合式流体腔 735（即，流体腔未被壁 736 分隔成四个单独的部段）之间。在这类实施例中，使用者可通过同时将转盘 745 致动（旋转）到各个第二、第三、第四或第五位置来填充全部四个样本储存器。

[0158] 本文描述的任何实施例都可与例如计量装置一起使用，计量装置可用于计量（例如，量化）流入前样本储存器和 / 或样本储存器的体液流。在一些情形中，实验室标准实践不能确保一致地遵从精确的体液（例如，血液样品）移入体积，因为实际上填充体积是临床医生和、或采血师视觉地确定的并因此存在人为误差。血液采集瓶上的体积指示器在被抓握时难以读数并且在抽取过程期间常常未竖直地抓握采集瓶的事实也可导致从患者接收

的体液样本的体积不准确。不足的样本体积（例如，低于制造商的建议值）可降低培养测试的敏感度，导致错误的阴性结果。此外，超过制造商建议值的填充体积可导致错误的阳性结果，如在用于特定类型的测试供给和设备（例如，被设计为与制造商生产的自动微生物检测系统一起使用的血液培养瓶，制造商诸如为新泽西州富兰克林湖的 Becton Dickinson）的概述材料和使用说明中指示的。因此，流计量和体积显示特征可容许实验室技术人员和/或医疗保健行业从业者（例如，采血师）根据需要如何处理样本在将样本储存器放入培养器或放入其他实验室测试仪器之前确认各个单个样本储存器中采集的体液的体积。实验室技术人员和/或采血师还可记录（例如，在病历卡、数据库、电子表格等中）精确的体积信息，以便临床医生在收到结果时评估，由此帮助降低错误地解释错误的阴性和/或错误的阳性结果的可能性。

[0159] 例如，图 41-45 图示可包括一个或多个计量装置的采集装置 800。采集装置 800 包括转移机构 820、流控制器 840、显示器 875 和样本储存器 880。如在此进一步描述的，采集装置 800 可在第一、第二和第三配置之间移动，以传递大体上不存在体外微生物（诸如，例如，皮肤驻留的微生物和/或其他有害外部污染物）的体液流。采集装置 800 可具有任何合适的形状、尺寸或配置。例如，采集装置 600 的一些方面和/或部分在形式和功能上可大体类似于上述采集装置 100、200、300、400、500、600 和/或 700 中任何装置的相应方面和/或部分。因此，这里不进一步详细描述这些类似的方面和/或部分。例如，在一些实施例中，采集装置 800 的样本储存器 880 在形式和功能上可大体类似于和/或等同于图 16-22 的采集装置 400 中包括的样本储存器 480。

[0160] 如图 41-43 所示，转移机构 820 包括致动器部分 822（例如，第一部分）、医疗部分 823（例如，第二部分）和耦接部分 824（例如，第三部分）。转移机构 820 的致动器部分 822 的大体圆柱形的，包括限定内部容积 806 的一组环形壁。更具体地，致动器部分 822 包括大体闭合的第一端部和与第一端部相反、大体开口以容许进入内部容积 806 的第二端部。以此方式，致动器部分 822 可以可移动地接纳流控制器 840 的至少一部分，如在此进一步详细描述的。致动器部分 822 还包括入口端口 821 和出口端口 831。入口端口 821 可流体耦接到限定用于将体液从患者抽取和/或输送到采集装置 800 的流体流路径的医疗装置（直接地或经由适配器 804 间接地），如上文详细描述的。

[0161] 致动器部分 822 的出口端口 831 可选择性地使致动器部分 822 的内部容积 806 与医疗部分 823 限定的内部容积 807 流体连通。如图 43 所示，医疗部分 823 位于致动器部分 822 和耦接部分 824 之间。尽管图 41-45 中未示出，但医疗部分 823 可包括计量装置，其可被配置为计量被传送到例如样本储存器 880 的体液的体积。例如，在一些实施例中，流计量装置可流体耦接到出口端口 831，以计量流过的体液流。如图 41 和 42 所示，医疗部分 823 包括显示器 875，其可为使用者提供与例如已流过出口端口 831 的体积相关的视觉指示和/或信息。在其他实施例中，流计量装置可被放置在转移机构 820 中或沿转移机构 820 的任何其他位置。

[0162] 耦接部分 824 可物理地和流体地耦接到医疗部分 823。例如，在一些实施例中，耦接部分 824 可部分地位于医疗部分 823 的内部容积 807 中并经由摩擦配合、压装配合、卡扣配合、螺纹耦接和/或粘合剂至少暂时地耦接到其上。耦接部分 824 被配置为接纳样本储存器 880 的一部分，并包括刺穿构件 855，其可用于穿透样本储存器 880 的真空密封件，这容

许体液开始流动，如上文详细描述的。

[0163] 采集装置 800 的流控制器 840 至少部分地位于致动器部分 822 限定的内部容积 806 中，并且可在第一配置、第二配置和第三配置之间移动。如图 42 和 43 所示，流控制器 840 包括具有第一密封构件 861、第二密封构件 862 和第三密封构件 863 的可移动构件 850 及偏置构件 859（例如，弹簧等）。密封构件 861、862 和 863 与限定内部容积 806 的致动器部分 822 的内表面接触。因此，密封构件 861、862 和 863 可各自与所述内表面形成大体流体密封的密封结构，例如，这可将致动器部分 822 的内部容积 806 划分成流体隔离的多个部分，如在此进一步详细描述的。

[0164] 可移动构件 850 可在内部容积 806 内在第一位置、第二位置和第三位置之间移动。可移动构件 850 的布置可使得当可移动构件 850 在其第一、第二和第三位置之间移动时，密封构件 861、862 和 863 可在内部容积 806 内选择性地移动。更具体地，当可移动构件 850 在其第一、第二和第三位置之间移动时，第一密封构件 861 可与可移动构件 850 同时移动。第二密封构件 862 和第三密封构件 863 可牢固地耦接到彼此（例如，彼此相距固定距离地放置）并且关于可移动构件 850 的一部分可滑动地放置，这可容许可移动构件 850 从其第一位置（例如，见图 43）移动至其第二位置（例如，见图 44），同时第二密封构件 862 和第三密封构件 863 相对于致动器部分 822 保持处于大体固定的位置。例如，当可移动构件 850 在其第一位置和第二位置之间移动时，第二密封构件 862 和第三密封构件 863 可保持处于大体固定的位置，从而使得入口端口 821 位于第二密封构件 862 的第一侧上，而出口端口 831 位于第二密封构件 862 的与第一侧相反的第二侧上。因此，当可移动构件 850 处于其第一位置（图 43）和其第二位置（图 44）时，入口端口 821 与被限定在第一密封构件 861 和第二密封构件 862 之间的内部容积 806 部分流体连通，并且出口端口与被限定在第二密封构件 862 和第三密封构件 863 之间的内部容积 806 部分流体连通，如在此进一步详细描述的。

[0165] 流控制器 840 的布置可使得，当可移动构件 850 从其第一位置移动到其第二位置时，第一密封构件 861 相对于第二密封构件 862 和第三密封构件 863 移动。第一密封构件 861 相对于第二密封构件 862 的移动可使得限定在其之间的空间增大，这可形成和 / 或以其他方式限定前样本储存器 870。此外，当密封构件 861 和 862 与致动器部分 822 的内表面形成大体流体密封的密封结构时，被限定在第一密封构件 861 和第二密封构件 862 之间的前样本储存器 870 与内部容积 806 的其他部分流体隔离。因此，当可移动构件 850 从其第一位置移动到其第二位置时，入口端口 821 可与前样本储存器 870 流体连通。当可移动构件 850 从其第二位置（例如，见图 44）移动到其第三位置（例如，见图 45）时，可移动构件 850 的一部分可接触第三密封构件 863，以在内部容积 806 内同时移动第一密封构件 861、第二密封构件 862 和第三密封构件 863。因此，可相对于入口端口 821 移动第二密封构件 862，从而使得入口端口 821 和出口端口 831 都与被限定在第二密封构件 862 和第三密封构件 863 之间的内部容积 806 的一部分流体连通，如在此进一步详细描述的。

[0166] 在操作时，采集装置 800 可用于从患者采集减少污染的体液（例如，血液、血浆、尿液等）。例如，采集装置 800 的入口端口 821 可流体耦接到针头或其他内腔限定装置（例如，柔性无菌管）。当入口端口 821 耦接到内腔限定装置时，可将流控制器 840 从其第一配置移动到其第二配置。以此方式，使用者可施加将可移动构件 850 从其第一位置移动到其第二位置的力，如图 44 的箭头 MM 所示。如上所述，第一密封构件 861 与可移动构件 850 同

时移动，从而增大被限定在第一密封构件 861 和第二密封构件 862 之间的空间，由此形成和 / 或限定前样本储存器 870。当第一密封构件 861 和第二密封构件 862 与限定内部容积 806 的致动器部分 822 的内表面形成大体流体密封的密封结构时，第一密封构件 861 和第二密封构件 862 之间空间的增大会在前样本储存器 870 中产生负压。因此，一旦在患者身体的一部分（例如，血管）和前样本储存器 870 之间建立了流体连通（例如，经由图 44 中的入口端口 821），在前样本储存器 870 和患者身体的所述部分之间限定的负压差就会通过入口端口 821 将体液抽入前样本储存器 870，如图 44 的箭头 NN 所示。在此第一配置中，流控制器 840 还使前样本储存器 870 与出口端口 831 流体隔离。因此，第一量（预定的或未定的）体液可在静脉穿刺（例如）之后立即被容纳到前样本储存器 870 中并与随后的样本隔离。以此方式，采集装置 800 可用于防止第一量体液（其最可能含有体表微生物和 / 或其他有害的外部污染物）污染随后量的体液样本，这些体液样本被采集并用于可受污染物影响的诊断或其他测试。在一些实施例中，计量装置可计量位于前样本储存器 870 中的体液的体积，并在显示器 875 上显示与体积相关的值。

[0167] 在前样本储存器 870 中采集了所述体积的体液前样本之后，将可移动构件 850 从其第二位置移动到其第三位置，以使流控制器处于其第三配置，如图 45 的箭头 OO 所示。如上所述，当将可移动构件 850 从其第二位置移动到其第三位置时，可移动构件 850 的所述部分与第三密封构件 863 接触。因此，可移动构件 850 可在内部容积 806 内大体同时地移动第一密封构件 861、第二密封构件 862 和第三密封构件 863。因此，可相对于入口端口 821 移动第二密封构件 862，从而使得入口端口 821 和出口端口 831 都与被限定在第二密封构件 862 和第三密封构件 863 之间的内部容积 806 的一部分流体连通，如在此进一步详细描述的。此外，当所述体积的体液被流体隔离在前样本储存器 870 中时，第二密封构件 862 和第三密封构件 863 沿第一密封构件 861 方向的移动受到限制（即，体液的基本不可压缩的流体）。以此方式，前样本体积的体液被隔绝在前样本储存器 870 中，并且被限定在第二密封构件 862 和第三密封构件 863 之间的空间限定在入口端口 821 和出口端口 831 之间的流体流路径。此外，流控制器 840 的布置使得，当处于其第三配置时，第一密封构件 861 与偏置构件 859 接触，并且使用者施加在可移动构件 850 上的力的至少一部分能够使偏置构件 859 变形、收缩、弯曲和 / 或以其他方式改变形状。因此，偏置构件 859 可在第一密封构件 861 上施加抵抗流控制器 840 从其第二配置移动到其第三配置的反作用力，如在此进一步详细描述的。

[0168] 相对于采集装置 800 放置样本储存器 880，从而使得刺穿构件 855 穿透样本储存器 880 的真空密封件，以位于样本储存器内，如上文详细描述的。样本储存器 880 和患者身体的所述部分之间的压力差（例如，真空或负压）将体液抽入样本储存器 880。换言之，在第二配置，流控制器 840 和转移机构 820 建立流体流路径，从而使得体液可通过入口端口 821、被限定在第二密封构件 862 和第三密封构件 863 之间的内部容积 806 部分和致动器部分 822 的出口端口 831，通过医疗部分 823 和耦接部分 824 的刺穿构件 855 从患者被抽入样本储存器 880 中，如图 45 的箭头 PP 所示。如上所述，计量装置（未示出）可计量被传送通过例如出口端口 831 的体液的体积，并且可在显示器 875 上显示与体积相关的值。

[0169] 一旦期望量的体液（例如，第二量）被采集在样本储存器 880 中，使用者就可去除和 / 或减小施加在可移动构件 850 上的力，由此容许偏置构件 859 将第一密封构件 861 和

可移动构件 850 从它们的第三位置移向它们的第二位置。此外，由于前样本储存器 870 中的体液基本不可压缩，因此第一密封构件 861 的移动会通过所述体积的体液传送力，以将第二密封构件 862 和第三密封构件 863 从它们的第三位置移向它们的第二位置。在一些实施例中，偏置构件 859 可在第一密封构件 861 上施加力，所述力能够相对于致动器部分 822 将第二密封构件 862 移动至可例如大体上阻塞入口端口 821 的第四位置。因此，入口端口 821 可与致动器部分 822 的内部容积 806 流体隔离。此外，可从样本储存器 880 移开刺穿构件 855，并且和密封件（例如，独立密封隔膜）可使体液样本与样本储存器 880 外的空间流体隔离。通过将刺穿构件 855 放入样本储存器并将流控制器 840 移动至第三位置以容许液体从患者流至样本储存器，可类似地填充随后的样本储存器。

[0170] 图 46-53 图示根据实施例的采集装置 900。采集装置 900 包括转移机构 920、流控制器 940 和样本储存器 980、980’、990 和 990’。如在此进一步描述的，采集装置 900 可在第一、第二、第三、第四和第五配置之间移动，以传递大体上不存在体外微生物（诸如，例如，皮肤驻留的微生物和 / 或其他有害外部污染物）的体液流。采集装置 900 可具有任何合适的形状、尺寸或配置。例如，采集装置 900 的一些方面和 / 或部分在形式和功能上可大体类似于上述采集装置 100、200、300、400、500、600、700 和 / 或 800 中任何装置的相应方面和 / 或部分。因此，这里不进一步详细描述这些类似的方面和 / 或部分。例如，在一些实施例中，采集装置 900 的样本储存器 980、980’、990 和 990’ 在形式和功能上可分别大体类似于和 / 或等同于图 26-33 的采集装置 600 中包括的样本储存器 680、680’、690 和 690’。。

[0171] 转移机构 920 包括外壳 901、分配构件 929 和可移动构件 950a、950b、950c 和 950d。外壳 901 物理地和流体地耦接到分配构件 929，并提供和 / 或限定用于从患者采集体液的一组流体流路径。外壳 901 包括一组显示器 975’（例如，液晶显示器 (LCD) 等），它们可被包括在流计量装置中和 / 或以其他方式耦接（例如，电气地和 / 或机械地）到流计量装置，如在此进一步详细描述的。外壳 901 限定凹口 966、出口孔口 903a、903b、903c、903d、903e 和可移动构件开口 950a、950b、950c、950d（在此也被称作“开口”）。凹口 966 被配置为容纳包括在流控制器 940 中的密封构件 941，如在此进一步详细描述的。第一出口孔口 903a、第二出口孔口 903b、第三出口孔口 903c、第四出口孔口 903d 和第五出口孔口 903e 各自被配置为限定与分配构件 929 的不同部分流体连通的不同流体流路径。更具体地，分配构件 929 限定和 / 或形成与第一出口孔口 903a 流体连通的前样本储存器 970 的至少一部分，以及与第二出口孔口 903b 流体连通的第一流通道 935a、与第三出口孔口 903c 流体连通的第二流通道 935b、与第四出口孔口 903d 流体连通的第三流通道 935c 和第五出口孔口 903e 流体连通的第四流通道 935d。

[0172] 如图 47 和 48 所示，分配构件 929 限定腔或空间，所述腔或空间限定前样本储存器 970 的至少一部分。前样本储存器 970 被配置为容纳体液，诸如，例如，血液、血浆和 / 或尿液等。外壳 901 的第一出口孔口 903a 可与前样本储存器 970 的开口部分大体对齐，以容许前样本储存器 970 接收来自患者的体液流，如上文参照图 16-22 的前样本储存器 470 详细描述的。流通道 935a-935d 从分配构件 929 的中心沿径向延伸并被布置为使得每个流通道 935a、935b、935c 和 935d 与前样本储存器 970 及其他流通道流体隔离。以此方式，流通道 935a、935b、935c 和 935d 可引导和 / 或以其他方式限定第一端部（限定分别与出口孔口 903b、903c、903d 和 903e 大体对齐的开口）和第二端部（限定被配置为分别接纳可移动构

件 950a、950b、950c、950d 的开口或端口）之间的流体流路径。尽管图 47 和 48 示出了分配构件 929 包括大体闭合的流通道 935a-935d，但在其他实施例中，流通道 935a-935d 可以是大体开放的，如上文参照图 17 和 18 的分配构件 429 示出和描述的。因此，采集装置 900 的分配构件 929 可以与采集装置 400 的分配构件 429 大体类似的方式起作用。

[0173] 可移动构件 950a、950b、950c 和 950d 可以可移动地位于外壳 901 的各个开口 905a、905b、905c 和 905d 中，以及由分配构件 929 的第二端部限定的相应开口中。尽管图 46-53 中未示出，但在一些实施例中，可移动构件 950a、950b、950c 和 950d 可以可操作地耦接到偏置构件等，如上文参照采集装置 200 的可移动构件 250 和 250' 详细描述的。以此方式，使用者可相对于外壳 901 和分配构件 929 从第一位置和第二位置致动（例如，移动）可移动构件 950a、950b、950c 和 950d，以将流体流分别引导入第一样本储存器 980、第二样本储存器 980'、第三样本储存器 990 和第四样本储存器 990'。可移动构件 950a、950b、950c 和 950d 大体相同，并因此参照图 49 中的单个可移动构件 950 进行描述。此外，可移动构件 950 的一些部分可大体类似于上述可移动构件 250 和 350。因此，这里不进一步详细描述可移动构件 950 的一些部分。可移动构件 950 限定与入口端口 953 和刺穿构件 955 流体连通的内部腔 952。刺穿构件大体类似于上文详细描述的那些。入口端口 953 延伸通过限定内部腔 952 的一组壁，以使可移动构件 950 的内部容积 952 与相应的流通道 935a、935b、935c 或 935d 流体连通。

[0174] 如图 49 所示，可移动构件 950 包括可旋转地位于内部容积 952 中并与入口端口 953 大体直接地流体连通的流控制机构 967。流计量机构 967 可以是例如可包括一组辐条或翅片的轮等。以此方式，体液可进入可移动构件 950 的入口端口 953 并流过流计量装置 967，这继而可致使流计量装置 967 相对于可移动构件 950 旋转。因此，流计量装置 967 的旋转特征可用于确定被传送到可移动构件 950 的内部容积 952 中的体液的体积和 / 或体积流率等。尽管图 46-53 中未示出，但可移动构件 950 的流控制机构 967 可操作地耦接到外壳 901 的显示器 975' 上。因此，当体液被传送到例如样本储存器 980、980'、990 和 / 或 990' 时，与体液流相关的体积信息可显示在显示器 975' 上。以此方式，使用者可操纵采集装置 900 从患者采集体液样本并且可使至少一个显示器 975' 可视化，以确定被传送到例如样本储存器 980 的体液样本的准确体积。

[0175] 采集装置 900 的流控制器 940 包括转盘 945 和密封构件 941。密封构件 941 位于外壳 901 的凹口 966 中。更具体地，流控制器 940 可耦接到外壳 901，从而使得密封构件 941 位于限定凹口 966 的外壳 901 的表面和转盘 945 的表面之间并与两个表面接触。密封构件 941 可被配置为与转盘 945 的表面和限定凹口 966 的外壳 901 的表面形成大体流体密封的密封结构，如上文详细描述的。如图 47 所示，密封构件 941 限定第一孔口 944a、第二孔口 944b、第三孔口 944c、第四孔口 944d 和第五孔口 944e。密封构件 941 的布置使得，当密封构件 941 处于凹口 966 中时，第一孔口 944a、第二孔口 944b、第三孔口 944c、第四孔口 944d 和第五孔口 944e 分别与外壳 901 的第一出口孔口 903a、第二出口孔口 903b、第三出口孔口 903c、第四出口孔口 903d 和第五出口孔口 903e 大体对齐。

[0176] 流控制器 940 的转盘 945 可旋转地耦接到外壳 901 上并且可相对于外壳 901 在第一位置、第二位置、第三位置、第四位置和第五位置之间移动。转盘 945 包括入口端口 921，其可流体耦接到限定用于将体液从患者抽取和 / 或输送到采集装置 900 的流体流路径的医

疗装置（直接地或经由适配器 904 间接地）。以此方式，入口端口 921 可被配置为选择性地使前样本储存器 970、第一样本储存器 980、第二样本储存器 980'、第三样本储存器 990 和第四样本储存器 990'与患者流体连通，如在此进一步详细描述的。转盘 945 可被配置为以与上文参照采集装置 400 的转盘 445 描述的大体类似的方式旋转通过第一位置、第二位置、第三位置、第四位置和第五位置，并且因此，这里不进一步详细描述。

[0177] 如图所示，转盘 945 可还包括显示器 975，其可被配置为显示与体液流相关的体积信息。例如，尽管图 46-53 中未示出，但转盘可包括流计量装置等，诸如可移动构件 950 包括的流计量装置 967。以此方式，流计量装置可计量流过例如入口端口 921 的体液流并且可以可操作地耦接到显示器 975，从而在转盘 945 的显示器 975 上显示通过入口端口 921 的体液流。

[0178] 在操作时，采集装置 900 可用于从患者采集减少污染的体液（例如，血液、血浆和/或尿液等）。例如，采集装置 900 的入口端口 921 可流体耦接到针头或其他内腔限定装置（例如，柔性无菌管）。在静脉穿刺（或其他体液获得方法）之后，致动（或旋转）转盘 945，直到它达到如图 50 和 51 所示的第一位置。替代性地，转盘 945 可被预设在第一位置，并且采集装置 900 可以其他方式被密封，以保持采集装置 900 的无菌性。

[0179] 如上所述，当转盘 945 处于第一位置时，流控制器 940 处于第一配置，并且密封构件 941 的第一孔口 944a 在入口端口 921 和第一出口端口 930（包括在外壳 901 中）之间建立流体连通，同时使入口端口 921 和四个流通道 935a-335d 流体隔离。此外，在第一配置中，样本储存器 980、980'、990 和 990'与入口端口 921 流体隔离，并且在患者身体的一部分（例如，血管）和前样本储存器 970 之间限定流体流路径，如图 51 的箭头 QQ 所示。在此第一配置，体液（例如，通过重力、真空等）从患者身体的一部分通过入口端口 921、密封构件 941 的第一孔口 944a、外壳 901 的第一出口端口 903a 流入前样本储存器 970。在第一配置，流控制器 940 还使前样本储存器 970 与流通道 935a-935d 流体隔离。因此，第一量（预定的或未定的）体液可在静脉穿刺（例如）之后立即被容纳到前样本储存器 970 中并与随后的样本隔离。以此方式，采集装置 900 可用于防止第一量体液（其最可能含有体表微生物和/或其他有害的外部污染物）污染随后量的体液样本，这些体液样本被采集并用于可受污染物影响的诊断或其他测试。此外，显示器 975 可显示例如从流控制机构（未示出）接收的与传送到前样本储存器 970 的体液体积相关的信息。因此，准确体积的体液可被传送到前样本储存器并被流体隔离在其中。

[0180] 在前样本储存器 970 中采集了体液前样本之后，可致动（或旋转）转盘 945 直到它达到第二位置，如图 52 和 53 所示。当转盘 945 处于第二位置时，流控制器 940 处于第二配置，并且密封构件 941 的第二孔口 944b 在入口端口 921 和流通道 935a 之间建立流体连通，同时使前样本储存器 970 与入口端口 921 流体隔离。当流控制器 940 处于第二配置时，使用者可将可移动构件 950a 从第一位置致动（例如，按压）到第二位置，以在患者（例如，血管）与第一样本储存器 880 之间建立流体连通。此外，可将可移动构件 950 从其第一位置移动到其第二配置，以使刺穿构件 955 穿过第一样本储存器 980 的真空密封件，以位于其中，如图 53 的箭头 RR 所示。

[0181] 当处于第二位置时，可移动构件 950 的入口端口 953 与第一流通道 935a 大体对齐并流体连通，这容许体液从第一流通道 935a 流入可移动构件 950 的内部腔 952，并从刺穿构

件 955 流入第一样本储存器 980。样本储存器 980 和第一流通道 935a 之间的压力差（例如，真空或负压）将体液抽入样本储存器 980。换言之，在第二配置，流控制器 940 和可移动构件 950a 在转盘 945 入口端口 921 和样本储存器 980 之间建立流体流路径，如图 53 的箭头 SS 所示。此外，流过可移动构件 950a 的体液流使流计量机构 967 相对于可移动构件 950 旋转。因此，流计量机构 967 的旋转可用于确定被传送到样本储存器 980 的体液样本的体积。此外，显示器 975’可显示例如从流控制机构 967 接收的与传送到样本储存器 980 的体液体积相关的信息。因此，准确体积的体液可被传送到样本储存器 980。例如，在一些情形中，采集装置 900 可用于分别在第一样本储存器 980、第二样本储存器 980’和第三样本储存器 990 中采集三个 20mL 体积的样本（即，采集的样本总体积为 60mL）。

[0182] 一旦期望量的体液（例如，第二量）被采集在第一样本储存器 980 中，使用者就可释放可移动构件 950，容许偏置构件（未示出）移回其第一位置。当可移动构件 950 返回其第一位置时，刺穿构件 955 被移离第一样本储存器 980，并且密封件（例如，独立密封隔膜）使第一样本储存器 980 与内部流通道 935 流体隔离。采集装置 900 可用于通过分别将转盘 945 旋转到其第三位置、第四位置和第五位置，将第二样本体积传送到第二样本储存器 980’、将第三样本体积传送到第三样本储存器 990 以及将第四样本体积传送到第四样本储存器 990’。

[0183] 在一些情形中，体液采集装置 900 可容许临床医生和 / 或采血师打开包含体液采集装置 900 的包装并仅移除外壳 901（其包含分配构件 929）并将外壳 901 拿到患者床边。临床医生和 / 或采血师可利用任何标准化技术对患者身体的所述部分（例如，血管）执行静脉穿刺（或采用任何其他获得患者体液的方法）。在静脉穿刺之后，临床医生和 / 或采血师可采集全部样本所需的总血液体积。例如，临床医生和 / 或采血师可采集 2.5mL 前样本转移体积并为四个样本储存器中的每个采集 10mL 样本体积，总计采集 42.5mL 体液（例如，血液）。在采集了期望量的体液之后，可从患者身体的所述部分（例如，血管）移走皮下注射针头，并且临床医生和 / 或采血师可将外壳 901（其包含体液）放置在 4 组式（或 2 组式）预消毒的样本储存器上方，所述样本储存器具有被预先放置在匹配外壳 901 的几何形状的定制托盘中的隔膜顶部。通过利用这种预消毒的一组样本储存器，临床医生不必执行用消毒试剂“擦拭”样本储存器顶部的过程步骤，由此减小的污染的可能性（例如，如果不适当地和不足地消毒储存器的顶部的话）。然后，临床医生和 / 或采血师可在准确地控制体积的情况下启动将体液自动移入样本储存器。在某些实施例中，在完成样本储存器的移入之后，可将显示每个单独样本储存器的体积信息的整个装置 900 送到实验室以便分析。在其他实施例中，样本储存器 980 和 / 或 990 可被单独移开并被送到实验室以便分析。

[0184] 尽管参照图 46-53 示出和描述了采集装置 900 包括可显示与被传送通过采集装置的一部分的体液的体积相关的体积数据的一组显示器 975 和 975’，但在其他实施例中，采集装置可包括具有任何合适的输出指示器的任何合适的流计量机构。例如，图 54 和 55 图示了根据实施例的转移机构 1020 和流控制器 1040。转移机构 1020 和流控制器 1040 在形式和功能上可分别与转移机构 920 和流控制器 940 大体类似。因此，在此不进一步详细描述类似部分。但是，转移机构 1020 和流控制器 1040 可在一组显示器 1075 的布置上不同。例如，转移机构 1020 包括被配置为可移动地接纳一组可移动构件 1050a、1050b、1050c 和 1050d 的外壳 1001，可移动构件可各自包括上文参照可移动构件 950 描述的流计量机构。因

此，可移动构件 1050a、1050b、1050c 和 1050d 可用于确定从其中传送通过的体液的准确体积。如图 55 所示，外壳 1001 的显示器 1075 可包括一组三个灯，第一灯对应小体积（例如，5mL）、第二灯对应中间体积（例如，20mL），并且第三灯对应可接受的和 / 或大体积（例如，40mL）。以此方式，当体液流通过流控制器 1040 和转移机构 1020 被传送到例如第一可移动构件 1050a 时，包括在其中的流计量机构可向显示器发送信号灯，显示器能够根据传送通过可移动构件 1050 的体液的体积点亮第一灯、第二灯和 / 或第三灯。

[0185] 在其他实施例中，可移动构件 1050a、1050b、1050c 和 1050d 可相对于外壳 1001 从第一位置移动到第二、第三或第四位置。在这类实施例中，位置可与例如待被传送到样本储存器的体液的目的体积相关。例如，在一些实施例中，使用者可将可移动构件 1050a 从其第一位置致动（例如，移动）到其第二位置。在这类实施例中，第二位置可与例如待被传送到样本储存器的小体积体液（例如，10mL）相关。在一些实施例中，外壳 1001 和 / 或可移动构件 1050a 可包括棘爪、锁、搭扣、突起和 / 或凹口等，它们可暂时保持可移动构件 1050a 处于第二位置，直到所述小体积的样本已被传送到样本储存器。此外，一旦位于第二位置，显示器 1075 就可被配置为点亮与小体积相关的第一灯，以向使用者指示待传送到样本储存器的体液的预设体积。一旦期望体积的体液被传送到样本储存器并被流体隔离在其中，转移机构 1020 就可被配置为使可移动构件 1050a 自动返回其第一位置。以此方式，转移机构 1020 和流控制器 1040 可物理地和流体地耦接到任意数量的样本储存器并用于将准确体积的体液传送到每个样本储存器。

[0186] 图 56 是图示利用流计量传送装置从患者获得预定样本体积的体液的方法 1190 的流程图。流计量传送装置可以是本文描述的任何传送装置（在此也被称作“采集装置”）。例如，在一些实施例中，传送装置可以是上文参照图 46-53 描述的采集装置 900。因此，传送装置可包括具有被配置为与患者选择性地流体连通的入口端口的转移机构、前样本储存器和样本储存器以及被配置为计量从患者流到前样本储存器和样本储存器的体液流的流计量机构。方法 1190 包括在步骤 1191 在患者和流计量传送装置之间建立流体连通。例如，端口可流体耦接到针头或其他内腔限定装置（例如，柔性无菌管），其继而可插入患者（例如，静脉穿刺事件或其他获得体液的方法）。

[0187] 当端口与患者流体连通时，在步骤 1192，在端口和前样本储存器之间建立流体连通。在一些实施例中，流计量传送装置可包括流控制器等（例如，诸如，采集装置 900 中包括的流控制器 940），流控制器等可被致动和 / 或被操纵（例如，旋转）到在端口和前样本储存器之间建立流体连通的位置（例如，第一位置）。在一些实施例中，致动流控制器可使得流控制器和转移机构共同限定端口和前样本储存器之间的流体流路径的至少一部分。在一些实施例中，前样本储存器可包括负压等，其可例如使体液流开始从患者流入前样本储存器。在其他实施例中，可以任何其他合适的方式（例如，重力等）使体液流开始流动。

[0188] 在步骤 1193，计量从患者传送到前样本储存器的体液流。例如，在一些实施例中，端口可包括可计量穿过端口的体液流的流控制机构（例如，以与上文参照采集装置 900 的流控制机构 967 描述的方式类似的方式）。因此，前样本体积的体液被传送到前样本储存器。方法 1190 包括在步骤 1194 包括经由流计量传送装置的流计量机构验证位于前样本储存器中的前样本体积的体液是预定前样本体积的体液。例如，流计量机构可以包括类似的显示器和 / 或可以可操作地耦接类似的显示器（例如，采集装置 900 的显示器 975 和 / 或

975’）。流计量机构可被配置为在显示器上显示体积信息，如上所述。

[0189] 在步骤 1195，一旦前样本体积的体液位于前样本储存器中，就使前样本储存器与端口流体隔离，以将前样本体积的体液隔绝在前样本储存器中。例如，在一些情形中，可将流控制器和 / 或转移机构从第一位置和 / 或配置致动（或旋转）到第二位置和 / 或第二配置。当流控制器和 / 或转移机构处于第二配置时，前样本储存器与前样本储存器外的空间流体隔离。在一些实施例中，在步骤 1196，当流控制器和 / 或转移机构被致动到其第二位置和 / 或配置时，在端口和样本储存器之间建立流体连通。例如，在一些实施例中，流计量传送装置可包括可移动构件（例如，可移动构件 950）等，其可包括被配置为刺穿样本储存器的一部分（例如，隔膜等）的刺穿构件。因此，当流控制器和 / 或转移机构处于其第二位置和 / 或配置时，刺穿样本储存器的所述部分会使样本储存器与端口流体连通。如上所述，样本储存器可包括可例如使体液流开始从患者流入样本储存器的负压等。

[0190] 在步骤 1197，计量从患者传送到前样本储存器的体液流。例如，如上所述，端口可包括可计量穿过端口的体液流的流控制机构（例如，以与上文参照采集装置 900 的流控制机构 967 描述的方式类似的方式）。在一些实施例中，流控制机构可包括在例如可移动构件等中，诸如图 49 的可移动构件 950。因此，样本体积的体液被传送到样本储存器。方法 1190 包括在步骤 1198 包括经由流计量传送装置的流计量机构验证位于样本储存器中的样本体积的体液是预定样本体积的体液。例如，显示器等可被配置为显示体积信息，如上所述。

[0191] 以此方式，采集了可包含例如外部驻留微生物的预定前样本体积的体液。例如，在一些实施例中，预定前样本体积可以是约 0.1mL、约 0.3mL、约 0.5mL、约 1.0mL、约 2.0mL、约 3.0mL、约 4.0mL、约 5.0mL、约 10.0mL、约 20mL、约 50mL 和 / 或其之间的任何体积或分数体积。在其他实施例中，前样本体积可大于 50mL 或小于 0.1mL。在其他实施例中，预定前样本体积可在约 2mL 和约 5mL 之间。在一个实施例中，预定前样本体积可为约 3mL。此外，通过采集预定前样本体积，位于一个或多个样本储存器中的预定样本体积可大体不存在外部驻留微生物。在一些实施例中，预定样本体积可在 10mL 和 60mL 之间。在其他实施例中，预定样本体积可在 30mL 和 60mL 之间。在其他实施例中，预定样本体积可为 60mL。尽管上文描述了将样本体积的体液传送到单个样本储存器，但在其他实施例中，流计量传送装置可用于将预定样本体积传送到多于一个样本储存器。例如，在一些实施例中，可将预定前样本体积的体液采集和流体隔离在前样本储存器中，如上所述。当前样本体积被流体隔离时，流计量传送装置可用于将预定样本体积传送到第一样本储存器，将预定样本体积传送到第二样本储存器以及将预定样本体积传送到第三样本储存器。在这类情形中，预定样本体积可以是例如 20mL，从而使得位于第一、第二和第三样本储存器中的总样本体积为 60mL。

[0192] 本文描述的体液采集装置的各个实施例可容许利用单次静脉穿刺采集两（或更多）组体液（例如，血液）样本。当前的医疗水平规定利用从不同的单独体液获取位置获得的样本（例如，经由两次单独的静脉穿刺，经由导管和静脉穿刺和 / 或其任意组合）进行某些测试（例如，血液培养）。本文描述的实施例可帮助从单个体液获取位置（例如，静脉穿刺）获得用于特定诊断测试（例如，血液培养测试）的多个样本，这可将获得这些样本所需的静脉穿刺年度次数降至原来的 1/2。这以类似的方式有益于患者和医疗保健行业从业者。减少静脉穿刺（和 / 或其他体液获得过程）的次数可显著降低针头刺伤医疗保健行业从业者的风险，并减少由这些过程导致的患者的相关并发症（例如，血肿、血栓、静脉炎、感

染等）。此外，减少体液获得过程（例如，静脉穿刺）的数量减少了与这些过程相关的补给、人力和废物。医疗保健系统实现的成本降低是重大的并且给出了更高效地使用资源以及改进患者结果的机会，这是因为提高了样本的完整性，由此产生更准确的患者诊断，鼓励治疗计划的形成和执行。体液采集装置还显著降低了在采集后分析中产生错误阳性结果的可能性。本文描述的体液采集装置还可简化体液采集过程并减少手动步骤和“接触点”的数量，由此降低外部污染的可能性。本文描述的装置还可最小化实验室技术人员和/或采血师被针头刺伤和感染的风险。

[0193] 在一些实施例中，本文描述的体液采集装置（例如，100、200、300、400、500、600、700、800 和 900）可包括抗菌饱和材料和/或部分地由该材料形成（例如，外壳 401）。当前水平依靠医疗保健行业从业者将各个抗菌材料（例如，异丙醇棉签）放置在各个样本储存器（例如，480、480’、490 和 490’）顶部。为了确保服从此准则，装置 400（例如）可包括位于装置 400 内的抗菌材料，从而使得当外壳 401 位于 4 组式（或 2 组式）瓶的顶部时，如图 16 所示，外壳 401 与样本储存器 480、480’、490 和 490’ 的顶部最先接触的点是抗菌材料。以此方式，可确保在将体液移入样本储存器之前合适地消毒样本储存器 480、480’、490 和 490’ 的顶部。

[0194] 尽管已经具体地示出和描述了各种实施例，但可对形式和细节进行各种改变。例如，尽管参照图 19-22 示出和描述了沿单个方向选择转盘 445（致动器），但在其他实施例中，可沿第一方向和与第一方向相反的第二方向旋转转盘 445（致动器）。在这类实施例中，沿第二方向的旋转可被配置为使采集装置移动通过任意数量的配置。在其他实施例中，可限制致动器沿第二方向的旋转。在一些实施例中，转盘可包括机械止动件或锁，以流体隔离从患者接收的第一体积的体液（即，受污染的样本）。换言之，一旦第一储存器（前样本储存器）被填充以预定体积的体液并且使用者已经旋转转盘（致动器）以开始抽入额外的样本，转盘（致动器）就不能向后移动以与第一样本体积（包含在前样本储存器中）建立流体连通。

[0195] 尽管上文已经描述了实施例，但是应该理解，它们仅是以举例方式给出的，并且不受限制。虽然各个实施例已经被描述为具有特定的特征和/或部件的组合，但其他实施例可具有来自本文描述的任何实施例的任何特征和/或部件的任意组合或子组合。例如，尽管参照图 34-40 示出和描述了采集装置 700 具有第一、第二、第三、第四或第五配置，但在其他实施例中，本文描述的采集装置可具有更多或更少的配置。此外，尽管参照图 2-13 示出和描述了采集装置 200 具有作为前样本储存器 270 的基于真空的采集管，但在其他实施例中，采集装置 200 可具有被容纳在外壳 201 中的腔，类似于图 16-22 给出的实施例的采集装置 400，其包括作为被容纳在分配构件 429 内的腔的前样本储存器 470，反之亦然。

[0196] 还可以改变各个部件的特定配置。例如，各个部件的尺寸和特定形状可与所示实施例不同，但仍提供如本文所述的功能。更具体地，可具体选择各个部件的尺寸和形状，以使体液流以期望速率流入流体储存器。此外，尽管图 49 具体示出了流计量机构 967，但本文描述的任何采集装置可与任何合适的流计量机构一起使用。例如，在一些实施例中，采集装置可包括流计量机构和/或被配置为测量体液的体积特征的任何其他机构、装置或方法，诸如，例如，压力传感器、电压传感器、光学传感器、速度传感器、流计量器、应变仪、阀、涡轮机、浮子、位移分析、密度分析、重量分析、光学分析、超声波分析、热能分析、多普勒分析、电

磁场 (emf) 分析、反射分析、障碍分析、面积分析、文丘里管分析、科里奥利分析、视觉分析和 / 或任何其他合适的传感器、分析法和 / 或计算法 (例如，应用和 / 或利用例如波义耳定律、理想气体定律和 / 或力计算法 (力＝质量＊加速度))。

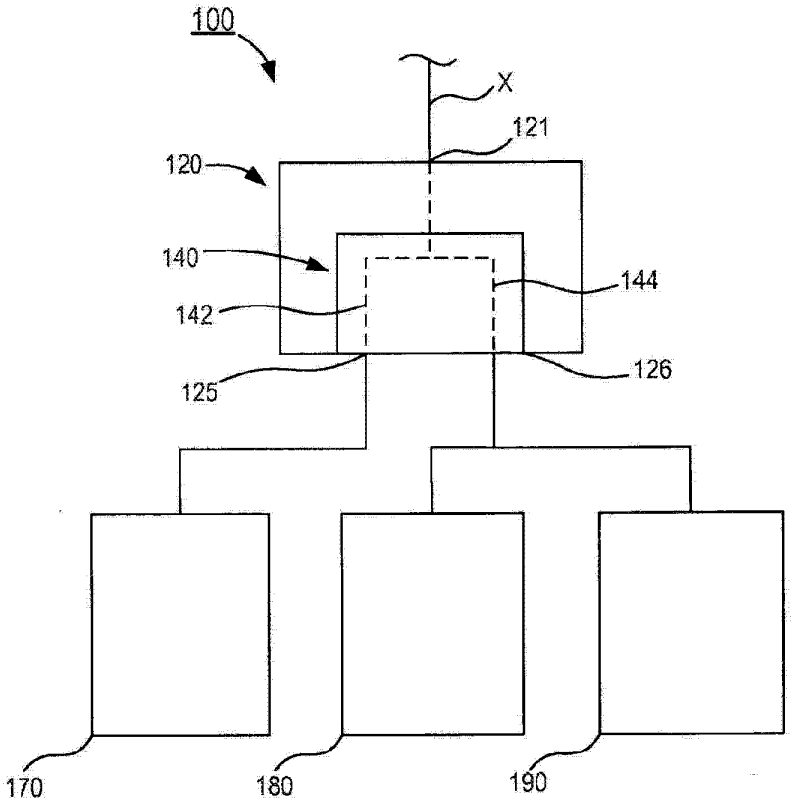


图 1

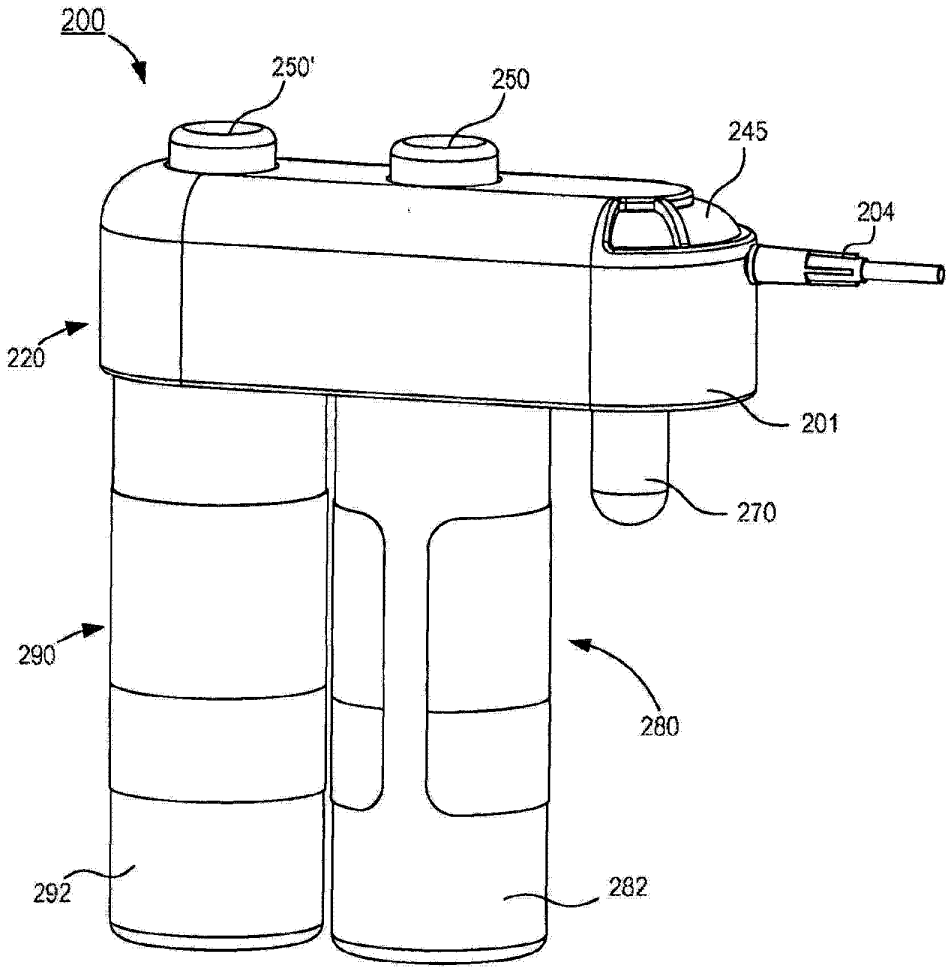


图 2

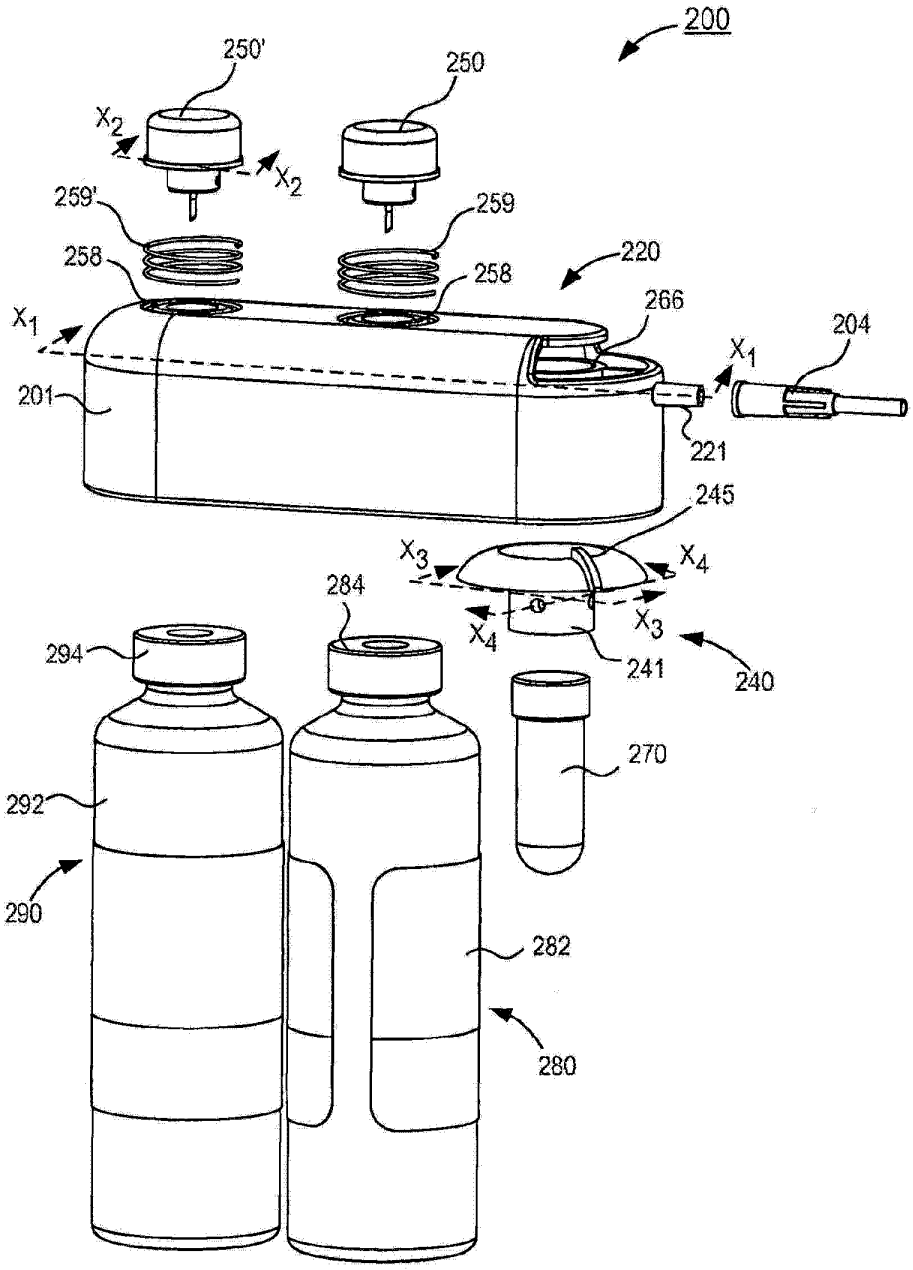

200
250'
250
X2
X2
259'
259
258
258
220
266
X1
X1
204
201
221
245
X3
X4
284
X4
X3
294
241
240
270
292
290
282
280

图 3

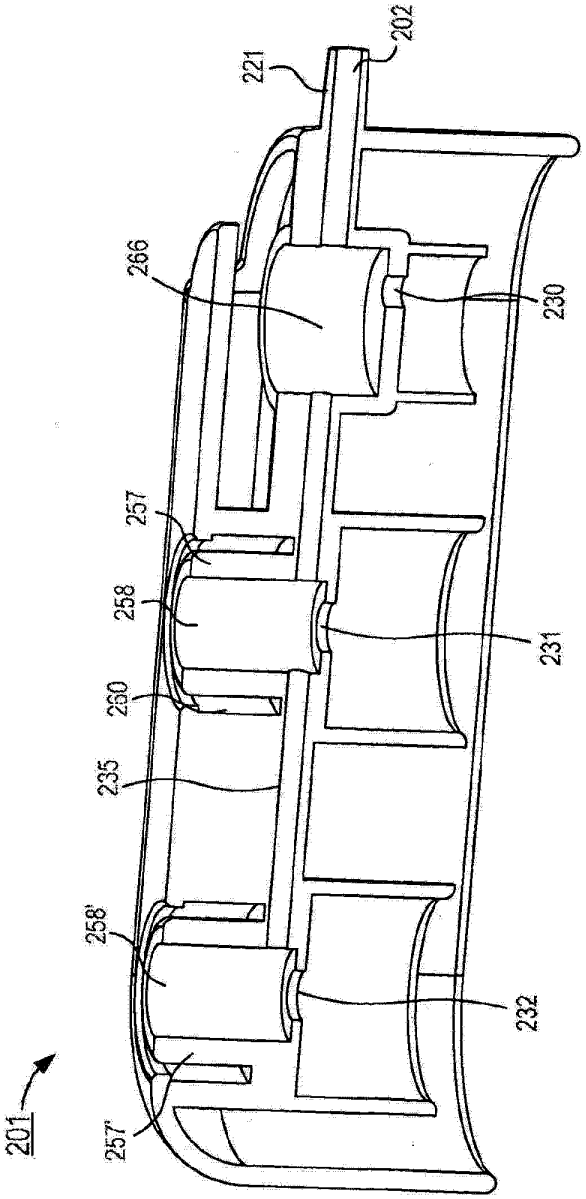


图 4

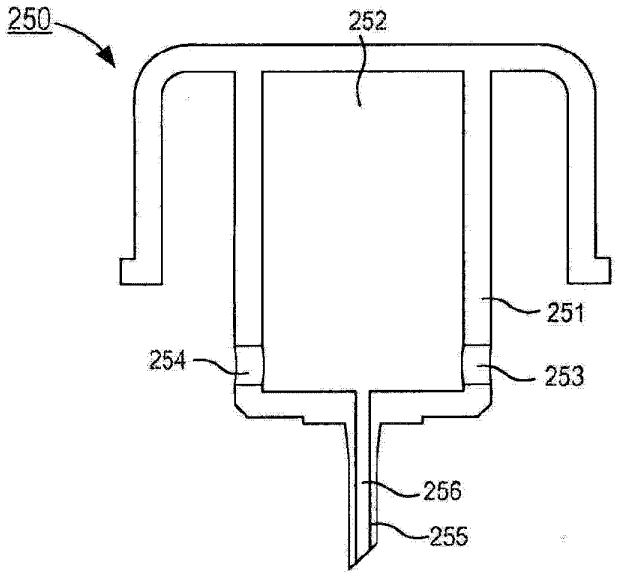


图 5

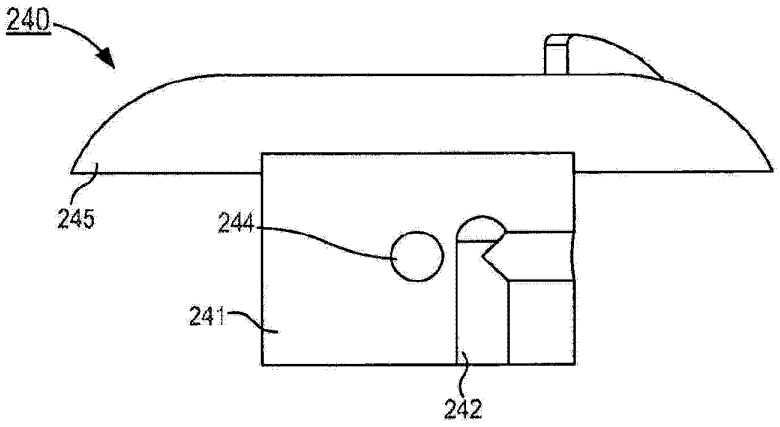


图 6

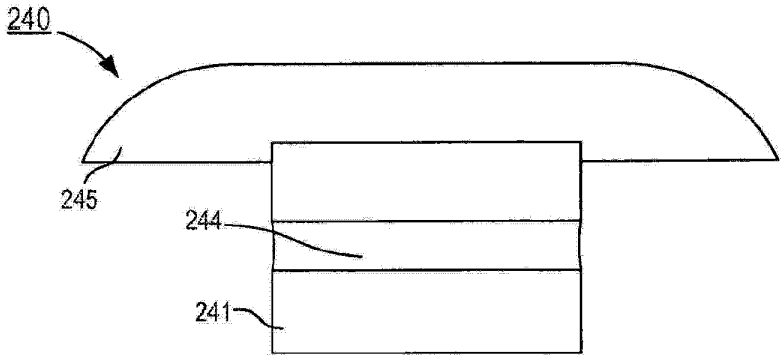


图 7

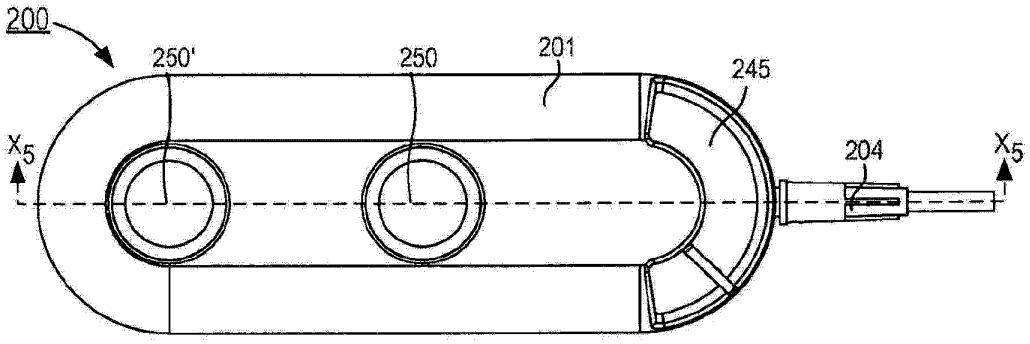


图 8

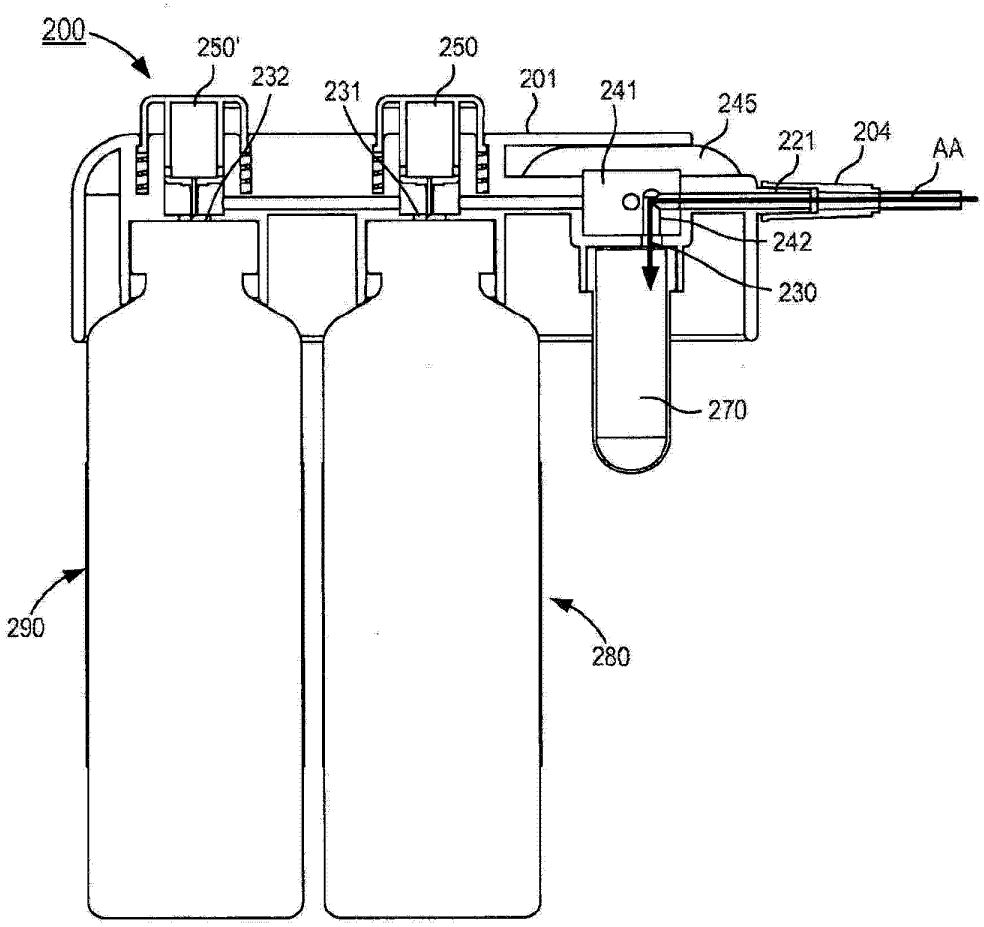

200
250'
232
231
250
201
241
245
221
204
AA
242
230
270
290
280

图 9

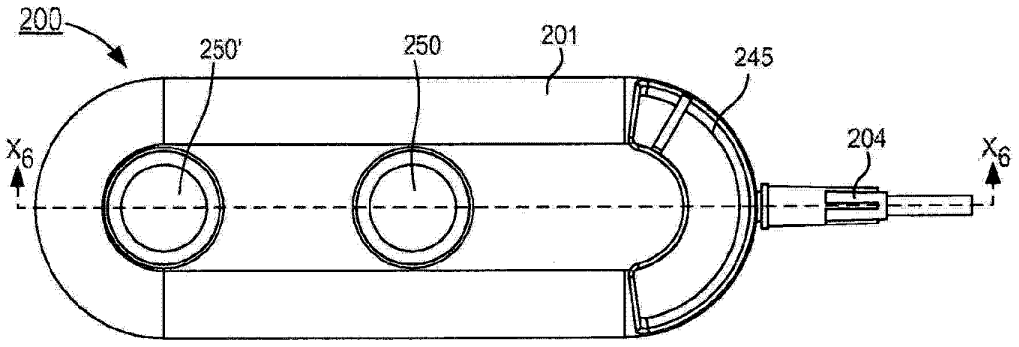

200
250'
250
201
245
204
X6
X6

图 10

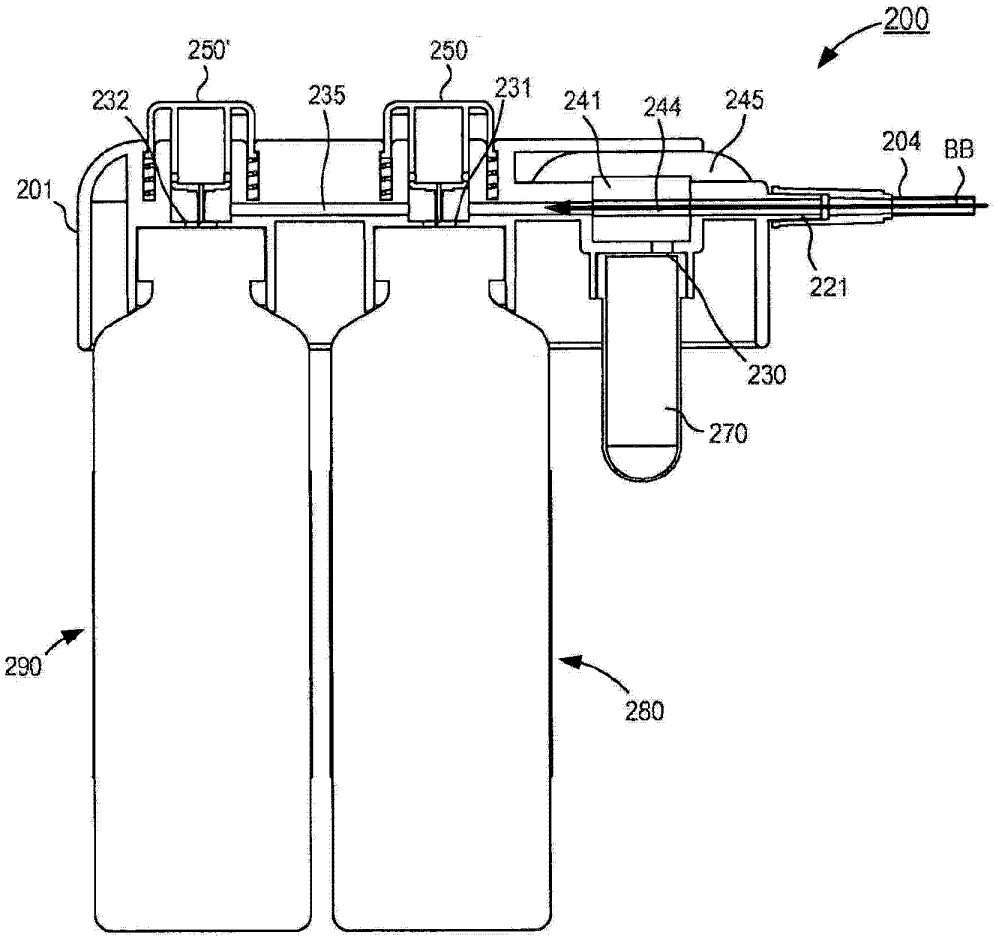
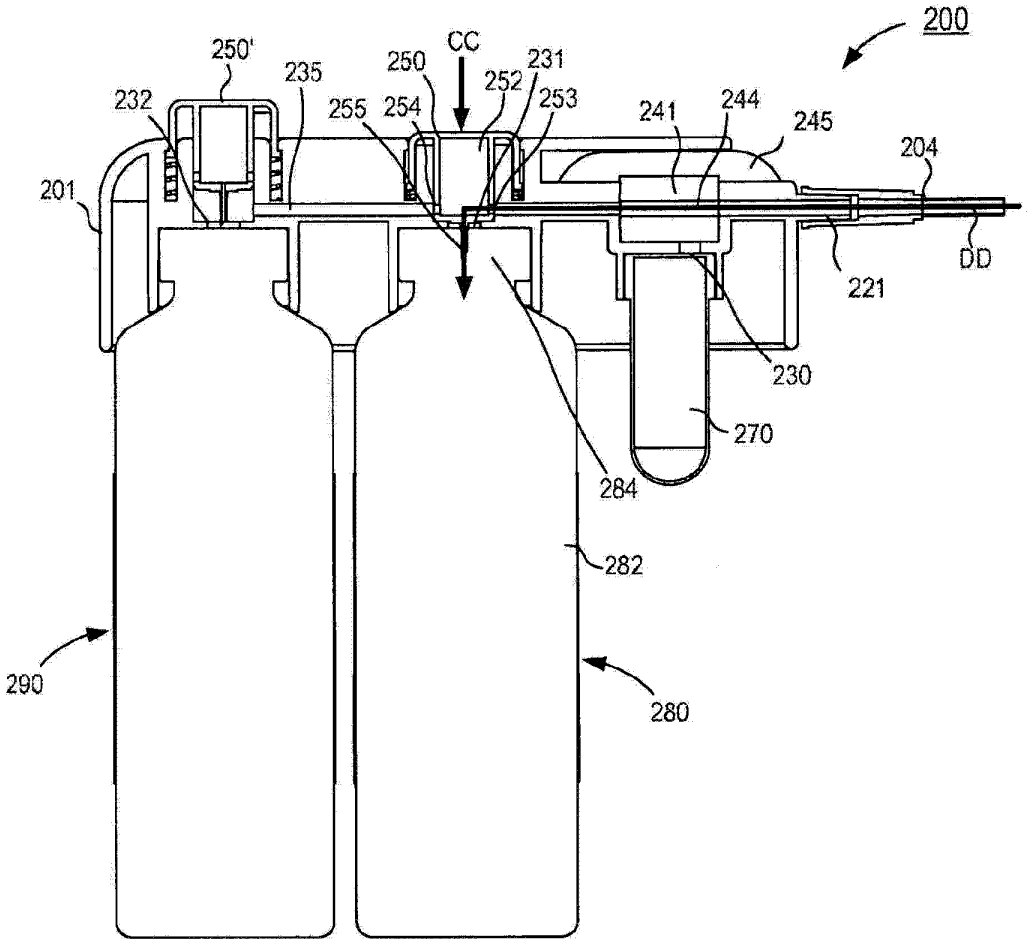

200
250'
250
232
235
231
241
244
245
204
BB
201
221
230
270
290
280

图 11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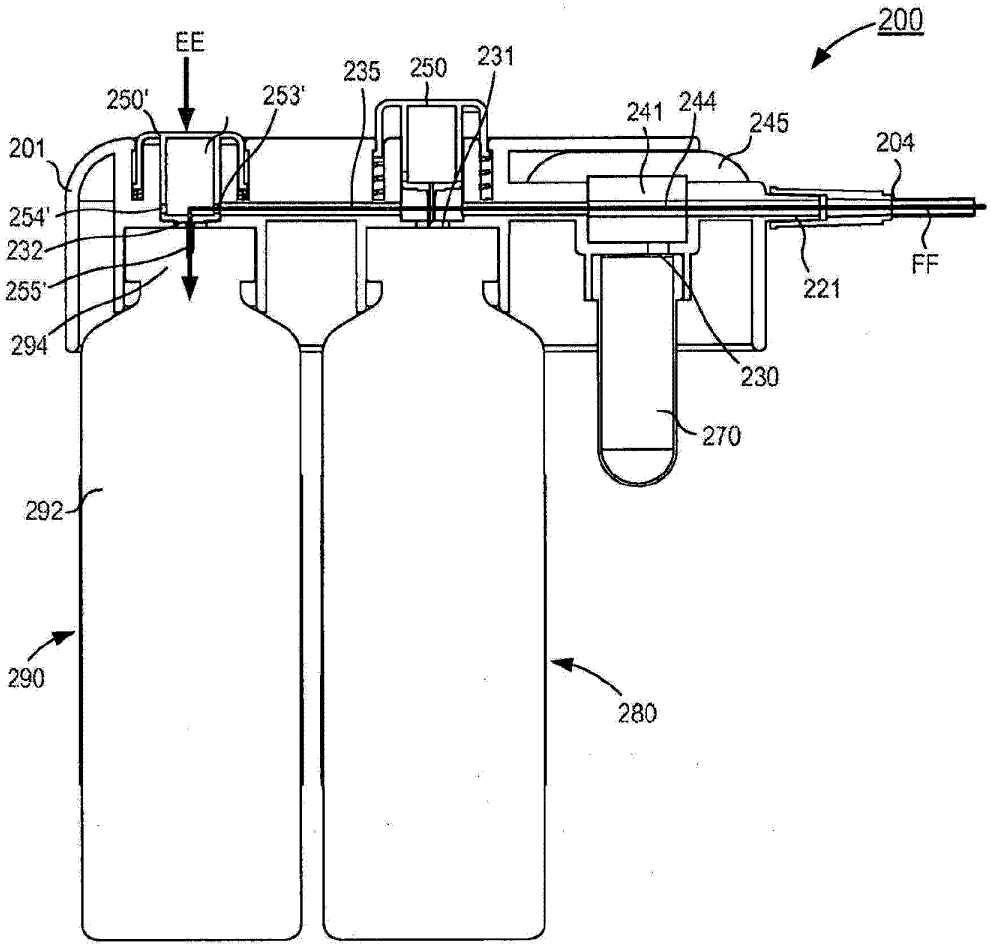
250'
235
CC
250
231
252
253
232
255
254
241
244
245
204
201
DD
221
230
270
284
282
290
280

图 12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EE
250'
253'
235
250
231
241
244
245
204
201
254'
232
255'
294
221
FF
230
270
292
290
280

图 13

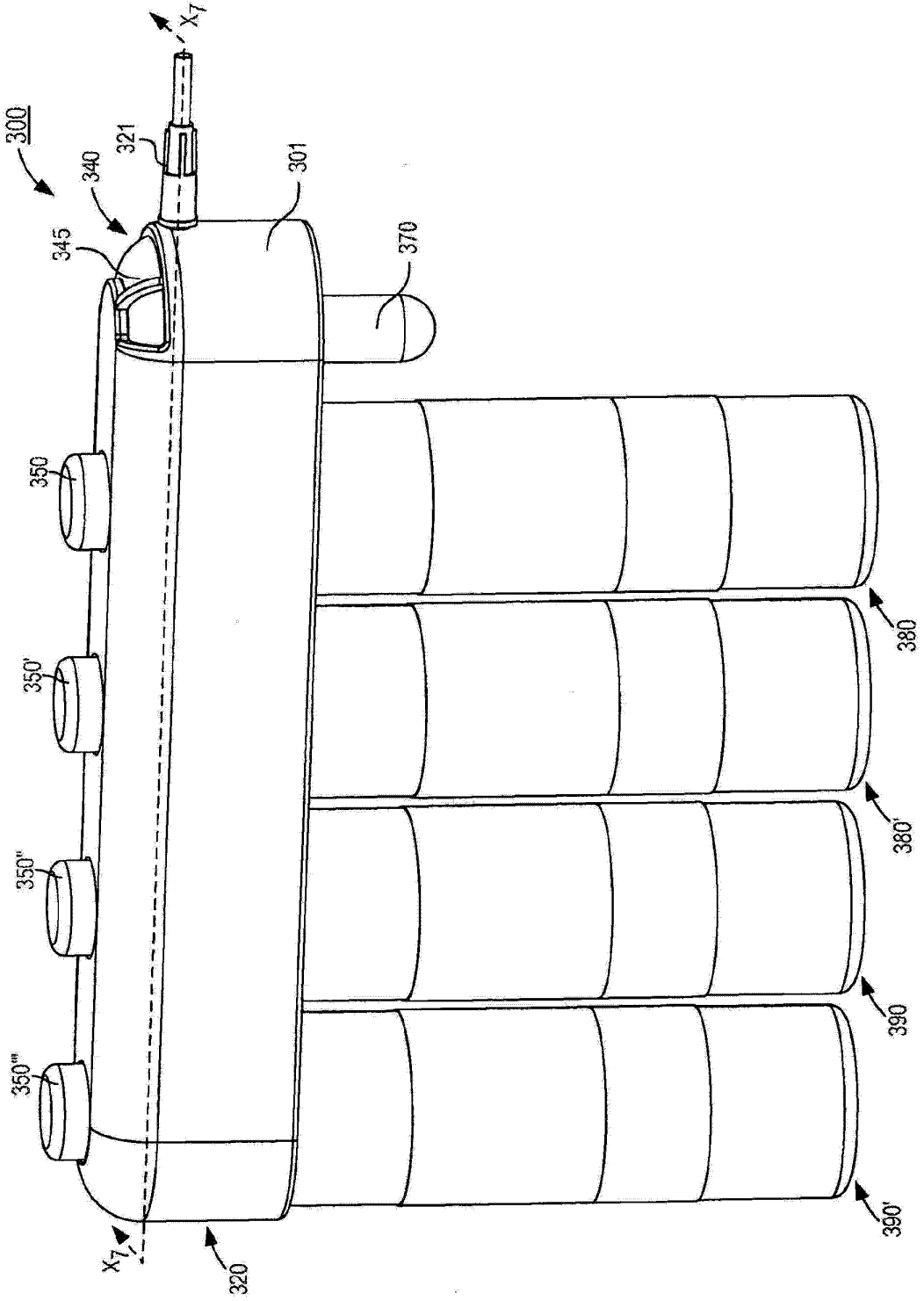


图 14

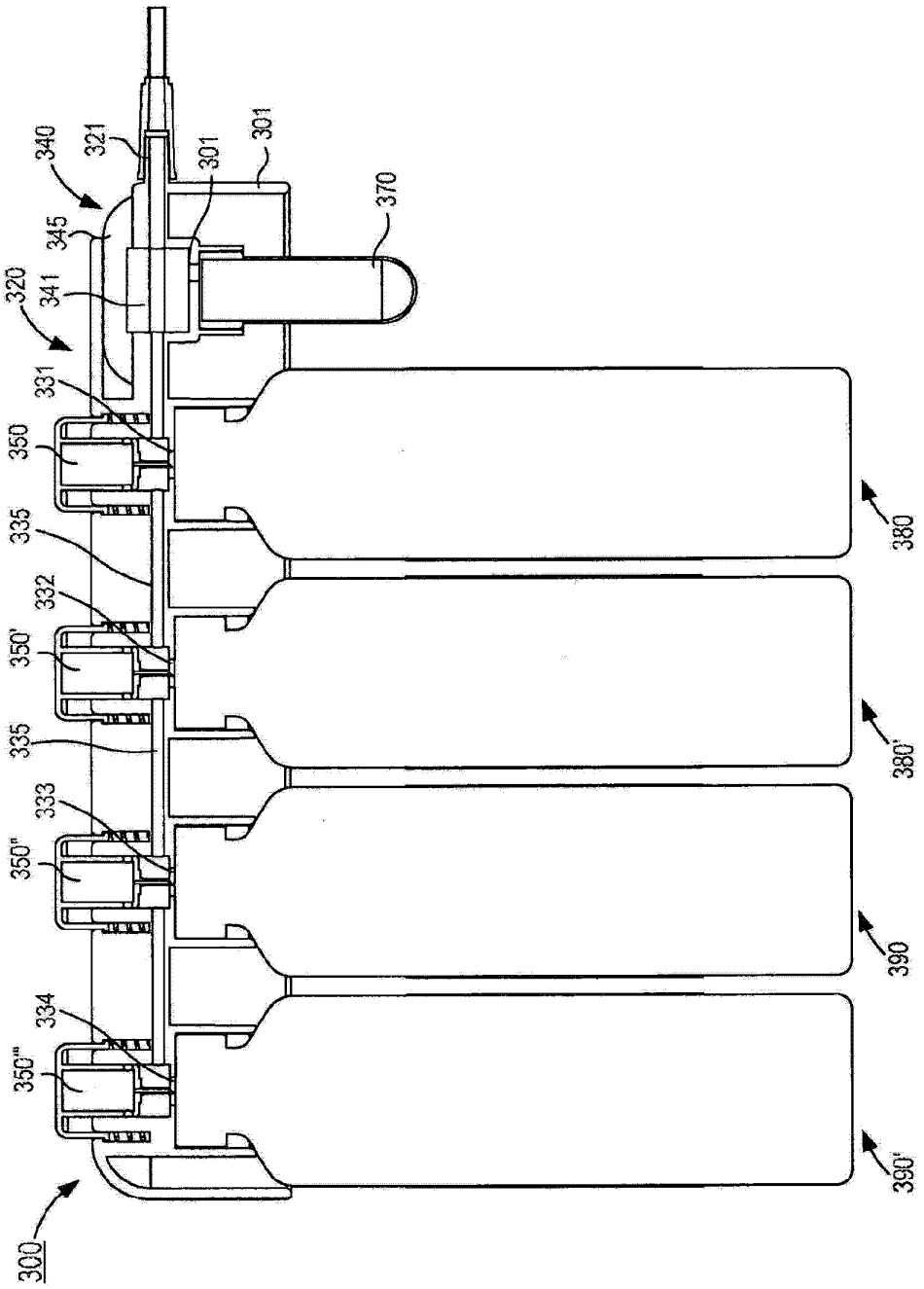

340
321
301
301
370
345
320
341
331
350
335
332
350'
335
333
350"
334
350'"
300
380
380'
390
390'

图 15

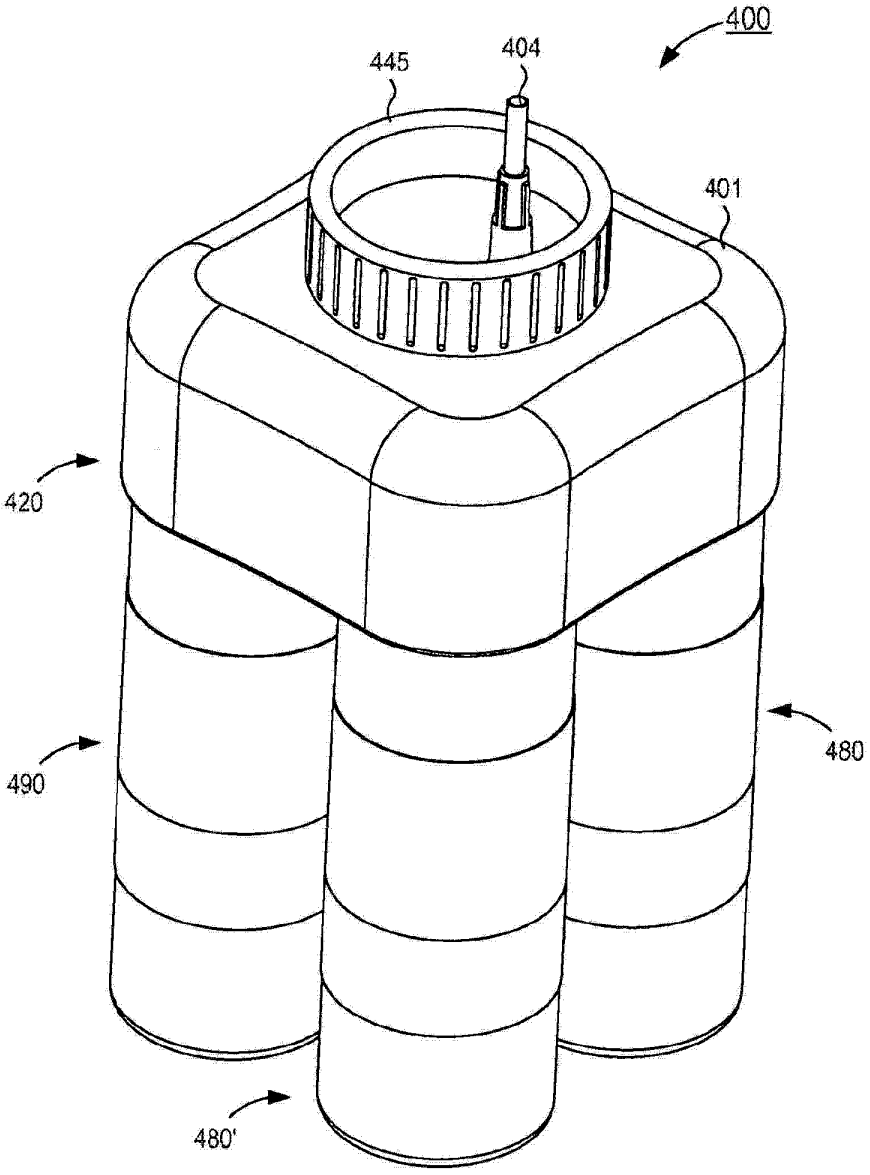


图 16

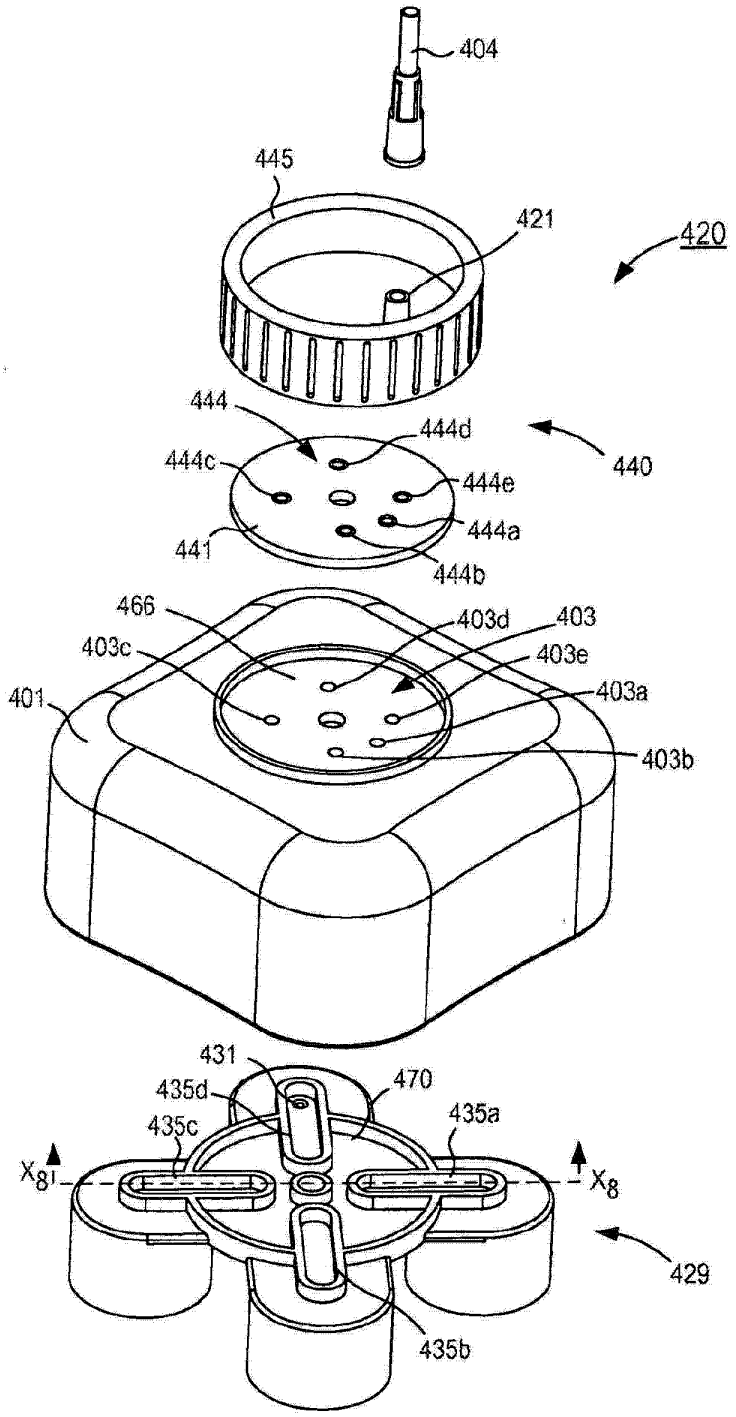

404
445
421
420
444
444d
440
444c
444e
444a
441
444b
466
403d
403
403c
403e
401
403a
403b
431
470
435d
435a
435c
X8
X8
429
435b

图 17

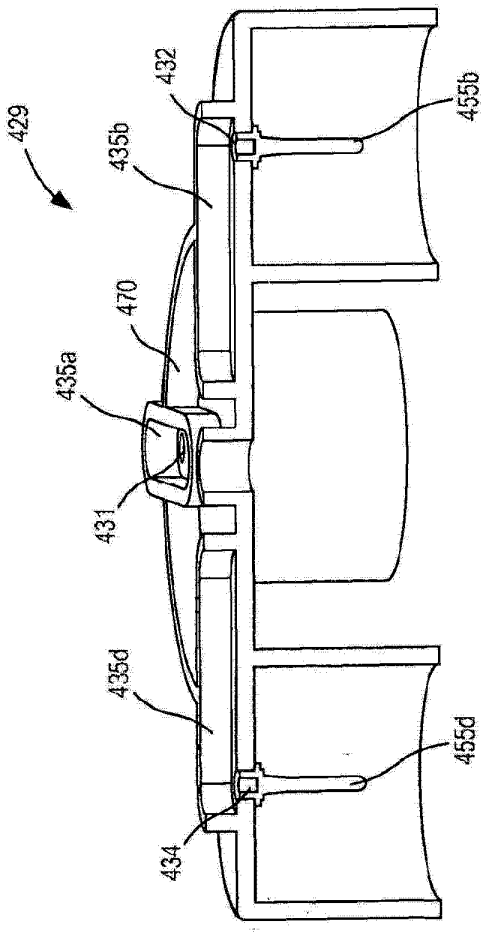


图 18

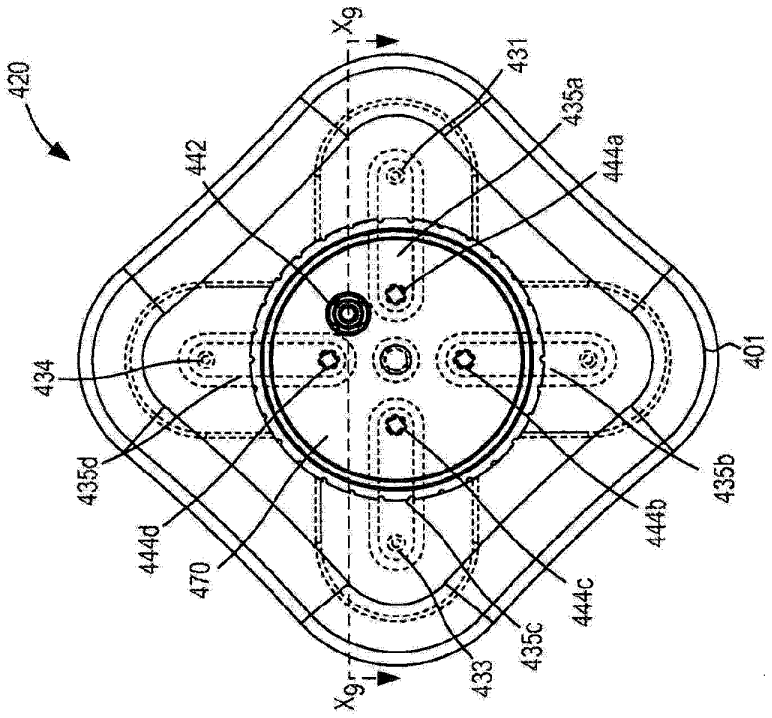

X9
420
431
435a
444a
442
434
401
435d
435b
444d
444b
470
444c
435c
433
X9r

图 19

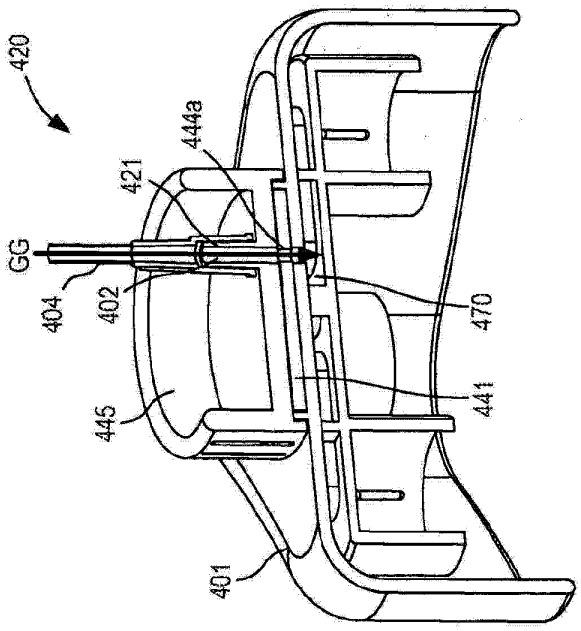

420
444a
421
GG
404
402
470
441
445
401

图 20

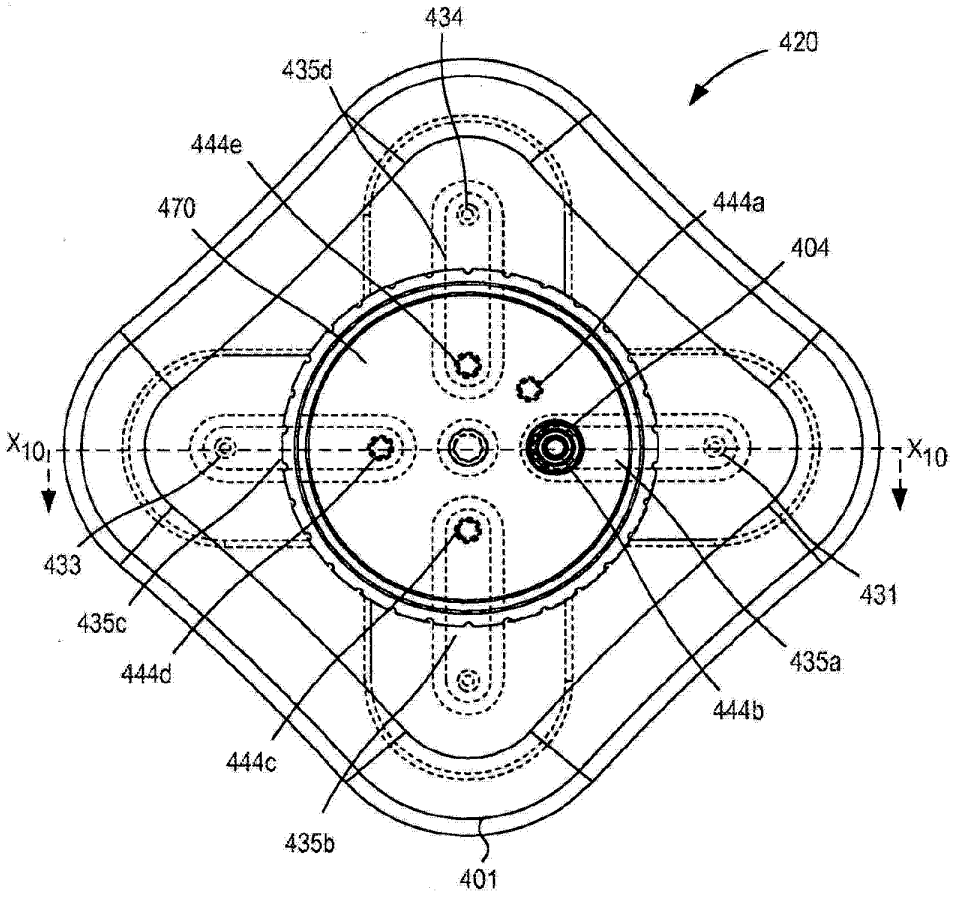

434
420
435d
444e
470
444a
404
X10
X10
433
431
435c
444d
435a
444b
444c
435b
401

图 21

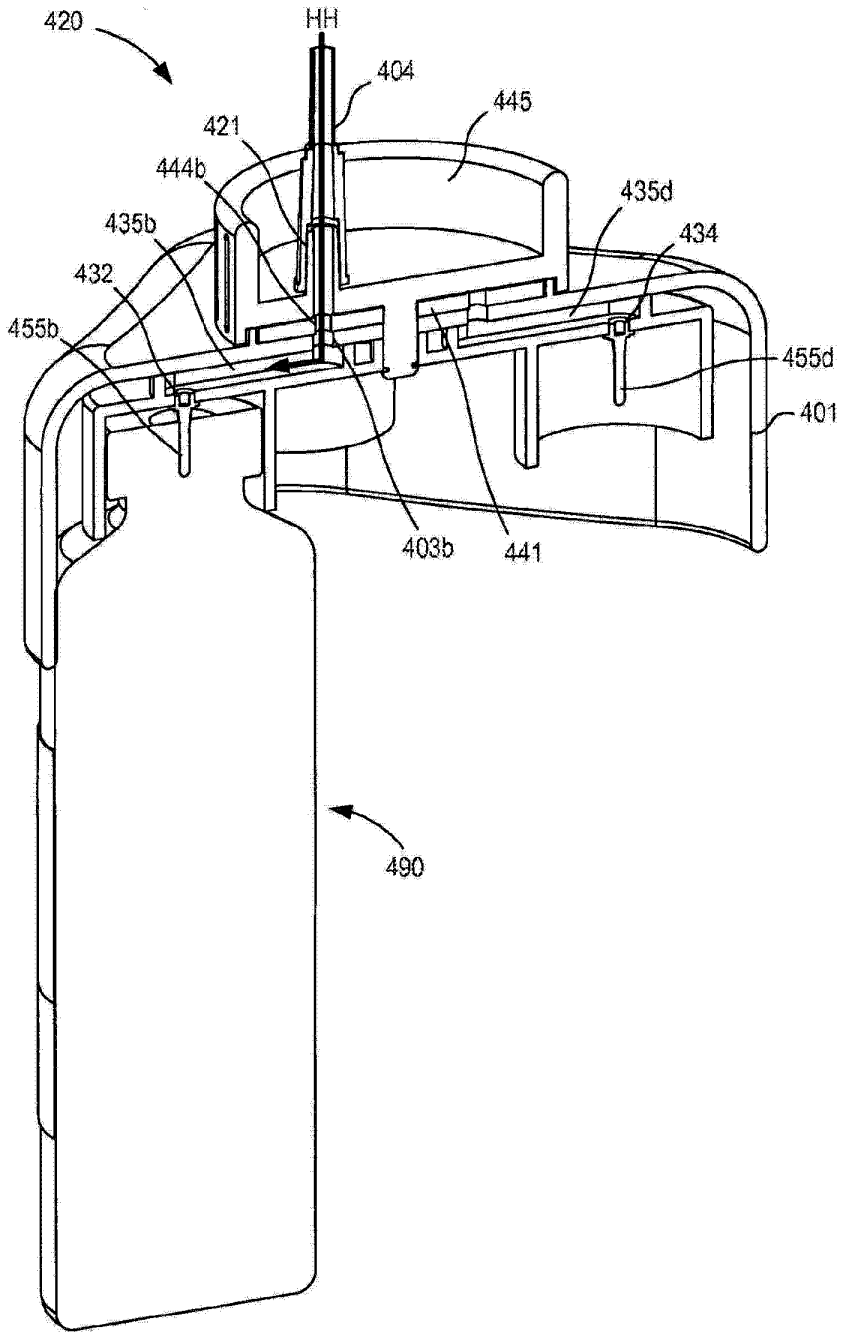

420
HH
404
445
421
444b
435d
435b
434
432
455b
455d
401
403b
441
490

图 22

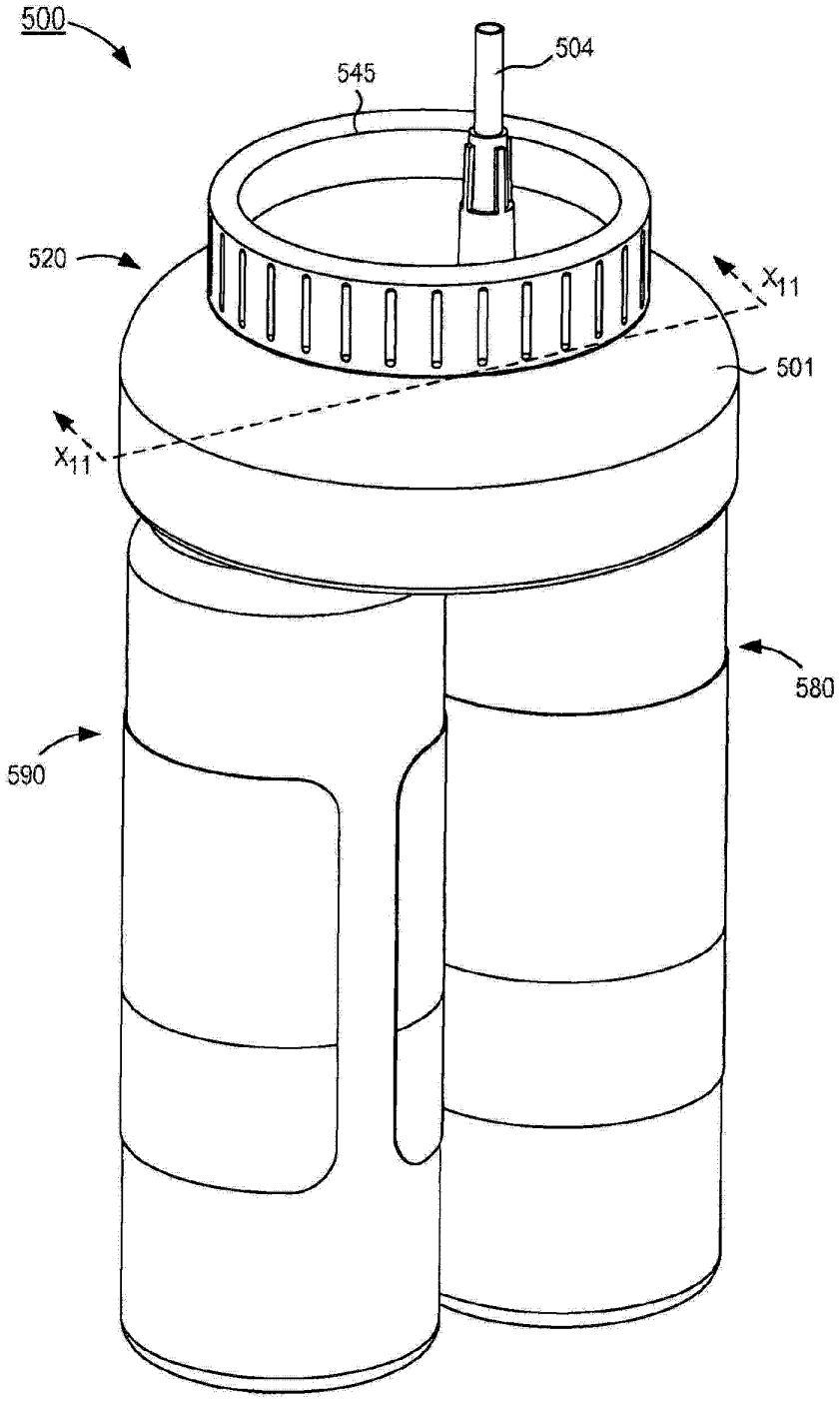


图 23

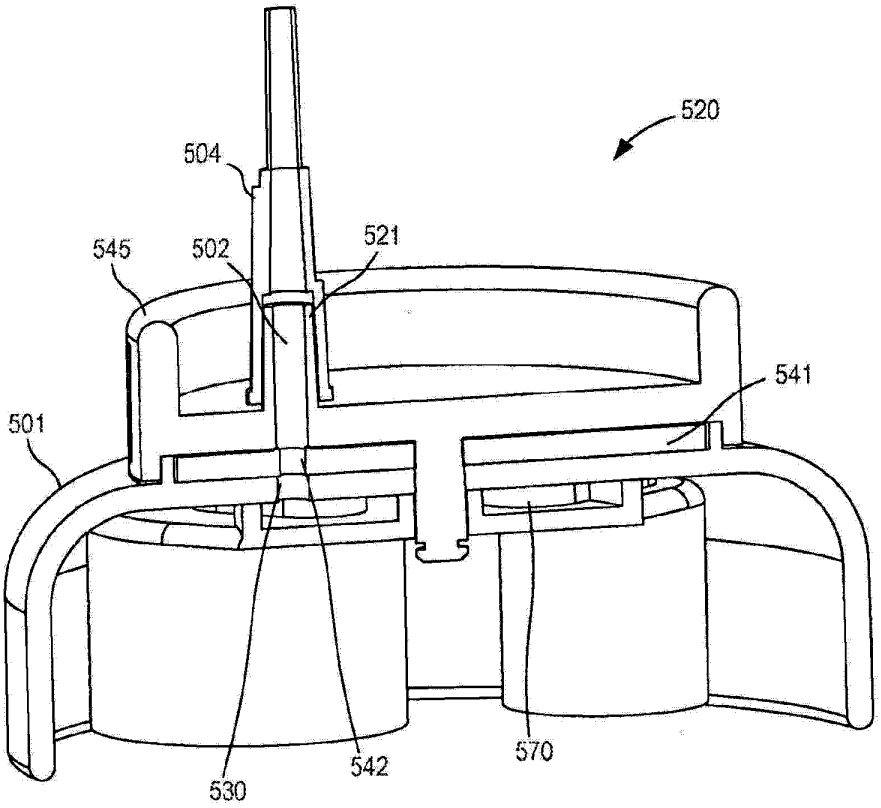
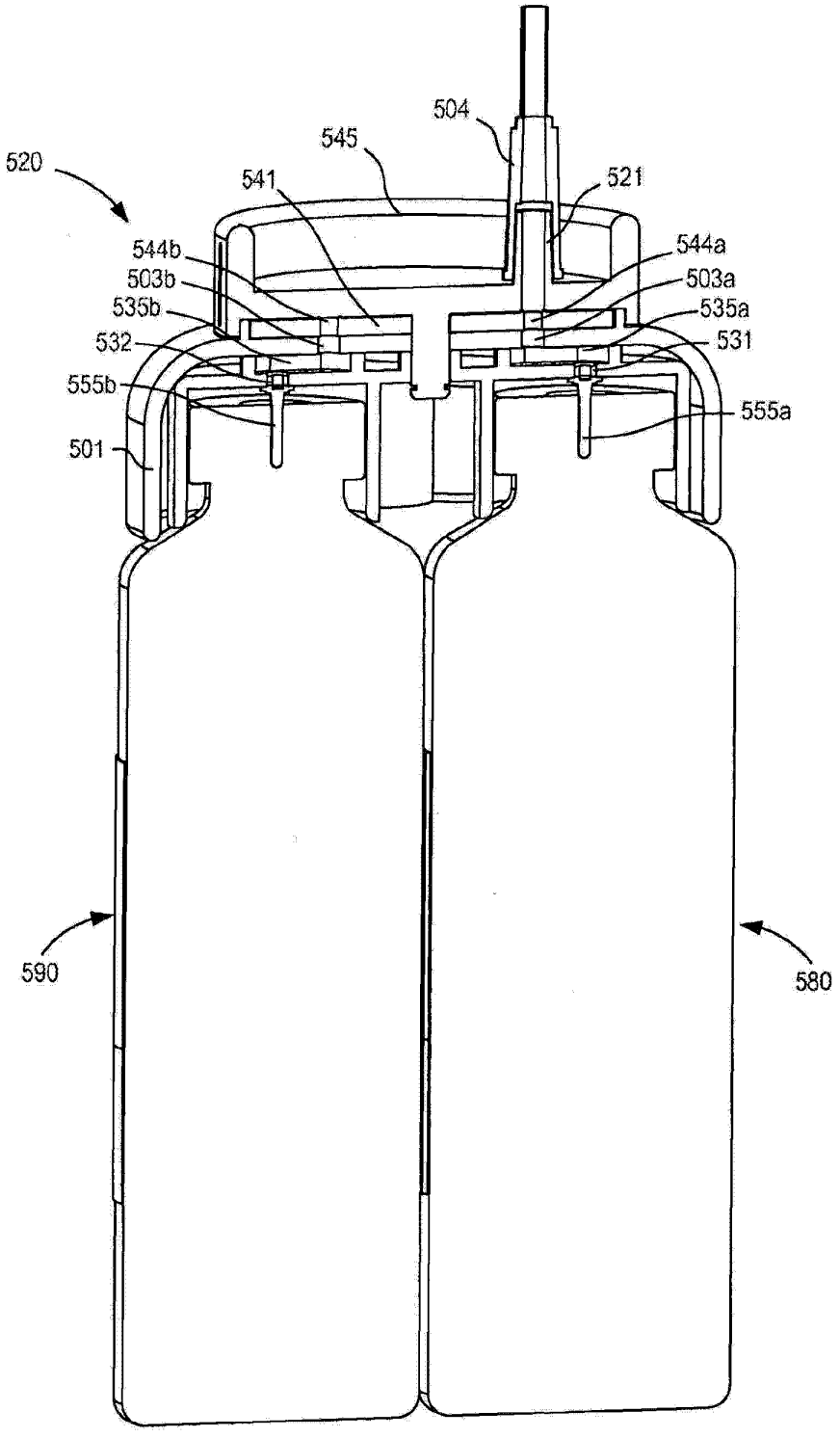


图 24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545
520
541
521
544b
544a
503b
503a
535b
535a
532
531
555b
555a
501
590
580

图 25

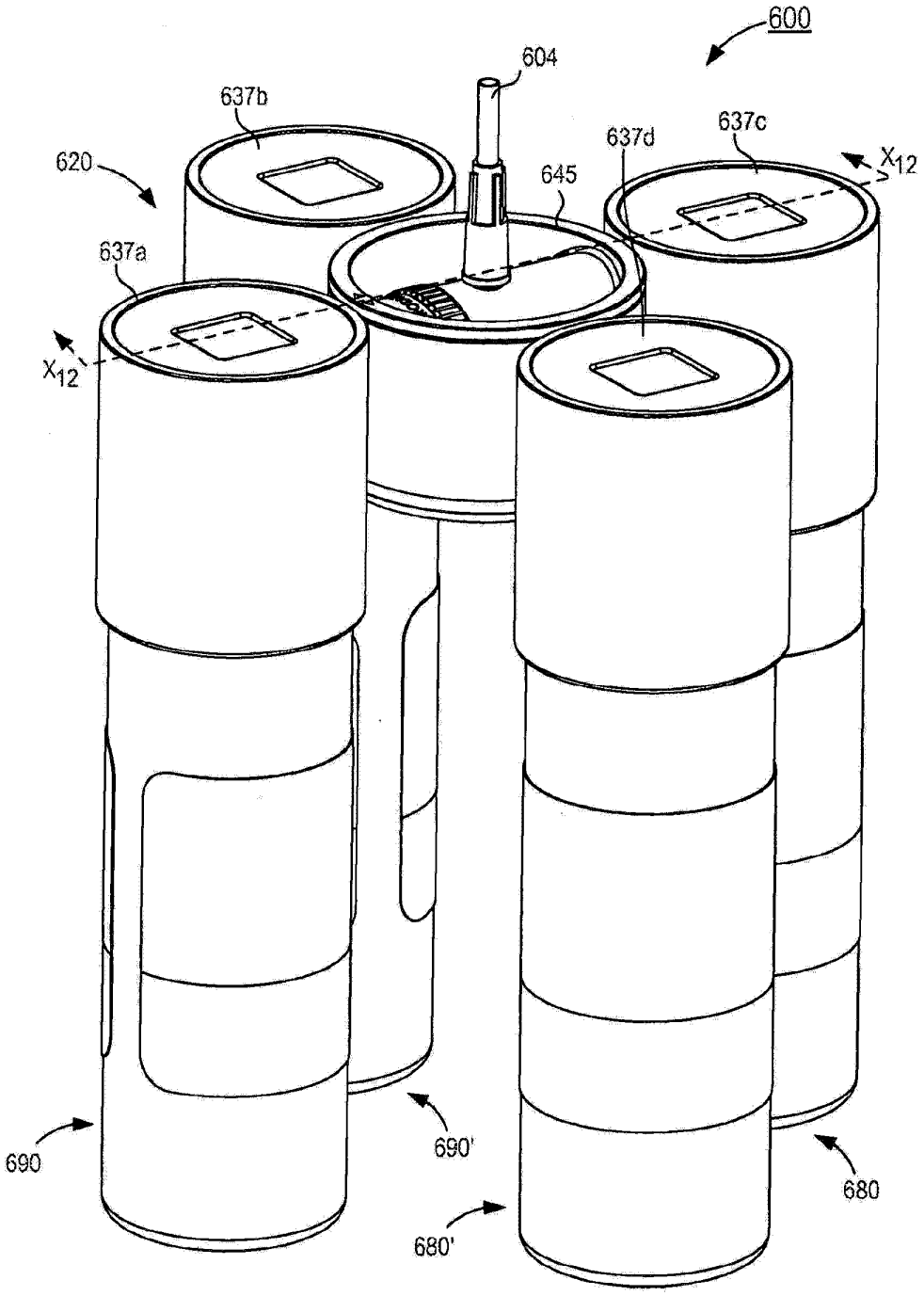
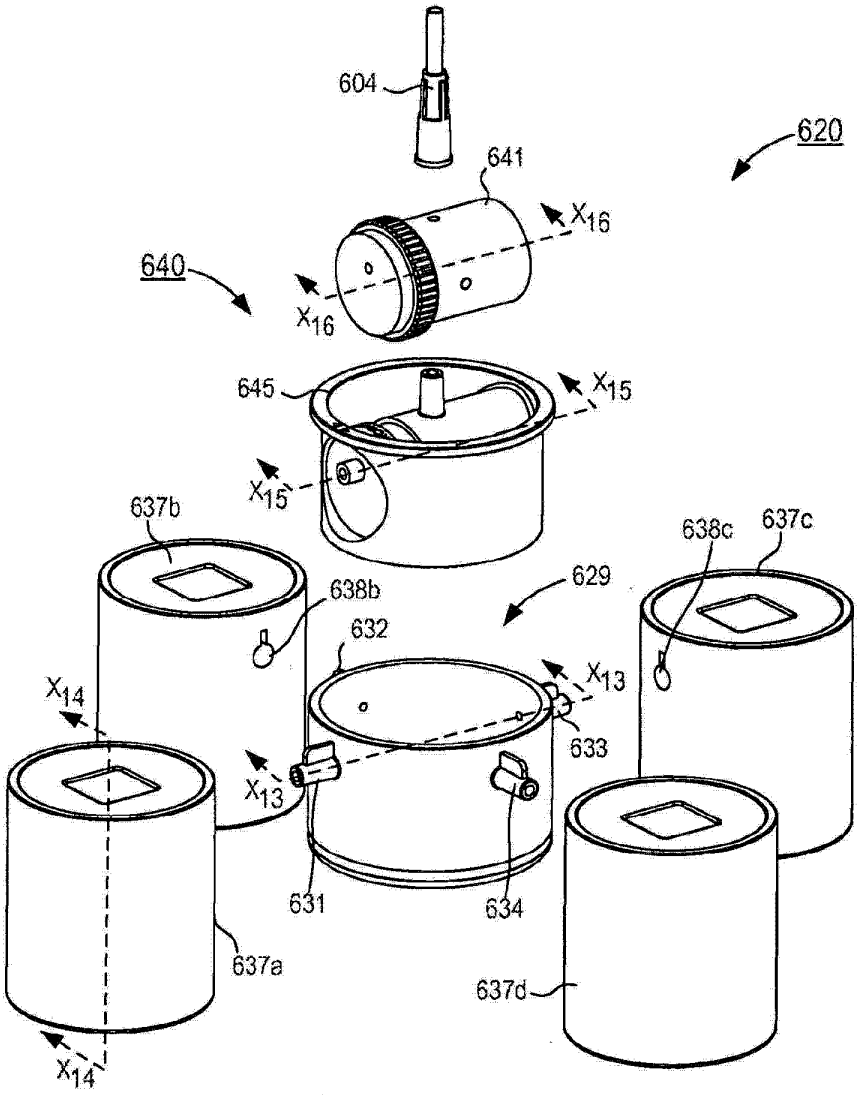


图 26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620
641
X_{16}
640
X_{16}
645
X_{15}
X_{15}
637b
638c
637c
638b
629
632
X_{14}
X_{13}
633
X_{13}
631
634
637a
637d
X_{14}

图 27

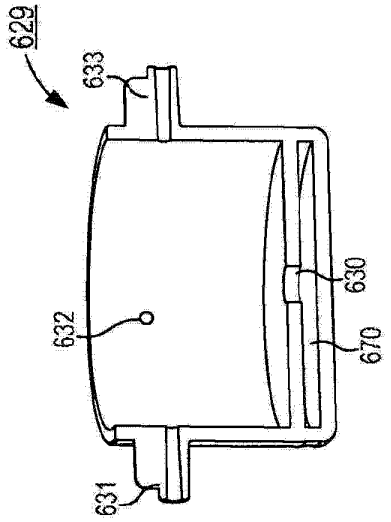


图 28

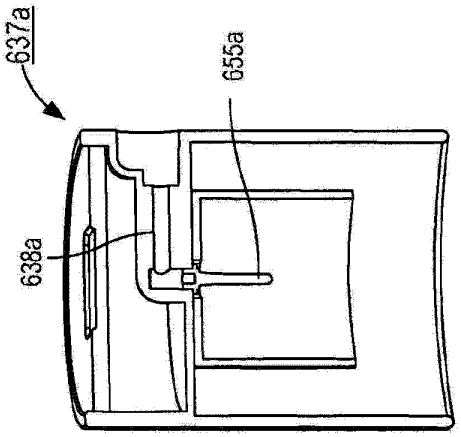


图 29

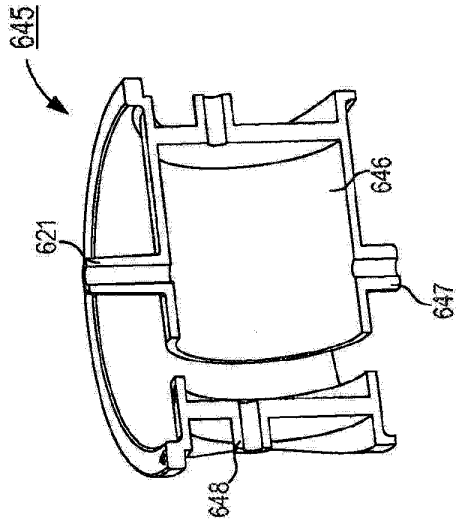


图 30

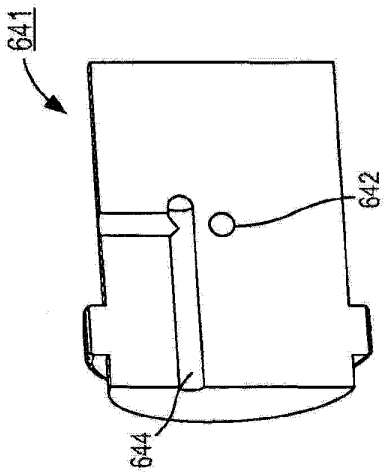
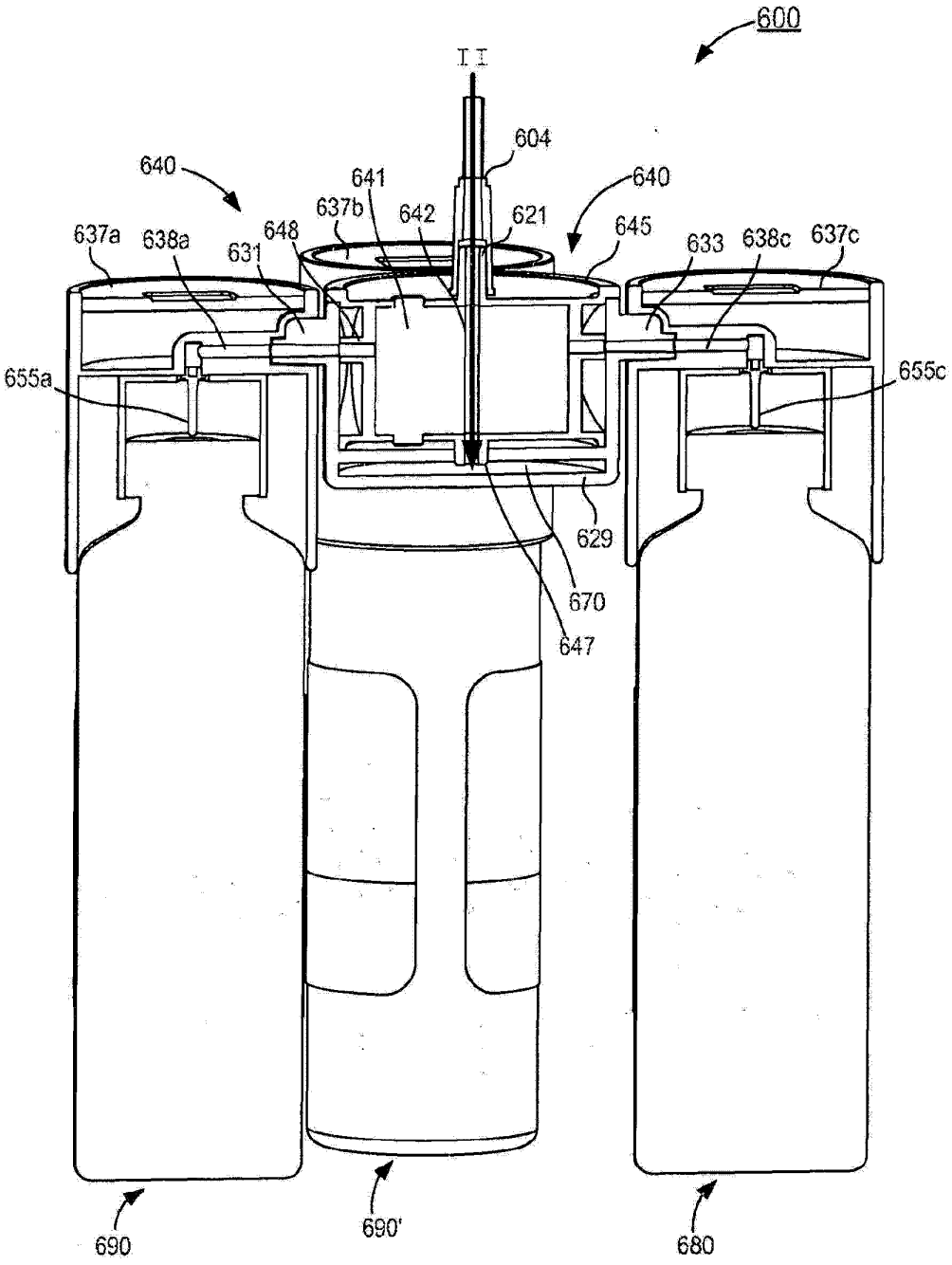


图 31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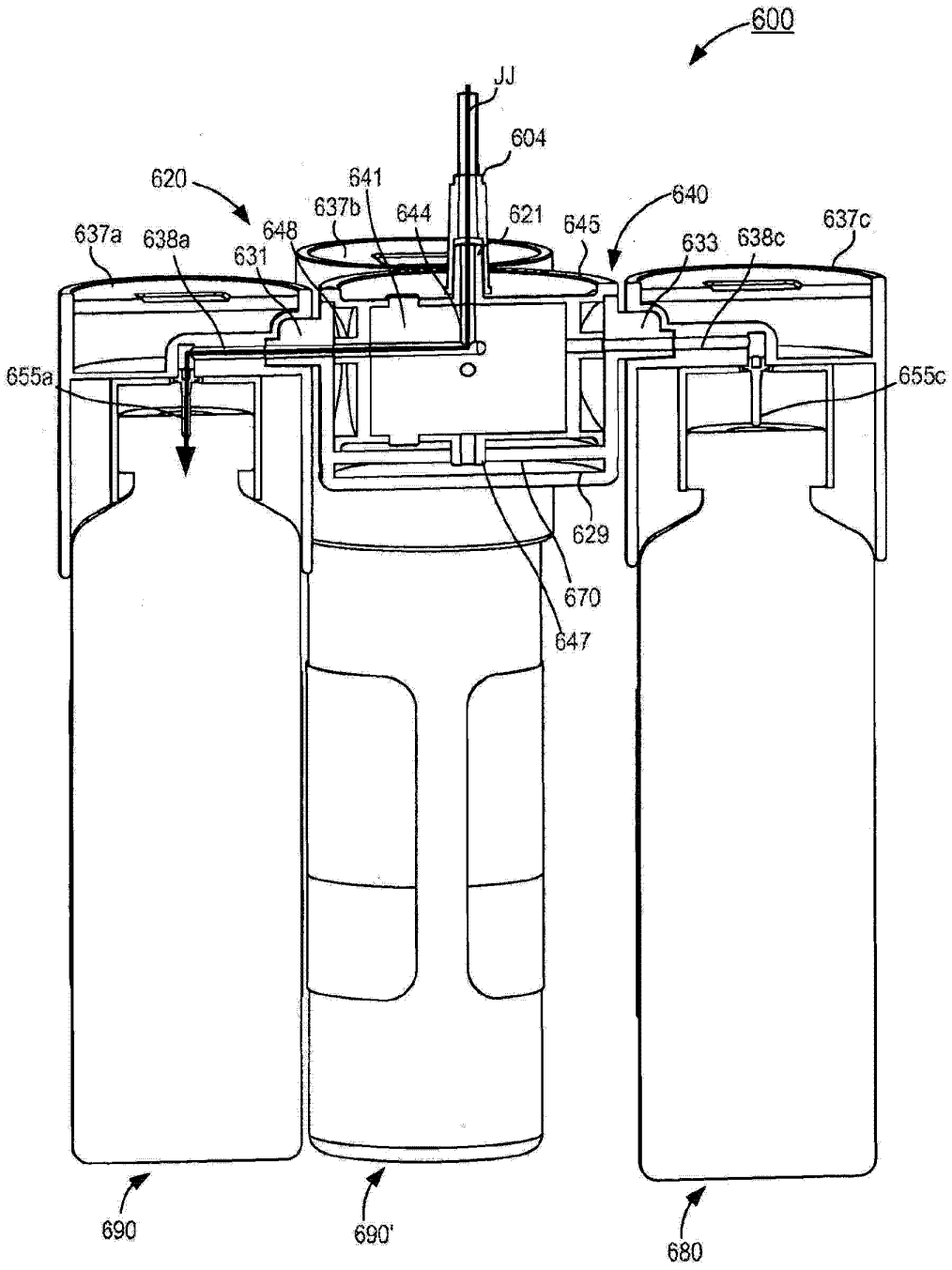
II
604
640
641
637b
642
621
640
637a
638a
648
631
645
633
638c
637c
655a
655c
629
670
647
690
690'
680

图 32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JJ
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637b
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621
640
637a
638a
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645
633
638c
637c
655a
655c
629
670
647
690
690'
680

图 33

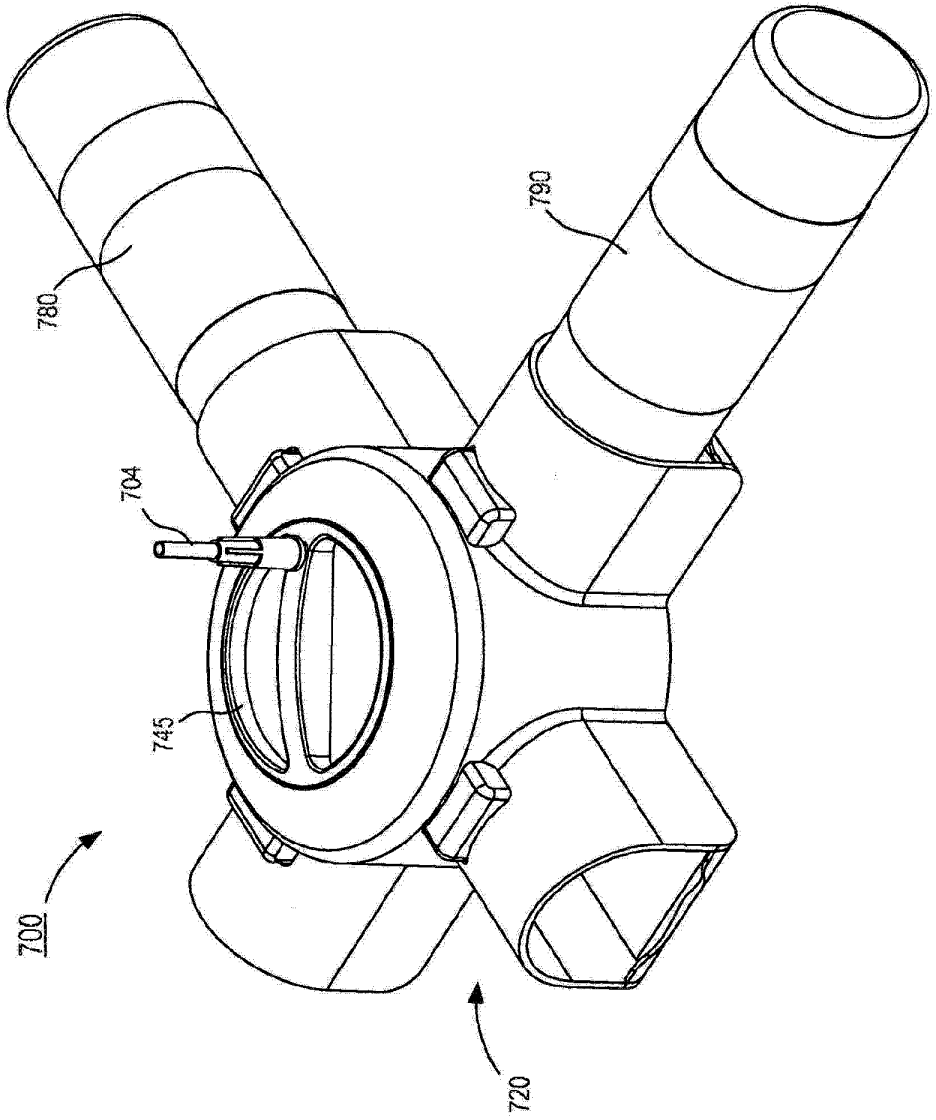
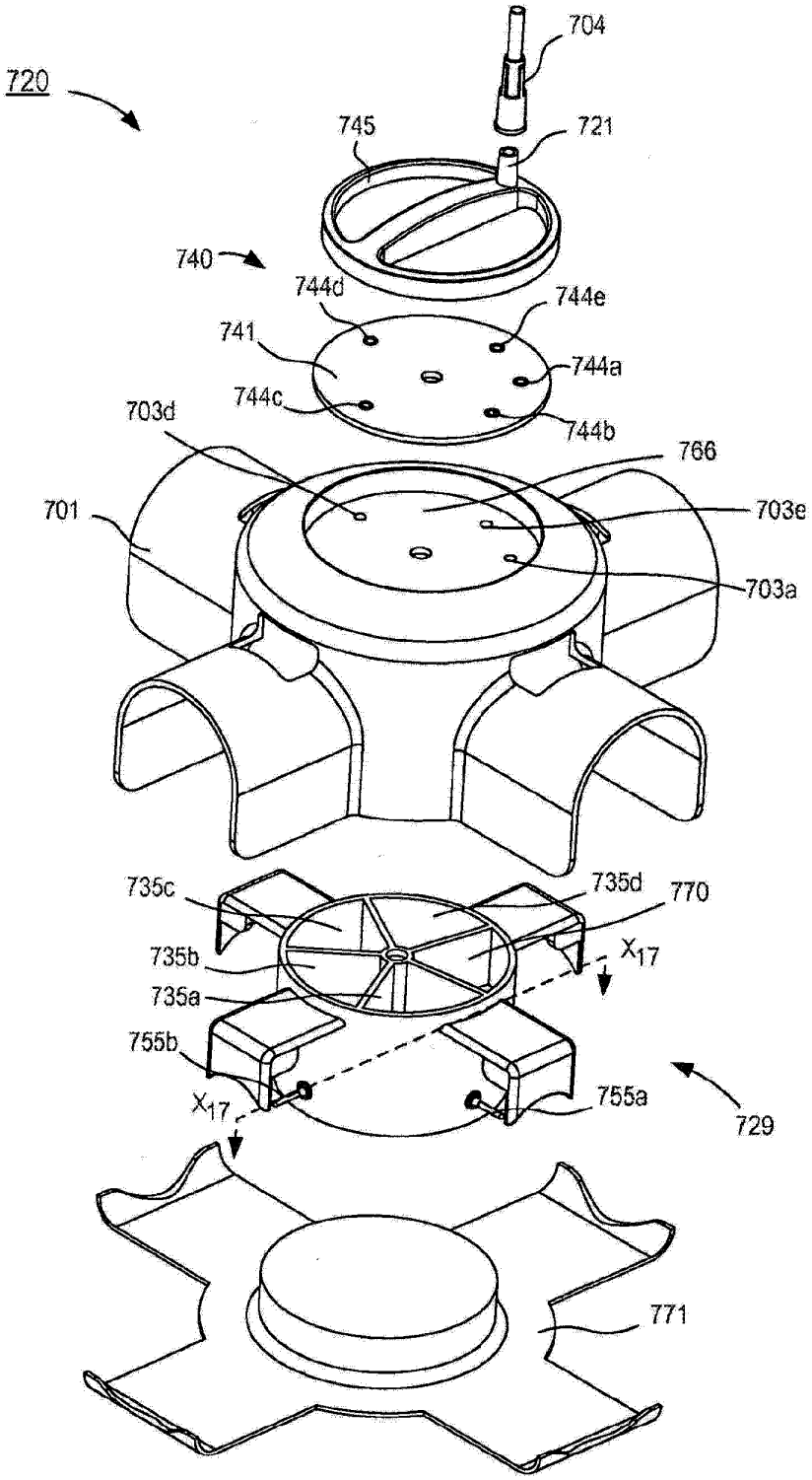


图 31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721
740
744d
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741
744a
744c
744b
703d
766
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703e
703a
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735d
770
735b
X_{17}
735a
755b
X_{17}
755a
729
771

图 35

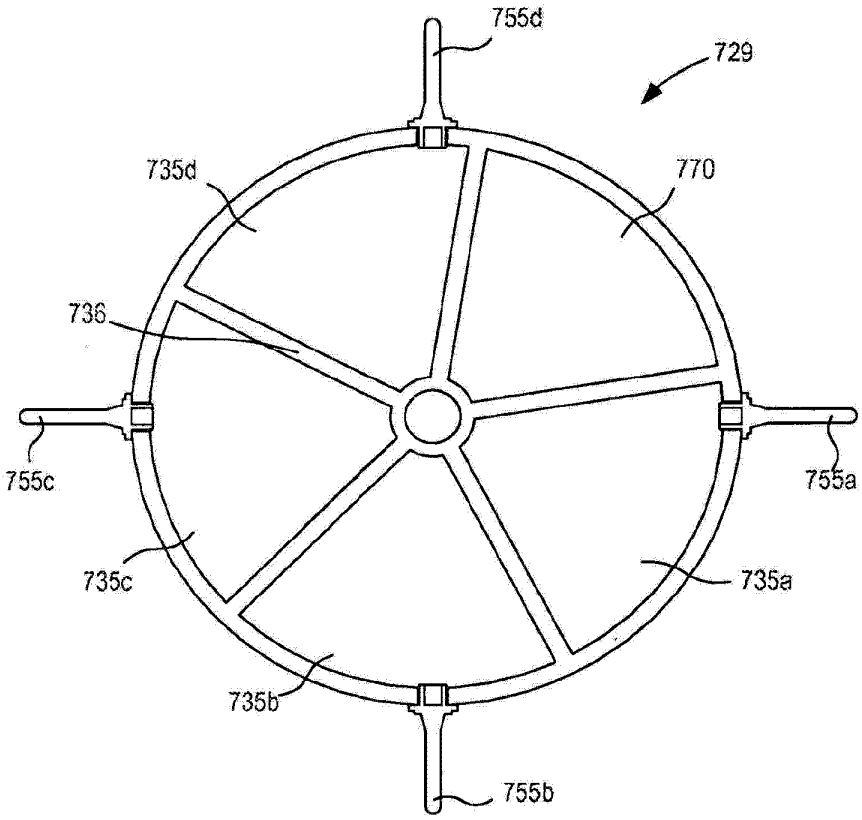


图 36

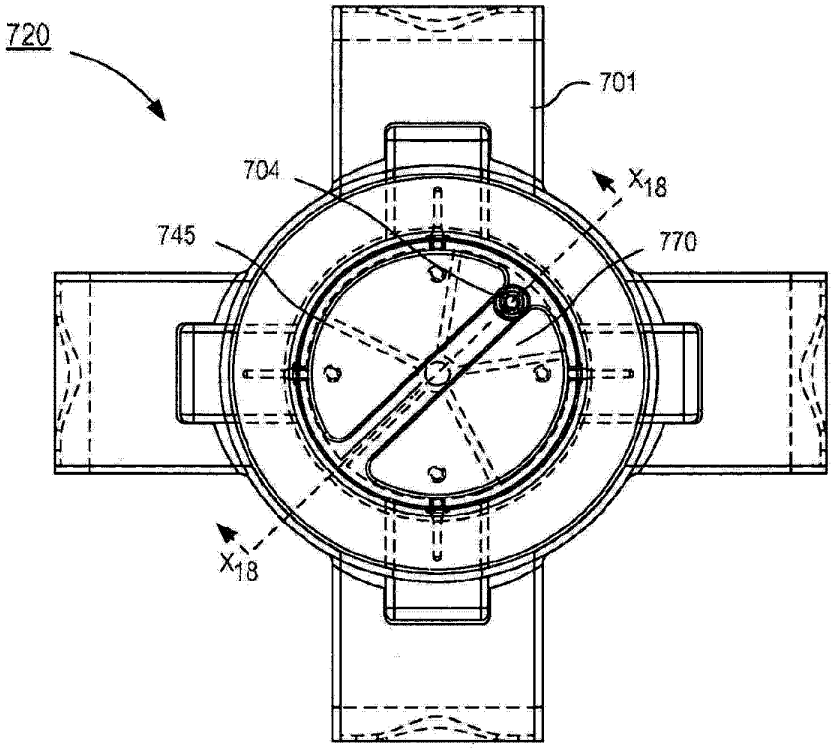


图 37

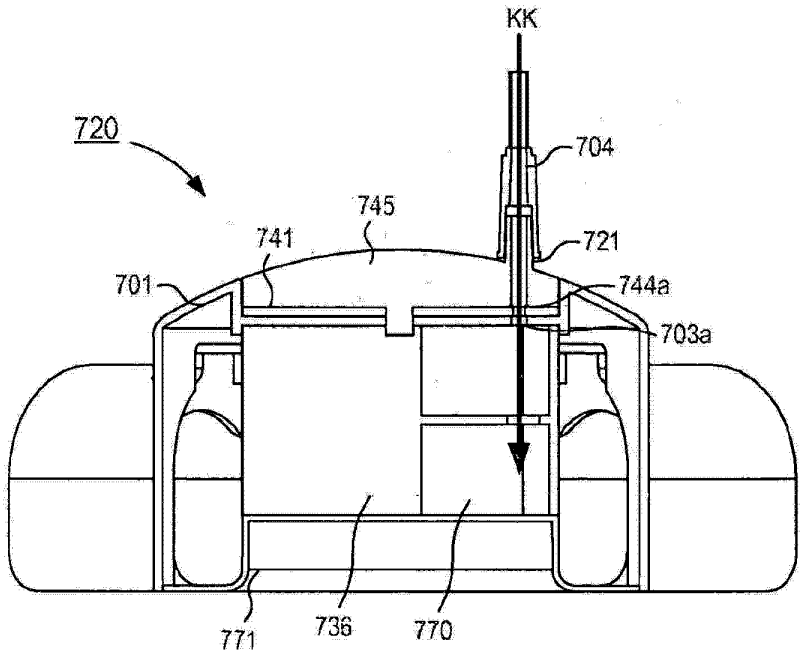


图 38

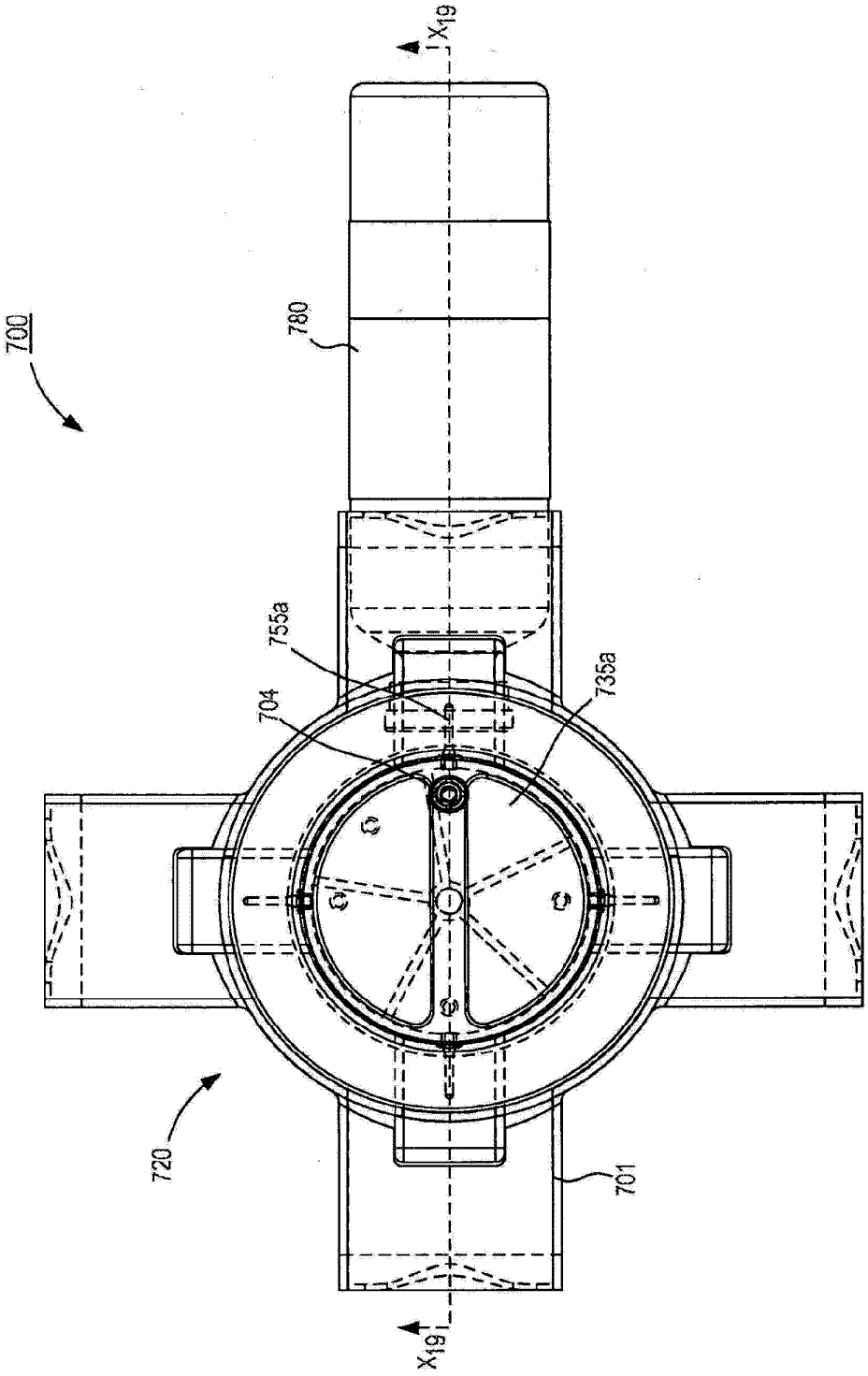
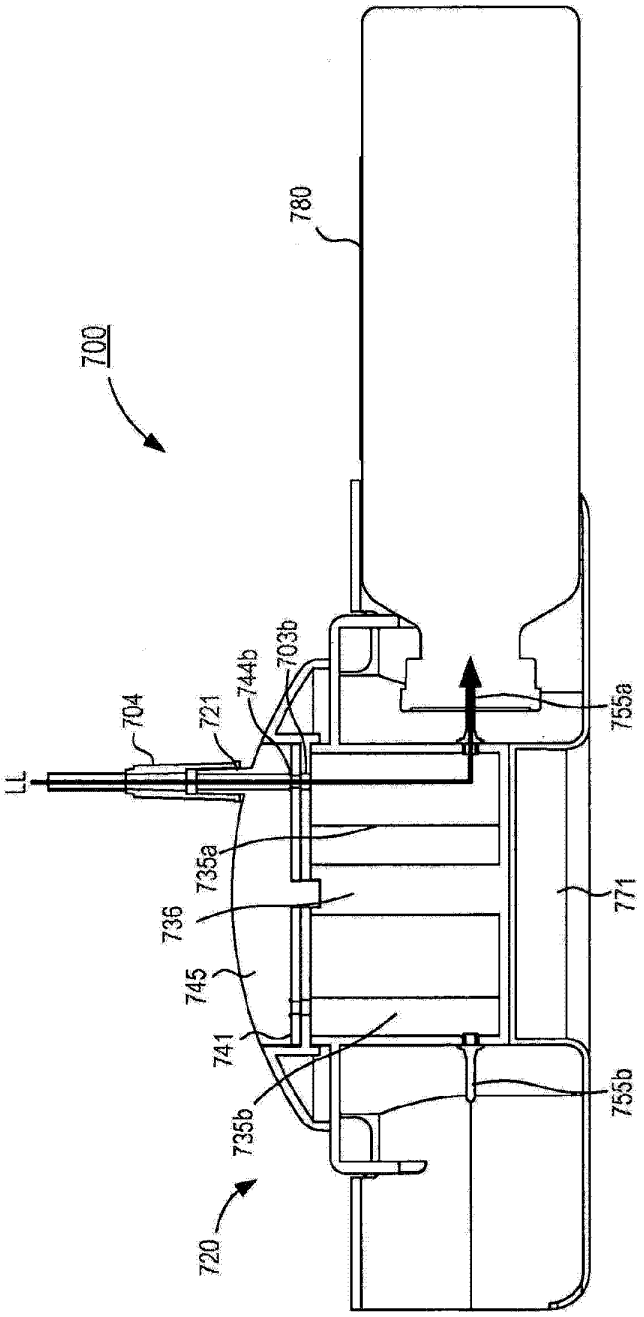


图 39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700
703b
744b
704
721
755a
LL
735a
771
736
745
741
735b
755b
720

图 40

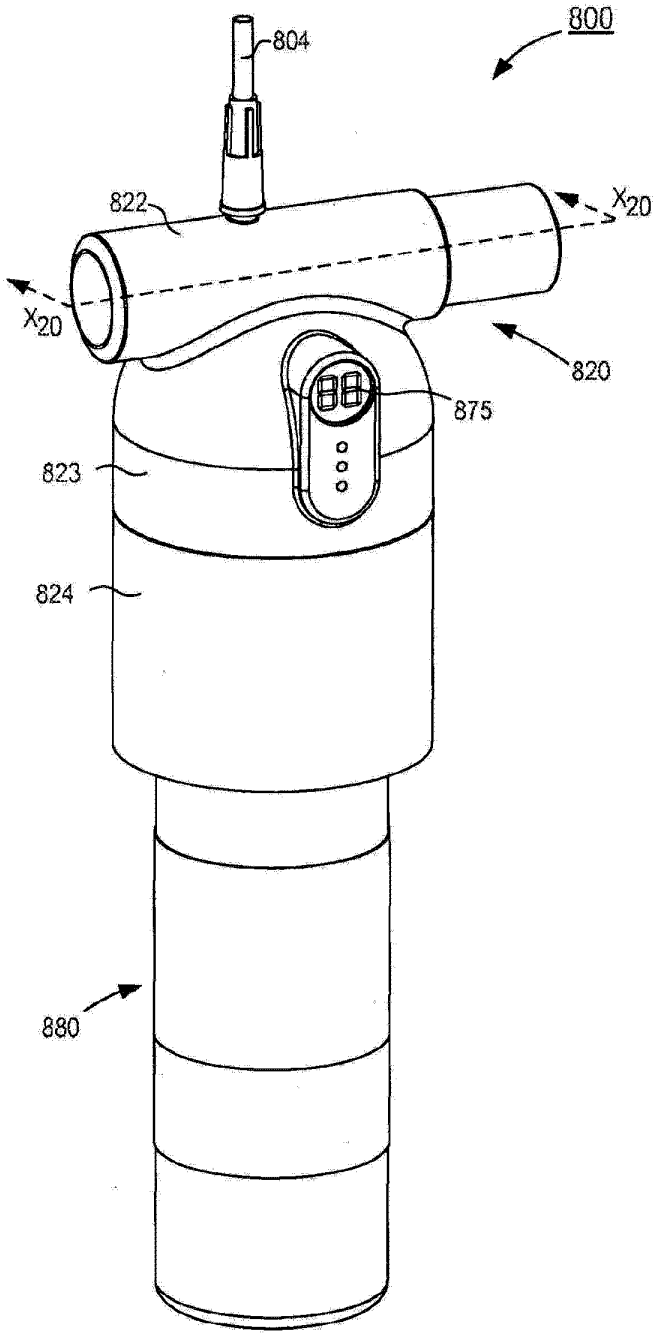


图 41

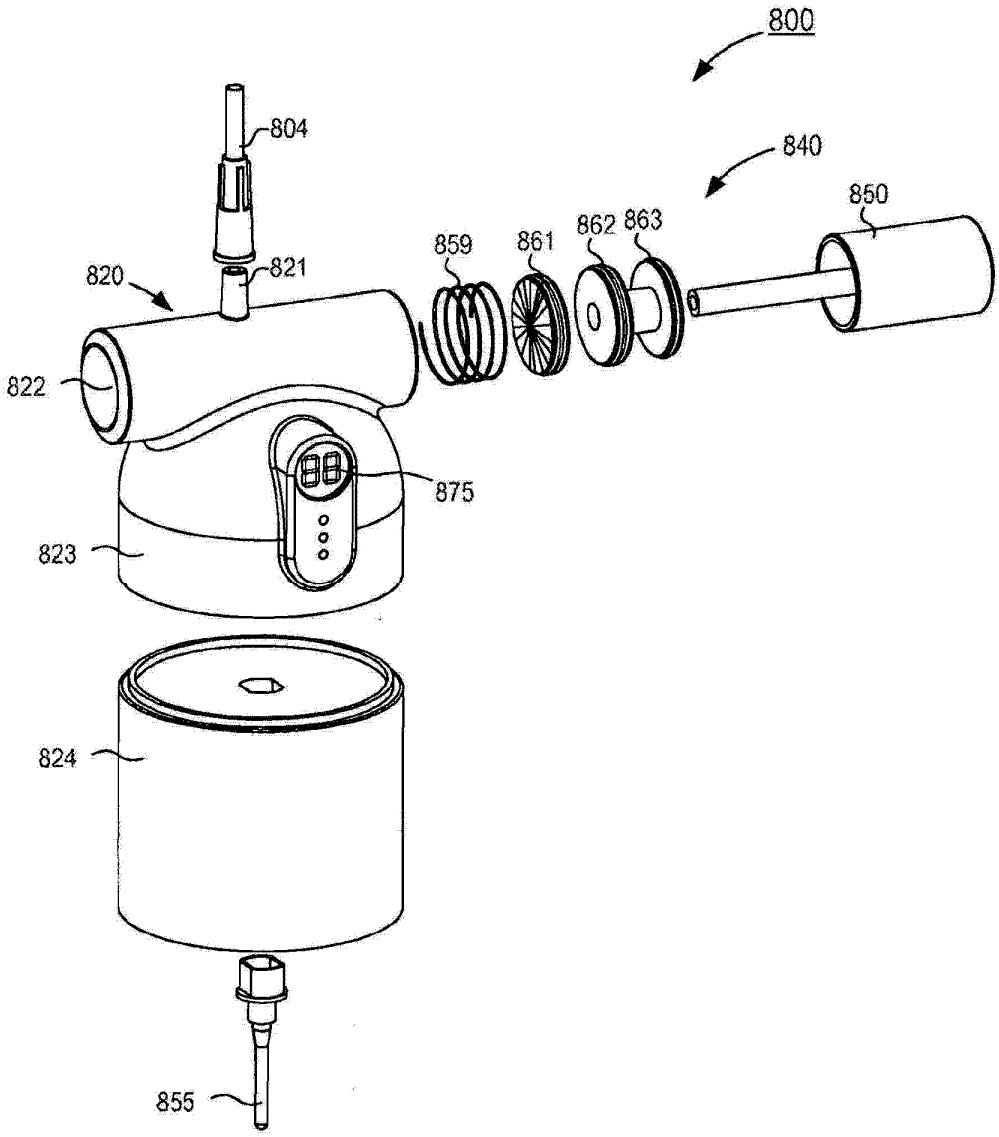
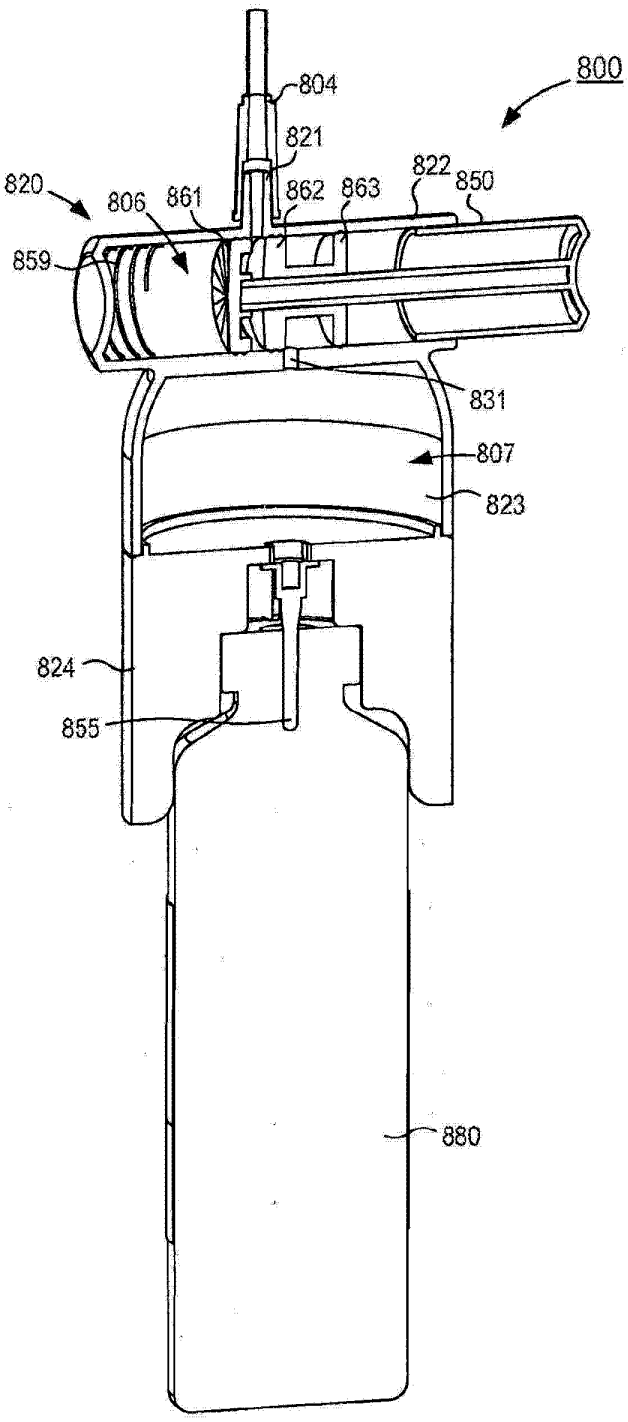


图 42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804
821
822
850
820
806
861
862
863
859
831
807
823
824
855
880

图 43

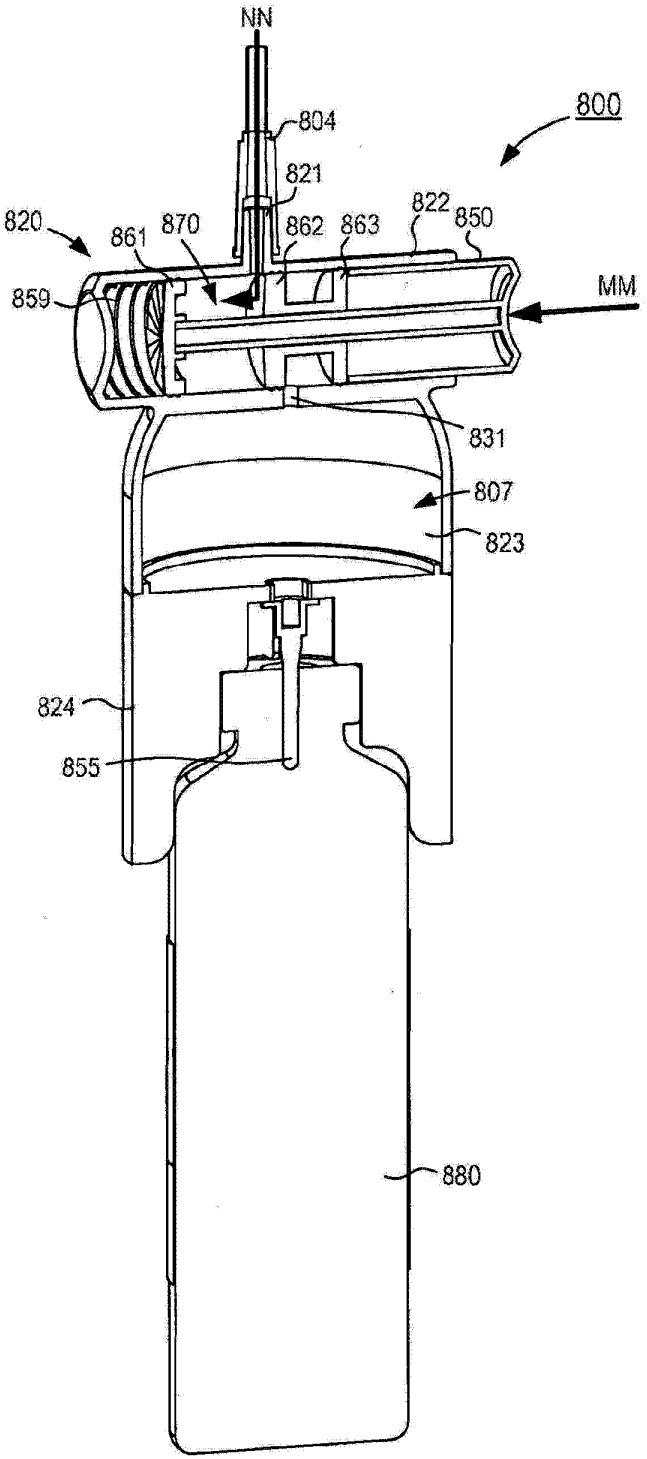
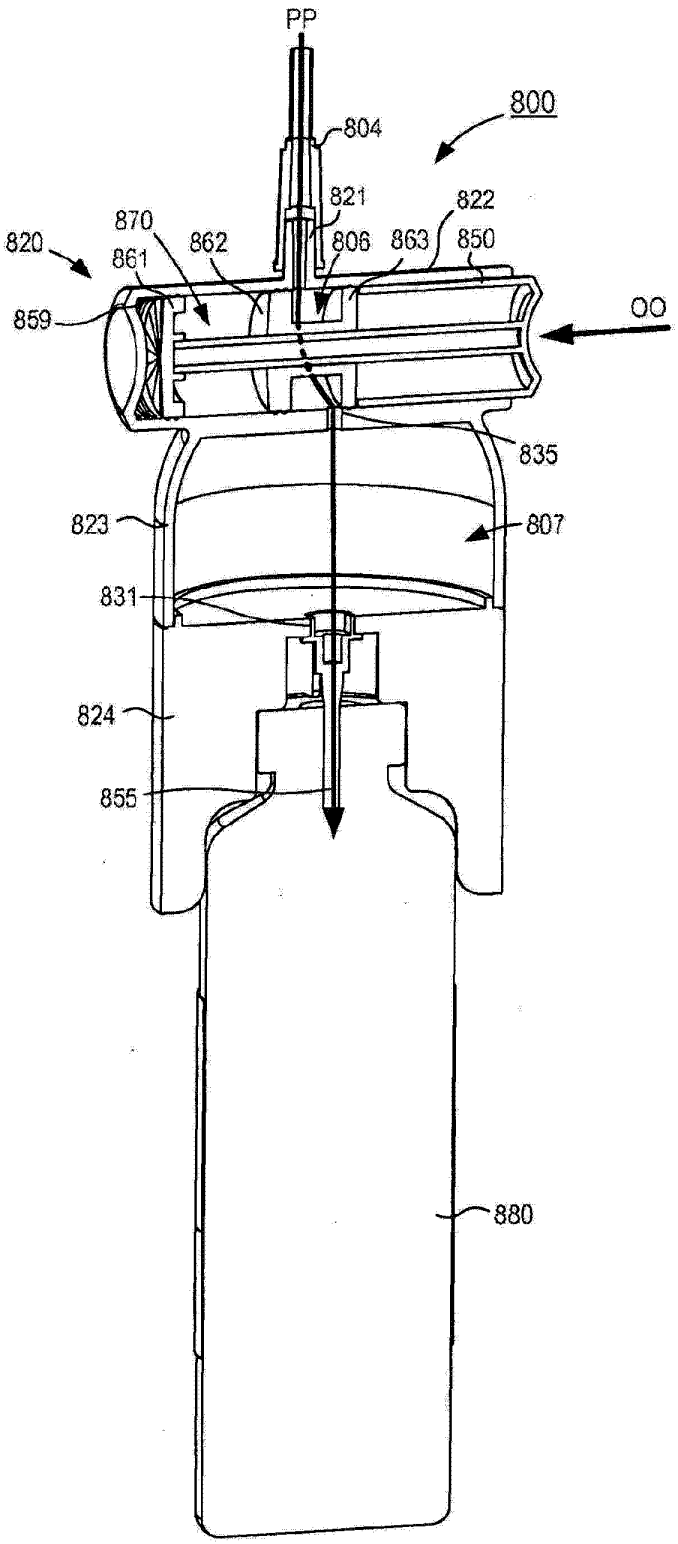

NN
800
804
821
822
850
820
861
870
862
863
MM
859
831
807
823
824
855
880

图 44


PP
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861
859
OO
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823
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831
824
855
880

图 45

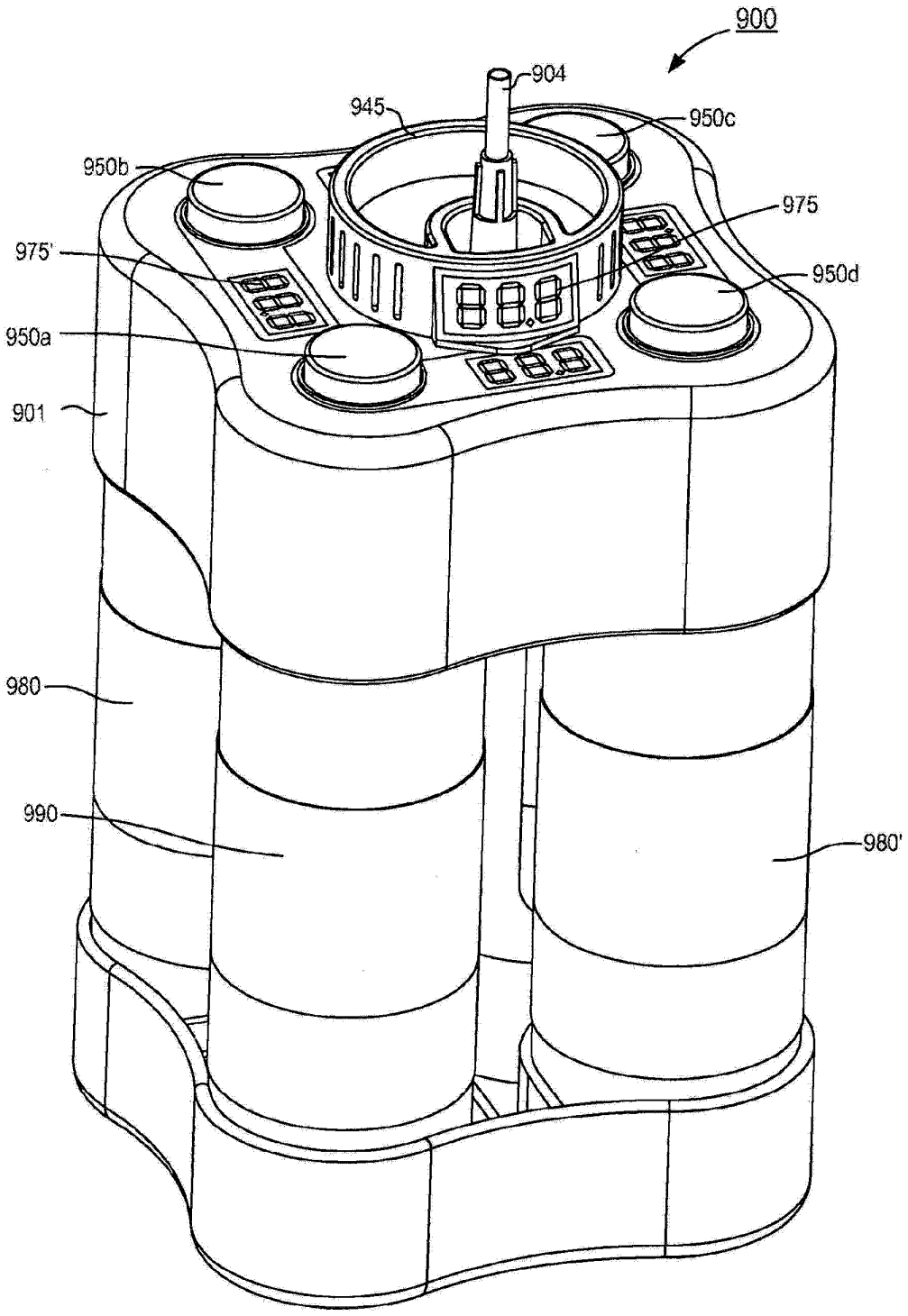


图 46

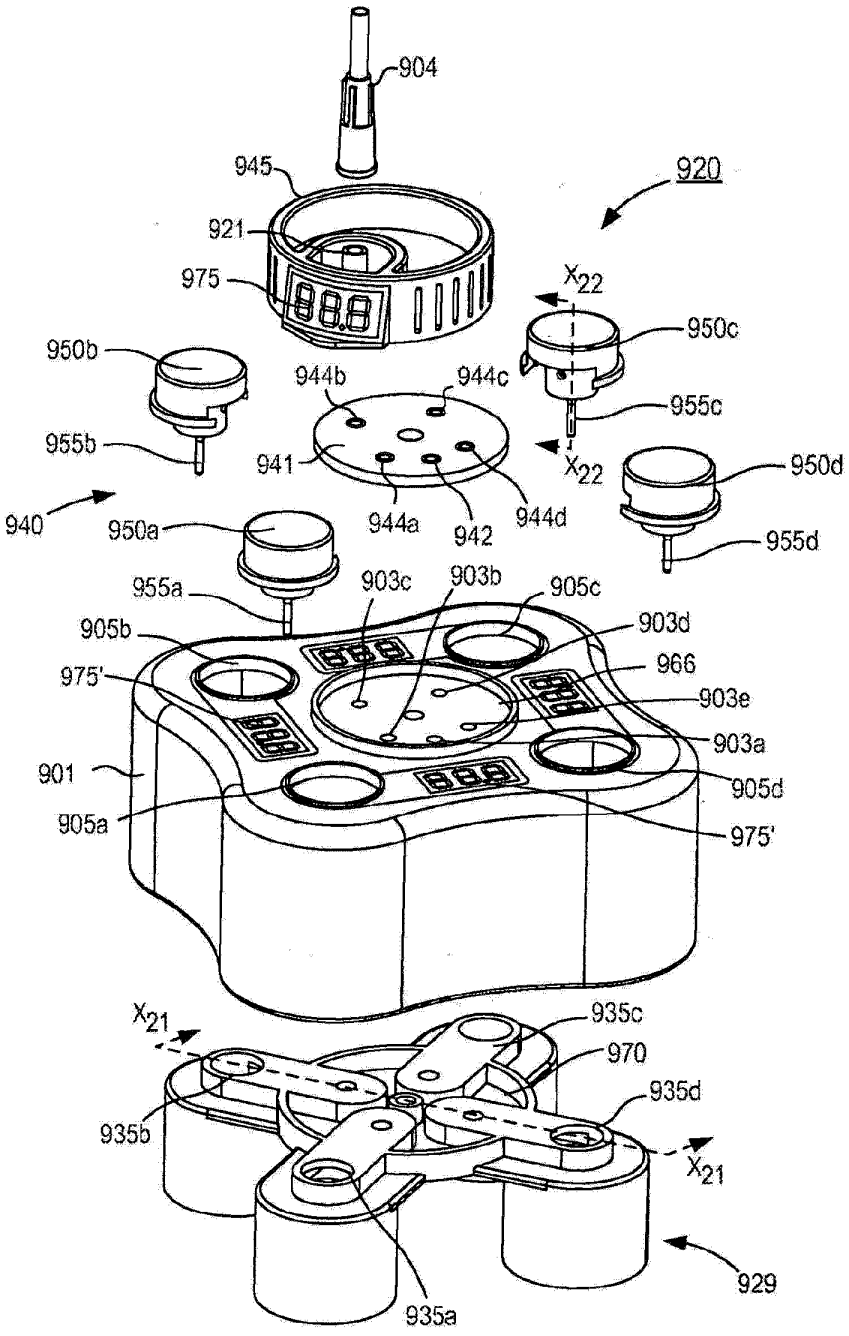

904
945
920
921
975
X22
950c
950b
944b
944c
955c
955b
941
X22
950d
940
950a
944a
942
944d
955d
955a
903c
903b
905c
905b
903d
975'
966
903e
903a
901
905d
905a
975'
X21
935c
970
935d
935b
X21
929
935a

图 47

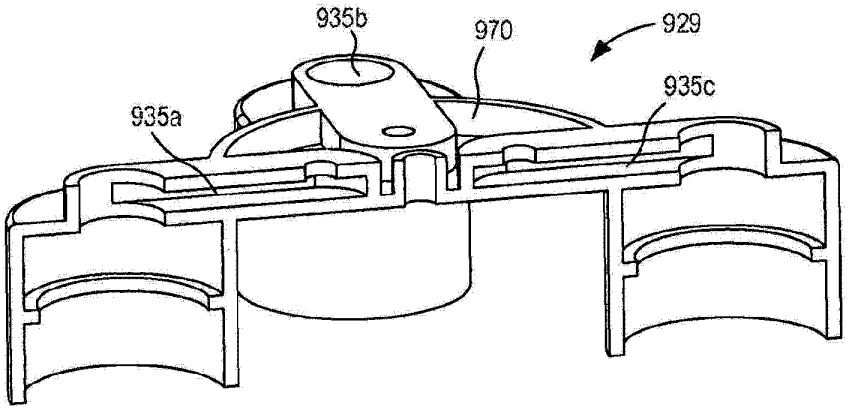


图 48

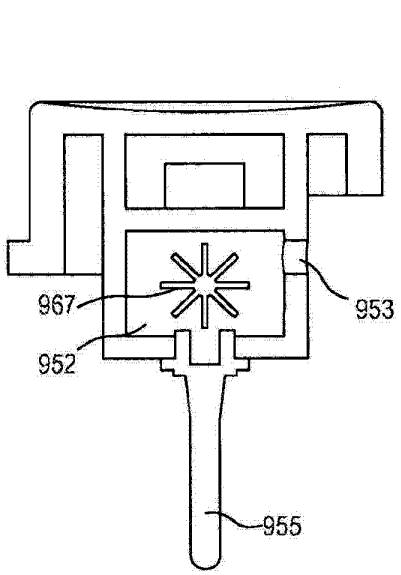
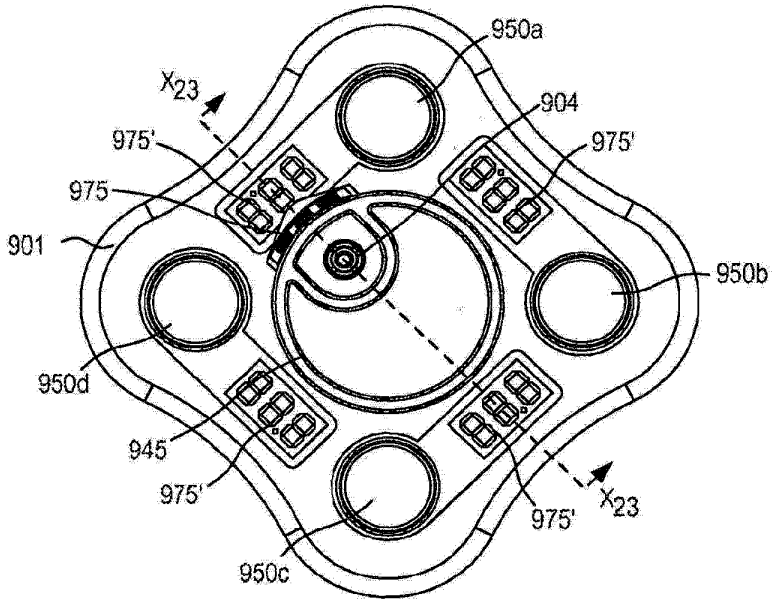


图 49


950a
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975'
975'
975
901
950b
950d
945
975'
975'
X_{23}
950c

图 50

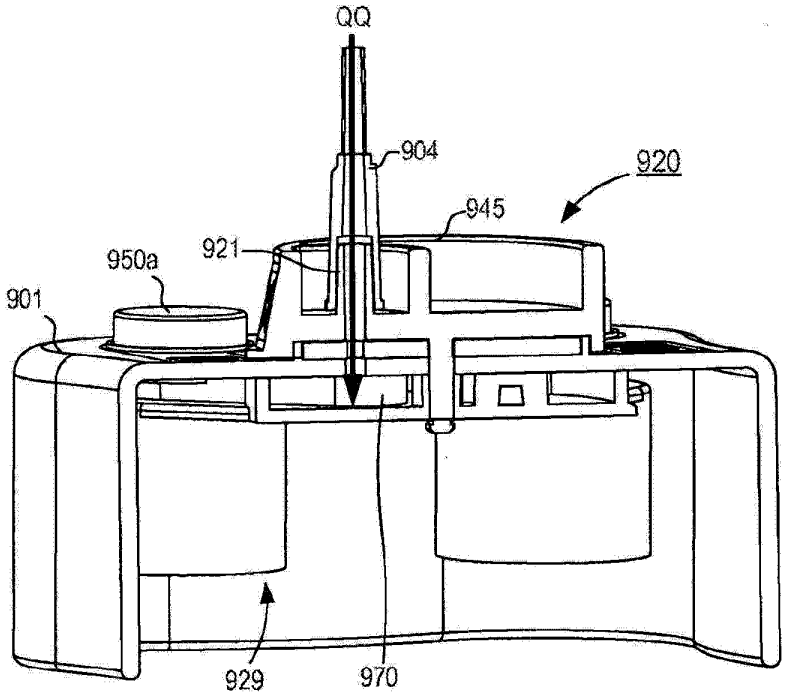

QQ
904
920
945
921
950a
901
929
970

图 51

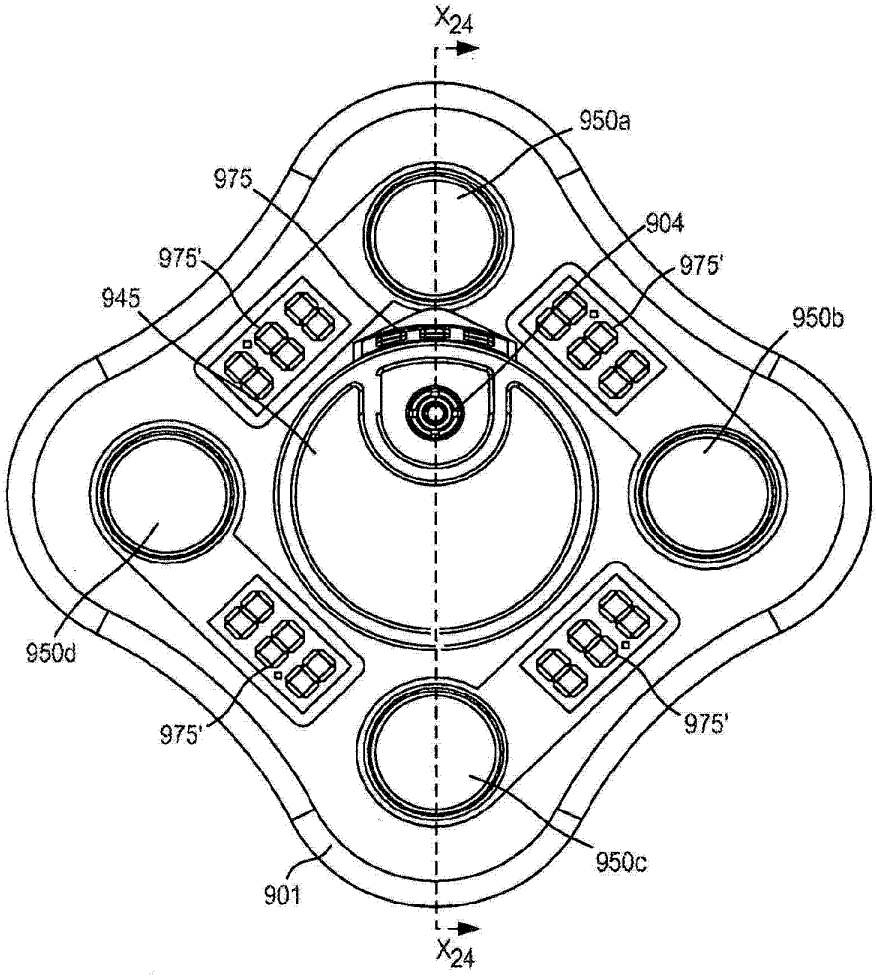
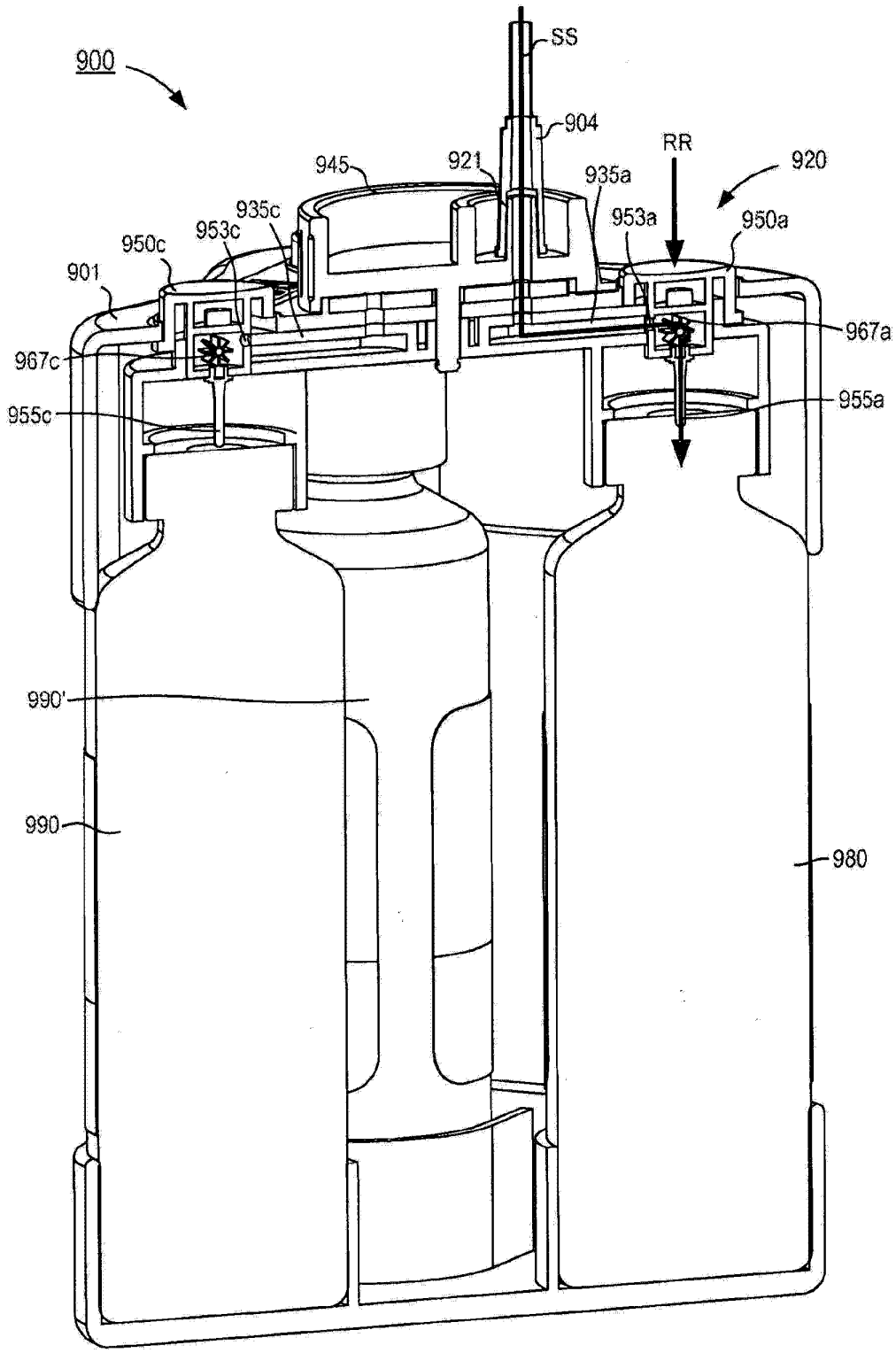


图 52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SS
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RR
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921
935a
935c
953c
953a
950a
950c
901
967a
967c
955a
955c
990'
990
980

图 53

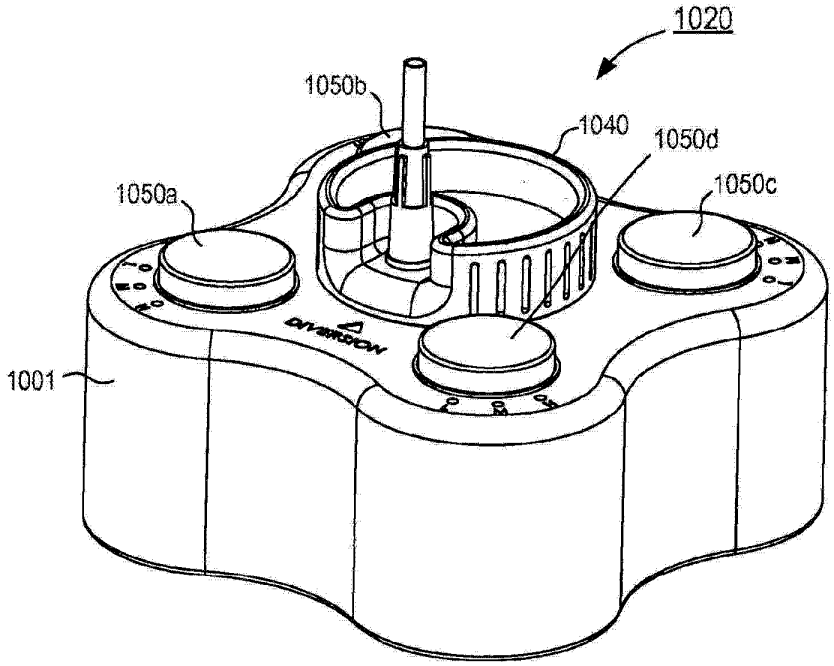
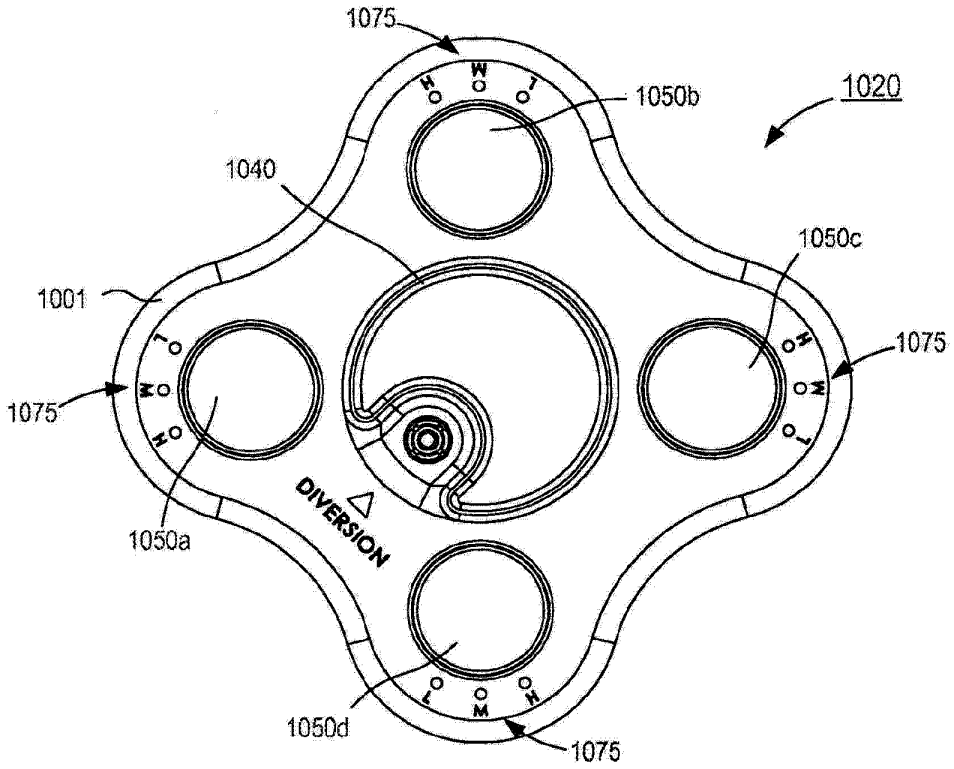


图 54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1020
1040
1050c
1001
1075
1075
1050a
DIVERSION
1050d
1075

图 55

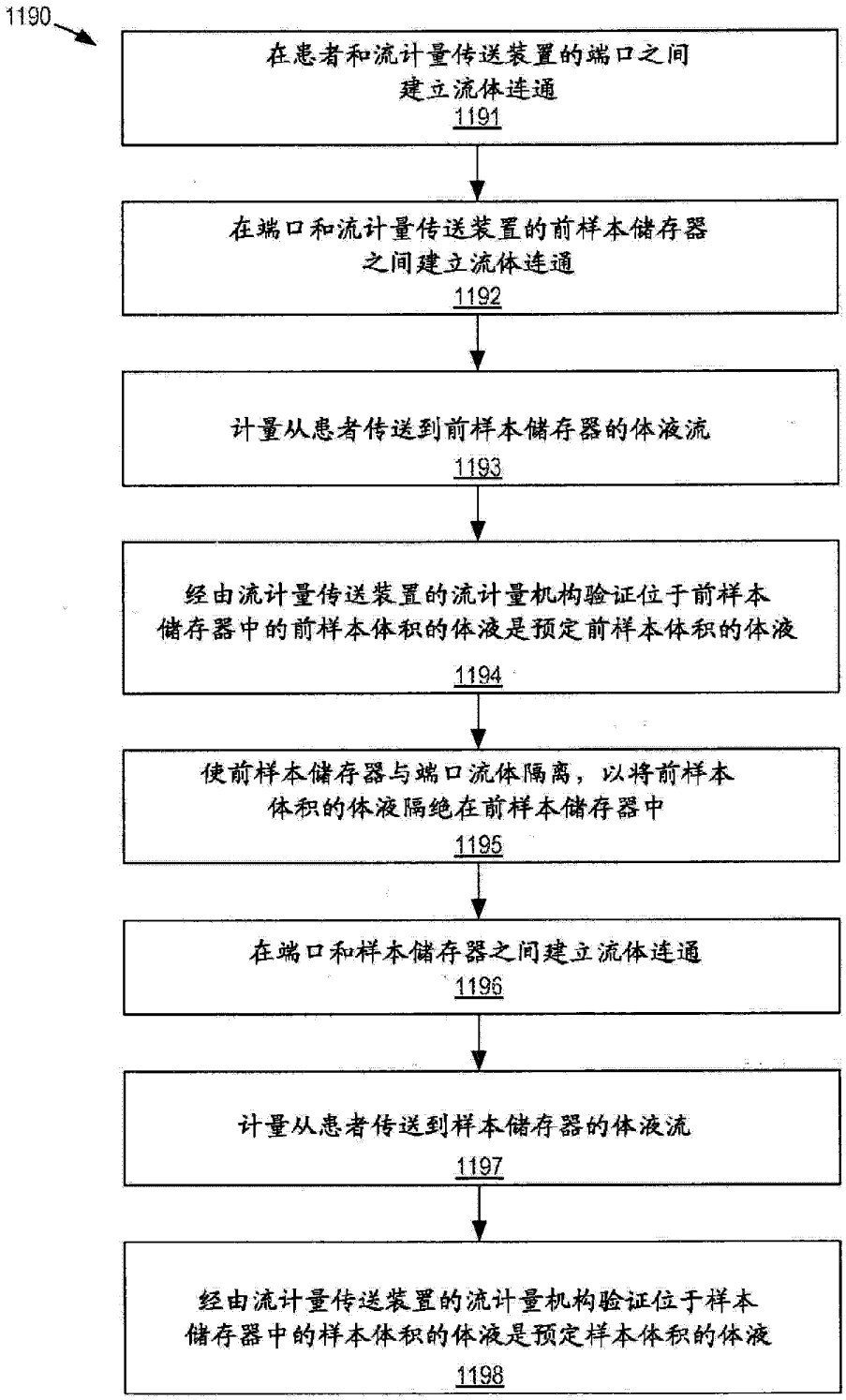
1190
在患者和流计量传送装置的端口之间建立流体连通
1191
在端口和流计量传送装置的前样本储存器之间建立流体连通
1192
计量从患者传送到前样本储存器的体液流
1193
经由流计量传送装置的流计量机构验证位于前样本储存器中的前样本体积的体液是预定前样本体积的体液
1194
使前样本储存器与端口流体隔离，以将前样本体积的体液隔绝在前样本储存器中
1195
在端口和样本储存器之间建立流体连通
1196
计量从患者传送到样本储存器的体液流
1197
经由流计量传送装置的流计量机构验证位于样本储存器中的样本体积的体液是预定样本体积的体液
1198

图 56

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

27500 7590 10/04/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
10/04/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/538,990	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 11/30/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 11/30/2011 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05/16/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 1 is objected to because of the following informalities: the phrase "blood" in lines 8 and 10 should be amended to read –the blood--. Appropriate correction is required.

4. Claim 1 is objected to because of the following informalities: the phrase "the junction being sized" in lines 7-8 should be amended to read –wherein the junction being sized--. Appropriate correction is required.

5. Claim 2 is objected to because of the following informalities: the phrase "blood" in line 3 should be amended to read –the blood--. Appropriate correction is required.

6. Claim 11 is objected to because of the following informalities: the phrase "an curved channel" in line 2 should be amended to read –the curved channel--. Appropriate correction is required.

7. Claim 12 is objected to because of the following informalities: the phrase "an air permeable blood barrier" in line 2 should be amended to read –the air permeable blood barrier--. Appropriate correction is required.

8. Claim 13 is objected to because of the following informalities: the phrase "the chamber" in line 9 should be amended to read –wherein the chamber--. Appropriate correction is required.

9. Claim 13 is objected to because of the following informalities: the phrase "bodily fluid" in lines 9-10, 12 and 13 should be amended to read –the bodily fluid--. Appropriate correction is required.

10. Claim 13 is objected to because of the following informalities: the phrase "from the inlet to bypass the chamber" in line 13 should be amended to read –to be directed from the inlet to bypass the chamber--. Appropriate correction is required.

11. Claim 16 is objected to because of the following informalities: the phrase "bodily fluid" in line 3 should be amended to read –the bodily fluid--. Appropriate correction is required.

Claim Interpretation

12. The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g.,

"means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word "means," but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

Limitation "junction" in claims 1, 6 and 13, the claims does not recite enough structure that corresponds to the claimed "junction", the specification disclose (junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A-17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608, par.0109) which can be interpreted as the structure that corresponds to the claimed "junction".

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the

claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

13. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specifications hall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

14. Claim 1 recites the limitation "the patient" in line2. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 6 recites the limitation "the blood control device" in line 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 6 recites the limitation "the sequestration chamber" in line 10. There is insufficient antecedent basis for this limitation in the claim. Examiner respectfully notes that the phrase “the sequestration chamber” is also recite in claim 7.

17. Claim 8 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 9 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

19. The statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a statutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of

activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are non-provisionally rejected on the ground of statutory double patenting as being unpatentable over claims 1-20 of U.S Patent Application No.11311219, claims 1-16 of U.S Patent Application No. 9820682, claims 1-23 of U.S Patent Application No.10143412, and claims 1-26 of U.S Patent Application No.11185266.

Also, claim 1-20 are provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-20 of U.S pending Application No.17/730118, and claims 1-18 and 20 of U.S pending Application No.17/094692.

Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent applications, pending applications and the instance application are claiming a common subject matter including: a blood sample device comprising; an inlet, an outlet; a chamber having a vent that includes an air permeable blood barrier; a sampling channel; and a junction connected between the inlet, the

chamber and the sampling channel, wherein the junction being sized and configured such that a first portion of blood conveyed from the patient flows into the chamber to displace air therein through the air permeable blood barrier, and such that a second portion of blood is allowed to bypass the chamber and the first portion of blood at least temporarily contained therein to be directed into the sampling channel toward the outlet.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and

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/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/538,990	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

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(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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	Application Number	17538990
	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	07/05/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

	22	2019534792A	JP		2019-12-05	プライメタルズ・テクノロジーズ・オーストリア・ゲーエムベーハー		☒
	23	H09504726A	JP		1997-05-13	BAXTER INT		☒
	24	9605875A1	WO		1996-02-29	BAXTER INT		☐
	25	2013181352A1	WO		2013-12-05	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐
	26	2014058945	WO		2014-04-17	BULLINGTON GREGORY J		☐
	27	2017019552A1	WO		2017-02-02	KURIN INC		☐
	28	2018125929A1	WO		2018-07-05	KURIN INC		☐
	29	S5825146A	JP		1983-02-15	BECTON DICKINSON CO		☒
	30	S5867238A	JP		1983-04-21	BECTON DICKINSON CO		☒
	31	5643474	JP		2014-12-17	ヴェロシス，インク.		☒
	32	5825146B2	JP		2015-12-02	JVC KENWOOD CORP,		☒

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	33	2020000340A	JP		2020-01-09	TOSHO INC		☒
	34	2013240628	JP		2013-12-05	COVIDIEN LP		☒
	35	H02224742	JP		1990-09-06	SPACELABS INC		☒
	36	S5789869	JP		1982-06-04	BECTON DICKINSON CO		☒
	37	2005349196	JP		2005-12-22	BECTON DICKINSON CO		☒
	38	10243129	DE		2004-04-01	RITTER GMBH		☒
	39	7203008	DE		1972-05-10	IMMUNO AG FUER CHEM-MED PROD		☒
	40	10038026	DE		2001-02-22	ZIERDEN PETER		☒
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	42	10134913	DE		2003-02-20	HIBERNA AG		☒
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	44	2541494	DE		1977-03-31	GUERRA LUIS A		☒
	45	2008101025	WO		2008-08-21	EDWARDS LIFESCIENCES CORP		☐
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	International Search Report and Written Opinion dated Nov. 5, 2015, for PCT application No. PCT/US2015/035870. 6 pages.	
	2	International Search Report and VVritten Opinion dated 16 July 2020 for PCT application no. PCT/US2020/026276. 9 pages.	
	3	Bullington, et al., Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in U.S. Appl. No. 62/517,681, dated Jun. 9, 2017, 131 pages.	
	4	Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.	

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	5	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	
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	10	European Patent Office, International Search Report and Written Opinion for PCT/US16/43709, dated Oct. 19, 2016, 14 pages.	
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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	07/05/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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卓霖(010-82800919) 许向彤(010-82800919)

发文日：

2023 年 09 月 27 日

申请号：202080000666.0　　**发文序号：**2023092702079090

申请人：酷睿有限公司

发明创造名称：非排气机体流体样品优化装置和系统

第 一 次 审 查 意 见 通 知 书

（进入国家阶段的 PCT 申请）

1.☒应申请人提出的实质审查请求，根据专利法第 35 条第 1 款的规定，国家知识产权局对上述发明专利申请进行实质审查。

☐根据专利法第 35 条第 2 款的规定，国家知识产权局决定自行对上述发明专利申请进行实质审查。

2.☒申请人要求以其在：

US 专利局的申请日 2019 年 04 月 01 日为优先权日。

3.☐经审查，申请人于_____提交的修改文件，不符合专利法实施细则第 51 条第 1 款的规定，不予接受。

4.☐审查是针对原始提交的国际申请的中文文本或中文译文进行的。

☒审查是针对下列申请文件进行的：

办理进入国家阶段手续时提交的权利要求书、说明书、摘要、摘要附图；2021 年 4 月 6 日提交的说明书附图。

5.☒本通知书引用下列对比文献（其编号在今后的审查过程中继续沿用）

编号	文 件 号 或 名 称	公 开 日 期（或抵触申请的申请日）
1	US2018271425A1	2018-09-27

6.审查的结论性意见：

关于说明书：

☐申请的内容属于专利法第 5 条规定的不授予专利权的范围。

☐说明书不符合专利法第 26 条第 3 款的规定。

☐说明书不符合专利法第 33 条的规定。

☐说明书的撰写不符合专利法实施细则第 17 条的规定。

☐_____

关于权利要求书：

☐权利要求_____不符合专利法第 2 条第 2 款的规定。

☐权利要求_____不符合专利法第 9 条第 1 款的规定。

☐权利要求_____不具备专利法第 22 条第 2 款规定的新颖性。

☒权利要求 1-20 不具备专利法第 22 条第 3 款规定的创造性。

☐权利要求_____不具备专利法第 22 条第 4 款规定的实用性。

纸件申请，回函请寄：100088 北京市海淀区蓟门桥西土城路 6 号 国家知识产权局专利局受理处收

电子申请，应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外，以纸件等其他形式提交的文件视为未提交。

□权利要求_____属于专利法第 25 条规定的不授予专利权的范围。
□权利要求_____不符合专利法第 26 条第 4 款的规定。
□权利要求_____不符合专利法第 31 条第 1 款的规定。
□权利要求_____不符合专利法第 33 条的规定。
□权利要求_____不符合专利法实施细则第 19 条的规定。
□权利要求_____不符合专利法实施细则第 20 条的规定。
□权利要求_____不符合专利法实施细则第 21 条的规定。
□权利要求_____不符合专利法实施细则第 22 条的规定。
□_____

□申请不符合专利法第 26 条第 5 款或者实施细则第 26 条的规定。
□申请不符合专利法第 19 条第 1 款的规定。
□分案申请不符合专利法实施细则第 43 条第 1 款的规定。

上述结论性意见的具体分析见本通知书的正文部分。

7. 基于上述结论性意见，审查员认为：

□申请人应当按照通知书正文部分提出的要求，对申请文件进行修改。

□申请人应当在意见陈述书中论述其专利申请可以被授予专利权的理由，并对通知书正文部分中指出的不符合规定之处进行修改，否则将不能授予专利权。

☒专利申请中没有可以被授予专利权的实质性内容，如果申请人没有陈述理由或者陈述理由不充分，其申请将被驳回。

□_____

8. 申请人应注意下列事项：

（1）根据专利法第 37 条的规定，申请人应在收到本通知书之日起的 4 个月内陈述意见，如果申请人无正当理由逾期不答复，其申请被视为撤回。

（2）申请人对其申请的修改应当符合专利法第 33 条的规定，不得超出原说明书和权利要求书记载的范围，同时申请人对专利申请文件进行的修改应当符合专利法实施细则第 51 条第 3 款的规定，按照本通知书的要求进行修改。

（3）申请人的意见陈述书和/或修改文本应当邮寄或递交国家知识产权局专利局受理处，凡未邮寄或递交给受理处的文件不具备法律效力。

（4）未经预约，申请人和/或代理师不得前来国家知识产权局与审查员举行会晤。

（5）对进入实质审查阶段的发明专利申请，在第一次审查意见通知书答复期限届满前（已提交答复意见的除外），主动申请撤回的，可以请求退还 50%的专利申请实质审查费。

9. 本通知书正文部分共有 6 页，并附有下列附件：

□引用的对比文件的复印件共_____份_____页。
□_____

审查员：李媛媛　　联系电话：0371-87791927　　审查部门：专利审查协作河南中心

纸件申请，回函请寄：100088 北京市海淀区蓟门桥西土城路 6 号　国家知识产权局专利局受理处收。
电子申请，应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外，以纸件等其他形式提交的文件视为未提交。

国 家 知 识 产 权 局

第 一 次 审 查 意 见 通 知 书

（进入国家阶段的 PCT 申请）

申请号:2020800006660

本申请涉及一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置，经审查，现提出如下审查意见。

1. 权利要求 1 不符合专利法第 22 条第 3 款的规定

权利要求 1 请求一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置，对比文件 1(US2018/0271425A1)公开了一种流体样品优化装置，具体的用于优化由流体收集装置从流体源收集流体样品(相当于一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置)，并具体公开了(参见说明书第 0141-0149 段，说明书附图 23A-23B)：

血液隔离装置 2300 的又一实施方式，其具有与患者针连接的入口端口 2302(相当于被配置为与所述流体源连接的入口)、与血液样本收集装置连接的出口端口 2304(相当于被配置为与流体收集装置接触的出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于污染物容纳储库)被填充至待隔离的潜在污染血液的初始等分部分，则隔离室 2306 被填充。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于污染物容纳储库在所述出口附近具有流阻器)。

从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于当入口和出口之间施加压差时，所述污染物容纳储库被布置为从所述流体源接收所述流体样品的第一部分，使得当接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库中)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物(相当于流体样品的第一部分潜在地具有污染物)。

少量血液可以进入采样通道 2308，采样通道 2308 最初被阀 2308 关闭。

当释放阀 2308 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液(相当于流体样品)将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于连接在所述入口和所述出口之间的样品路径)朝向出口端口 2304 并至收集装置(相当于当所述入口和所述出口之间施加后续压差时，所述流体样品的后续部分能够由所述样品路径从所述入口传送到所述出口)。

权利要求 1 请求保护的技术方案与对比文件 1 相比，其区别技术特征为：流阻器为透气的，通过所述透气的流阻器和所述出口置换其中的空气。

针对上述区别技术特征：对比文件 1 中已经记载了从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312

纸件申请，回函请寄：100088 北京市海淀区蓟门桥西土城路 6 号 国家知识产权局专利局受理处收
电子申请，应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外，以纸件等其他形式提交的文件视为未提交。

并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻隔器；因此为了使得血液能在真空的作用下使得被吸入隔离室 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

在对比文件 1 的基础上结合本领域常规技术手段以获得该权利要求所要求保护的技术方案，对所属技术领域的技术人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步，因而不具第 22 条第 3 款规定的创造性。

2. 权利要求 2-5 不符合专利法第 22 条第 3 款的规定

权利要求 2-5 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述污染物容纳储库中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312，从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料)；

在对比文件 1 的基础上，根据需要可以选择污染物容纳储库包括曲折路径；

对比文件 1 中记载了当释放阀 2308 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于每个压差由所述流体收集装置提供的真空压力提供)；因此对比文件 1 公开了权利要求 5 的附加技术特征；

因此，当其引用的权利要求不具备创造性时，权利要求 2-5 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

3. 权利要求 6 不符合专利法第 22 条第 3 款的规定

权利要求 6 请求一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置，对比文件 1 公开了一种流体样品优化装置，具体的用于优化由流体收集装置从流体源收集流体样品(相当于一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置)，并具体公开了(参见说明书第 0141-0149 段，说明书附图 23A-23B)：

血液隔离装置 2300 的又一实施方式，其具有与患者针连接的入口端口 2302(相当于被配置为与所述流体源连接的入口)、与血液样本收集装置连接的出口端口 2304(相当于被配置为与流体收集装置接触的出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于污染物容纳储库)被填充至待隔离的潜在污染血液的初始等分部分，则隔离室 2306 被填充，结合说明书附图 23A 可以明确隔离室 2306 设置在入口和出口之间(相当于连接在所述入口和所述出口之间的污染物容纳储库)。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于流阻器，相当于污染物容纳储库在所述出口附近还具有流阻器)。

从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样(相当于流体样品的第一部分)将接触疏水塞 2312（相当于流阻器）并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于当所述入口和所述出口之间施加压差时，所述污染物容纳储库被布置为从所述流体源接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物。可以确定对比文件 1 中接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库中。

少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310(相当于阻力塞)关闭(相当于样品路径还具有阻力塞，该阻力塞被配置为抑制所述流体样品的第一部分的至少一部分和污染物进入所述样品路径中)。

当释放阀 2310 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液(相当于流体样品)将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于连接在所述入口和所述出口之间的样品路径)朝向出口端口 2304 并至收集装置(相当于当所述入口和所述出口之间施加后续压差时，流体样品的后续部分能够被迫通过所述阻力塞，并由所述样品路径从所述入口传送到所述出口)。

权利要求 6 请求保护的技术方案与对比文件 1 相比，其区别技术特征为：流阻器为透气的，以通过所述透气的流阻器和所述出口置换其中的空气。

针对上述区别技术特征：对比文件 1 中已经记载了从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻隔器；因此为了使得血液能在真空的作用下使得被吸入隔离室 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

在对比文件 1 的基础上结合本领域常规技术手段以获得该权利要求所要求保护的技术方案，对所属技术领域的技术人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步，因而不具第 22 条第 3 款规定的创造性。

4. 权利要求 7-13 不符合专利法第 22 条第 3 款的规定

权利要求 7-13 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述污染物容纳储库中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312，从出

口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料)；

在对比文件 1 的基础上，根据需要可以选择污染物容纳储库包括曲折路径；

对比文件 1 中记载了当释放阀 2308 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于每个压差由所述流体收集装置提供的真空压力提供)；因此对比文件 1 公开了权利要求 5 的附加技术特征；

对比文件 1 中已经公开了采样通道 2308 最初被阀 2310(相当于阻力塞)关闭；在对比文件 1 的基础上，关于阻力塞的设置方式是根据需要可以选择的，具体的阻力塞包括被后续第一压差可刺穿的膜，阻力塞还包括刺穿构件，该刺穿构件被配置为当后续第一压差施加在所述膜的相对侧上时刺穿所述膜是可以选择的设置方式；此外还可以选择其它的设置方式，具体的阻力塞包括具有可溶解材料的网，该可溶解材料在与流体样品的后续第一部分接触时溶解也是不难确定出的一种方式。

因此，当其引用的权利要求不具备创造性时，权利要求 7-13 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

5. 权利要求 14 不符合专利法第 22 条第 3 款的规定

权利要求 14 请求保护一种用于优化流体样品的流体样品优化装置,对比文件 1 公开了一种流体样品优化装置，具体的为一种优化流体样品的流体样品优化装置(相当于一种用于优化流体样品的流体样品优化装置)，并具体公开了(参见说明书第 0141-0149 段，说明书附图 23A-23B)：

血液隔离装置 2300 的又一实施方式，其具有与患者针连接的入口端口 2302(相当于入口)、与血液样本收集装置连接的出口端口 2304(相当于出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于污染物容纳储库)被填充至待隔离的潜在污染血液的初始等分部分，则隔离室 2306 被填充，结合说明书附图 23A 可以明确隔离室 2306 设置在入口和出口之间(相当于连接在所述入口和所述出口之间的污染物容纳储库)；样品路径设置在入口和出口之间(相当于连接在所述入口和所述出口之间的样品路径)。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于流阻器，污染物容纳储库在所述出口附近具有透气的流阻器)。

从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样(相当于流体样品的第一部分)将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于当所述入口和所述出口之间施加压差时，所述污染物容纳储库被布置为接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物(相当于流体样品的第一部分潜在地具有污染物)。可以确定对比文件 1 中接收到流体样品的第一部分并将污染物

容纳在所述污染物容纳储库中。

少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310 关闭。

当释放阀 2310 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液(相当于流体样品)将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308 朝向出口端口 2304 并至收集装置(相当于当所述入口和所述出口之间施加后续压差时，所述流体样品的后续部分能够由所述样品路径从所述入口传送到所述出口)。

权利要求 14 请求保护的技术方案与对比文件 1 相比，其区别技术特征为：流阻器为透气的，以通过所述透气的流阻器和所述出口置换其中的空气。

针对上述区别技术特征：对比文件 1 中已经记载了从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻隔器；因此为了使得血液能在真空的作用下使得被吸入隔离室 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

在对比文件 1 的基础上结合本领域常规技术手段以获得该权利要求所要求保护的技术方案，对所属技术领域的技术人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步，因而不具第 22 条第 3 款规定的创造性。

6. **权利要求 15 不符合专利法第 22 条第 3 款的规定**

权利要求 15 对其引用的权利要求作了进一步限定，对比文件 1 中进一步公开了少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310(相当于阻力塞)关闭(相当于该阻力塞被配置为在接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库期间，抑制所述流体样品的第一部分的至少一部分和污染物进入所述样品路径)。

当释放阀 2310 时，并且在进一步的真空力或其他力的作用下，后续量的血液将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308 朝向出口端口 2304 并至收集装置。

因此，当其引用的权利要求不具备创造性时，权利要求 15 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

7. 权利要求 16-20 不符合专利法第 22 条第 3 款的规定

权利要求 16-20 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述污染物容纳储库中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口端口 2302 最远的远端处的疏水塞 2312，从出

口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料)；

在对比文件 1 的基础上，根据需要可以选择污染物容纳储库包括曲折路径；

对比文件 1 中记载了当释放阀 2308 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于每个压差由所述流体收集装置提供的真空压力提供)；因此对比文件 1 公开了权利要求 5 的附加技术特征；

对比文件 1 中已经公开了采样通道 2308 最初被阀 2310(相当于阻力塞)关闭；在对比文件 1 的基础上，关于阻力塞的设置方式是根据需要可以选择的，具体的阻力塞包括被后续第一压差可刺穿的膜，阻力塞还包括刺穿构件，该刺穿构件被配置为当后续第一压差施加在所述膜的相对侧上时刺穿所述膜是可以选择的设置方式。

因此，当其引用的权利要求不具备创造性时，权利要求 16-20 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

基于上述理由，本申请的独立权利要求以及从属权利要求都不具备创造性，同时说明书中也没有记载其他任何可以授予专利权的实质性内容，因而即使申请人对权利要求进行重新组合和/或根据说明书记载的内容作进一步的限定，本申请也不具备被授予专利权的前景。如果申请人不能在本通知书规定的答复期限内提出表明本申请具有创造性的充分理由，本申请将被驳回。

在第一次审查意见通知书答复期限届满前（已提交答复意见的除外）主动申请撤回的，可以退还 50%的专利申请实质审查费。审查员电话 0371-87791927，或审查值班电话 0371-87792282 代为转达。

审查员姓名:李媛媛
审查员代码:30110854

国 家 知 识 产 权 局

检 索 报 告

申请号：2020800006660	申请日：2020 年 04 月 01 日	首次检索
申请人：酷睿有限公司	最早的优先权日：2019 年 04 月 01 日	
权利要求项数：20	说明书段数：95	

审查员确定的 IPC 分类号：G01N1/10,G01N1/02,A61B5/15

检索记录信息：US2018271425A1: 参考国际检索报告以及美局通知书

EP3324845A1: 参考同族检索报告

US2014112841A1: 参考同族检索报告

WO2019232196A1: 参考同族检索报告

CN104107054A: CNTXT 语义检索,语义基准:2020800006660

CN104981203A: CNTXT 语义检索,语义基准:CN213588280U

CN1717280A: 425 CNTXT, (G01N1/IC) and (((阻隔 or 阻塞 or 流阻 or 阻力塞) and ((流体 or 血 or 样品) s 污染)) and (真空 or 压差 or 负压))

相 关 专 利 文 献

类型	国别以及代码[11] 给出的文献号	代码[43]或[45] 给出的日期	IPC 分类号	相关的段落 和/或图号	涉及的权 利要求
X	US2018271425A1	2018-09-27	A61B5/15	说明书第 0141-0149 段，说明书附图 23A-23B	1-20
A	EP3324845A1	2018-05-30	A61M39/06	全文	1-20
A	US2014112841A1	2014-04-24	B01L3/00	全文	1-20
L	WO2019232196A1	2019-12-05	A61B5/15	全文	1-20

A	CN104107054A	2014-10-22	A61B5/151	全文	1-20
A	CN104981203A	2015-10-14	A61B5/155	全文	1-20
A	CN1717280A	2006-01-04	B01L3/00	全文	1-20

相 关 非 专 利 文 献					
类型	书名（包括版本号和卷号）	出版日期	作者姓名和出版者名称	相关页数	涉及的权利要求
类型	期刊或文摘名称 （包括卷号和期号）	发行日期	作者姓名和文章标题	相关页数	涉及的权利要求
类型	网址	网络发布日 或公开日	作者姓名和网页标题	相关部分	涉及的权利要求

表格填写说明事项：

1. 审查员实际检索领域的 IPC 分类号应当填写到大组和／或小组所在的分类位置。
2. 期刊或其它定期出版物的名称可以使用符合一般公认的国际惯例的缩写名称。
3. 相关文件的类型说明：

   X：单独影响权利要求的新颖性或创造性的文件；

   Y：与本检索报告中其他 Y 类文件组合后影响权利要求的创造性的文件；

   A：背景技术文件，即反映权利要求的部分技术特征或者有关的现有技术的文件；

   R：任何单位或个人在申请日向专利局提交的、属于同样的发明创造的专利或专利申请文件。

   P：中间文件，其公开日在申请的申请日与所要求的优先权日之间的文件，或者会导致需要核实该申请优先权的文件；

E：单独影响权利要求新颖性的抵触申请文件；

T：申请日或优先权日当天或之后公布的，可以对所要求保护发明的理论或原理提供清楚解释的文件，或者可显示出所要求保护发明的推理或事实不成立的文件；

L：除 X、Y、A、R、P、E 和 T 类文件之外的文件。

审 查 员：李媛媛　　审查部门：专利审查协作河南中心
2023 年 09 月 25 日

(Translation)

Reference No.: Letter No.: 150687 Mailing Date: April 4, 2023 1

Notice of Allowance

(Divisional)

Application Serial No.:	2020-118498
Drafting Date:	March 23, 2023
Examiner:	ISONO Koji 3411 2Q00
Title of the Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
Number of Claims:	15
Applicant(s):	KURIN, INC.
Agent:	MURAKOSHI, Satoshi

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.
Certificated: March 28, 2023
Administrative Official of Ministry of Economy, Trade and Industry, Takashi SATO

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

- Type of Application: Divisional Application
- Cited References: Yes
- Grace Period under Patent Act Article 30: No
- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: Letter No.: 150687 Mailing Date: April 4, 2023 /E

Reference Information

Application Serial No.: 2020-118498

- FI

  A61B 5/15 100 ,
  A61B 5/15 200

- Search Fields (IPC, DB Name):

  A61B 5/00-5/398

- References Cited :

US Patent Application Publication No.2008/0145933	(US,A1)
Japanese Patent Application Publication No.2001-000424	(JP,A)
Japanese Patent Application Publication No.H09-504726	(JP,A)
US Patent Application Publication No.2006/0009713	(US,A1)
Japanese Patent Application Publication No.S58-025146	(JP,A)
Japanese Patent Application Publication No.H02-224742	(JP,A)
US Patent Application Publication No.2011/0306899	(US,A1)

- Non-patent literatures:

特許査定

（分割）

特許出願の番号	特願２０２０－１１８４９８
起案日	令和　５年　３月２３日
特許庁審査官	磯野　光司　３４１１　２Ｑ００
発明の名称	血液サンプル最適化システム及び血液隔離装置
請求項の数	１０
特許出願人	クリン　インコーポレイテッド
代理人	村越　智史（ほか　４名）

この出願については、拒絶の理由を発見しないから、特許査定をします。

上記はファイルに記録されている事項と相違ないことを認証する。
認証日　令和 5年 3月28日　経済産業事務官　佐藤　隆

注意：この書面を受け取った日から３０日以内に特許料の納付が必要です。

・出願種別　分割
・参考文献　有
・特許法第３０条適用　無
・発明の名称の変更　無

・菌寄託

参考情報

特許出願の番号　特願２０２０－１１８４９８

・ＦＩ

Ａ６１Ｂ　５／１５　１００　，
Ａ６１Ｂ　５／１５　２００

・調査した分野（ＩＰＣ，ＤＢ名）

Ａ６１Ｂ　５／００－５／３９８

・参考特許文献

米国特許出願公開第２００８／０１４５９３３	（ＵＳ，Ａ１）
特開２００１－０００４２４	（ＪＰ，Ａ）
特表平０９－５０４７２６	（ＪＰ，Ａ）
米国特許出願公開第２００６／０００９７１３	（ＵＳ，Ａ１）
特開昭５８－０２５１４６	（ＪＰ，Ａ）
特開平０２－２２４７４２	（ＪＰ，Ａ）
米国特許出願公開第２０１１／０３０６８９９	（ＵＳ，Ａ１）

・参考図書雑誌

(Translation)

Reference No.: F1729JP01 Letter No.: 327992 Mailing Date: July 9, 2024 1

Notice of Allowance

Application Serial No.:	2021-558648
Drafting Date:	July 4, 2024
Examiner:	ISONO, Koji 3411 2Q00
Title of the Invention:	NON-VENTING BODILY FLUID SAMPLE OPTIMIZATION DEVICE AND SYSTEM
Number of Claims:	18
Applicant(s):	KURIN, INC.
Agent:	MURAKOSHI, Satoshi (4 others)

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.
Certificated: July 8, 2024
Administrative Official of Ministry of Economy, Trade and Industry, AKUTSU,Masamitsu

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

- Type of Application: Non-Divisional Application
- Cited References: Yes
- Grace Period under Patent Act Article 30: No
- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: F1729JP01 Letter No.: 327992 Mailing Date: July 9, 2024 3/E

Reference Information

Application Serial No.: 2021-558648

- FI

  A61B 5/154 200 ,
  G01N 1/10 V

- Search Fields (IPC, DB Name):

  A61B 5/15-5/157
  G01N 1/10

- References Cited :

  US Patent Application Publication No.2018/0271425 (US,A1)
  International Patent Application Publication No.2019/055487 (WO,A1)

- Non-patent literatures:

(Translation)

Reference No.: F1729JP01 Letter No.: 327992 Mailing Date: July 9, 2024 1

Notice of Allowance

Application Serial No.:	2021-558648
Drafting Date:	July 4, 2024
Examiner:	ISONO, Koji 3411 2Q00
Title of the Invention:	NON-VENTING BODILY FLUID SAMPLE OPTIMIZATION DEVICE AND SYSTEM
Number of Claims:	18
Applicant(s):	KURIN, INC.
Agent:	MURAKOSHI, Satoshi (4 others)

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.
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Administrative Official of Ministry of Economy, Trade and Industry, AKUTSU,Masamitsu

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

- Type of Application: Non-Divisional Application
- Cited References: Yes
- Grace Period under Patent Act Article 30: No
- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: F1729JP01 Letter No.: 327992 Mailing Date: July 9, 2024 3/E

Reference Information

Application Serial No.: 2021-558648

- FI

  A61B 5/154 200 ,
  G01N 1/10 V

- Search Fields (IPC, DB Name):

  A61B 5/15-5/157
  G01N 1/10

- References Cited :

  US Patent Application Publication No.2018/0271425 (US,A1)
  International Patent Application Publication No.2019/055487 (WO,A1)

- Non-patent literatures:

特許査定

特許出願の番号	特願２０２１－５５８６４８
起案日	令和　６年　７月　４日
特許庁審査官	磯野　光司　３４１１　２Ｑ００
発明の名称	非通気性体液サンプル最適化装置及びシステム
請求項の数	１８
特許出願人	クリン　インコーポレイテッド
代理人	村越　智史（ほか　４名）

この出願については、拒絶の理由を発見しないから、特許査定をします。

上記はファイルに記録されている事項と相違ないことを認証する。
認証日　令和 6年 7月 8日　経済産業事務官　圷　政光

注意：この書面を受け取った日から３０日以内に特許料の納付が必要です。

・出願種別　通常
・参考文献　有
・特許法第３０条適用　無
・発明の名称の変更　無

・菌寄託

参考情報

特許出願の番号　特願２０２１－５５８６４８

・ＦＩ

Ａ６１Ｂ	５／１５４	２００	,
Ｇ０１Ｎ	１／１０	Ｖ	

・調査した分野（ＩＰＣ，ＤＢ名）

Ａ６１Ｂ	５／１５－５／１５７
Ｇ０１Ｎ	１／１０

・参考特許文献

米国特許出願公開第２０１８／０２７１４２５	（ＵＳ，Ａ１）
国際公開第２０１９／０５５４８７	（ＷＯ，Ａ１）

・参考図書雑誌

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/094,692	11/10/2020	Bobby E. ROGERS	KURIN4CON	8012

158174 7590 11/04/2022

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
11/04/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficeaction@appcoll.com
jsnolan1@hotmail.com
kurin@virtualipsupport.com

Office Action Summary	Application No. 17/094,692	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 02/04/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-18 and 20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-18 and 20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 11/10/2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☐ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Objections

2. Claim 14 is objected to because of the following informalities: the phrase "into chamber" in line 8 should be amended to read –into the chamber--. Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-18 and 20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of U.S Patent Application No. 10827964. Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent Application and the instance application are claiming a common subject matter including: a blood sequestration/optimization device comprising; an inlet port; an outlet port; a chamber connected with the inlet port, the sequestration chamber having a vent configured to allow air to be displaced by a first portion of blood entering the inlet port and into sequestration chamber; a plug/closure to enclose the vent to inhibit air from reentering the sequestration chamber; a sampling

channel having a proximal end connected with the inlet port and a distal end connected with the outlet port, the sampling channel being configured to convey subsequent portions of blood past the sequestration chamber and to the outlet port after the first portion of blood has entered the sequestration chamber; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is

available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20080319346-A1	12-2008	Crawford; Jamieson	A61B5/150389	600/576
*	B	US-4412548-A	11-1983	Hoch; Louis	A61B5/150213	600/577
*	C	US-5222502-A	06-1993	Kurose; Katsutoshi	A61B5/150732	600/584
*	D	US-5520193-A	05-1996	Suzuki; Issei	A61B5/1545	604/126
*	E	US-20100057004-A1	03-2010	Christensen; Kelly D.	A61M39/22	604/122
*	F	US-20070088279-A1	04-2007	Shue; Ming-Jeng	A61M25/0693	604/168.01
*	G	US-20080145933-A1	06-2008	Patton; Richard G.	A61B5/154	435/379
*	H	US-20040054333-A1	03-2004	Theeuwes, Felix	A61M5/14276	604/248
*	I	US-9022951-B2	05-2015	Bullington; Gregory	A61B10/0048	600/576
*	J	US-6569117-B1	05-2003	Ziv; David	A61M39/02	604/246
*	K	US-3741197-A	06-1973	Sanz; Manuel C.	A61B5/150267	600/583
*	L	US-20100010372-A1	01-2010	BROWN; LEROY R.	A61B5/15003	600/573
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NON-PATENT DOCUMENTS

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*	B	US-20080167577-A1	07-2008	Weilbacher; Eugene E.	A61B5/1545	600/576
*	C	US-20080086085-A1	04-2008	Brown; Leroy R.	A61B5/150389	604/122
*	D	US-9877675-B2	01-2018	Baid; Rishi	A61B5/150389	1/1
*	E	US-4444203-A	04-1984	Engelman; Allan	A61B5/150496	600/576
*	F	US-20070083162-A1	04-2007	O'Reagan; James	A61M39/26	604/167.03
*	G	US-6398743-B1	06-2002	Halseth; Thor R.	A61B5/15003	604/164.12
*	H	US-9022950-B2	05-2015	Bullington; Gregory	A61B5/150389	600/576
*	I	US-9155495-B2	10-2015	Bullington; Gregory J.	A61B5/150633	1/1
*	J	US-20160008579-A1	01-2016	Burkholz; Jonathan Karl	A61M5/158	604/164.08
*	K	US-20120016266-A1	01-2012	Burkholz; Jonathan Karl	A61B5/150992	600/581
*	L	US-4436098-A	03-1984	Kaufman; Joseph	A61B5/1545	604/199
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*	B	US-8568371-B2	10-2013	Siopes; William	A61M39/26	251/903
*	C	US-8540663-B2	09-2013	Davey; Christopher T.	A61M1/30	604/93.01
*	D	US-8523826-B2	09-2013	Layton, Jr.; Russell K.	A61M39/16	604/533
*	E	US-20160174888-A1	06-2016	Berthier; Erwin	A61B5/150503	600/573
*	F	US-8197420-B2	06-2012	Patton; Richard G.	A61B5/150503	600/573
*	G	US-4057050-A	11-1977	Sarstedt; Walter	A61B5/150351	604/125
*	H	US-20050240161-A1	10-2005	Crawford, Jamieson William McLean	A61B5/150572	604/264
*	I	US-20040147855-A1	07-2004	Marsden, Stewart	A61B5/150496	600/576
*	J	US-8864684-B2	10-2014	Bullington; Gregory J.	A61B10/0048	600/576
*	K	US-8535241-B2	09-2013	Bullington; Gregory	A61B5/150946	604/249
*	L	US-20040073171-A1	04-2004	Rogers, Bobby E.	A61M39/26	604/164.13
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*	B	US-5749857-A	05-1998	Cuppy; Michael J.	A61M25/0606	604/161
*	C	US-9060724-B2	06-2015	Bullington; Gregory J.	A61B5/150099	1/1
*	D	US-9204864-B2	12-2015	Bullington; Gregory J.	A61B10/0096	1/1
*	E	US-20020004647-A1	01-2002	Leong, Alvin Tan Chee	A61B5/1545	604/168.01
*	F	US-3817240-A	06-1974	Ayres; Waldemar A.	A61B5/150221	600/584
*	G	US-3874367-A	04-1975	Ayres; Waldemar A.	A61B5/15003	600/577
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*	I	US-4106497-A	08-1978	Percarpio; Edward P.	A61B5/150389	600/579
*	J	US-4154229-A	05-1979	Nugent; Edward L.	A61B5/150473	600/577
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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
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	16	✓								
	17	✓								
	18	✓								
	19	-								
	20	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/094,692	ROGERS et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	Date	Examiner
A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503	10/13/2022	MA

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
class/subclass search, text search, inventor name search	10/13/2022	MA

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

PE2E SEARCH - Search History (Prior Art)

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L58	5898	L57 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/04/13 04:29 PM
L59	114	L58 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/04/13 04:29 PM
L60	2	("2007/0088279").URPN.	(USPAT)	OR	OFF	OFF	2017/04/13 05:58 PM
L61	1	("6358217").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/04/21 02:02 PM
L62	6	("2002/0004647").URPN.	(USPAT)	OR	OFF	OFF	2017/09/27 12:48 PM
L63	2	("14493796").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:21 PM
L64	2	("14494208").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:23 PM
L65	1	("15140443").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/27 01:28 PM
L66	1	("20080145933").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:51 PM
L67	9	("2008/0145933").URPN.	(USPAT)	OR	OFF	OFF	2017/09/27 01:55 PM
L68	1	("20040054333").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 01:59 PM

L69	1	("20120109034").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 02:37 PM
L70	1	("20100228206").PN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/27 02:39 PM
L71	3	("2010/0228206").URPN.	(USPAT)	OR	OFF	OFF	2017/09/27 02:47 PM
L72	66	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:41 PM
L73	4	L72 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:42 PM
L74	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 01:58 PM
L75	845	L74 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:58 PM
L76	9	L75 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 01:59 PM
L77	86	("2007/0083162").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 01:59 PM
L78	1	("15140443").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 01:59 PM
L79	9	("2008/0145933").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 02:04 PM
L80	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2017/09/28 02:20 PM
L81	1071	L80 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:20 PM
L82	78	L81 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 02:21 PM
L83	282596	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L84	6183	L83 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2017/09/28 04:01 PM
L85	387	L84 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:01 PM
L86	362	L85 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:02 PM
L87	12	("2005/0010189").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 04:03 PM
L88	1363	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:04 PM
L89	74	L88 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:05 PM
L90	21	("3965910" | "3996923"	(US-PGPUB; USPAT;	OR	OFF	OFF	2017/09/28

		| "4131127" | "4301811" | "4450854" | "4506691" | "4819684" | "5147333" | "5393035" | "5636975").PN. OR ("6569117").URPN.	USOCR)				04:09 PM
L91	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2017/09/28 04:12 PM
L92	18	L91 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:12 PM
L93	9	("2008/0145933").URPN.	(USPAT)	OR	OFF	OFF	2017/09/28 04:13 PM
L95	67	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:23 PM
L96	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:25 PM
L97	4	L96 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:25 PM
L98	3	L97 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:26 PM
L99	1733	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 04:50 PM
L100	13	L99 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:50 PM
L101	255	("1779451" | "2004050" | "2700385" | "2836942" | "2854976" | "2953243" | "3021942" | "3073307" | "3074542" | "3255873" | "3294231" | "3323523" | "3329146" | "3333682" | "3367488" | "3382865" | "3485239" | "3537452" | "3585984" | "3610240" | "3658061" | "3664879" | "3817240" | "3828775" | "3859998" | "3874367" | "3886930" | "3890971" | "3904033" | "3934722" | "3968876" | "4106497" | "4108175" | "4113090" | "4139009" | "4154229" | "4166450" | "4175008" | "4193400" | "4207870" | "4269186" | "4300678" | "4312362" | "4317445" | "4340068" | "4375849" | "4398544" | "4409990" | "4412548" | "4416290" | "4416291" | "4418703" | "4430082" | "4436098" | "4444203" | "4592744"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/01/09 04:51 PM

		| "4634428" | "4643722" | "4659330" | "4664249" | "4664654" | "4671408" | "4679571" | "4681567" | "4695274" | "4702738" | "4723943" | "4728320" | "4728321" | "4731059" | "4735311" | "4735618" | "4737144" | "4738663" | "4743233" | "4746008" | "4747836" | "4747837" | "4772272" | "4778453" | "4781697" | "4782841" | "4788986" | "4790828" | "4793484" | "4795432" | "4795443" | "4801295" | "4804372" | "4813426" | "4816022" | "4816024" | "4819659" | "4820277" | "4826490" | "4826491" | "4838871" | "4842587" | "4844089" | "4846796" | "4850968" | "4850976" | "4850977" | "4850978" | "4850994" | "4850996" | "4858607" | "4863434" | "4863435" | "4863436" | "4865592" | "4867746" | "4872552" | "4874383" | "4874384" | "4883469" | "4886072" | "4886503" | "4888001" | "4892107" | "4892521" | "4894052" | "4900309" | "4909791" | "4909792").PN. OR ("4921096" | "4927018" | "4944397" | "4966591" | "4971068" | "4976699" | "4982842" | "5011475" | "5011479" | "5030207" | "5032116" | "5033476" | "5055102" | "5069225" | "5078693" | "5078698" | "5092845" | "5112327" | "5116325" | "5120319" | "5122121" | "5135509" | "5137518" | "5139489" | "5151089" | "5154285" | "5181523" | "5188611" | "5197954" | "5201794" | "5207653" | "5217025" | "5222502" | "5232454" | "5232455" | "5242411" | "5242417" | "5277311" | "5290246" | "5295969" | "5303713" | "5306259" | "5312369" | "5401251" | "5405332" | "5423765"					

		| "5450856" | "5462534" | "5485854" | "5486163" | "5490841" | "5496281" | "5509907" | "5520193" | "5533984" | "5542932" | "5584816" | "5599313" | "5599318" | "5603699" | "5632732" | "5643219" | "5662617" | "5665075" | "5669889" | "5693022" | "5697914" | "5702369" | "5733265" | "5755701" | "5807351" | "5830190" | "5836920" | "5885249" | "5893844" | "5913846" | "5984895" | "5993426" | "6059737" | "6077244" | "6077253" | "6080137" | "6096006" | "6110160" | "6120482" | "6156010" | "6190370" | "6261263" | "6511439" | "6533760" | "6964658" | "7160267" | "RE31086").PN. OR ("7615033").URPN.					
L102	215	L101 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:51 PM
L103	1347	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:11 PM
L104	17	L103 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L105	19	("2009/0312711").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L106	11	("2007/0106220").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L107	288967	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L108	6321	L107 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L109	121	L108 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:17 PM
L110	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:31 PM
L111	6	L110 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:31 PM
L113	71	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:31 PM
L114	0	("15140443").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:38 PM

L115	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:38 PM
L116	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:40 PM
L117	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 01:56 PM
L118	854	L117 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:56 PM
L119	91	L118 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:57 PM
L120	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:06 PM
L121	1074	L120 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L122	80	L121 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L123	301210	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L124	6556	L123 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L125	3664	L124 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L126	12749	"19" and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L127	117	L125 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L128	1348	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:16 PM
L129	75	L128 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:17 PM
L130	1	("20120291564").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:21 PM
L131	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:25 PM
L132	18	L131 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:25 PM
L133	98	("20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054333" | "20040147855" | "20050004524" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:44 PM

		"20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6626884" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7744573" | "8197420" | "8231546" | "8337418").PN. OR ("8535241").URPN.					
L134	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:47 PM
L135	23	("4166450").PN. OR ("4412548").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L136	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L137	4	("2007/0088279").URPN.	(USPAT)	OR	ON	ON	2018/07/24 02:48 PM
L138	1	(14/990763).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:58 PM
L139	9	(blood and sequest$5 and junction and first and portion and sampl$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 03:07 PM

L140	1	(15/287421).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/25 09:39 PM
L141	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/26 11:56 AM
L142	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:24 PM
L143	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:25 PM
L144	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"20080145933"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 05:53 PM
L145	272	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian")) OR (("GARRETT") near3 ("Chad"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/11/07 05:57 PM
L146	9	L145 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 05:58 PM
L147	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"20080145933"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"38743	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 06:26 PM

		67"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.					
L148	5	L147 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 06:29 PM
L149	6	("2010/0057004").URPN.	(USPAT)	OR	ON	ON	2019/11/07 06:40 PM
L150	0	L149 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:20 PM
L151	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:21 PM
L152	4	L151 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L153	1766	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:21 PM
L154	13	L153 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L155	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:22 PM
L156	48	L155 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:22 PM
L157	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L158	17	L157 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:43 PM
L159	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L160	6	L159 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L161	333030	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L162	6981	L161 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L163	139	L162 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L164	117	L163 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:45 PM
L165	1	L146 and (enclos$3 near4 mechanism)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:51 PM
L166	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/08 04:57 PM

L167	1	(15/139716).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/11 12:09 PM
L168	1	(15/520430).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 11:02 AM
L169	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:11 PM
L170	1	("20120253321").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:13 PM
L171	1	(15/861959).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:14 PM
L172	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 02:17 PM
L173	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:14 PM
L174	1	("20080167577").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:19 PM
L175	4	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2019/12/09 03:30 PM
L176	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:31 PM
L177	39	(US-20040073171-$ or US-20160174888-$ or US-20050240161-$ or US-20040147855-$ or US-20130317391-$ or US-20050004524-$ or US-20030105414-$ or US-20020004647-$ or US-20100057004-$ or US-20070088279-$ or US-20080145933-$ or US-20040054333-$ or US-20100010372-$ or US-20080319346-$ or US-20080167577-$).did. or (US-9138572-$ or US-8568371-$ or US-8540663-$ or US-8523826-$ or US-8197420-$ or US-4057050-$ or US-8864684-$ or US-8535241-$ or US-5749857-$ or US-9060724-$ or US-9204864-$ or US-3817240-$ or US-3874367-$ or US-3886930-$ or US-4106497-$ or US-4154229-$ or US-4207870-$ or US-4412548-$ or US-5222502-$ or US-5520193-$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:37 PM

		9022951-$ or US-6569117-$ or US-3741197-$ or US-8603009-$).did.					
L178	8	("20040054333"|"8197420"|"9855001"|"9861306"|"10045724"|"10028687"|"8337418"|"10028689").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:42 PM
L179	100	("20020002349" | "20020183651" | "20030055381" | "20040010228" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047").PN. OR ("8197420").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 03:43 PM
L180	70	L179 and (blood near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 03:43 PM
L181	43	L180 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 03:44 PM
L182	270	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/12/09 04:13 PM

		("Jay")) OR (("GAW") near3 ("Shan"))).INV.					
L183	335813	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L184	7259	L183 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L185	325	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 04:33 PM
L186	594	L184 and (flash$6 and seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L187	476	L186 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L188	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:14 PM
L189	1123	L188 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L190	1013	L189 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L191	10	L190 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:16 PM
L192	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:23 PM
L193	1143	L192 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L194	1038	L193 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L195	3	L194 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L196	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:24 PM
L197	618	L196 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L198	557	L197 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L199	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:25 PM
L200	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:31 PM
L201	219	L200 and ((blood or	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09

		fluid$4) near4 (sequest$5 or sampl$4 or flash$4))					05:33 PM
L202	199	L201 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L203	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:36 PM
L204	44	L203 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:37 PM
L205	1	(15/508871).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/10 11:58 AM
L206	342199	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/03/16 12:53 PM
L207	4239	L206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:53 PM
L208	146	L207 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:54 PM
L209	101	L208 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:55 PM
L210	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:38 PM
L211	1123	L210 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:38 PM
L212	1013	L211 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L213	22	L212 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L214	108	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 01:46 PM

		"20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" | "5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.					
L215	26	L214 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:47 PM

L216	27	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:47 PM
L217	23	("2003/0105414").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:48 PM
L218	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:52 PM
L219	1143	L218 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L220	25	L219 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L221	353695	((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:54 PM
L222	3643	L221 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L223	1926	L222 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L224	785	L223 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:56 PM
L225	7046	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 02:32 PM
L226	14	L225 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:35 PM
L227	1352	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:36 PM
L228	135	L227 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L229	19	L228 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L230	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:47 PM
L231	3	L230 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:47 PM
L232	19	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/03/16 02:48 PM
L233	795	(600/576).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:58 PM
L234	71	L233 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:58 PM

L235	57	L234 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:59 PM
L236	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:12 PM
L237	11	L236 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:12 PM
L238	45	("20040054333"|"20050240161"|"4412548"|"5749857"|"8197420"|"9855001"|"9861306"|"20020004647"|"20100057004"|"3741197"|"20040073171"|"3874367"|"4057050"|"4106497"|"8197420"|"8535241"|"8540663"|"8603009"|"8864684"|"10045724"|"3817240"|"10028687"|"20030105414"|"5222502"|"5520193"|"6569117"|"8568371"|"20040147855"|"20070088279"|"20080145933"|"20100010372"|"3886930"|"8523826"|"9060724"|"9204864"|"8337418"|"20050004524"|"20080167577"|"20080319346"|"20130317391"|"4154229"|"9022951"|"10028689"|"20160174888"|"4207870"|"9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:13 PM
L239	6	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2020/03/16 03:13 PM
L240	118	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 03:15 PM
L241	6	("2008/0167577").URPN.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 03:15 PM
L242	274	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2020/03/16 03:25 PM

L243	61	L242 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:25 PM
L244	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:47 PM
L245	0	(14/502498).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:11 PM
L246	1	("20110082383").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L247	1	("8150506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L252	1	(15/057214).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/17 11:28 AM
L253	348964	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L254	7453	L253 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L255	155	L254 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:23 PM
L256	77	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:35 PM
L257	343953	(blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:40 PM
L258	11	L256 and (blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:41 PM
L259	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:50 PM
L260	121	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:19 PM
L261	32	L260 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:20 PM
L262	1	("3648684").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L263	1	("4056101").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L264	329	(600/577).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/06/10

							06:39 PM
L265	11	L264 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:39 PM
L266	29	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/06/10 06:40 PM
L267	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:40 PM
L268	72	L267 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:40 PM
L269	1767	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:44 PM
L270	31	L269 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:45 PM
L271	77	("4676249" | "4787891" | "4850960" | "4874382" | "4886067" | "4886500" | "4900307" | "4904242" | "4917102" | "4950252" | "4955862" | "5046508" | "5116353" | "5125718" | "5129884" | "5163911" | "5217435" | "5290244" | "5295974" | "5314503" | "5318585" | "5330432" | "5360410" | "5366441" | "5376075" | "5395337" | "5531692" | "5695475" | "5695479" | "5702367" | "5735813" | "5749857" | "5788654" | "5800395" | "5846226" | "5871470" | "5882342" | "5919172" | "5935108" | "5935113" | "5989220" | "6050976" | "6077244" | "6099504" | "6126641" | "6162195").PN. OR ("6398743").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:46 PM
L272	18	L271 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:46 PM
L273	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:48 PM
L274	7050	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:49 PM
L275	14	L274 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:49 PM
L276	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:51 PM
L277	7	L276 and ((blood or	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10

		fluid$4) near4 (sequest$5 or flash$4))					06:51 PM
L278	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:52 PM
L279	135	L278 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:52 PM
L280	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 07:08 PM
L281	3	L280 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 07:08 PM
L282	20	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/06/10 07:08 PM
L286	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 08:56 PM
L287	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:16 PM
L288	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:17 PM
L289	100	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/03/01 09:17 PM
L290	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:36 PM
L291	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:39 PM
L292	180	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/03/02 12:19 PM
L293	11	L292 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 12:20 PM
L294	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:47 PM
L295	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:49 PM
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L297	1	("20040174525").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:49 PM
L298	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:09 PM
L299	27321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/03/02 03:17 PM

		A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.					
L300	4594	L299 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:27 PM
L301	3762	L300 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:28 PM
L302	257	L301 and (air near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L303	420	L301 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L304	1	("20110167658").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:30 PM
L305	5	("2015/0306288").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:15 PM
L306	1	(16/208559).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 04:32 PM
L307	2	("2009/0043225").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:49 PM
L308	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/03/02 05:00 PM
L309	1363	L308 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:00 PM
L310	73	L309 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L311	73	L310 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L312	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:34 PM
L313	711	L312 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L314	58	L313 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L315	58	L314 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L316	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:42 PM
L317	277	L316 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:42 PM

L318	20	L317 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:43 PM
L319	336	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/03/02 05:44 PM
L320	210	L319 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L321	196	L320 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L322	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:48 PM
L323	1208	L322 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L324	73	L323 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L325	73	L324 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:49 PM
L326	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:59 PM
L327	271	L326 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L328	10	L327 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L329	268	L327 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L330	182	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/07/08 02:22 PM
L331	27660	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/07/08 03:27 PM
L332	4684	L331 and ((blood or fluid$4) near4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:28 PM

		(sequest$5 or sampl$4 or flash$4 or collect$4))					
L333	3769	L332 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L334	579	L333 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L335	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:54 PM
L336	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:56 PM
L337	337	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:19 PM
L338	211	L337 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L339	196	L338 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L340	37	L339 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L341	221	("20010021827" | "20020004650" | "20020055716" | "20020072715" | "20020103464" | "20020103465" | "20020107488" | "20020151856" | "20020193748" | "20030028171" | "20030036730" | "20030050608" | "20030055385" | "20030078544" | "20030093009" | "20030105414" | "20030114797" | "20030120222" | "20030176842" | "20030181873" | "20030191438" | "20030199827" | "20030216687" | "20030220614" | "20030229315" | "20030229316" | "20040024370" | "20040059302" | "20040092872" | "20040102740" | "20040111068" | "20040193120" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

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		| "5303713" | "5312372" | "5318547" | "5336199" | "5344408" | "5348544" | "5356392" | "5389085" | "5403286" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5549558" | "5595566" | "5599313" | "5607402" | "5662617" | "5665075" | "5669889" | "5672161" | "5676658" | "5681295" | "5685855" | "5687740" | "5688241" | "5695474" | "5702369" | "5704920" | "5718239" | "5733265" | "5755522" | "5769826" | "5795336" | "5879337" | "5893845" | "5910130" | "5921964" | "5957892" | "5984899" | "6149629" | "6171284" | "6183445" | "6224576" | "6254575" | "6261263" | "6261265" | "6298541" | "6344032" | "6419658" | "6436086" | "6440104" | "6471677" | "6475191" | "6485469" | "6524277" | "6533760" | "6554807" | "6575939" | "6592556" | "6623456" | "6623461" | "6635032" | "6641555" | "6648855" | "6648856" | "6659983" | "6695819" | "6699217" | "6712792" | "6716199" | "6761704" | "6773419" | "6780169" | "6805689" | "6811545" | "6835190" | "6837877" | "6846302" | "6860872" | "6869415" | "6905483" | "6918891" | "6958054" | "6974423" | "6984223" | "6997913" | "7001363" | "7083600" | "7101355" | "7128726" | "7147624" | "7160267" | "7163526" | "7201740" | "7211065" | "7223258" | "7226432" | "7361159" | "7396343" | "7428773" | "7524308" | "7537581" | "7670320" | "7727190" | "7766879" | "7938808" | "8066679" | "8282605" | "8795198" | "D422700" | "D442280" | "D604836" | "D604837"					

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L343	148	("20020193748" | "20030105414" | "20030229315" | "20040059302" | "20040092872" | "20050004524" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245885" | "20060036219" | "20070106220" | "20070167914" | "20080086085" | "20080177202" | "4106497" | "4207870" | "4305406" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5672161" | "5676658" | "5702369" | "5704920" | "5755522" | "5984899" | "6149629" | "6261263" | "6298541" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "D422700" | "D442280").PN. OR ("7766879").URPN.					
L344	41	("2735430" | "2798487" | "3187749" | "3240209" | "3585984" | "3817240" | "4166450" | "4207870" | "4295477" | "4312362").PN. OR ("4436098").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:22 PM
L345	163	L341 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:22 PM
L346	163	L345 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:23 PM
L347	22	("2005/0283093").URPN.	(USPAT)	OR	ON	ON	2021/07/08 04:23 PM
L348	163	L345 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L349	163	L348 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L350	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/08 04:37 PM
L351	1363	L350 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:37 PM
L352	1346	L351 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L353	136	L352 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L354	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:41 PM
L355	711	L354 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L356	699	L355 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L357	123	L356 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L358	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:44 PM
L359	277	L358 and ((blood or fluid$4) near4 (sequest$5 or sampl$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM

		or flash$4 or collect$4))					
L360	260	L359 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L361	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:46 PM
L362	1208	L361 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:46 PM
L363	1194	L362 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L364	1194	L363 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L366	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:05 PM
L367	319	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/02/02 03:14 PM
L368	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:35 PM
L369	190	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 03:36 PM
L370	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:41 PM
L371	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L372	1	("9060725").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L373	1	("9060724").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:43 PM
L374	1	("9022950").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L375	1	("9022951").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L376	1	("10292633").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:46 PM
L377	1	("10433779").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:47 PM
L378	1	("10436554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:48 PM
L379	1	("10736554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L380	1	("10912506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L381	1	("10010282").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2022/02/02

			USOCR)				03:49 PM
L382	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:50 PM
L383	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:51 PM
L384	276	(600/579).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:52 PM
L385	204	L384 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 03:53 PM
L386	37427	(A61B5/150221 or A61B5/15003 or A61B5/150236 or A61B5/150244 or A61B5/150251 or A61B5/150389 or A61B5/150503 or A61B5/150992 or A61B5/153 or A61B5/155 or A61B10/0048 or A61B10/0051 or A61B10/007 or A61B2010/0061 or A61B2010/0077 or A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 04:35 PM
L387	7279	L386 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L388	4442	L387 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L389	874	L388 and (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:38 PM
L390	26	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:52 PM
L391	44	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:59 PM
L392	385	L386 and ((blood or fluid) near4 (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L393	171	L392 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L394	355	(604/103).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 05:52 PM
L395	7	L394 and ((blood or fluid) near4 (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:52 PM

L396	1	(16/328127).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/03 12:00 PM
L397	0	"1020130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L398	8	"20130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L399	14	"2013021595"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:18 PM
L400	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/04 07:10 PM
L401	1	(15/746656).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/05 11:48 AM
L402	0	(17/388440).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/07 09:34 AM
L403	1	("20050048465").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/07 09:34 AM
L404	196	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:08 PM
L405	16	L404 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L406	16	L404 and ((blood or chamber) near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L407	16	L406 and (junct$4 or bypass$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L408	16	L406 and junct$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L409	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:54 PM
L410	4525	L409 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:55 PM
L411	3810	L410 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:56 PM
L412	820	L411 and ((vent$4 or	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18

		open$4 or apertur$4) near4 air)					03:57 PM
L413	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 05:51 PM
L414	4603	L413 and ((blood or fluid$4 or chamber) same (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:51 PM
L415	511	L414 and ((junct$4 or bypass$4 or divert$4) near4 (blood or fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:52 PM
L416	355	L415 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:53 PM
L417	1	(16/819033).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:10 PM
L418	1	(17/094692).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L419	1	(17/538990).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L420	1	("11311219").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:27 PM
L421	1	("11185266").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:30 PM
L422	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:31 PM
L423	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:32 PM
L424	252	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/10/13 01:41 PM
L425	38	424 AND (closur$4 OR enclos$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:42 PM

L426	42781	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/13 01:47 PM
L427	5205	426 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:50 PM
L428	4803	427 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:51 PM
L429	519	428 AND ((closur$4 OR enclos$4 OR pug$4) near5 (vent OR open$4 OR air))	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:54 PM
L430	169	"5749857"	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
L431	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
L432	346	427 AND ((junct$4 OR bypass$4 OR divert$4) near4 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:18 PM
L433	186	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").pn. OR ("5749857").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/13 02:32 PM
L434	124	433 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4 OR optimiz$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:34 PM
L435	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13

							02:34 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N94	1	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:15 PM
N112	3	(port and sequest$5 and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:39 PM
N248	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N249	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow$4 and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N250	495	(blood and fluid$4 and allow$4 and initial$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N251	107	(blood and fluid$4 and allow$4 and initial$4 and subsequent$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N283	9	((blood or fluid$4) and sequestrat$4 and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N284	530	((blood or fluid$4) and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N285	84	((blood or fluid$4) and chamber and cap and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:32 PM
N365	6	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:49 PM

Bibliographic Data

Application No: 17/094,692

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/ Examiner's Signature | Initials

Title: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD BARRIER WITH CLOSURE MECHANISM

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/10/2020	600	3791	KURIN4CON
RULE			

APPLICANTS

KURIN, INC., San Diego, CA, UNITED STATES

INVENTORS

Bobby E. ROGERS, San Diego, CA, UNITED STATES

Gino KANG, Irvine, CA, UNITED STATES

David Karl STROUP, San Diego, CA, UNITED STATES

Jonas Dean COCHRAN, Santee, CA, UNITED STATES

Arthur DEPTALA, Santee, CA, UNITED STATES

John DETLOFF, San Diego, CA, UNITED STATES

Lonnie POGUE, San Diego, CA, UNITED STATES

Brian MACOWSKI, San Diego, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 15893518 02/09/2018 PAT 10827964

15893518 has PRO of 62467016 03/03/2017

15893518 has PRO of 62457764 02/10/2017

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

02/02/2021

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

Kurin, Inc.

P.O. Box 371710
San Diego, CA 92137
UNITED STATES

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$830

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Thum, Bernhard
Thum & Partner
Thum Mötsch Weickert
Patentanwälte PartG mbB
Siebertstr. 6
81675 München
ALLEMAGNE

Date
15.11.2022

Reference	Application No./Patent No.
KUR-18996-P-EP	20781928.5 - 1122 / 3948211 PCT/US2020026276
Applicant/Proprietor	
Kurin, Inc.	

Communication pursuant to Rules 70(2) and 70a(2) EPC

A supplementary European search report has been drawn up concerning the above-identified European patent application (publication number: 3948211).

Since the request for examination has been filed (R. 70(1), 159(1)(f), Art. 94(1) EPC) prior to the transmission of the supplementary European search report, you are hereby invited to indicate within

six months

of notification of this communication whether you wish to proceed further with the European patent application.

If you do not indicate in due time that you wish to proceed further with the European patent application, it **will be deemed to be withdrawn** (R. 70(3) EPC).

You are invited, within the above-mentioned six-month period, to comment on the objections raised in the opinion accompanying the European search report and/or to file any amendments to the description, claims and drawings correcting any deficiencies noted in the opinion (R. 70a(2), R. 137(2) EPC; Guidelines for Examination in the EPO, B-XI, 8).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the Examining Division requesting that you correct this deficiency (R. 137(4) EPC).

Should the reply to the invitation pursuant to Rule 70a(2) EPC be filed in an admissible non-EPO language, a translation is to be submitted within one month of its filing (R. 6(2) EPC).

Should you not comply with this invitation within the time limit, the application **will be deemed to be withdrawn** in accordance with Rule 70a(3) EPC.

Receiving Section

Europäisches Patentamt • European Patent Office • Office européen des brevets

Registered Letter

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

27500 7590 10/04/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
10/04/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/538,990	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 11/30/2021.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 11/30/2011 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05/16/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 1 is objected to because of the following informalities: the phrase "blood" in lines 8 and 10 should be amended to read –the blood--. Appropriate correction is required.

4. Claim 1 is objected to because of the following informalities: the phrase "the junction being sized" in lines 7-8 should be amended to read –wherein the junction being sized--. Appropriate correction is required.

5. Claim 2 is objected to because of the following informalities: the phrase "blood" in line 3 should be amended to read –the blood--. Appropriate correction is required.

6. Claim 11 is objected to because of the following informalities: the phrase "an curved channel" in line 2 should be amended to read –the curved channel--. Appropriate correction is required.

7. Claim 12 is objected to because of the following informalities: the phrase "an air permeable blood barrier" in line 2 should be amended to read –the air permeable blood barrier--. Appropriate correction is required.

8. Claim 13 is objected to because of the following informalities: the phrase "the chamber" in line 9 should be amended to read –wherein the chamber--. Appropriate correction is required.

9. Claim 13 is objected to because of the following informalities: the phrase "bodily fluid" in lines 9-10, 12 and 13 should be amended to read –the bodily fluid--. Appropriate correction is required.

10. Claim 13 is objected to because of the following informalities: the phrase "from the inlet to bypass the chamber" in line 13 should be amended to read –to be directed from the inlet to bypass the chamber--. Appropriate correction is required.

11. Claim 16 is objected to because of the following informalities: the phrase "bodily fluid" in line 3 should be amended to read –the bodily fluid--. Appropriate correction is required.

Claim Interpretation

12. The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g.,

"means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word "means," but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

Limitation "junction" in claims 1, 6 and 13, the claims does not recite enough structure that corresponds to the claimed "junction", the specification disclose (junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A-17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608, par.0109) which can be interpreted as the structure that corresponds to the claimed "junction".

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the

claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

13. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specifications hall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

14. Claim 1 recites the limitation "the patient" in line2. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 6 recites the limitation "the blood control device" in line 2. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 6 recites the limitation "the sequestration chamber" in line 10. There is insufficient antecedent basis for this limitation in the claim. Examiner respectfully notes that the phrase “the sequestration chamber” is also recite in claim 7.

17. Claim 8 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 9 recites the limitation "the blood sampling pathway" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

19. The statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a statutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of

activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are non-provisionally rejected on the ground of statutory double patenting as being unpatentable over claims 1-20 of U.S Patent Application No.11311219, claims 1-16 of U.S Patent Application No. 9820682, claims 1-23 of U.S Patent Application No.10143412, and claims 1-26 of U.S Patent Application No.11185266.

Also, claim 1-20 are provisionally rejected on the ground of non-statutory double patenting as being unpatentable over claims 1-20 of U.S pending Application No.17/730118, and claims 1-18 and 20 of U.S pending Application No.17/094692.

Although the claims at issue are not identical, they are not patentably distinct from each other because the U.S Patent applications, pending applications and the instance application are claiming a common subject matter including: a blood sample device comprising; an inlet, an outlet; a chamber having a vent that includes an air permeable blood barrier; a sampling channel; and a junction connected between the inlet, the

chamber and the sampling channel, wherein the junction being sized and configured such that a first portion of blood conveyed from the patient flows into the chamber to displace air therein through the air permeable blood barrier, and such that a second portion of blood is allowed to bypass the chamber and the first portion of blood at least temporarily contained therein to be directed into the sampling channel toward the outlet.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and

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/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/538,990	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

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*	K	US-3741197-A	06-1973	Sanz; Manuel C.	A61B5/150267	600/583
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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

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(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	07/05/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The information provided by you in this form will be subject to the following routine uses:

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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	2	5432084		1995-07-11	BRUBAKER DANIEL B	
	3	5972294		1999-10-26	SMITH JOHN L	
	4	6187347		2001-02-13	PATTERSON JAMES A	
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	8	9060724		2015-06-23	BULLINGTON GREGORY J	

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	Attorney Docket Number	069366-0572201_KUR2C03US

	9	9155495		2015-10-13	BULLINGTON GREGORY J	
	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
	18	9877675		2018-01-30	BAID RISHI	
	19	4444203		1984-04-24	ENGELMAN ALLAN	

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	20	6398743		2002-06-04	HALSETH THOR R	
	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
	24	8568371		2013-10-29	SIOPES WILLIAM	
	25	8540663		2013-09-24	DAVEY CHRISTOPHER T	
	26	8523826		2013-09-03	LAYTON JR RUSSELL K	
	27	4057050		1977-11-08	SARSTEDT WALTER	
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	29	5749857		1998-05-12	CUPPY MICHAEL J	
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	31	3874367		1975-04-01	AYRES WALDEMAR A	
	32	3886930		1975-06-03	RYAN GEORGE R	
	33	4106497		1978-08-15	PERCARPIO EDWARD P	
	34	4154229		1979-05-15	NUGENT EDWARD L	
	35	4980297		1990-12-25	HAYNES JOHN L	
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	42	3817240		1974-06-18	AYRES W	
	43	3648684		1972-03-14	BARNWELL CLEORA W	
	44	4056101		1977-11-01	GEISSLER ULRICH C	
	45	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
	46	8070725		2011-12-06	CHRISTENSEN KELLY D	
	47	4349035		1982-09-14	THOMAS JOSEPH J	
	48	4813433		1989-03-21	DOWNEY JOHN M	
	49	5401262		1995-03-28	KARWOSKI THEODORE	
	50	3859998		1975-01-14	THOMAS JOSEPH JOHN	
	51	4373535		1983-02-15	MARTELL MICHAEL D	
	52	4690154		1987-09-01	WOODFORD TIMOTHY	

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	54	5865803		1999-02-02	MAJOR MIKLOS	
	55	5873841		1999-02-23	BRANNON JAMES K	
	56	6013037		2000-01-11	BRANNON JAMES K	
	57	6913580		2005-07-05	STONE BENJAMIN CURTIS	
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	59	6626884		2003-09-30	DILLON JAGMOHANBIR SINGH	
	60	4904240		1990-02-27	HOOVER ROCKLIN L	
	61	4673386		1987-06-16	GORDON MARK G	
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	65	3848579		1974-11-19	VILLA REAL A	
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	71	5811658		1998-09-22	VAN DRIEL MICHAEL R	
	72	3604410		1971-09-14	WHITACRE GARY L	
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	76	4193400		1980-03-18	LOVELESS JAMES C	
	77	6843775		2005-01-18	HYUN DONGCHUL D	
	78	7666166		2010-02-23	EMMERT MICHAEL	
	79	7479131		2009-01-20	MATHIAS JEAN-MARIE	
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	88	6945948		2005-09-20	BAINBRIDGE MARLENE	
	89	7306736		2007-12-11	COLLINS GREGORY R	
	90	5691486		1997-11-25	BEHRINGER BRUCE E	
	91	5980830		1999-11-09	SAVAGE DOUGLAS ROBERT	
	92	5045185		1991-09-03	OHNAKA YUKIHIRO	
	93	5632906		1997-05-27	ISHIDA NOBORU	
	94	6695004		2004-02-24	RAYBUCK JOHN L	
	95	6733433		2004-05-11	FELL CLAUDE	
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	98	5439450		1995-08-08	HAEDT LORI E	
	99	6905483		2005-06-14	NEWBY C MARK	
	100	5431811		1995-07-11	TUSINI ANDREA	
	101	6736783		2004-05-18	BLAKE KEVIN R	
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	4	20040116830		2004-06-17	TRUDEAU WILLIAM M	
	5	20090299253		2009-12-03	HURSEY FRANCIS X	
	6	20130158506		2013-06-20	HARRIS ADRIENNE ROSE	
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	11	20180140240		2018-05-24	BULLINGTON GREGORY J	
	12	20140112841		2014-04-24	SCHOEN CHRISTIAN	
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	15	20100057004		2010-03-04	CHRISTENSEN KELLY D	
	16	20070088279		2007-04-19	SHUE MING-JENG	
	17	20080145933		2008-06-19	PATTON RICHARD G	
	18	20040054333		2004-03-18	THEEUWES FELIX	
	19	20100010372		2010-01-14	BROWN LEROY R	
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	21	20080086085		2008-04-10	BROWN LEROY R	
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	26	20160174888		2016-06-23	BERTHIER ERWIN	
	27	20050240161		2005-10-27	CRAWFORD JAMIESON W M	
	28	20040147855		2004-07-29	MARSDEN STEWART	
	29	20040073171		2004-04-15	ROGERS BOBBY E	
	30	20050004524		2005-01-06	NEWBY C MARK	
	31	20030105414		2003-06-05	LEONG ALVIN TAN CHEE	
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	33	20140155781		2014-06-05	BULLINGTON GREGORY J	
	34	20030208151		2003-11-06	KRAUS MENACHEM	
	35	20090227953		2009-09-10	TAN CHEE LEONG	

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	39	20050007524		2005-01-13	LUO FANG-CHEN	
	40	20140039348		2014-02-06	BULLINGTON GREGORY J	
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	52	20150351678		2015-12-10	BULLINGTON GREGORY	
	53	20220160271		2022-05-26	IVOSEVIC MILAN	
	54	20050161112		2005-07-28	EHWALD RUDOLF	
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	International Search Report and Written Opinion dated Nov. 5, 2015, for PCT application No. PCT/US2015/035870. 6 pages.	
	2	International Search Report and VVritten Opinion dated 16 July 2020 for PCT application no. PCT/US2020/026276. 9 pages.	
	3	Bullington, et al., Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in U.S. Appl. No. 62/517,681, dated Jun. 9, 2017, 131 pages.	
	4	Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17538990
	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

	5	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	
	6	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	
	7	European Patent Office; Communication pursuant to Article 94(3) EPC; dated Oct. 31, 2018; 11 pages.	
	8	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	
	9	International Search Report and Written Opinion dated Jun. 19, 2020, for PCT application No. PCTUS2020/023617. 12 pages.	
	10	European Patent Office, International Search Report and Written Opinion for PCT/US16/43709, dated Oct. 19, 2016, 14 pages.	
	11	International Search Report/Written Opinion for PCT/US17/68569 dated Apr. 25, 2018. 9 pages.	
	12	European Patent Office, International Search Report/Written Opinion for PCT/US17/068569 dated Apr. 25, 2018, 9 pages.	
	13	International Search Report and Written Opinion for PCT/US16/43709, Dated October 19,2016. 13 pages.	
	14	Retractable Techs., Inc. v. Becton Dickinson & Co., CA No. 2:07-CV-250, Claim Construction Order (E.D. Tex., Jan. 20, 2009). 20 pages.	
	15	Hillyer, Christopher D., et al. "Bacterial Contamination of Blodd Components: Risks, Strategies and Regulation," Hematology, 2003, pp. 575-589.	

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	16	De Korte, Dirk, et al. "Diversion of first blood volume results in a reduction of bacterial contamination for whole-blood collections." Vox sanguinis 83.1 (2002): 13-16.	
	17	Brecher, Mark E., et al. "Bacterial contamination of blood components." Clinical microbiology reviews 18.1 (2005): 195-204.	
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	20	Li, Yiwen, et al. "Direct labeling and visualization of blood vessels with lipophilic carbocyanine dye DiI." Nature protocols 3.11 (2008): 1703-1708.	
	21	Page, Catherine, et al. "Blood conservation devices in critical care: a narrative review." Annals of intensive care 3 (2013): 1-6.	
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	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

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	33	NCCLS. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition. H3-A5, Vol. 23, No. 32. Replaces H3-A4; Vol. 18, No. 7. 1-52 pages. http://demo.nextlab.ir/Organization/Documents/CLSI-Standards/CLSI-H3-A5.aspx	
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	37	Sheppard, Chelsea A., et al. "Bacterial contamination of platelets for transfusion: recent advances and issues." Laboratory Medicine 36.12 (2005): 767-770.	

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	47	Sheppard, et al., Bacterial Contamination of Platelets for Transfusion: Recent Advances and Issues, LABMEDICINE, Vol. 36, No. 12, Dec. 2005 ("Sheppard 2005").	
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17538990
	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	07/05/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-16
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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ABN: 38 113 072 755

1 March 2023

Notice of acceptance for patent application

Griffith Hack
Level 15, 376-390 Collins Street
Melbourne VIC 3000
Australia

Your reference	P108089.AU.1
Application number	2021202622
Applicant name	KURIN, INC.

Dear Griffith Hack,

This patent application was accepted on 21 February 2023. The accepted specification incorporates the following amendments:

S104 amendments up to and including item number: 4

The total number of claims at acceptance has been reported as: 15

Notice of the acceptance will appear in the Australian Official Journal of Patents on 16 March 2023.

Please review the acceptance details attached to this letter to ensure that they are correct. If you wish to amend any details prior to the grant please do so within 3 months of the advertisement of acceptance.

An Invitation to Pay (ITP) the acceptance fee will be issued to you. This fee will include an additional component if the number of claims exceeds 20.

Details of this patent application can be viewed on AusPat, our Australian patent search database.

Yours sincerely,

IP Australia

Acceptance summary

Standard patent details

Patent number:	2021202622
Title:	Blood sample optimization system and blood contaminant sequestration device and method
Your reference:	P108089.AU.1
Number of claims at acceptance:	15

Applicant and inventor details

Applicant name(s) and address(es) *(as it will appear on certificate/s)* **:**

KURIN, INC. of 10755 Scripps Poway Parkway, No. 257 San Diego CA 92131 United States of America

Inventor name(s):	ROGERS, Bobby KANG, Gino DETLOFF, John

Agent details

Agent Name	Griffith Hack
Address for correspondence:	Level 15, 376-390 Collins Street Melbourne VIC 3000 Australia
Address for legal service:	Level 15, 376-390 Collins Street Melbourne VIC 3000 Australia

Prior art details

Prior art documents:
WO 2011/162772 A1
WO 96/05875 A1
US 2013/0317391 A1
US 4207870 A
US 4416291 A
US 2008/0145933 A1
JP 2001000424 A

Priority details

Divisional of:	2016297849

Your reference	P108089.AU.1
Application number	2021202622

International classification

A61B 5/15 (2006.01)
A61B 5/153 (2006.01)
A61B 5/154 (2006.01)

Relevant dates

Acceptance date:	21 February 2023
Acceptance to be advertised:	16 March 2023
Complete filing date:	28 April 2021
OPI date:	27 May 2021
Continuation fee due date:	22 July 2023
Date of patent:	22 July 2016
Expiry date:	22 July 2036
National phase entry date:	Not Applicable

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 09/08/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 09/08/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	12/08/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 09/08/2023
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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	12/08/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-577000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

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2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

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❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715

27500 7590 09/08/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 09/08/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 18/113,710	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 08/29/2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 17-31 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☑ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☑ Other A.NE.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05/10/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Allowable Subject Matter

3. Claims 17-31 are allowed.

4. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Christensen et al (2010/0057004) teaches a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable.

The prior art does not teach, disclose and/or fairly suggest a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/113,710	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20160073937-A1	03-2016	Burkholz; Jonathan Karl	A61B5/150251	604/524
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	18113710
Filing Date	2023-02-24
First Named Inventor	Bobby E. ROGERS
Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5200325		1993-04-06	BLATT JOEL M	
	2	5432084		1995-07-11	BRUBAKER DANIEL B	
	3	5972294		1999-10-26	SMITH JOHN L	
	4	6187347		2001-02-13	PATTERSON JAMES A	
	5	6599474		2003-07-29	EVTODIENKO VLADIMIR	
	6	8197420		2012-06-12	PATTON RICHARD G	
	7	8535241		2013-09-17	BULLINGTON GREGORY	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

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	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

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	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
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	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
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	32	3886930		1975-06-03	RYAN GEORGE R	
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	43	3648684		1972-03-14	BARNWELL CLEORA W	
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	45	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

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	76	4193400		1980-03-18	LOVELESS JAMES C	
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	85	8827958		2014-09-09	BIERMAN STEVEN F	

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If you wish to add additional U.S. Patent citation information please click the Add button. Add

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20010044615		2001-11-22	AMANO YOSHIKAZU	
	2	20030082074		2003-05-01	JURIK FRANKLIN A	

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	4	20040116830		2004-06-17	TRUDEAU WILLIAM M	
	5	20090299253		2009-12-03	HURSEY FRANCIS X	
	6	20130158506		2013-06-20	HARRIS ADRIENNE ROSE	
	7	20150246352		2015-09-03	BULLINGTON GREGORY J	
	8	20150342510		2015-12-03	BULLINGTON GREGORY J	
	9	20160361006		2016-12-15	BULLINGTON GREGORY J	
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	Attorney Docket Number	069366-0574153_KUR2C04US

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Japanese Patent Application No. 2020-118498
Your Ref: KURIN2JP-DIV2
Our Ref: TS/KRN-C0137JP03
September 2, 2021

Translation of "Notice of Reasons for Rejection"

Patent Application Number: JP 2020-118498
Date of Delivery: August 10, 2021
Applied Provision: Patent Law Articles 29(2), and 36

The present application should be rejected for the following reasons. The applicant may present an argument against the reasons within three months from the date of delivery of this notice.

Reasons

1. The inventions of the following claims should not be granted a patent under Patent Law Article 29(2) as lacking inventive step over the documents listed below.

2. The following claims do not comply with the requirements under Patent Law Article 36(6)(ii) as being unclear.

Remarks (See the Document List below)

- Reason 1 (Inventive step)
- Claims 1 to 10
- Documents D1 and D2

[Claim 1]

D1 ([0019]-[0055], Figs. 5-8) discloses

a blood sample optimization system (sample-procurement system; [0038], etc.) for optimizing a blood sample ([0020], etc.) collected by a blood collector (sample vessels 506; [0038], etc.), the system comprising:

a patient needle (first needle 508; [0038], etc.) configured for a venipuncture of a patient to access a sample of blood of a patient, at least a first portion of the sample of blood containing contaminants ([0021], etc.);

a blood sampling pathway connected with the patient needle configured for conveying the sample of blood (see Fig. 5, etc.); and

a sample needle configured for receiving the blood collector to collect a second portion of the sample of blood(see suggestions in Fig. 5, etc.); and

a blood sequestration device connected on the blood sampling pathway between the patient needle and the sample needle, the blood sequestration device comprising;

an inlet port (sterile input tubing 514; [0039], etc.) configured for receiving the sample of blood;

a sequestration chamber (pre-sample reservoirs 504; [0038], etc.) connected with the inlet port, the sequestration chamber configured for receiving the first portion of the sample of

blood to contain the contaminants in the first portion of the blood sample; and

a sampling channel (second sterile output tubing 518; [0038], Fig. 5, etc.) having a proximal end connected with the inlet port, configured for receiving the second portion of the sample of blood,

the sequestration chamber, the sampling channel and the inlet port being configured to allow the second portion of the sample of blood to bypass the sequestration chamber and direct the second portion of the sample of blood toward an outlet port that is configured to output the second portion of the sample of blood to the blood collector ([0038], etc.).

D2 ([0012]-[0013] etc.) discloses arts in a blood sample optimization system (blood sampling needle) of configuring a sequestration chamber having a vent comprising an air permeable blood barrier (air permeable blood impermeable member 23) to displace air in the sequestration chamber through the vent, and of configuring a housing (needle tube support 2) that houses and defines ports, the sequestration chamber and a channel.

Those disclosed in D1 and D2 belong to the same technical field called the blood collection field. It is easy for those skilled in the art to configure the one disclosed in D1 to have an air permeable blood barrier and a housing similar to the invention of claim 1 of the present application, with reference to the arts disclosed in D2.

[Claims 2 and 4]

See [0012]-[0013] of D2.

[Claim 3]

Placing a seal on the sample needle can be said to be a design matter.

[Claim 5]

See [0011] of D2.

[Claim 6]

See Fig. 5 of D1.

[Claims 7-10]

See the above explanations including the descriptions of D1 and D2.

- Reason 2 (Clarity)
- Claims 1 to 10

The recitations of claims 1-10 are unclear in the following points. Therefore, the

inventions of claims 1-10 are unclear.

(1) Claim 1

The recitation of "a sample of blood of a patient, at least a first portion of the sample of blood containing contaminants" is unclear in Japanese as to whether "at least containing contaminants" is related to the "a sample of blood" or to the "a first portion of the sample of blood". The same applies to the claims referring to claim 1.

(2) Claims 4 and 7

The recitation of "subsequent portion of the blood sample" is unclear as to what portion the "subsequent portion" follows. The same applies to the claims referring to claim 4 or 7.

Document List

D1: US 2008/0145933A

D2: JP 2001-000424A

Record of the Result of Prior Art Search

Technical field(s) searched	IPC A61B 5/00-5/398
Prior art document(s)	JP S58-025146A
	JP H09-504726A
	JP H02-224742A
	US 2011/0306899A

This record is not a component of the reasons for rejection.

拒絶理由通知書

特許出願の番号	特願２０２０－１１８４９８
起案日	令和　３年　８月　２日
特許庁審査官	岡▲さき▼　潤　　３３３０　２Ｑ００
特許出願人代理人	三好　秀和（ほか　３名）　様
適用条文	第２９条第２項（進歩性） 第３６条第６項第２号（明確性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（進歩性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第２９条第２項の規定により特許を受けることができない。

２．（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第２号に規定する要件を満たしていない。

記　　（引用文献等については引用文献等一覧参照）

●理由１（進歩性）について

・請求項　１－１０

・引用文献等　１－２

・備考

[請求項１について]

引用文献１（[0019]-[0055],図5-8）には、

採血器（sample vessels 506;[0038]等）によって集められる血液サンプル（[0020]等）を最適化するための血液サンプル最適化システム（sample-procurement system;[0038]等）であって、

患者の血液サンプル、少なくとも汚染物質を含む（[0021]等）前記血液サンプルの第１の部分を取り出せるようにするために患者の静脈穿刺用に構成された患者針（first needle 508;[0038]等）と、

前記患者針に接続され、前記血液サンプルを運ぶように構成された採血経路と（図5等参照）、

前記血液サンプルの第２の部分を集めるために前記採血器を受け入れるように構成されたサンプル針（図5等の示唆参照）と、

前記患者針と前記サンプル針との間の前記採血経路に接続された血液隔離装置であって、

前記血液サンプルを受け入れるように構成された入口ポート（sterile input tubing 514;[0039]等）と、

前記入口ポートに接続され、隔離チャンバであって、前記血液サンプルの第１の部分を受け入れ、前記血液サンプルの第１の部分に汚染物質を含むように構成された隔離チャンバ（pre-sample reservoirs 504;[0038]等）と、

前記入口ポートに接続される近位端を有し、前記血液サンプルの第２の部分を受け入れるように構成されたサンプリング流路と（second sterile output tubing 518;[0038],図5等）を含み、

前記隔離チャンバ、前記サンプリング流路及び前記入口ポートは、前記血液サンプルの第２の部分が前記隔離チャンバを迂回することを可能にし、前記血液サンプルの第２の部分を前記出口ポートに向かわせるように構成され、前記出口ポートは、前記血液サンプルの第２の部分を前記採血器に排出するように構成される（[0038]等）、血液隔離装置とを含む、血液サンプル最適化システム、

が記載されている。

引用文献２（[0012]-[0013]等）には、血液サンプル最適化システム（採血針）において、空気透過性血液バリア（空気透過性血液不透過性部材２３）を含む通気口を有する隔離チャンバであって、通気口を通して隔離チャンバ内の空気を追い出す隔離チャンバを構成する技術、ポート、隔離チャンバ及び流路を収容及び画定するハウジング（針管支持体２）を構成する技術、が開示されている。

引用文献１－２に記載のものは、採血分野という同一の技術分野に属する。

引用文献１に記載のものにおいて、引用文献２に記載の技術を参考として、本願の請求項１に係る発明と同様の空気透過性血液バリアとハウジングを具備するよう構成することは、当業者にとって容易である。

[請求項２，４について]

引用文献２の[0012]-[0013]を参照。

[請求項３について]

サンプル針に密封材を配置することは、設計的な事項といえる。

[請求項５について]

引用文献２の[0011]参照。

[請求項６について]

引用文献１の図5を参照。

[請求項７－１０について]

引用文献１－２の記載を含め既述の説示を参照。

●理由２（明確性）について

・請求項　１－１０

請求項１－１０の記載は、以下の点で不明確である。よって、請求項１－１０に係る発明は、明確でない。

（１）請求項１の記載について

請求項１の「患者の血液サンプル、少なくとも汚染物質を含む前記血液サンプルの第１の部分」との記載は、「少なくとも汚染物質を含む」ことが「血液サンプル」に係っているのか、「前記血液サンプルの第１の部分」に係っているのか、日本語として不明確である。引用項においても同様。

（２）請求項４，７の記載について

請求項４，７の「前記血液サンプルの後続の部分」との記載は、いかなる部分に「後続」するものを特定しているのか不明確である。引用項においても同様。

＜引用文献等一覧＞

１．米国特許出願公開第２００８／０１４５９３３号明細書

２．特開２００１－０００４２４号公報

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

＜先行技術文献調査結果の記録＞

・調査した分野　　ＩＰＣ　Ａ６１Ｂ　　５／００　－　５／３９８

ＤＢ名

・先行技術文献　　特開昭５８－０２５１４６号公報

特表平０９－５０４７２６号公報

特開平０２－２２４７４２号公報

米国特許出願公開第２０１１／０３０６８９９号明細書

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません

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＜補正をする際の注意＞
（１）明細書、特許請求の範囲について補正をする場合は、補正により記載を変更した個所に下線を引いてください（特許法施行規則様式第１３備考６、７）。
（２）補正は、この出願の外国語書面の翻訳文（又は誤訳訂正書による補正後の明細書、特許請求の範囲若しくは図面）に記載した事項の範囲内で行わなければなりません。また、意見書で、各補正事項について補正が適法なものである理由を、根拠となる翻訳文（又は誤訳訂正書による補正後の明細書、特許請求の範囲若しくは図面）の記載箇所を明確に示したうえで主張してください。
（３）特許請求の範囲について補正をする際には、特許法第１７条の２第４項に違反する補正とならないよう、注意してください。

この拒絶理由通知の内容に関するお問合せ又は面接のご希望がありましたら、次の連絡先までご連絡ください。電子メール等で補正案等の送付を希望される場合は、その旨を電話でお知らせください。

審査第一部分析診断（医学診断）　岡崎　潤
ＴＥＬ．０３－３５８１－１１０１　内線３２９１

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(71) Applicant *(for all designated States except US)*: **TELEFLEX MEDICAL, INC.** [US/US]; 2400 Bernville Road, Reading, Pennsylvania 19605 (US).

(72) Inventors; and
(71) Applicants *(for US only)*: **GUPTA, Nisha** [US/US]; 111 Condor Ridge Court, Audubon, Pennsylvania 19403 (US). **ROWE, David** [US/US]; 3 States Avenue, Sinking Spring, Pennsylvania 19608 (US). **DENLINGER, Rodney** [US/US]; 4 Jamestown Court, Lancaster, Pennsylvania 17602 (US).

(74) Agent: **GLUCK, Peter**; Baker Hostetler, LLP, 1050 Connecticut Avenue NW, Suite 1100, Washington, District of Columbia 20036 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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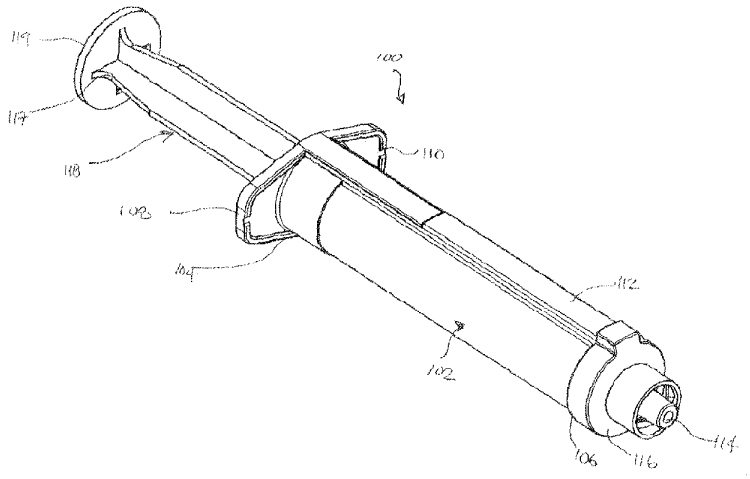
Published:

— *with international search report (Art. 21(3))*

(54) Title: DEVICE WITH INTEGRATED ALLERGY TESTING



(57) Abstract: The disclosure provides an allergy detection system for use during catheterization. The allergy detection system is incorporated into specialized syringes, connectors for use with standard syringes, or can be an independent test module designed for the sole purpose of allergy detection. The detection system features a test strip, such as an immunochromatographic test strip, and a structure to couple the system to a connector, syringe, or a housing, to form an independent test module. The detection system, by way of test strips, is used to detect potential allergic reactions.

WO 2013/082301 A1

INTERNATIONAL APPLICATION FOR DEVICE WITH INTEGRATED ALLERGY TESTING

Related applications

[0001] This application claims the full Paris Convention priority to and benefit of U.S. Provisional Application Serial No. 61/564,593, filed on November 29, 2011, the contents of which are hereby incorporated by this reference, as if fully set forth herein in their entirety.

Field of the disclosure

[0002] The present disclosure generally relates to a medical testing device. More particularly, the present disclosure pertains to a device having an integrated allergy testing system.

Background of the disclosure

[0003] During surgical procedures and other medical procedures, it is often necessary to determine if a patient has any allergies that may be aggravated during the procedure. Testing for allergies can be a long process. Often, an immediate answer is needed during the procedure.

[0004] Extensive use of certain compounds in home and health care products (oral care products, contact lens care products, dressings, ointments, soaps, cosmetics) is causing a larger population to become pre-sensitized to such particular agents. When a pre-sensitized person comes in contact with such an agent, there is a high probability that person could develop much stronger symptoms as severe as anaphylactic shock with cardiac arrest. Currently known tests for such allergies cannot be performed at the patient bedside as they are time consuming, and involve numerous steps and equipment.

[0005] It is therefore desirable to provide a device for integrating allergy testing into a medical device.

Summary of the disclosure

[0006] The disclosure provides an allergy detection system for use during catheterization. The allergy detection system is incorporated into specialized syringes, connectors for use with standard syringes, or can be an independent test module designed for the sole purpose of allergy detection. The detection system features a test strip, such as an immunochromatographic test strip, and a structure to couple the system to a connector, syringe, or a housing, to form an independent test module. The detection system, by way of test strips, is used to detect potential allergic reactions.

[0007] In embodiments, the present disclosure provides a device for testing the presence or absence of a substance in blood, comprising: a coupler or hub that is capable of coupling with a needle, wherein the needle is for withdrawing blood from a subject and for introducing the withdrawn blood into the device; a first chamber for receiving the withdrawn blood; a second chamber configured for holding a test strip; a test strip that is held within the second chamber; a wall or panel that separates the first chamber from the second chamber; at least one aperture in the wall or panel configuring for allowing blood to pass from the first chamber to the second chamber; wherein the second chamber comprises a window for viewing the test strip, wherein the test strip is capable of producing a visible signal that indicates the presence or absence of the substance in the withdrawn blood; and, wherein the window is configured to allow visual detection of the visible signal.

[0008] Also provided is the above device, that comprises a syringe and wherein the first chamber is defined by the housing of the syringe. Also provided is the above device, that does not comprises a syringe. Also provided is the above device, that is capable of being coupled to a syringe and to a needle, wherein the device has a hub that is capable of coupling to the hub of the syringe, and wherein the device has a coupler that is capable of coupling to a needle. Moreover, what is provided is the above device, wherein the substance is an antibody. Furthermore, what is contemplated is the above device, wherein the substance is an antibody of the class IgG, IgA, or IgE. Additionally,

what is embraced is the above device, wherein the substance is an antibody that specifically binds to an antimicrobial agent, e.g., antiseptic or antibiotic.

[0009] In embodiments, what is provided is the above device that is capable of: testing for the presence or absence of a first substance in the blood; and, testing for the presence or absence of a second substance in the blood; wherein the test strip is capable of separately providing a first visual signal for the first substance and a second visual signal for the second substance. Also, what is provided is the above device, wherein the first substance is an IgE antibody that specifically binds latex and the second substance is an IgE antibody that specifically binds an antiseptic. What is further embraced is the above device, wherein the second chamber comprises a flexible dome, and wherein the flexible dome is capable of flexing radially outward; wherein in use the flexible dome flexes radially outwards and creates a partial vacuum that is capable of drawing blood out of the first chamber and into the second chamber; wherein a sliding latch is operably linked with the flexible dome; wherein in use the sliding latch is capable of being slid over the dome to compress the flexible dome radially downwards and increase the pressure within the second chamber; and wherein in use the sliding latch is capable of being slid away from the dome to release the dome and allow the dome to flex radially outwards thereby creating a partial vacuum in the second chamber. Alternatively, the first substance can be an antibody of the IgG, IgA, IgM, or IgD class. Alternatively, the second substance can be an antibody of the IgG, IgA, IgM, or IgD class.

[0010] In yet another aspect, what is provided is the above device, further comprising an end-cap, wherein the end-cap is configured for contacting and stabilizing the test strip, and configured for contacting and stabilizing the proximal portion of a needle that is coupled to said device. Also provided is the above device, wherein the second chamber comprises a proximal end and a distal end, and wherein one or both of the proximal end and distal ends comprises an opening for installing the test strip from the second chamber. In yet another aspect, what is provided is the above device, wherein the second chamber comprises a proximal end and a distal end, and wherein one or both of the proximal end and distal ends comprises an opening for installing the test

strip from the second chamber, further comprising one or more end caps that capable of capping one or both of the proximal end and the distal end.

[0011] What is further embraced, is the above device further comprising a needle, wherein the needle is reversibly coupled to the coupler. Also contemplated is the above device that does not comprise a needle.

[0012] In yet another embodiment, what is contemplated is a device for testing the presence or absence of IgE in blood, comprising: a coupler or hub that is capable of coupling with a needle, wherein the needle is for withdrawing blood from a subject and for introducing the withdrawn blood into the device; a first chamber for receiving the withdrawn blood;a second chamber configured for holding a test strip; a test strip that is held within the second chamber; a wall or panel that separates the first chamber from the second chamber; at least one aperture in the wall or panel configuring for allowing blood to pass from the first chamber to the second chamber; wherein the second chamber comprises a window for viewing the test strip; wherein the test strip is capable of producing a visible signal that indicates the presence or absence, in the withdrawn blood, of an antibody of the IgE class that specifically binds to an antiseptic or an antibiotic; and, wherein the window is configured to allow visual detection of the visible signal. Also provided is the above device, wherein the test strip is an immunochromatographic test strip.

[0013] In a process embodiment, what is provided is a process for allergy detection during catheterization, comprising: the step of drawing blood from a subject into the first chamber of a device that comprises: (a) a coupler or hub that is capable of coupling with a needle, wherein the needle is for withdrawing blood from a subject and for introducing the withdrawn blood into the device; (b) a first chamber for receiving the withdrawn blood; (c) a second chamber configured for holding a test strip; (d) a test strip that is held within the second chamber; (e) a wall or panel that separates the first chamber from the second chamber; (f) at least one aperture in the wall or panel configuring for allowing blood to pass from the first chamber to the second chamber; (g) wherein the second chamber comprises a window for viewing the test strip, (h) wherein the test strip is capable of producing a visible signal that indicates the presence or absence of the substance in the withdrawn blood; and, (i) wherein the window is configured to allow

visual detection of the visible signal; the step of allowing at least some of the drawn blood to enter the second chamber of the device; wherein a needle is coupled to the device; and, wherein in use, at least some of the withdrawn blood enters the needle and then enters the first chamber, then enters the second chamber, and then contacts the test strip.

[0014] In yet another process embodiment, what is provided is the above process, further comprising a reaction that is mediated by the test strip, wherein the reaction produces a visual signal that indicates presence or absence of a substance that mediates an allergy. Also provided is the above process, wherein the drawing blood into the first chamber is urged by one or more of: (a) Blood pressure of the subject; (b) Vacuum produced by a syringe plunger of the device; (c) Vacuum produced by a flexible dome of the device; and (d) Capillary action of the test strip of the device. In yet another process embodiment, the disclosure provides the above process wherein the test strip is configured for detecting an antibody that specifically binds an antimicrobial agent, e.g., antiseptic or antibiotic; wherein in use the test strip provides a visual signal that the blood does not contain detectable antibodies that specifically bind to the specific antimicrobial agent, e.g., antiseptic or antibiotic; followed by the step of inserting a catheter into the subject, wherein the catheter is impregnated or coated with the antimicrobial agent, e.g., antiseptic or antibiotic.

[0015] Also provided is the above process, wherein the test strip is configured for detecting an antibody that specifically binds an antimicrobial agent, e.g., antiseptic or antibiotic; wherein in use the test strip provides a visual signal that the blood does contain detectable antibodies that specifically bind to the specific antiseptic or antibiotic; followed by the step of making a decision on whether or not to insert a catheter that is impregnated or coated with the antiseptic or antibiotic; and, wherein the decision is to refrain from inserting the catheter in the subject, followed by the step of inserting a catheter into the subject, wherein the catheter is not impregnated or coated with the antiseptic or antibiotic.

[0016] In a system embodiment, the disclosure provides a system comprising, in combination, a medical instrument that is capable of holding blood, and a medical device that comprises: (a) a coupler or hub that is capable of coupling with a needle,

wherein the needle is for withdrawing blood from a subject and for introducing the withdrawn blood into the device; (b) a first chamber for receiving the withdrawn blood; (c) a second chamber configured for holding a test strip;(d) a test strip that is held within the second chamber; (e) a wall or panel that separates the first chamber from the second chamber;

[0017] (f) at least one aperture in the wall or panel configuring for allowing blood to pass from the first chamber to the second chamber;(g) wherein the second chamber comprises a window for viewing the test strip, (h) wherein the test strip is capable of producing a visible signal that indicates the presence or absence of the substance in the withdrawn blood; and, (i) wherein the window is configured to allow visual detection of the visible signal. What is also embraced, is the above system, wherein the combination is a reversible combination or a permanent combination. Furthermore, what is provided is the above system, wherein the combination is a reversible combination, wherein the device and the medical instrument are held in combination by one or more of a clip, snap, lock, or tab. Also disclosed, is the above system, wherein the combination is a permanent combination, wherein the device and the medical instrument are held in combination by one or more of an adhesive or integral molding. In yet another system embodiment, what is provided is the above system, wherein the medical instrument comprises one or more of a syringe, trocar, catheter, introducer, sheath, hub, pump, or valve.

[0018] The foregoing needs are met, to a great extent, by the present disclosure, wherein in some embodiments a device with an integrated allergy testing system that is capable of overcoming the disadvantages described herein at least to some extent is provided.

[0019] In accordance with an embodiment of the present disclosure an allergy testing device for testing a sample includes a housing having a proximal end and a distal end. The housing can also include an outer wall defining an inner chamber extending through at least a portion of the housing. The device can also include a needle extending from a distal end of the housing. Additionally, the device can include an immunochromatographic test strip configured to indicate whether a predetermined antibody is present in the sample. The test strip can be positioned in the housing.

[0020] In accordance with another embodiment of the present disclosure, a syringe with an integrated allergy testing system includes a syringe housing having an outer wall defining an inner chamber extending through at least a portion of the syringe housing and the syringe housing having a proximal end and a distal end. The syringe can also include a needle extending from a distal end of the housing. Additionally a syringe plunger can be movably disposed within the inner chamber of the syringe housing. The syringe can also include an immunochromatographic test component configured to indicate whether a predetermined antibody is present in a sample, where the sample can be aspirated into the syringe, and wherein the test component is positioned in the syringe housing.

[0021] In accordance with another embodiment of the present disclosure, an attachment for a medical device having an integrated allergy testing system can include a housing having a proximal end and a distal end, wherein the proximal end is configured to couple to a medical device and the distal end is configured to receive a needle. The attachment can also include an immunochromatographic test component configured to indicate whether a predetermined antibody is present in a sample, wherein the test component is positioned in the housing. The sample can be aspirated into the housing. Additionally, the attachment can include a window disposed in the housing such that the test component is viewable.

[0022] There has thus been outlined, rather broadly, certain embodiments of the invention in order that the detailed description thereof, herein may be better understood, and in order that the present contribution to the art may be better appreciated. There are, of course, additional embodiments of the invention that will be described below and which will form the subject matter of the claims appended hereto.

[0023] In this respect, before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and to the arrangements of the components set forth in the following description or illustrated in the drawings. The invention is capable of embodiments in addition to those described and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein, as well as the abstract, are for the purpose of description and should not be regarded as limiting.

[0024] As such, those skilled in the art will appreciate that the conception upon which this disclosure is based may readily be utilized as a basis for the designing of other structures, methods and systems for carrying out the several purposes of the present disclosure. It is important, therefore, that the claims be regarded as including such equivalent constructions insofar as they do not depart from the spirit and scope of the present disclosure.

[0025] Components for the methods and devices of the disclosure are available, for example, from any major medical device company, for example, Medtronic of Minneapolis, MN; Advanced Cardiovascular Systems in Santa Clara, CA; Baxter International of Deerfield, IL; Abbott Laboratories at Abbott Park, IL, Edwards Lifesciences, Irvine, CA, and Boston Scientific of Natick, MA. Components of the present disclosure can be made, without limitation, by molding, blow molding, slush molding, injection molding, rotational molding, compression molding, extrusion, thermoforming, stamping, calendaring, and so on (Brazel, CS; Rosen, SL (2012) Fundamental Principles of Polymeric Materials. Wiley, Hoboken, NJ).

Brief descriptions of the drawings

[0026] FIG. 1 illustrates a test strip in accordance with an embodiment of the invention.

[0027] FIGS. 2 and 3 illustrate a perspective view of an independent allergy testing module in accordance with an embodiment of the invention.

[0028] FIGS. 4 and 5 illustrate a sectional view of the independent allergy testing module illustrated in FIGS. 2 and 3 in accordance with an embodiment of the invention.

[0029] FIG. 6 illustrates an exploded view of the independent allergy testing module illustrated in FIGS. 2-5 in accordance with an embodiment of the invention.

[0030] FIG. 7 illustrates a syringe with integrated allergy testing in accordance with an embodiment of the invention.

[0031] FIG. 8 illustrates a sectional view of the syringe with integrated allergy testing illustrated in FIG. 7 in accordance with an embodiment of the invention.

[0032] FIG. 9 illustrates an exploded view of the syringe with integrated allergy testing illustrated in FIGS. 7 and 8 in accordance with an embodiment of the invention

[0033] FIG. 10 illustrates a connector with integrated allergy testing in accordance with an embodiment of the invention.

[0034] FIG. 11 illustrates a sectional view of the connector with integrated allergy testing illustrated in FIG. 10 in accordance with an embodiment of the invention.

[0035] FIG. 12 illustrates an exploded view of the connector with integrated allergy testing illustrated in FIGS. 10 and 11 in accordance with an embodiment of the invention.

[0036] FIG. 13 (A, B) illustrates the cap that is a part of the module embodiment, and structures in the vicinity of the cap.

Detailed description

[0037] The present disclosure provides in some embodiments, an allergy detection system for integration into medical devices. For instance, in accordance with embodiments of this invention, the allergy detection system can be incorporated into a specialized syringe, a connector for use with a standard syringe, or an independent test module, designed for the sole purpose of allergy detection. The detection system can include, without limitation, an immunochromatographic membrane and structure to couple it to a connector or syringe or a housing to form an independent test module. The detection system can be used to detect any potential allergies that can be identified using immunochromatography.

[0038] In embodiments, what is provided is a device and related methods for point of care testing. For example, where a needle is introduced for use in the Seldinger technique, the needle can be used in conjunction with device and method of the present disclosure for detecting antibodies and predicting adverse allergic reactions. The *Seldinger* technique, includes the initial step of inserting a needle into a patient's blood vessel, where the Seldinger technique concludes with replacing the needle with a catheter or other medical device. The end-result is that the catheter or other medical device is situated in a subject's blood vessel or other body cavity. The *Seldinger* technique, and variations thereof, and devices used to perform this technique, are described in Seldinger (1953) Acta Radiologica 39:368-376; U.S. Pat. No. 7,722,567 issued to Tal, 7,972,307 issued to Kraus, et al, and 7,938,806 issued to Fisher, et al, which are incorporated by reference. Following testing by device and method of the present disclosure, and where the test gives a negative result (indicating that the subject is not allergic), the clinician can proceed with the *Seldinger* technique, and replace the needle with a catheter that contains the antigenic drug, antigenic antiseptic,

antigenic adhesive, or antigenic latex. Alternatively, if the test gives a positive result and indicates that the subject is likely to be allergic to the antigenic drug, antigenic antimicrobial agent, antigenic antiseptic, antigenic adhesive, or antigenic latex, then the clinician refrains from using the medical device. Where the test gives a positive result, the clinician can use an alternative medical device that does not contain the offending drug, antiseptic, adhesive, or latex, and the like.

[0039] In this way, the device and procedure of the present disclosure is used at the point of care, and is integrated into the procedure for using any medical device of interest, and where the device and procedure of the present disclosure can give the clinician a yes/no answer. The device of the present disclosure can be a physical part of a device used for the medical procedure of interest, for example, the device can be connected to a syringe that is used in the *Seldinger* technique or other procedure. This connection can be by way of a luer lock, Storz lock, or other coupler. Alternatively, the device of the present procedure can be integrated into a syringe, that is, permanently molded into the syringe, that is used in the *Seldinger* technique or other procedure.

[0040] In exclusionary embodiments, the present disclosure includes only test-strip devices that are integrated into a syringe. In another exclusionary embodiment, the present disclosure excludes test-strip devices that are not integrated into a syringe. In exclusionary embodiments, the present disclosure includes only test-strip devices that are integrated into a needle hub, trocar, dilator, syringe, syringe barrel, introducer, and the like. In another exclusionary embodiment, the present disclosure excludes test-strip devices that are not integrated into a needle hub, that are not integrated into a trocar, that are not integrated into a dilator, that are not integrated into a syringe or syringe barrel, that are not integrated into an introducer, and the like.

Immune disorders arising from exposure to medical devices and pharmaceuticals

[0041] In embodiments, the present disclosure provides a device and related methods, for detecting antibodies against components of medical devices or components of pharmaceuticals, and for quantitating or for predicting allergic reactions in a subject to be exposed to the medical device or the pharmaceutical. What can be quantitated is, for example, antibodies of one or more of the classes IgG, IgA, IgM, IgD, or IgE, that are present in a subject's bloodstream or in any biological fluid. The device and related methods are configured for quantifying or for predicting anaphylactic-type reactions or

bronchospasm (Layton et al (1989) Clin. Exp. Allergy. 19:307-314; Terazawa et al(1998) Anesthesiology. 89:1298-1300), allergic contact dermatitis, irritant contact dermatitis, photoallergic contact dermatitis, or immediate type contact reactions (Kutzscher (2012) Clin. J. Oncol. Nurs. 16:E48-55; Krasteva (1999) Eur. J. Dermatol. 9:144-159), arising from exposure to an antimicrobial agent or an antiseptic, e.g., a biguanide antiseptic.

Allergic reactions against and antibodies to antimicrobial agents, and to other components of medical devices

[0042] Device and methods of the present disclosure can detect antibodies, present in a subject's blood, serum, or other biological fluid, where the antibodies specifically bind to an antimicrobial agent, such as an antiseptic or antibiotic (Torres et al (2009) 19:67-68), antibiotics such as rifampicin (Feng et al (2011) Eur. J. Dermatol. 21:696-699), adhesives on catheters (Meikle et al (2012) Can. J. Anaesth. 59:815-816), thimerosol or other preservatives in medical devices (Ancona et al (1990) Dermatol. Clin. 8:95-105). Allergic reactions to latex, and antibodies against latex, have been described (Patriarca et al (2002) J. Investig. Allergol. Clin. Immunol. 12:169-176; Unsel et al (2012) Int. Arch. Allergy Immunol. 158:281-287). Allergic reactions (analphylaxis) can occur in response to medical devices impregnated with one or more antiseptics (Darouiche and Raad (1999) New Engl. J. Med. 1762 (1 page)). Antibodies of the classes IgG and IgA are associated with drug-induced eruptions (pemphigus folicaeus) (Feng et al (2011) Eur. J. Dermatol. 21:696-699). Antibodies of the classes IgG and IgE are associated with allergic reactions to antiseptics (Layton et al (1987) Mol. Immunol. 24:133-141). Antibodies of the IgE class have been identified that are responsible for hypersensitivity to various beta-lactam antibiotics (Gunez et al (2012) J. Investig. Allergol. Clin. Immunol. 22:41-47). IgE antibodies have also been identified that specifically react against latex (Galindo et al (2011) J. Investig. Allergol. Clin. Immunol. 21:459-465).

[0043] The term "antimicrobial" encompasses, but is not limited to, antiseptics and antibiotics.

Detecting antibodies and other molecules that can provoke adverse events

[0044] Antibodies in blood or in other biological fluids can be detected, for example, by way of reagents in a test strip. The reagents can be covalently or non-covalently attached to the surface of a test strip, the reagents can be adsorbed to a test strip, the

reagents can be absorbed to a test strip, the reagents can be covalently or non-covalently bound to interior of test strip, such as porous interior or fibrous interior, or any combination of the above. Reagents, test strips, substrates, for immune assays, including color reactions, and the like, are provided, for example, from US 7,544,324 issued to Tung et al, US 7,438,852 issued to Tung et al, US 7,989,217 issued to Yee et al, 7,910,381 of Ford et al, each of which is individually incorporated herein by reference, each in its entirety. The present disclosure encompasses detection of antibodies, such as IgG, IgA, IgM, IgD, or IgE, detecting B cells that express IgE or other classes of antibodies, by way of test strip technology. Several antibody classes can be simultaneously expressed in the body, and that recognize the same antigen. Accordingly, the present disclosure provides a test strip that can detect antibodies two or more of the classes IgG, IgA, IgM, IgA, IgD, or IgE. In one embodiment, the test strip detects two different classes, and provides two different colors. In another embodiment, the test strip detects two different classes, and provides the same color for both of the respective color reactions, but at different locations in the test strip. In yet another embodiment, the test strip detects a plurality of different antibody classes (or detects a plurality of different specific antibodies that bind to respective different antigens, where all of these specific antibodies are in one particular class). Combinations of the previous embodiments are also provided, e.g., detecting IgG that binds to an antibiotic, and detecting IgE that binds to latex, or detecting an antibody that binds to an antimicrobial and an antibody that binds to a pathogen. Color reaction can be provided by a label that comprises a metal, a colloidal particle such as colloidal gold, a dye particle, or results from a reaction catalyzed by peroxidase or alkaline phosphatase (see US 7,262019 issued to Kovalenko, US 5,200,312 issued to Oprandy, US 5,637,468 issued to Mason, and US 6,503,726 issued to Anne, which are each incorporated herein in their entirety). Where a gold labeled anti-IgE antibody is used, for example, a test sample (e.g., blood) reacts with the gold labeled anti-IgE antibody, forming a complex. The complex travels across a membrane where immobilized allergens capture the complex, resulting in a colored line (see US 7,629,127 issued to Hubscher, which is incorporated herein by reference).

[0045] The following provides a non-limiting example. For detection of anti-antiseptic antibodies, blood can be deposited at a sample receiving area located at a first end of

the test strip. Flow of solvent from the first end of the test strip towards the opposite end of the test strip draws any antibodies towards the test strip, and draws the antibodies over a region of the test strip that contains conjugates of gold-antiseptic. When the antibodies migrate over the area that contains gold-antiseptic, the result is an insoluble complex that forms a visually detectable line. Conjugates of gold-antiseptic that are not trapped as part of this insoluble complex continue to migrate on the test strip, and do not contribute to the visual signal of the line. As an alternative to using a conjugate of gold-antiseptic, what can be used is a conjugate of gold with an antibody that specifically binds to anti-antiseptic antibodies (anti-idiotype antibodies). The above narrative applies to anti-antiseptic antibodies, but also to embodiments where the antigen is an antibiotic, a pharmaceutical, a drug, latex, an adhesive, and the like.

[0046] In a non-limiting embodiment, what is provided is a device that encompasses an immunoassay with all reagents embedded on a test strip that performs without the use of instruments. Total IgE in a biological fluid is bound by anti-human IgE immobilized on test strips in the IgE reactive field of the test strip. Visualization of captured IgE is indicated by colloidal gold labeled anti-human IgE. Excess labeled antibodies are captured by antibodies in the control field. A control line appears in the control field and determines when enough of the biological fluid has been collected. The presence of IgE in the sample is visualized by the appearance of a dark-colored line, e.g., a red line, in the reactive field and the control field. Absence of a line in the control field, regardless of the presence of line in the reactive field, indicates an invalid assay result. The area on the support identifying the reactive field and control field are on the back surface of the support in two colors. A sample with IgE in the normal reference range lacks a line in the reactive field but has a line in the control field. The presence of lines in the reactive and control fields indicates a sample with elevated total IgE levels. The device provides a qualitative/semi-quantitative measure of total IgE in the biological fluid when the intensity of color on the test strip is visually observed. The skilled artisan can divide or classify the different intensities of signal as negative or as positive, and the skilled artisan can prepare a standard operating procedure (SOP) that sets forth these different intensities. What is also provided is the above embodiment, but where it applies to other antibody classes, e.g., IgG, IgA, IgM, or IgD.

[0047] In a non-limiting embodiment, what is provided is a device that comprises a series of capillary beds (elements), for example, made of cellulose. The first element (a sample pad) acts as a sponge and can hold an excessive amount of biological fluid. Then, the fluid migrates to the second element (conjugate pad). The second element is manufactured with a conjugate, a dried format of particles in a soluble matrix that contains reagents that promote the desired chemical reaction between the target molecule (antigen) and its binding partner (antibody) that has been immobilized on the surface of the particle. At the time that the sample fluid dissolves the soluble matrix, it also dissolves the particles and the sample and conjugate mix while flowing through the porous structure. In this way, the analyte binds to the particles while migrating further through the third capillary bed. This material has one or more regions or stripes where a third molecule has been immobilized. By the time the sample-conjugate mix has migrated to these stripes, analyte has been bound on the particle and the third capture molecule binds the complex. When additional fluid passes the stripes, particles accumulate and the stripe-area changes color. In embodiments, there can be two stripes: one (the control) that captures any particle and demonstrates that reaction is in working order, the second contains a specific capture molecule and only captures those particles on which an analyte molecule has been immobilized.

Duration of detection

[0048] In embodiments, what is provided is a device that is capable of detecting an antibody responsible for an allergic reaction, for example, to an antibiotic or antiseptic,
(1) During a blood draw that is dedicated to this detection;

(2) Only during a blood draw that is dedicated to this detection, with no capability during subsequent procedures, e.g., during insertion of a catheter or other medical instrument. This is an exclusionary embodiment;

(3) During a period of time when a catheter or other medical instrument is indwelling in a subject, that is, when a catheter or other medical instrument is operably linked to a subject. This period of time can be, e.g., at least ten minutes, at least one hour, at least one day, at least one week, at least one month, and the like;

(4) Only during a period of time when a catheter or other medical instrument is indwelling in a subject, but not capable of detecting the antibody during a blood draw

that is solely dedicated to the detection of the antibody. This is an exclusionary embodiment.

Antibodies and other reagents

[0049] "Specifically" or "selectively" binds, when referring to a ligand/receptor, nucleic acid/complementary nucleic acid, antibody/antigen, or other binding pair (e.g., a cytokine to a cytokine receptor) indicates a binding reaction which is determinative of the presence of the protein in a heterogeneous population of proteins and other biologics. Thus, under designated conditions, a specified ligand binds to a particular receptor and does not bind in a significant amount to other proteins present in the sample. Specific binding can also mean, e.g., that the binding compound, nucleic acid ligand, antibody, or binding composition derived from the antigen-binding site of an antibody, of the contemplated method binds to its target with an affinity that is often at least 25% greater, more often at least 50% greater, most often at least 100% (2-fold) greater, conventionally at least ten times greater, more normally at least 20-times greater, more typically at least 100-times greater, and most typically at least 1000-fold than the affinity with any other binding compound (see, e.g., US 2012/0121643 of Dubensky, which is incorporated by reference).

[0050] In a typical embodiment an antibody will have an affinity that is greater than about 10^9 liters/mol, as determined, e.g., by Scatchard analysis (Munsen, et al. (1980) Analyt. Biochem. 107:220-239). It is recognized by the skilled artisan that some binding compounds can specifically bind to more than one target, e.g., an antibody specifically binds to its antigen, binds to lectins by way of the antibody's oligosaccharide, and also binds to an Fc receptor by way of the antibody's Fc region.

[0051] In embodiments, the disclosure provides test strip that is capable of detecting antibodies in blood, where the antibodies specifically bind to a pathogen. Anti-pathogen antibodies have been characterized. Reagents and kits are available for detecting antibodies that specifically bind to viruses (e.g., HIV, HCV,HBV), fungi, and bacteria (see, e.g., Novack et al (2006) J. Clin. Microbiol. 44:2909-2913; Hennessey et al (2009) J. Urban Health. 86:93-105; Thurman et al (2009) Clin. Infect. Dis. 48:1244-1249; Alexander et al (1996) J. Clin. Microbiol. 34:1180-1183).

[0052] "Sample" refers to a sample from a human, animal, placebo, or research sample, e.g., a cell, tissue, organ, fluid, gas, aerosol, slurry, colloid, or coagulated material. The "sample" may be tested in vivo, e.g., without removal from the human or animal, or it may be tested in vitro. The sample may be tested after processing, e.g., by histological methods. "Sample" also refers, e.g., to a cell comprising a fluid or tissue sample or a cell separated from a fluid or tissue sample. "Sample" may also refer to a cell, tissue, organ, or fluid that is freshly taken from a human or animal, or to a cell, tissue, organ, or fluid that is processed or stored.

[0053] A composition that is "labeled" is detectable, either directly or indirectly, by spectroscopic, photochemical, biochemical, immunochemical, isotopic, or chemical methods. For example, useful labels include ^{32}P, ^{33}P, ^{35}S, ^{14}C, ^{3}H, ^{125}I, stable isotopes, epitope tags fluorescent dyes, electron-dense reagents, substrates, or enzymes, e.g., as used in enzyme-linked immunoassays, or fluorettes (see, e.g., Rozinov and Nolan (1998) Chem. Biol. 5:713-728).

Detailed descriptions of the figures

[0054] The invention will now be described with reference to the drawing figures, in which like reference numerals refer to like parts throughout. As illustrated in FIG. 1, the allergy detection system can include an immunochromatographic membrane 2 (PVDF or nitrocellulose material) in strip or cassette format that can detect elevated levels of an allergen by employing a highly sensitive detecting antibody and a carrier-protein conjugated hapten. The antibody is labeled with a signal generator (e.g., colloidal gold), which is placed in the dry state at a predetermined site on the membrane. Using this novel approach the clinician (catheter inserters) would be able to determine if a patient is at risk of developing an allergic reaction before potentially introducing an allergen into a patient's system. The system also provides ease of use to the hospital staff as it does not require any additional step, equipment or time other than what is needed for standard procedures.

[0055] FIGS. 2 and 3 illustrate an independent testing module in accordance with an embodiment of this invention. FIG. 2 illustrates the independent testing module 10 in its inactive state and FIG. 3 illustrates the independent testing module 10 in its active state. The independent testing module 10 includes a housing 12 having a proximal end 14 and a distal end 16. A needle 18 can extend from the distal end 16 of the housing 12.

The needle 18 can include a sharpened distal end 20 and a proximal end 22 that extends into the housing 12. The needle 18 can be generally configured as a hypodermic-type needle with a bore 24 extending through its length. The testing module 10 can also include a viewing window 26, through which test strip 28 can be observed. The test strip 28 is disposed within the housing 12 behind the window 26, such that the operator can view any changes in the strip 28 during use. The testing module 10 can also include a slide 30 and a vacuum button 32 (as illustrated in FIGS. 4-6). In the inactive state illustrated in FIG. 2, the slide 30 is positioned toward the distal end of the testing module 10. When the needle 18 is inserted into the patient and testing is required the slide 30 can be moved from its distal, forward position to a proximal position. Slot 34, positioned on a side 36 of housing 12 in FIGS. 2 and 3, is configured to lock the slide 30 into place after it has been activated into the proximal position.

[0056] The button can comprise an elastic material, for example, silicone, latex, or polyurethane. In one non-limiting embodiment, button is thinner at the peak of the button's dome, and is thicker at the base of the dome.

[0057] FIGS. 4 and 5 illustrate a sectional view of the independent testing module 10 illustrated in FIGS. 2 and 3. FIG. 4 is a sectional view of the independent testing module 10 in the inactive position, as illustrated in FIG. 2, and FIG. 5 is a sectional view of the independent testing module 10 in the active position, as illustrated in FIG. 3. The housing 12 can define an inner space 38 near the proximal end 14 of the testing module 10. The test strip 28 can be disposed in this inner space 38. In addition, an absorbent pad 40 can be integrated into the bottom of the test strip 28 in this inner space 38. The test strip 28 can include a proximal end 42 and a distal end 44. Cap 46 is positioned on top of the junction between the proximal end of the needle 22 and the distal end 44 of the test strip 28.

[0058] The following concerns non-limiting embodiments of cap (46). The cap holds or positions the test strip. The cap holds or positions the proximal end of the needle. Also, the cap creates or defines small vacuum pathways from the vacuum button to the proximal end of the needle. In a preferred embodiment, the cap (46), is not removable.

[0059] In a non-limiting embodiment of the present disclosure, the absorbent pad is an integrated part of the test strip. In another non-limiting embodiment, the absorbent pad

is separate from, and does not occupy the same space as, the test strip. The absorbent pad increases the total volume of sample that enters the test strip. The absorbent pad can block the migration of blood cells, and thereby provide a clean field for development and detection (by clinician's eyes) of the color reaction. In addition, or alternatively, the absorbent pad can draw the biological fluid by way of capillary attraction, resulting in wetting of a broad area of the test strip. In another embodiment, the device comprises only a test strip and does not contain any absorbent pad. In one embodiment that does not contain an absorbent pad, the test strip does not disperse fluid by way of capillary attraction, and the biological fluid is sufficiently dispersed without capillary attraction. In another embodiment, the test strip is sufficiently thick (or thin but sufficiently opaque) that it blocks passage of red blood cells to the viewable area where the color reaction takes place. In yet another embodiment, the test strip has capillary attraction and is also sufficiently thick (or thin but sufficiently opaque) to block passage of red blood cells, and to prevent the red blood cells from residing in the viewable area where the color reaction takes place). Absorbent pad can comprise cellulose, polyvinylidene fluoride (PVDF), nitrocellulose, and the like. Filter material suitable as a matrix for test strips, and for serving as a reaction area for color reagents, and optionally for blocking red blood cells, and optionally for serving as a capillary attractant for attracting and dispersing a biological fluid, are available (EMD Millipore, Darmstadt, Germany; Millipore, Billerica, MA; Membrane Solutions, Plano, TX). US 4,855,240 of Rosenstein, US 4,703,017 of Campbell, and US 4,376,110 of David et al, disclose absorbent materials, capillary materials, test strips, labels, and immunoassays, are incorporated herein by reference in their entirety.

[0060] FIGS. 4 and 5 also illustrate a vacuum button 32 of the independent testing module 10. In the inactivated position illustrated in FIG. 4, the vacuum button 32 is depressed by slide 30. This keeps the vacuum button 32 depressed until the needle 18 is inserted and ready to extract blood. As illustrated in FIG. 5, once the device is in position, the slide 30 is retracted to the active position, releasing vacuum button 32, thus creating a vacuum and allowing blood to flow into the bore 24 of the needle 18. Locking the slide 30 in the active position prevents depression of the vacuum button 32, when the needle 18 is inserted into a vein of the patient, in turn preventing air from potentially being pushed into the access point or blood being squirted from the device

after it has been used. The blood aspirated into the testing module 10 is absorbed from the bottom end of the testing strip 28. The absorbent pad 40 can absorb the plasma sample after the completion of the signal detection reaction. The absorbent pad 40 can also include a porous backing and an absorbent dispersed, adsorbed, or coated into the pores of the porous backing. A color signal can appear within approximately 10 minutes within the viewing window 26, but could take less time or more time depending on the detecting antibodies contained in the test strip.

[0061] FIG. 6 illustrates an exploded view of the independent testing module 10 as shown in FIGS. 2-5. As shown in FIG. 6, the testing module includes the housing 12 and a needle 18 coupled to a distal end 16 of the housing 12. The housing 12 also defines the inner space 38 near the proximal end 14 of the testing module 10. The test strip 28 can be disposed in this inner space 38. In addition, an absorbent pad 40 can be integrated into the test strip 28 in this inner space 38. The test strip 28 can include a proximal end 42 and a distal end 44. Cap 46 is positioned on top of the junction between the proximal end of the needle 22 and the distal end 44 of the absorbent pad 40. FIG. 6 also illustrates the slide 30 and the vacuum button 32 which work together to release the vacuum for the independent testing module such that it can aspirate the blood sample. The slide 30 and vacuum button 32 also prevent the vacuum button from being re-depressed to prevent pushing any air into the entry site or allowing any blood to spurt out after use. The vacuum button 32 sits within an opening 48 defined by the housing 12. The slide 30 can lock into position via the slot 34, also illustrated in FIGS. 2 and 3. As illustrated, tab 31 interacts with a notch 31' in the architecture of slot 34 in order to lock the slide 30 into place. However, any suitable means of locking the slide into place can be used. Locking the slide 30 in the active position prevents depression of the vacuum button 32, when the needle 18 is inserted into a vein of the patient, in turn preventing air from potentially being pushed into the access point or blood being squirted from the device after it has been used. Cap 46 is also shown and is placed over the junction between the testing strip 28 and the proximal end 22 of the needle 18.

[0062] FIG. 7 illustrates a syringe with integrated allergy testing, in accordance with another embodiment of the integrated allergy testing system. As shown in FIG. 7, the syringe 100 includes a housing 102 having a proximal end 104 and a distal end 106. The proximal end 104 of the housing 102 can include flanges 108, 110 which can serve

as finger rests during use of the syringe 100. The housing 102 can include a window 112 positioned such that test strip positioned below the window is visible to a user of the syringe 100. The test strip resides within its own lumen or channel, such that only the distal end of the test strip is exposed to the blood that is aspirated within the syringe housing 102. A needle hub 114 can be positioned at the distal end 106 of the housing 102 and can be configured to couple to a hypodermic-type needle for aspirating blood into a lumen of the syringe 100. A syringe housing cap 116 can be coupled to the distal end 106 to hold the test strip in the housing 102. The syringe 100 can also include a plunger 118 extending into the lumen of the housing 102 for creating negative pressure to aspirate blood into the lumen of the syringe. The plunger 118 can include a thumb rest 119 positioned at a proximal end 117 of the plunger 118.

[0063] In embodiments, where test strip resides in its own lumen or channel, blood or other biological sample enters channel through a hole, slit, passage, or crevice, that is about 5% the distal-to-proximal length of the channel, about 10% the distal-to-proximal length of the channel, about 15%, about 20%, about 25%, about 30%, about 35%, about 40%, about 45%, about 50%, about 55%, about 60%, about 65%, about 70%, about 75%, about 80%, about 85%, about 90%, about 95%, about 100%, or longer, than the distal-to-proximal length of the channel. Where the slit or crevice is about 100% the distal-to-proximal length of the channel, the result is that blood entering the syringe, or entering a corresponding structure in the module (10), contacts that entire test strip essentially simultaneously.

[0064] Regarding the orientation of the channel with respect to the hole, slit, passage, or crevice, the hole, slit, or crevice, can start at a point corresponding to the distal-most portion of the channel, and then migrate proximally. Alternatively, the hole, slit, or crevice, can start at a point corresponding to the proximal-most portion of the channel, and then migrate distally. In yet another alternative, the hole, slit, passage, or crevice, can be situated entirely between the distal-most and proximal-most portions of the channel. For example, the hole or passage can be situated near the half-way point of the channel, where blood entering the hole migrates both in the proximal and in the distal directions.

[0065] In embodiments where the hole, slit, passage, or crevice, is about 5% the distal-to-proximal length of the channel, it may be the case that only about 5% of the

test strip is wetted by the blood or other biological sample. Alternatively, in embodiments where the hole, silt, passage, or crevice, is about 5% the distal-to-proximal length of the channel, it may be the case that greater than about 5% of the test strip is wetted by the blood or other biological sample, where this greater than amount results from migration of the biological sample through the test strip. Migration can by via diffusion, capillary force, or by a combination of diffusion and capillary force. The above narrative also applies to configurations where the hole, slit, passage, or crevice, is less than 90%, less than 80%, less than 70%, less than 60%, less than 50%, less than 40%, less than 30%, less than 20%, less than 10%, less than 5%, of the length of the distal-to-proximal length of the channel.

[0066] FIG. 8 illustrates a sectional view of the syringe illustrated in FIG. 7. As shown in FIG. 8, the syringe 100 includes the housing 102 defining a lumen 120, extending therethrough. The plunger 118 is shown extending into the lumen 120 of the housing 102. Additionally, FIG. 8 illustrates test strip 122 positioned within the housing 102 beneath window 112. The syringe housing cap 116 holds the test strip 122 in place beneath the window 112 for observation by the practitioner. Alternately, the test strip 122 can take the form of a cassette or any other appropriate form for positioning within the syringe 100. In addition, an absorbent pad 124 can be integrated into the test strip 122. The absorbent pad 124 can absorb the plasma sample after the completion of the signal detection reaction. The absorbent pad 124 can also include a porous backing and an absorbent dispersed, adsorbed, or coated into the pores of the porous backing. A color signal can appear within approximately 10 minutes within the viewing window 112, but could take less time or more time depending on the antibodies contained in the test strip.

[0067] FIG. 9 illustrates an exploded view of the syringe illustrated in FIGS. 7 and 8. FIG. 9 shows the housing 102 having a window 112 for the test strip 122. The syringe housing cap 116 can be used to hold the test strip in place, such that it does not move during testing. The plunger 118 can be configured to slide within the lumen 120 of the housing 112.

[0068] FIG. 10 illustrates a connector design for the integrated testing system in accordance with an embodiment of the invention. The connector 200, includes a housing 201, having a proximal end 202 and a distal end 204, and can be configured for

placement between a syringe body and a needle for the syringe. The connector 200 can be connected to the syringe body in a variety of different ways such as frictional hold, tabs, or any other suitable coupling. As illustrated in FIG. 10, the connector 200 can be coupled to the syringe via luer threads 206 positioned at the proximal end 202 of the connector 200. The connector 200 can also include a coupling 208 for coupling the connector 200 to a needle. The needle can take the form of a hypodermic-type needle or any other needle suitable for aspirating blood through the connector 200. The connector also includes a window 210 through which test strip (not shown) can be visualized.

[0069] FIG. 11 illustrates a sectional view of the embodiment shown in FIG. 10 and FIG. 12 illustrates an exploded view of the embodiment illustrated in FIGS. 10 and 11. FIGS. 11 and 12 illustrate the test strip 214 disposed within the connector housing 201. As illustrated, the test strip 214 is spirally wound within the connector housing 201. The test strip 214 can be viewed through window 210 in the housing 201. Blood can be aspirated into a lumen 212 defined by housing 201, when testing is required. In addition, an absorbent pad 216 can be positioned beneath the test strip 214. The absorbent pad 216 integrated into the test strip 228 can absorb the plasma sample after the completion of the signal detection reaction. The absorbent pad 216 can also include a porous backing and an absorbent dispersed, adsorbed, or coated into the pores of the porous backing. A color signal can appear within approximately 10 minutes within the viewing window 210, but could take less time or more time depending on the antibodies contained in the blood sample.

[0070] Alternately test strip, for example, an immunochromatographic test strip, can be incorporated into a number of different medical devices. One such example is an test strip incorporated into a "hemo-hopper," such as a blood reservoir in a medical tray or kit. The blood aspirated during access to the vessel would be disposed into the hemo-hopper. The sample could then be absorbed into the test strip. In addition, an absorbent pad can be positioned beneath the test strip. The absorbent pad can absorb the plasma sample after the completion of the signal detection reaction. The absorbent pad can also include a porous backing and an absorbent dispersed, adsorbed, or coated into the pores of the porous backing. A color signal can appear within

approximately 10 minutes, but could take less time or more time depending on the antibodies contained in the blood sample.

[0071] FIG. 13 (A, B) illustrates the end-cap that is a part of the module embodiment, and structures in the vicinity of the cap. The end-cap (346) is in contact with needle (318). The end-cap (346) defines part of cavity (348) where the vacuum button (32) can fit. A non-limiting embodiment of vacuum button (32) is shown in FIGS. 4-6. FIG. 13(A) shows cap without test strip, and FIG. 13 (B) shows cap with test strip.

[0072] While the method and apparatus have been described in terms of what are presently considered to be the most practical and preferred embodiments, it is to be understood that the disclosure need not be limited to the disclosed embodiments. It is intended to cover various modifications and similar arrangements included within the spirit and scope of the claims, the scope of which should be accorded the broadest interpretation so as to encompass all such modifications and similar structures. The present disclosure includes any and all embodiments of the following claims.

[0073] It should also be understood that a variety of changes may be made without departing from the essence of the invention. Such changes are also implicitly included in the description. They still fall within the scope of this invention. It should be understood that this disclosure is intended to yield a patent covering numerous aspects of the invention both independently and as an overall system and in both method and apparatus modes.

[0074] Further, each of the various elements of the invention and claims may also be achieved in a variety of manners. This disclosure should be understood to encompass each such variation, be it a variation of an embodiment of any apparatus embodiment, a method or process embodiment, or even merely a variation of any element of these.

[0075] Particularly, it should be understood that as the disclosure relates to elements of the invention, the words for each element may be expressed by equivalent apparatus terms or method terms -- even if only the function or result is the same.

[0076] Such equivalent, broader, or even more generic terms should be considered to be encompassed in the description of each element or action. Such terms can be

substituted where desired to make explicit the implicitly broad coverage to which this invention is entitled.

[0077] It should be understood that all actions may be expressed as a means for taking that action or as an element which causes that action.

[0078] Similarly, each physical element disclosed should be understood to encompass a disclosure of the action which that physical element facilitates.

[0079] Any patents, publications, or other references mentioned in this application for patent are hereby incorporated by reference.

[0080] Finally, all references listed in the Information Disclosure Statement or other information statement filed with the application are hereby appended and hereby incorporated by reference; however, as to each of the above, to the extent that such information or statements incorporated by reference might be considered inconsistent with the patenting of this/these invention(s), such statements are expressly not to be considered as made by the applicant.

[0081] In this regard it should be understood that for practical reasons and so as to avoid adding potentially hundreds of claims, the applicant has presented claims with initial dependencies only.

[0082] Support should be understood to exist to the degree required under new matter laws -- including but not limited to United States Patent Law 35 USC §132 or other such laws -- to permit the addition of any of the various dependencies or other elements presented under one independent claim or concept as dependencies or elements under any other independent claim or concept.

[0083] To the extent that insubstantial substitutes are made, to the extent that the applicant did not in fact draft any claim so as to literally encompass any particular embodiment, and to the extent otherwise applicable, the applicant should not be understood to have in any way intended to or actually relinquished such coverage as the applicant simply may not have been able to anticipate all eventualities; one skilled in the art, should not be reasonably expected to have drafted a claim that would have literally encompassed such alternative embodiments.

[0084] Further, the use of the transitional phrase "comprising" is used to maintain the "open-end" claims herein, according to traditional claim interpretation. Thus, unless the context requires otherwise, it should be understood that the term "compromise" or variations such as "comprises" or "comprising", are intended to imply the inclusion of a stated element or step or group of elements or steps but not the exclusion of any other element or step or group of elements or steps.

[0085] Such terms should be interpreted in their most expansive forms so as to afford the applicant the broadest coverage legally permissible.

[0086] The many features and advantages of the invention are apparent from the detailed specification, and thus, it is intended by the appended claims to cover all such features and advantages of the invention which fall within the true spirit and scope of the invention. Further, because numerous modifications and variations will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation illustrated and described, and accordingly, all suitable modifications and equivalents may be resorted to falling within the scope of the invention.

What is claimed is:

Claim 1. A device for testing the presence or absence of a substance in blood, comprising:

a coupler or hub that is capable of coupling with a needle, wherein the needle is for withdrawing blood from a subject and for introducing the withdrawn blood into the device;

a first chamber for receiving the withdrawn blood;

a second chamber configured for holding a test strip;

a test strip that is held within the second chamber;

a wall or panel that separates the first chamber from the second chamber;

at least one aperture in the wall or panel configuring for allowing blood to pass from the first chamber to the second chamber;

wherein the second chamber comprises a window for viewing the test strip,

wherein the test strip is capable of producing a visible signal that indicates the presence or absence of the substance in the withdrawn blood; and,

wherein the window is configured to allow visual detection of the visible signal.

Claim 2. The device of claim 1, that comprises a syringe and wherein the first chamber is defined by the housing or barrel of the syringe.

Claim 3. The device of claim 1 that is capable of being coupled to a syringe and to a needle, wherein the device has a hub that is capable of coupling to the hub of the syringe, and wherein the device has a coupler that is capable of coupling to a hub of a needle.

Claim 4. The device of claim 1, wherein the substance is an antibody that specifically binds to an antimicrobial agent.

Claim 5. The device of claim 1, wherein the substance is an antibody of the class IgG, IgA, IgM, or IgE.

Claim 6. The device of claim 1, wherein the second chamber comprises a flexible dome, and

wherein the flexible dome is capable of flexing radially outward;

wherein in use the flexible dome flexes radially outwards and creates a partial vacuum that is capable of drawing blood out of the first chamber and into the second chamber;

wherein a sliding latch is operably linked with the flexible dome;

wherein in use the sliding latch is capable of being slid over the dome to compress the flexible dome radially downwards and increase the pressure within the second chamber; and

wherein in use the sliding latch is capable of being slid away from the dome to release the dome and allow the dome to flex radially outwards thereby creating a partial vacuum in the second chamber.

Claim 7. The device of claim 1, further comprising an end-cap, wherein the end-cap is configured for contacting and stabilizing the test strip, and configured for contacting and stabilizing the proximal portion of a needle that is coupled to said device.

Claim 8. The device of claim 1, further comprising a needle, wherein the needle is reversibly coupled to the coupler.

Claim 9. The device of claim 1 that does not comprise a needle.

Claim 10. The device of claim 1, wherein the test strip is an immunochromatographic test strip.

Claim 11. A device for testing the presence or absence of an antibody in blood, wherein the antibody specifically binds to an antimicrobial agent, comprising:

a coupler that is capable of coupling with a hub of a needle, wherein the needle is for withdrawing blood from a subject and for introducing the withdrawn blood into the device;

a first chamber for receiving the withdrawn blood;

a second chamber configured for holding a test strip;

a test strip that is held within the second chamber;

a wall or panel that separates the first chamber from the second chamber;

at least one aperture in the wall or panel configuring for allowing blood to pass from the first chamber to the second chamber;

wherein the second chamber comprises a window for viewing the test strip;

wherein the test strip is capable of producing a visible signal that indicates the presence or absence, in the withdrawn blood, of the antibody that specifically binds to the antimicrobial agent; and,

wherein the window is configured to allow visual detection of the visible signal.

Claim 12. A process for allergy detection during catheterization, comprising:

the step of drawing blood from a subject into the first chamber of a device that comprises:

(a) a coupler or hub that is capable of coupling with a needle, wherein the needle is for withdrawing blood from a subject and for introducing the withdrawn blood into the device;

(b) a first chamber for receiving the withdrawn blood;

(c) a second chamber configured for holding a test strip;

(d) a test strip that is held within the second chamber;

(e) a wall or panel that separates the first chamber from the second chamber;

(f) at least one aperture in the wall or panel configuring for allowing blood to pass from the first chamber to the second chamber;

(g) wherein the second chamber comprises a window for viewing the test strip,

(h) wherein the test strip is capable of producing a visible signal that indicates the presence or absence of the substance in the withdrawn blood; and,

(i) wherein the window is configured to allow visual detection of the visible signal;

the step of allowing at least some of the drawn blood to enter the second chamber of the device;

wherein a needle is coupled to the device; and,

wherein in use, at least some of the withdrawn blood enters the needle and then enters the first chamber, then enters the second chamber, and then contacts the test strip.

Claim 13. The process of claim 12, further comprising a reaction that is mediated by the test strip, wherein the reaction produces a visual signal that indicates presence or absence of a substance that mediates an allergy.

Claim 14. The process of claim 12, wherein the drawing blood into the first chamber is urged by one or more of: (a) Blood pressure of the subject; (b) Vacuum produced by a syringe plunger of the device; (c) Vacuum produced by a flexible dome of the device; and (d) Capillary action of the test strip of the device.

Claim 15. The process of claim 12, wherein the test strip is configured for detecting an antibody that specifically binds an antimicrobial agent;

wherein in use the test strip provides a visual signal that the blood does not contain detectable antibodies that specifically bind to the specific antimicrobial agent;

followed by the step of inserting a catheter into the subject, wherein the catheter is impregnated or coated with the antimicrobial agent.

Claim 16. The process of claim 12, wherein the test strip is configured for detecting an antibody that specifically binds an antimicrobial agent;

wherein in use the test strip provides a visual signal that the blood does contain detectable antibodies that specifically bind to the specific antimicrobial agent;

followed by the step of making a decision on whether or not to insert a catheter that is impregnated or coated with the antimicrobial agent; and,

wherein the decision is to refrain from inserting the catheter in the subject,

followed by the step of inserting a catheter into the subject, wherein the catheter is not impregnated or coated with the antimicrobial agent.

Claim 17. A system comprising, in combination, a medical instrument that is capable of holding blood, and a medical device that comprises:

(a) a coupler or hub that is capable of coupling with a needle, wherein the needle is for withdrawing blood from a subject and for introducing the withdrawn blood into the device;

(b) a first chamber for receiving the withdrawn blood;

(c) a second chamber configured for holding a test strip;

(d) a test strip that is held within the second chamber;

(e) a wall or panel that separates the first chamber from the second chamber;

(f) at least one aperture in the wall or panel configuring for allowing blood to pass from the first chamber to the second chamber;

(g) wherein the second chamber comprises a window for viewing the test strip,

(h) wherein the test strip is capable of producing a visible signal that indicates the presence or absence of the substance in the withdrawn blood; and,

(i) wherein the window is configured to allow visual detection of the visible signal.

Claim 18. The system of claim 17, wherein the combination is a reversible combination or a permanent combination.

Claim 19. The system of claim 17, wherein the combination is a reversible combination, wherein the device and the medical instrument are held in combination by one or more of a clip, snap, lock, or tab.

Claim 20. The system of claim 17, wherein the medical instrument comprises one or more of a syringe, trocar, catheter, introducer, sheath, hub, pump, or valve.

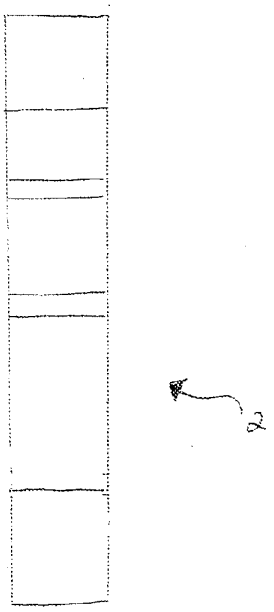


FIG. 1

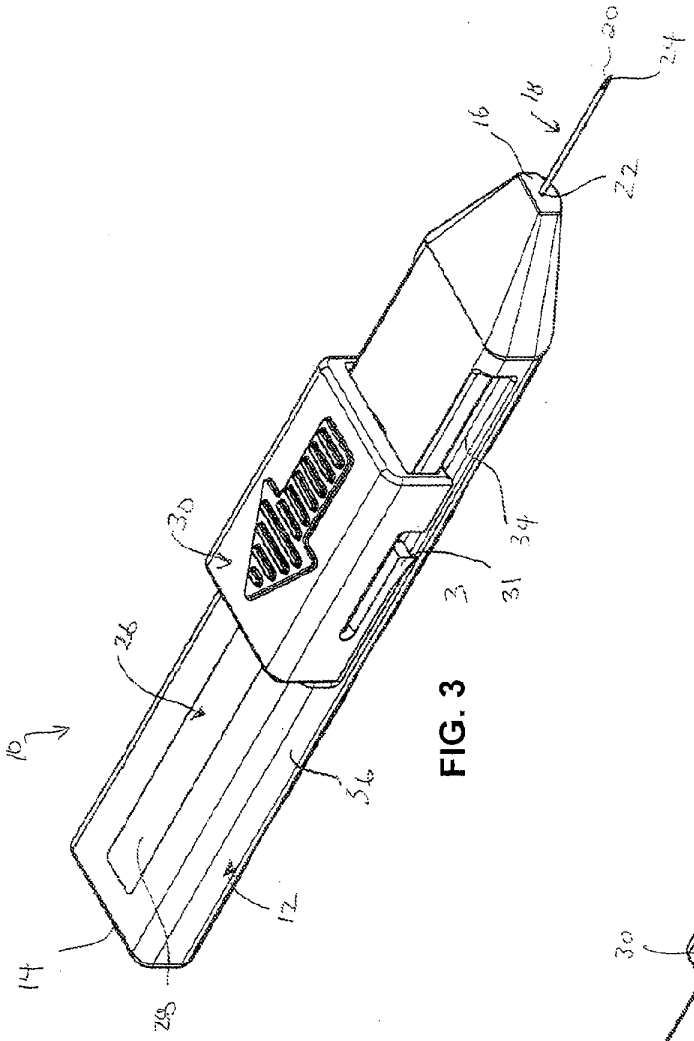

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FIG. 3

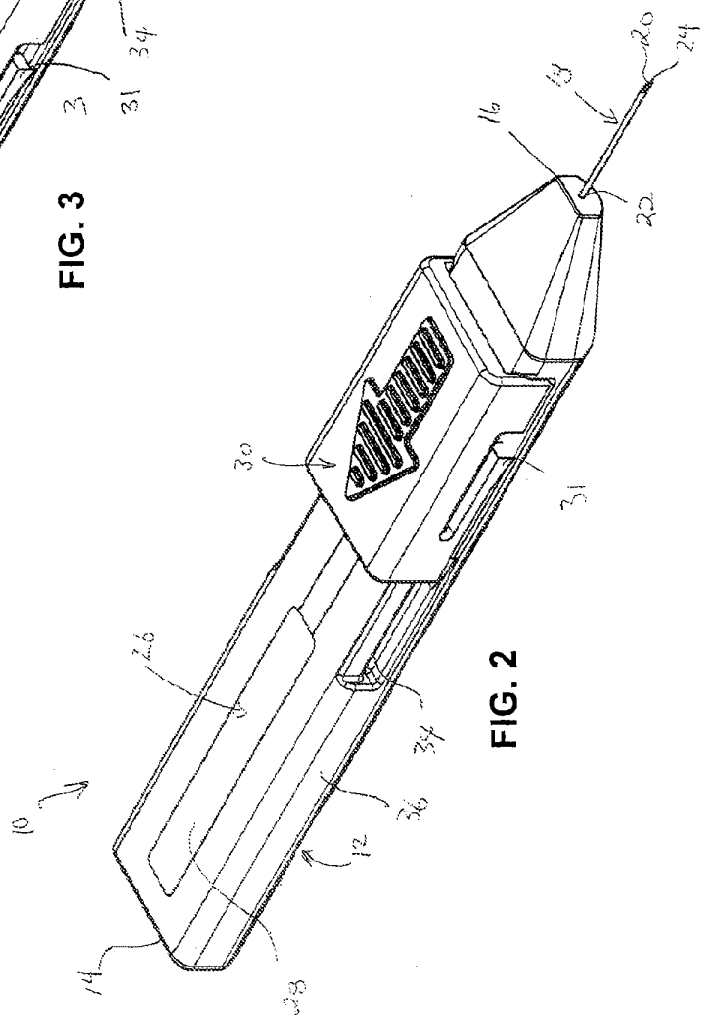
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FIG. 2

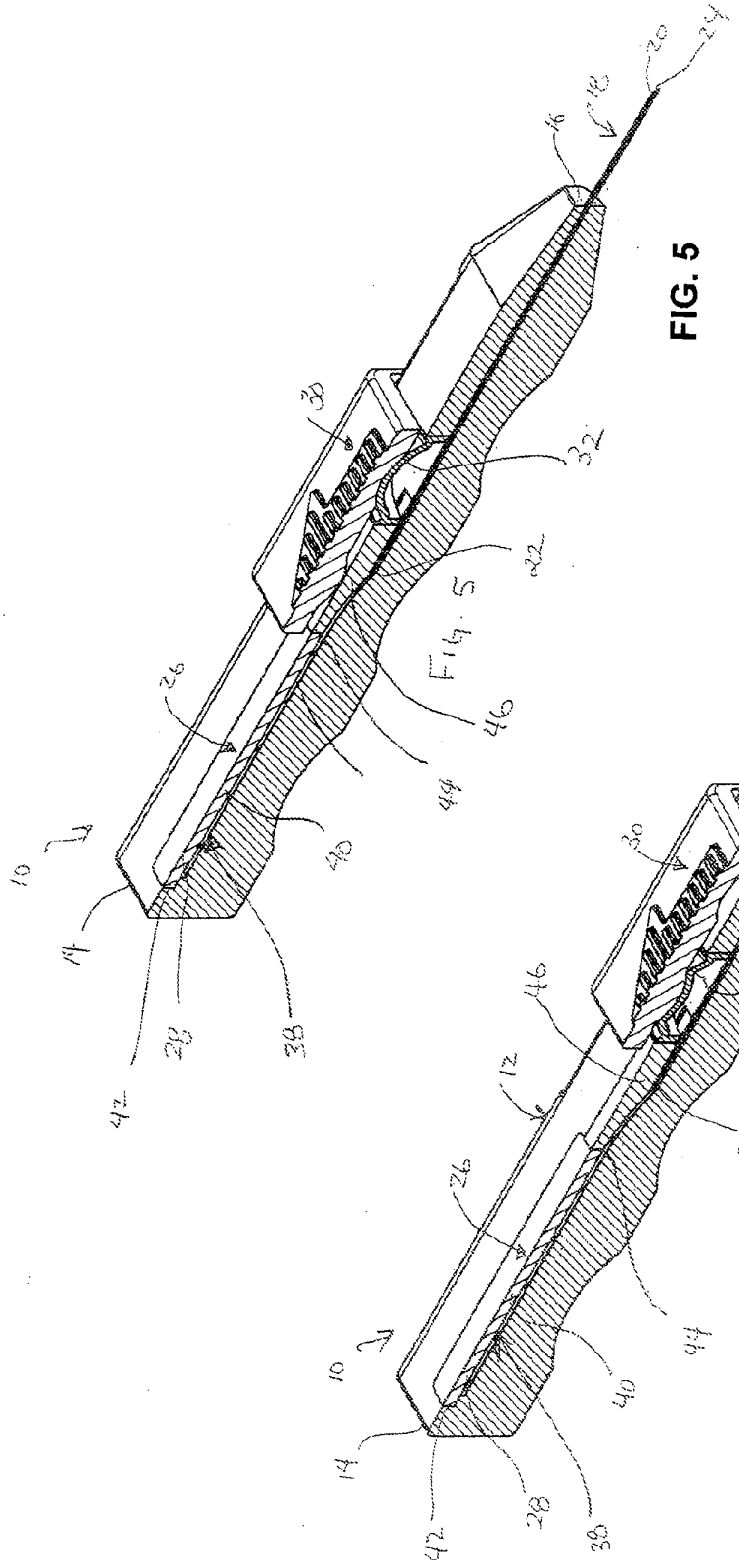


FIG. 5

FIG. 4

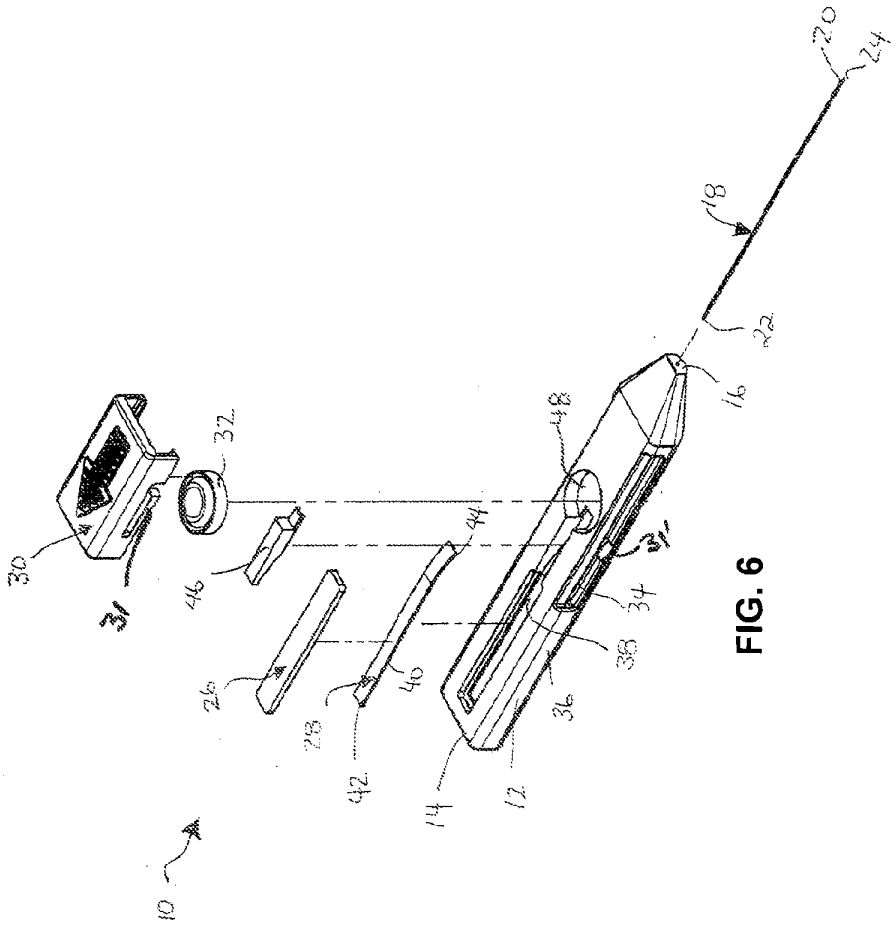


FIG. 6

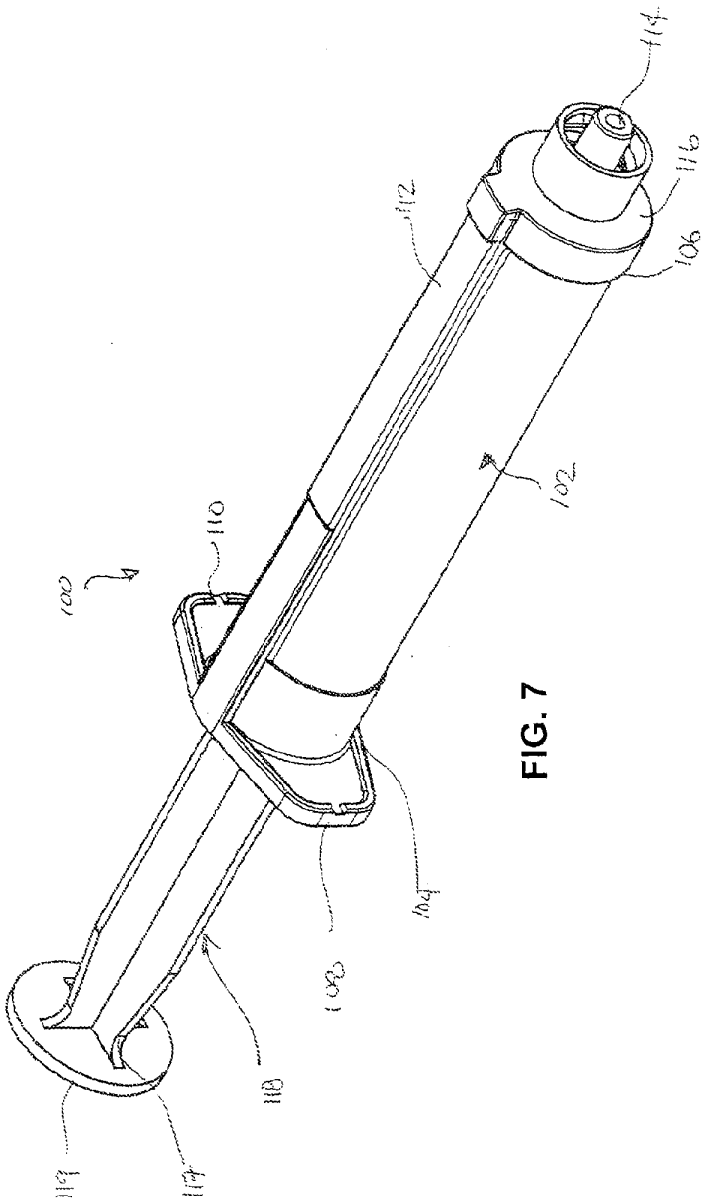


FIG. 7

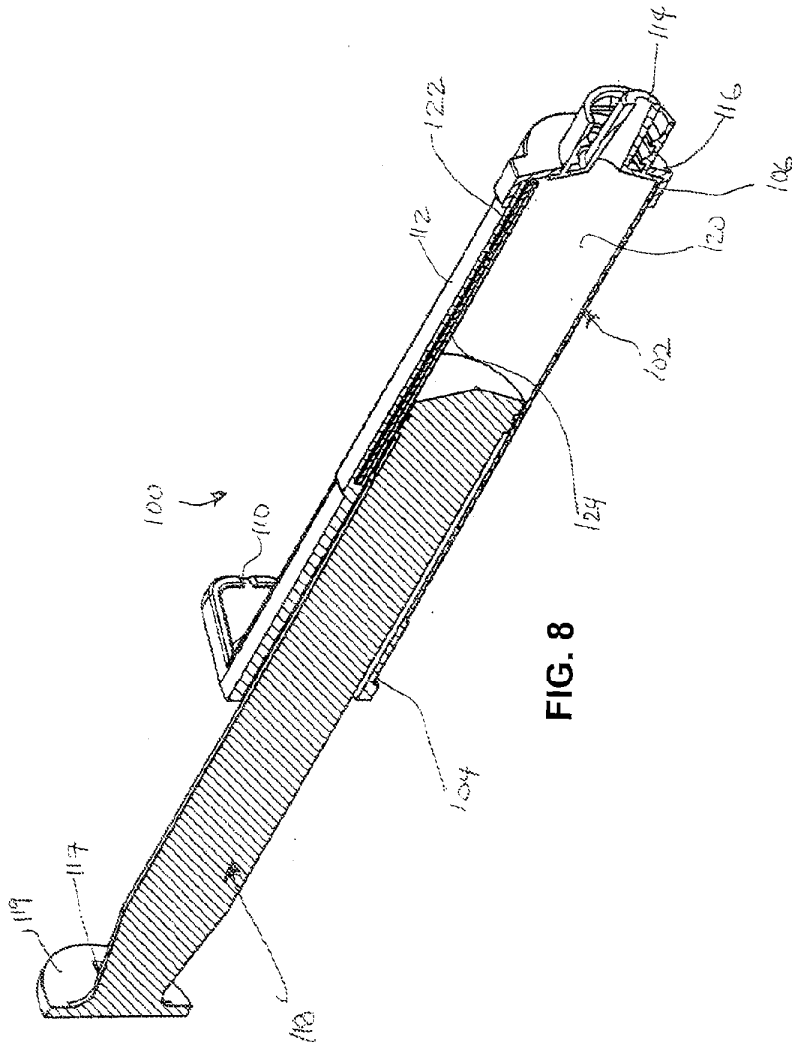


FIG. 8

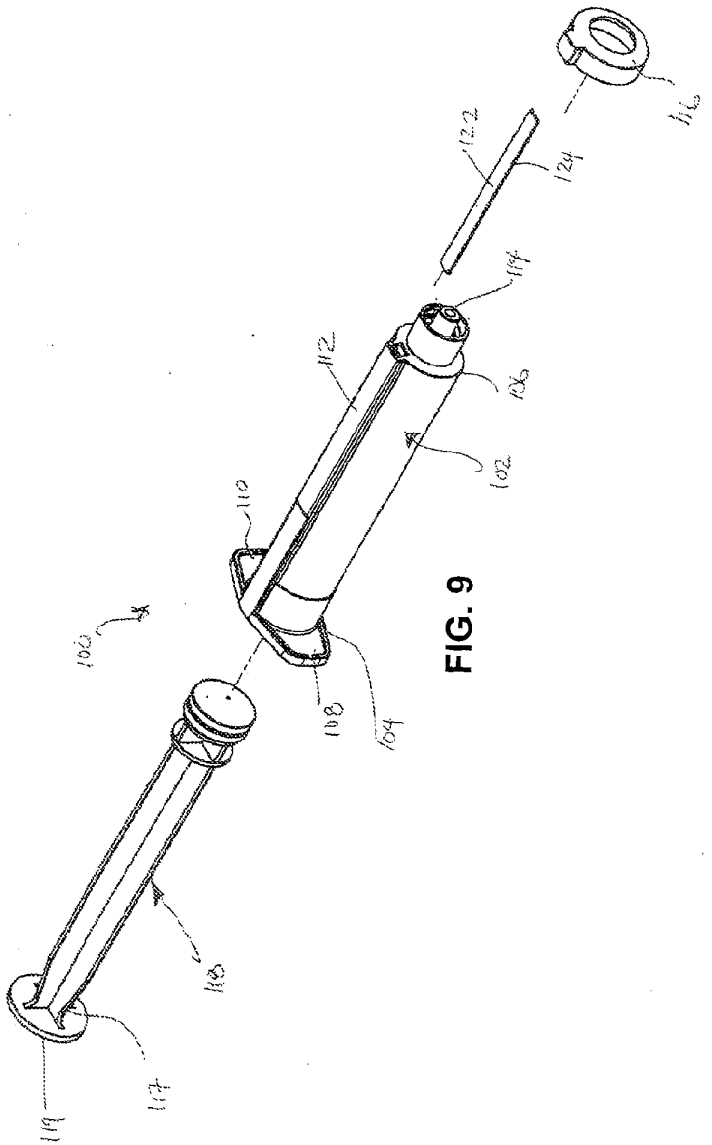


FIG. 9

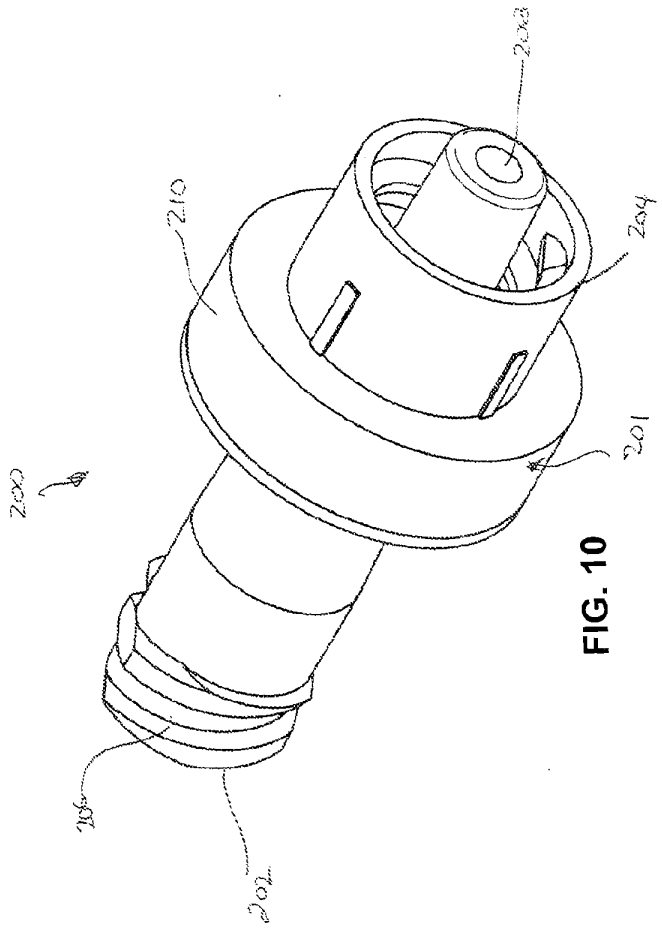


FIG. 10

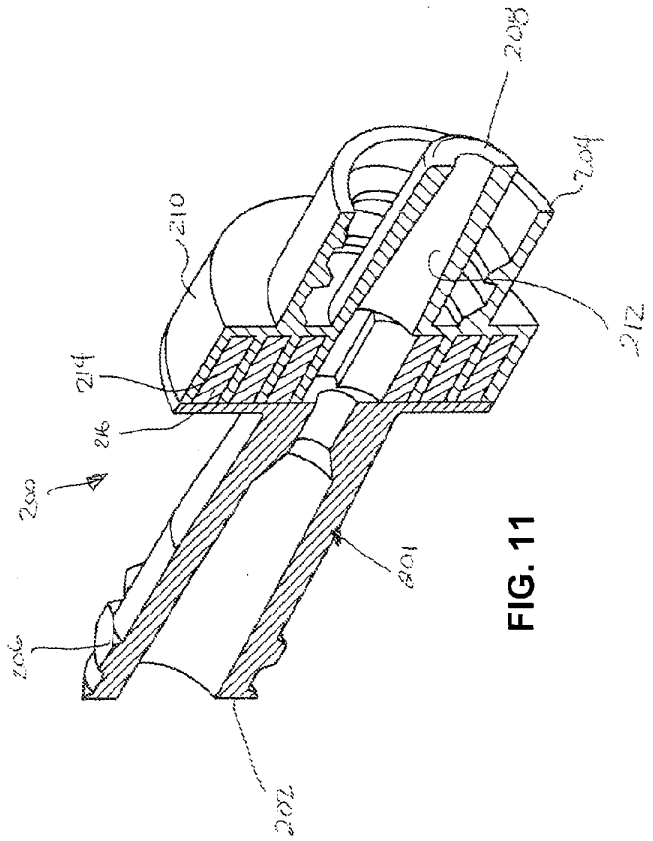


FIG. 11

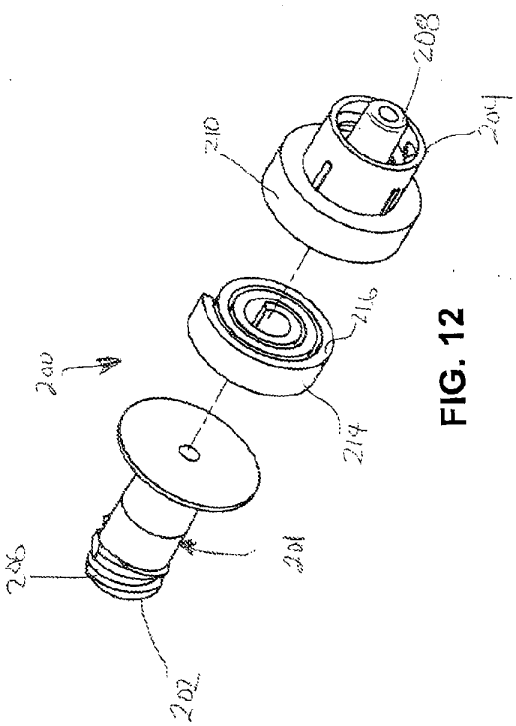
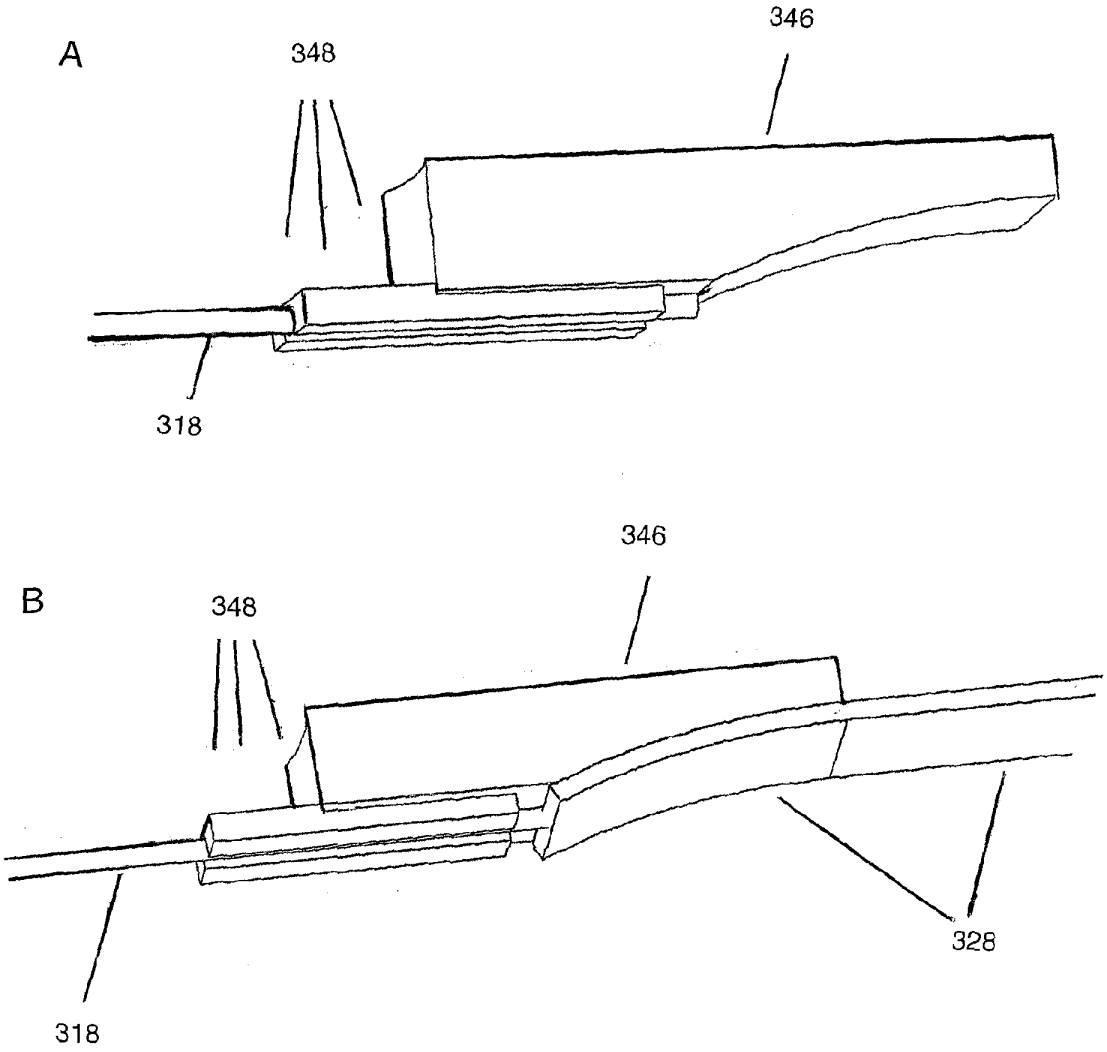


FIG. 12

Fig. 13



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2012/067095

A. CLASSIFICATION OF SUBJECT MATTER

G01N 33/50(2006.01)i, G01N 33/52(2006.01)i, G01N 33/53(2006.01)i

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

G01N 33/50; C25C 3/02; A61B 5/151; G01N 17/00; B32B 38/04; A61B 5/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

eKOMPASS(KIPO internal) & keywords: test strip, coupling, needle, chamber, window

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009-0112125 A1 (TAMIR, NILI) 30 April 2009 See paragraph [0100]; claims 1 and 5-6; figure 5.	1-20
A	US 2003-0109777 A1 (KLOEPFER, HANS G. et al.) 12 June 2003 See paragraph [0107]; claim 1; figures 1 and 5.	1-20
A	US 2003-0150745 A1 (TEODORCZYK, MARIA et al.) 14 August 2003 See claims 1, 8 and 13; figure 3.	1-20
A	US 2007-0161926 A1 (IMAMURA, TAKESHI et al.) 12 July 2007 See paragraph [0032]; claim 1; figure 2A.	1-20
A	US 2011-0046453 (KEIL, MICHAEL) 24 February 2011 See paragraphs [0017] and [0019]; claims 14-16; figures 1 and 7.	1-20

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents,such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 FEBRUARY 2013 (28.02.2013)	**04 MARCH 2013 (04.03.2013)**
Name and mailing address of the ISA/KR Facsimile No. 82-42-472-7140	Authorized officer LEE, Dong Yun Telephone No. 82-42-481-8734

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US2012/067095

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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Form PCT/ISA/210 (patent family annex) (July 2009)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/US2012/067095

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Form PCT/ISA/210 (patent family annex) (July 2009)

China National Intellectual Property Administration

1110-11, A, Floor 11, Chengjian Plaza, 18 Beitaipingzhuang Road, Haidian District, Beijing 100088, PR China Beijing Pat SF Intellectual Property Agency Co Ltd	Issue Date: September 27, 2023

Application No. or patent No.: 202080000666.0 Issue serial No.: 2023092702079090

Applicant（s）: KURIN, INC.

Title of invention-creation: NON-VENTING BODILY FLUID SAMPLE OPTIMIZATION DEVICE AND SYSTEM

First Office Action

1 ☒ Upon the request of the applicant for substantive examination, the China National Intellectual Property Administration has performed the examination for the above-identified application for a patent for invention according to the provisions of Article 35.1 of the Patent Law.

☐ The China National Intellectual Property Administration itself has decided to perform the substantive examination for the above-identified application for a patent for invention according to the provisions of Article 35.2 of the Patent Law.

2 ☒ The applicant requested to designate the filing date of

April 1, 2019 in the Patent Office of US as the priority date;

_ in the Patent Office of _ as the priority date.

3 ☐ After examination, the amendment submitted on_____is not in conformity with the provisions of Rule 51.1 of the Implementing Regulations of the Patent Law, so it has not been accepted.

4 ☐ Examination is made based on the Chinese text or translation of the international application as originally filed.

☒ Examination is made based on the following documents:

description, claims, abstract and drawing of abstract as filed on 6 May 2020;

drawings as filed on April 6, 2021.

5 ☒ This notification cited reference documents as follows:（its code will continue to be used in the future when examined.）

code	File No. or title	Publication date (or filing date of conflicting application)
1	US2018271425A1	2018-09-27

6 The conclusion of the examination:

In regard to the Description:

☐ The subject matter of the application belongs to the objects mentioned in Article 5 of the Patent Law, for which no patent right shall be granted.

☐ The description is not in conformity with the provisions of Article 26.3 of the Patent Law.

☐ The description is not in conformity with the provisions of Article 33 of the Patent Law.

☐ The description is not in conformity with the provisions of Rule 17 of Implementing Regulations of the Patent Law.

☐

In regard to the Claims:

☐ Claims_____are not in conformity with the provisions of Article 2.2 of the Patent Law.

☐ Claims_____are not in conformity with the provisions of Article 9.1 of the Patent Law.

☐ Claims_____do not possess the novelty under Article 22.2 of the Patent Law.

☒ Claims 1-20 do not possess the inventiveness under Article 22.3 of the Patent Law.

☐ Claims_____do not possess the practical applicability under Article 22.4 of the Patent Law
☐ Claims_____belong to the objects mentioned in Article 25 of the Patent Law, for which no patent right shall be granted.
☐ Claims_____are not in conformity with the provisions of Article 26.4 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 31.1 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 33 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 19 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 20 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 21 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Rule 22 of Implementing Regulations of the Patent Law.
☐ _____
☐ The application is not in conformity with the provisions of Article 26.5 of the Patent Law or with the provisions of Rule 26 of Implementing Regulations of the Patent Law.
☐ The application is not in conformity with the provisions of Article 20.1 of the Patent Law.
☐ The division application is not in conformity with the provisions of Rule 43.1 of Implementing Regulations of the Patent Law.

7. According to the above conclusion, the examiner deems that:
☐ The applicant shall amend the application documents as required by the text of Office Action.
☐ The applicant shall state the reason why the application can be accepted and amend the part that is indicated not to be in conformity with the provisions, otherwise the application will be rejected.
☒ No subject matter in the application is patentable, the application will be rejected if the applicant does not make a statement or the statement is not convincing.
☐ ___

8. The applicant shall pay attention to the following items:
(1) In accordance with the provisions of Article 37 of the Patent Law, the applicant shall submit the observations within **4** months from the date of receiving this notification. If the applicant, without any justified reason, fails to reply within the time limit, the application shall be deemed to have been withdrawn.
(2) The amendments to the application made by the applicant shall be in conformity with the provisions of Article 33 of the Patent Law. The amended text shall not go beyond the disclosure scope of the initial description and claims. The amendment should be in conformity with the provisions of Rule 51.3 of the Implementing Regulations of the Patent Law. The applicant shall make the amendment according to the request of this notification.
(3) Any observation and/or amended text shall be mailed or sent by hand to the Receiving Division of the Patent Office. Any document that is not mailed or sent by hand to the Receiving Division does not have legal effect.
(4) The applicant and/or his agent shall not go to the Patent Office to hold an interview with the examiner if no interview is arranged in advance.
(5) For an invention patent application that entered the substantive examination stage, if the applicant withdraws the application on his own initiative before the due date for responding to the first Office Action (except for the case that a response has already been filed), the applicant can request a refund of 50% of the substantive examination fee.

9. The text of the notification embraces 6 pages, along with the enclosures herein:
☐ _____Copy(ies) of the cited references is enclosed in pages of _____.
☐ _____

Examiner:
Tel:

Examining Department:

210402 2012.7 With regard to the paper application, Mail to: 100088, 6 Xitucheng Road, Jimen Bridge, Haidian District, Beijing, China
With regard to the electronic application, the relevant documents shall be filed in the form of electronic documents through the electronic system of patent application. The application documents filed by paper or other forms are deemed not to have been submitted unless there are particular provisions.

Text of the First Office Action

(PCT application entering the national phase)

Application number: 202080000666.0

The present application relates to a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source. Upon examination, the following examination opinions are hereby set forth.

1. Claim 1 does not comply with the provisions under Article 22.3[1] of the Patent Law.

Claim 1 claims a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source. Reference 1 (US2018/0271425A1) discloses a fluid sample optimization device, specifically, a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source (equivalent to: a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source), and in particular discloses the following (see paragraphs [0141] to [0149] of the description, and FIGS. 23A-23B of the description):

A blood sequestration device 2300 in another implementation, having an inlet port 2302 to connect with a patient needle (equivalent to: an inlet configured to connect with the fluid source), an outlet port 2304 to connect with a blood sample collection device (equivalent to: an outlet configured to connect with

[1] **[Article 22.3]** Inventiveness means that, as compared with the prior art, the invention possesses prominent substantive features and represents a notable progress and that the utility model possesses substantive features and represents a progress.

the fluid collection device), a sequestration chamber 2306, and a sampling channel 2308 (equivalent to: a sample path). Once the sequestration chamber 2306 (equivalent to: a contaminant containment reservoir) is filled to an initial aliquot of potentially contaminated blood to be sequestered, the sequestration chamber 2306 is filled.

The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302 (equivalent to: the contaminant containment reservoir having a fluid resistor proximate the outlet).

A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there (equivalent to: the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir). It could be clear that a first portion of the blood sample in Reference 1 potentially has contaminants (equivalent to: a first portion of the fluid sample potentially having contaminants).

A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308.

Upon release of the valve 2308, and under further force of the vacuum or other force (equivalent to: subsequent pressure differentials are applied),

follow-on amounts of blood (equivalent to: the fluid sample) will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 (equivalent to: a sample path connected between the inlet and the outlet) toward the outlet port 2304 and to the collection device (equivalent to: subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet).

The distinguishing technical features of the technical solution claimed by claim 1 over Reference 1 are: the fluid resistor is air permeable, and "to displace air therein through the air permeable fluid resistor and the outlet".

With regard to the above distinguishing technical features: as has been recorded in Reference 1, [a] vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. Therefore, in order to allow the blood to be drawn into sequestration chamber 2306 under the action of vacuum, it would not be difficult for those skilled in the art to envisage that the specific hydrophobic plug 2312 is air permeable and to ensilage displacing air therein through the air permeable fluid resistor and the outlet.

It would be obvious for those skilled in the art to obtain the technical solution claimed by claim 1 based on Reference1 in combination with conventional technical means in the art. Therefore, the technical solution claimed by claim 1 neither has any prominent substantive feature nor represents a notable progress, and thus does not possess inventiveness prescribed under Article 22.3 of the Patent Law.

2. Claims 2-5 do not comply with the provisions under Article 22.3 of the Patent Law.

Claims 2-5 further define the claim to which they refer. On the basis of Reference 1, those skilled in the art could select to arrange a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir.

Reference 1 records: [t]he sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there (equivalent to: the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample).

On the basis of Reference 1, it could be selected as needed that the contaminant containment reservoir includes a tortuous path.

Reference 1 records: [u]pon release of the valve 2308, and under further force of the vacuum or other force (equivalent to: subsequent pressure differentials are applied), follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 (equivalent to: each pressure differential is provided by a vacuum pressure provided by the fluid collection device). Therefore, Reference 1 discloses the additional technical features of claim 5.

Therefore, where the claim to which claims 2-5 refer does not possess inventiveness, claims 2-5 neither have any prominent substantive feature nor represent a notable progress, failing to comply with the provisions regarding inventiveness under Article 22.3 of the Patent Law.

3. Claim 6 does not comply with the provisions under Article 22.3 of the Patent Law.

Claim 6 claims a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source. Reference 1 discloses a fluid sample optimization device, especially for optimizing a fluid sample collected by a fluid collection device from a fluid source (equivalent to: a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source), and in particular discloses the following (see paragraphs [0141] to [0149] of the description, and FIGS. 23A-23B of the description):

A blood sequestration device 2300 in another implementation, having an inlet port 2302 to connect with a patient needle (equivalent to: an inlet configured to connect with the fluid source), an outlet port 2304 to connect with a blood sample collection device (equivalent to: an outlet configured to connect with the fluid collection device), a sequestration chamber 2306, and a sampling channel 2308 (equivalent to: a sample path). Once the sequestration chamber 2306 (equivalent to: a contaminant containment reservoir) is filled to an initial aliquot of potentially contaminated blood to be sequestered, the sequestration chamber 2306 is filled. As it is clear in combination with FIG. 23A of the description, the sequestration chamber 2306 is disposed between the inlet and the outlet (equivalent to: a contaminant containment reservoir connected between the inlet and the outlet).

The sequestration chamber 2306 includes a hydrophobic plug 2312 (equivalent to: a fluid resistor) at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302 (equivalent to: the contaminant containment reservoir further having a fluid resistor proximate the outlet).

A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood (equivalent to: a first portion of the fluid sample) will contact the hydrophobic plug 2312 (equivalent to: the fluid resistor) and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there (equivalent to: the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source). It could be clear that a first portion of the blood sample in Reference 1 potentially has contaminants. Receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir could be determined with respect to Reference 1.

A small amount of blood may make its way into the sampling channel 2308 (equivalent to: a sample path), which is initially closed off by valve 2310 (equivalent to: a resistive plug) (equivalent to: the sample path further having a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path).

Upon release of the valve 2310, and under further force of the vacuum or other force (equivalent to: subsequent pressure differentials are applied), follow-on amounts of blood (equivalent to: the fluid sample) will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through

sampling channel 2308 (equivalent to: a sample path connected between the inlet and the outlet) toward the outlet port 2304 and to the collection device (equivalent to: subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet).

The distinguishing technical features of the technical solution claimed by claim 6 over Reference 1 are: the fluid resistor is air permeable to displace air therein through the air permeable fluid resistor and the outlet.

With regard to the above distinguishing technical features: as has been recorded in Reference 1, [a] vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. Therefore, in order to allow the blood to be drawn into sequestration chamber 2306 under the action of vacuum, it would not be difficult for those skilled in the art to envisage that the specific hydrophobic plug 2312 is air permeable and to ensilage displacing air therein through the air permeable fluid resistor and the outlet.

It would be obvious for those skilled in the art to obtain the technical solution claimed by claim 6 based on Reference1 in combination with conventional technical means in the art. Therefore, the technical solution claimed by claim 6 neither has any prominent substantive feature nor represents a notable progress, and thus does not possess inventiveness prescribed under Article 22.3 of the Patent Law.

4. Claims 7-13 do not comply with the provisions under Article 22.3 of the Patent Law.

Claims 7-13 further define the claim to which they refer. On the basis of Reference 1, those skilled in the art could select to arrange a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir.

Reference 1 records: [t]he sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there (equivalent to: the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample).

On the basis of Reference 1, it could be selected as needed that the contaminant containment reservoir includes a tortuous path.

Reference 1 records: [u]pon release of the valve 2308, and under further force of the vacuum or other force (equivalent to: subsequent pressure differentials are applied), follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 (equivalent to: each pressure differential is provided by a vacuum pressure provided by the fluid collection device). Therefore, Reference 1 discloses the additional technical features of claim 5 <*Translator's note: it might intend to indicate claim 10*>.

Reference 1 has already disclosed a sampling channel 2308, which is initially closed off by valve 2310 (equivalent to: a resistive plug). On the basis of Reference 1, the arrangement mode of the resistive plug could be selected as needed. The specific features "the resistive plug includes a film that is pierceable by a first of the subsequent pressure differentials" and "the resistive plug further includes a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film" are arrangement means that could be selected. In addition, other arrangement means could also be selected. In particular, the feature "the resistive plug includes a mesh with a dissolvable material that dissolves upon contact with a first of the subsequent portions of the fluid sample" would also be a means not difficult to determine.

Therefore, where the claim to which claims 7-13 refer does not possess inventiveness, claims 7-13 neither have any prominent substantive feature nor represent a notable progress, failing to comply with the provisions regarding inventiveness under Article 22.3 of the Patent Law.

5. Claim 14 does not comply with the provisions under Article 22.3 of the Patent Law.

Claim 14 claims a fluid sample optimization device for optimizing a fluid sample. Reference 1 discloses a fluid sample optimization device, specifically a fluid sample optimization device for optimizing a fluid sample (equivalent to: a fluid sample optimization device for optimizing a fluid sample), and in particular discloses (see paragraphs [0141] to [0149] of the description, and FIGS. 23A-23B of the description):

[Y]et another implementation of a blood sequestration device 2300, having an

inlet port 2302 to connect with a patient needle (equivalent to: an inlet), an outlet port 2304 to connect with a blood sample collection device (equivalent to: an outlet), a sequestration chamber 2306, and a sampling channel 2308 (equivalent to: a sample path). Once the sequestration chamber 2306 (equivalent to: a contaminant containment reservoir) is filled to an initial aliquot of potentially contaminated blood to be sequestered, the sequestration chamber 2306 is filled. As it is clear in combination with FIG. 23A of the description, the sequestration chamber 2306 is disposed between the inlet and the outlet (equivalent to: a contaminant containment reservoir connected between the inlet and the outlet). The sample path is disposed between the inlet and the outlet (equivalent to: a sample path connected between the inlet and the outlet).

The sequestration chamber 2306 includes a hydrophobic plug 2312 (equivalent to: a fluid resistor) at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302 (equivalent to: a fluid resistor, the containment reservoir having an air permeable fluid resistor proximate the outlet).

A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood (equivalent to: a first portion of the fluid sample) will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there (equivalent to: the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample). It could be clear that a first portion of the blood sample in Reference 1 potentially has contaminants (equivalent to: a first portion of the fluid sample potentially having contaminants). Receipt of the

first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir could be determined with respect to Reference 1.

A small amount of blood may make its way into the sampling channel 2308 (equivalent to: a sample path), which is initially closed off by valve 2310.

Upon release of the valve 2310, and under further force of the vacuum or other force (equivalent to: subsequent pressure differentials are applied), follow-on amounts of blood (equivalent to: the fluid sample) will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device (equivalent to: subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet).

The distinguishing technical features of the technical solution claimed by claim 14 over Reference 1 are: the fluid resistor is air permeable to displace air therein through the air permeable fluid resistor and the outlet.

With regard to the above distinguishing technical features: as has been recorded in Reference 1, [a] vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. Therefore, in order to allow the blood to be drawn into sequestration chamber 2306 under the action of vacuum, it would not be difficult for those skilled in the art to envisage that the specific hydrophobic plug 2312 is air permeable and to ensilage displacing air therein through the

air permeable fluid resistor and the outlet.

It would be obvious for those skilled in the art to obtain the technical solution claimed by claim 14 based on Reference1 in combination with conventional technical means in the art. Therefore, the technical solution claimed by claim 14 neither has any prominent substantive feature nor represents a notable progress, and thus does not possess inventiveness prescribed under Article 22.3 of the Patent Law.

6. Claim 15 does not comply with the provisions under Article 22.3 of the Patent Law.

Claim 15 further defines the claim to which it refers. Reference 1 further discloses: [a] small amount of blood may make its way into the sampling channel 2308 (equivalent to: a sample path), which is initially closed off by valve 2310 (equivalent to a resistance plug) (equivalent to: the resistive plug is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path during receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir).

Upon release of the valve 2310, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

Therefore, where the claim to which claim 15 refers does not possess inventiveness, claim 15 neither has any prominent substantive feature nor represent a notable progress, failing to comply with the provisions regarding inventiveness under Article 22.3 of the Patent Law.

7. Claims 16-20 do not comply with the provisions under Article 22.3 of the Patent Law.

Claims 16-20 further define the claim to which they refer. On the basis of Reference 1, those skilled in the art could select to arrange a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir.

Reference 1 records: [t]he sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there (equivalent to: the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample).

On the basis of Reference 1, it could be selected as needed that the contaminant containment reservoir includes a tortuous path.

Reference 1 records: [u]pon release of the valve 2308, and under further force of the vacuum or other force (equivalent to: subsequent pressure differentials are applied), follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 (equivalent to: each pressure differential is provided by a vacuum pressure provided by the fluid collection device). Therefore, Reference 1 discloses the additional technical features of claim 5.

Reference 1 has already disclosed a sampling channel 2308, which is initially closed off by valve 2310 (equivalent to: a resistive plug). On the basis of Reference 1, the arrangement mode of the resistive plug could be selected as needed. The specific features "the resistive plug includes a film that is pierceable by a first of the subsequent pressure differentials" and "the resistive plug further includes a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film" are arrangement means that could be selected.

Therefore, where the claim to which claims 16-20 refer does not possess inventiveness, claims 16-20 neither have any prominent substantive feature nor represent a notable progress, failing to comply with the provisions regarding inventiveness under Article 22.3 of the Patent Law.

For the above reasons, neither the independent claims nor the dependent claims of the present application possess inventiveness. Meanwhile, the description does not contain any other patentable substantive contents. Therefore, the present application does not have a prospect of grant even if the Applicant would recombine and/or further define the claims according to the contents disclosed in the description. The present application will be finally rejected if the Applicant cannot present sufficient reasons as to why the present application possesses inventiveness within the time limit for response specified in the present office action.

If an invention patent application that has entered the substantive examination stage is withdrawn by the Applicant before expiration of the deadline for responding to the First Office Action (except where a response has been submitted), 50% of the substantive examination fee of the patent application may be refunded. The Examiner could be reached directly at 0371-87791927,

or via the operator on duty at 0371-87792282.

Examiner: Yuanyuan LI

Code: 30110854

国 家 知 识 产 权 局

100088

北京市朝阳区安定路 5 号院 8 号楼 1 至 21 层 101 五层 503 室 北京卅峰知识产权代理有限公司

卓霖(010-82800919) 许向彤(010-82800919)

发文日：

2023 年 09 月 27 日

申请号：202080000666.0　　**发文序号：**2023092702079090

申请人：酷睿有限公司

发明创造名称：非排气机体流体样品优化装置和系统

第 一 次 审 查 意 见 通 知 书

（进入国家阶段的 PCT 申请）

1.☒应申请人提出的实质审查请求，根据专利法第 35 条第 1 款的规定，国家知识产权局对上述发明专利申请进行实质审查。

☐根据专利法第 35 条第 2 款的规定，国家知识产权局决定自行对上述发明专利申请进行实质审查。

2.☒申请人要求以其在：

US 专利局的申请日 2019 年 04 月 01 日为优先权日。

3.☐经审查，申请人于_____提交的修改文件，不符合专利法实施细则第 51 条第 1 款的规定，不予接受。

4.☐审查是针对原始提交的国际申请的中文文本或中文译文进行的。

☒审查是针对下列申请文件进行的：

办理进入国家阶段手续时提交的权利要求书、说明书、摘要、摘要附图；2021 年 4 月 6 日提交的说明书附图。

5.☒本通知书引用下列对比文献（其编号在今后的审查过程中继续沿用）

编号	文 件 号 或 名 称	公 开 日 期（或抵触申请的申请日）
1	US2018271425A1	2018-09-27

6.审查的结论性意见：

关于说明书：

☐申请的内容属于专利法第 5 条规定的不授予专利权的范围。

☐说明书不符合专利法第 26 条第 3 款的规定。

☐说明书不符合专利法第 33 条的规定。

☐说明书的撰写不符合专利法实施细则第 17 条的规定。

☐_____

关于权利要求书：

☐权利要求_____不符合专利法第 2 条第 2 款的规定。

☐权利要求_____不符合专利法第 9 条第 1 款的规定。

☐权利要求_____不具备专利法第 22 条第 2 款规定的新颖性。

☒权利要求 1-20 不具备专利法第 22 条第 3 款规定的创造性。

☐权利要求_____不具备专利法第 22 条第 4 款规定的实用性。

纸件申请，回函请寄：100088 北京市海淀区蓟门桥西土城路 6 号 国家知识产权局专利局受理处收

电子申请，应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外，以纸件等其他形式提交的文件视为未提交。

□权利要求_____属于专利法第 25 条规定的不授予专利权的范围。
□权利要求_____不符合专利法第 26 条第 4 款的规定。
□权利要求_____不符合专利法第 31 条第 1 款的规定。
□权利要求_____不符合专利法第 33 条的规定。
□权利要求_____不符合专利法实施细则第 19 条的规定。
□权利要求_____不符合专利法实施细则第 20 条的规定。
□权利要求_____不符合专利法实施细则第 21 条的规定。
□权利要求_____不符合专利法实施细则第 22 条的规定。
□_____

□申请不符合专利法第 26 条第 5 款或者实施细则第 26 条的规定。
□申请不符合专利法第 19 条第 1 款的规定。
□分案申请不符合专利法实施细则第 43 条第 1 款的规定。

上述结论性意见的具体分析见本通知书的正文部分。

7. 基于上述结论性意见，审查员认为：

□申请人应当按照通知书正文部分提出的要求，对申请文件进行修改。

□申请人应当在意见陈述书中论述其专利申请可以被授予专利权的理由，并对通知书正文部分中指出的不符合规定之处进行修改，否则将不能授予专利权。

☒专利申请中没有可以被授予专利权的实质性内容，如果申请人没有陈述理由或者陈述理由不充分，其申请将被驳回。

□_____

8. 申请人应注意下列事项：

（1）根据专利法第 37 条的规定，申请人应在收到本通知书之日起的 4 个月内陈述意见，如果申请人无正当理由逾期不答复，其申请被视为撤回。

（2）申请人对其申请的修改应当符合专利法第 33 条的规定，不得超出原说明书和权利要求书记载的范围，同时申请人对专利申请文件进行的修改应当符合专利法实施细则第 51 条第 3 款的规定，按照本通知书的要求进行修改。

（3）申请人的意见陈述书和/或修改文本应当邮寄或递交国家知识产权局专利局受理处，凡未邮寄或递交给受理处的文件不具备法律效力。

（4）未经预约，申请人和/或代理师不得前来国家知识产权局与审查员举行会晤。

（5）对进入实质审查阶段的发明专利申请，在第一次审查意见通知书答复期限届满前（已提交答复意见的除外），主动申请撤回的，可以请求退还 50%的专利申请实质审查费。

9. 本通知书正文部分共有 6 页，并附有下列附件：

□引用的对比文件的复印件共_____份_____页。
□_____

审查员：李媛媛　　联系电话：0371-87791927　　审查部门：专利审查协作河南中心

纸件申请，回函请寄：100088 北京市海淀区蓟门桥西土城路 6 号　国家知识产权局专利局受理处收。
电子申请，应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外，以纸件等其他形式提交的文件视为未提交。

国 家 知 识 产 权 局

第 一 次 审 查 意 见 通 知 书

（进入国家阶段的 PCT 申请）

申请号:2020800006660

本申请涉及一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置，经审查，现提出如下审查意见。

1. 权利要求 1 不符合专利法第 22 条第 3 款的规定

权利要求 1 请求一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置，对比文件 1(US2018/0271425A1)公开了一种流体样品优化装置，具体的用于优化由流体收集装置从流体源收集流体样品(相当于一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置)，并具体公开了(参见说明书第 0141-0149 段，说明书附图 23A-23B)：

血液隔离装置 2300 的又一实施方式，其具有与患者针连接的入口端口 2302(相当于被配置为与所述流体源连接的入口)、与血液样本收集装置连接的出口端口 2304(相当于被配置为与流体收集装置接触的出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于污染物容纳储库)被填充至待隔离的潜在污染血液的初始等分部分，则隔离室 2306 被填充。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于污染物容纳储库在所述出口附近具有流阻器)。

从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于当入口和出口之间施加压差时，所述污染物容纳储库被布置为从所述流体源接收所述流体样品的第一部分，使得当接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库中)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物(相当于流体样品的第一部分潜在地具有污染物)。

少量血液可以进入采样通道 2308，采样通道 2308 最初被阀 2308 关闭。

当释放阀 2308 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液(相当于流体样品)将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于连接在所述入口和所述出口之间的样品路径)朝向出口端口 2304 并至收集装置(相当于当所述入口和所述出口之间施加后续压差时，所述流体样品的后续部分能够由所述样品路径从所述入口传送到所述出口)。

权利要求 1 请求保护的技术方案与对比文件 1 相比，其区别技术特征为：流阻器为透气的，通过所述透气的流阻器和所述出口置换其中的空气。

针对上述区别技术特征：对比文件 1 中已经记载了从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312

并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻隔器；因此为了使得血液能在真空的作用下使得被吸入隔离室 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

在对比文件 1 的基础上结合本领域常规技术手段以获得该权利要求所要求保护的技术方案，对所属技术领域的技术人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步，因而不具第 22 条第 3 款规定的创造性。

2. 权利要求 2-5 不符合专利法第 22 条第 3 款的规定

权利要求 2-5 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述污染物容纳储库中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312，从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料)；

在对比文件 1 的基础上，根据需要可以选择污染物容纳储库包括曲折路径；

对比文件 1 中记载了当释放阀 2308 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于每个压差由所述流体收集装置提供的真空压力提供)；因此对比文件 1 公开了权利要求 5 的附加技术特征；

因此，当其引用的权利要求不具备创造性时，权利要求 2-5 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

3. 权利要求 6 不符合专利法第 22 条第 3 款的规定

权利要求 6 请求一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置，对比文件 1 公开了一种流体样品优化装置，具体的用于优化由流体收集装置从流体源收集流体样品(相当于一种用于优化由流体收集装置从流体源收集的流体样品的流体样品优化装置)，并具体公开了(参见说明书第 0141-0149 段，说明书附图 23A-23B)：

血液隔离装置 2300 的又一实施方式，其具有与患者针连接的入口端口 2302(相当于被配置为与所述流体源连接的入口)、与血液样本收集装置连接的出口端口 2304(相当于被配置为与流体收集装置接触的出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于污染物容纳储库)被填充至待隔离的潜在污染血液的初始等分部分，则隔离室 2306 被填充，结合说明书附图 23A 可以明确隔离室 2306 设置在入口和出口之间(相当于连接在所述入口和所述出口之间的污染物容纳储库)。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于流阻器，相当于污染物容纳储库在所述出口附近还具有流阻器)。

从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样(相当于流体样品的第一部分)将接触疏水塞 2312（相当于流阻器）并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于当所述入口和所述出口之间施加压差时，所述污染物容纳储库被布置为从所述流体源接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物。可以确定对比文件 1 中接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库中。

少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310(相当于阻力塞)关闭(相当于样品路径还具有阻力塞，该阻力塞被配置为抑制所述流体样品的第一部分的至少一部分和污染物进入所述样品路径中)。

当释放阀 2310 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液(相当于流体样品)将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于连接在所述入口和所述出口之间的样品路径)朝向出口端口 2304 并至收集装置(相当于当所述入口和所述出口之间施加后续压差时，流体样品的后续部分能够被迫通过所述阻力塞，并由所述样品路径从所述入口传送到所述出口)。

权利要求 6 请求保护的技术方案与对比文件 1 相比，其区别技术特征为：流阻器为透气的，以通过所述透气的流阻器和所述出口置换其中的空气。

针对上述区别技术特征：对比文件 1 中已经记载了从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻隔器；因此为了使得血液能在真空的作用下使得被吸入隔离室 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

在对比文件 1 的基础上结合本领域常规技术手段以获得该权利要求所要求保护的技术方案，对所属技术领域的技术人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步，因而不具第 22 条第 3 款规定的创造性。

4. 权利要求 7-13 不符合专利法第 22 条第 3 款的规定

权利要求 7-13 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述污染物容纳储库中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312，从出

口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料)；

在对比文件 1 的基础上，根据需要可以选择污染物容纳储库包括曲折路径；

对比文件 1 中记载了当释放阀 2308 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于每个压差由所述流体收集装置提供的真空压力提供)；因此对比文件 1 公开了权利要求 5 的附加技术特征；

对比文件 1 中已经公开了采样通道 2308 最初被阀 2310(相当于阻力塞)关闭；在对比文件 1 的基础上，关于阻力塞的设置方式是根据需要可以选择的，具体的阻力塞包括被后续第一压差可刺穿的膜，阻力塞还包括刺穿构件，该刺穿构件被配置为当后续第一压差施加在所述膜的相对侧上时刺穿所述膜是可以选择的设置方式；此外还可以选择其它的设置方式，具体的阻力塞包括具有可溶解材料的网，该可溶解材料在与流体样品的后续第一部分接触时溶解也是不难确定出的一种方式。

因此，当其引用的权利要求不具备创造性时，权利要求 7-13 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

5. 权利要求 14 不符合专利法第 22 条第 3 款的规定

权利要求 14 请求保护一种用于优化流体样品的流体样品优化装置,对比文件 1 公开了一种流体样品优化装置，具体的为一种优化流体样品的流体样品优化装置(相当于一种用于优化流体样品的流体样品优化装置)，并具体公开了(参见说明书第 0141-0149 段，说明书附图 23A-23B)：

血液隔离装置 2300 的又一实施方式，其具有与患者针连接的入口端口 2302(相当于入口)、与血液样本收集装置连接的出口端口 2304(相当于出口)、隔离室 2306 和旁路的采样通道 2308(相当于样品路径)。一旦隔离室 2306(相当于污染物容纳储库)被填充至待隔离的潜在污染血液的初始等分部分，则隔离室 2306 被填充，结合说明书附图 23A 可以明确隔离室 2306 设置在入口和出口之间(相当于连接在所述入口和所述出口之间的污染物容纳储库)；样品路径设置在入口和出口之间(相当于连接在所述入口和所述出口之间的样品路径)。

隔离室 2306 包括在隔离室 2306 的距入口 2302 最远的远端处的疏水塞 2312(相当于流阻器，污染物容纳储库在所述出口附近具有透气的流阻器)。

从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样(相当于流体样品的第一部分)将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于当所述入口和所述出口之间施加压差时，所述污染物容纳储库被布置为接收所述流体样品的第一部分)。可以明确对比文件 1 中血液的第一部分潜在地具有污染物(相当于流体样品的第一部分潜在地具有污染物)。可以确定对比文件 1 中接收到流体样品的第一部分并将污染物

容纳在所述污染物容纳储库中。

少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310 关闭。

当释放阀 2310 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液(相当于流体样品)将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308 朝向出口端口 2304 并至收集装置(相当于当所述入口和所述出口之间施加后续压差时，所述流体样品的后续部分能够由所述样品路径从所述入口传送到所述出口)。

权利要求 14 请求保护的技术方案与对比文件 1 相比，其区别技术特征为：流阻器为透气的，以通过所述透气的流阻器和所述出口置换其中的空气。

针对上述区别技术特征：对比文件 1 中已经记载了从出口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里流阻隔器；因此为了使得血液能在真空的作用下使得被吸入隔离室 2306，具体的疏水塞 2312 为透气的，通过透气的流阻器和所述出口置换其中的空气是本领域技术人员不难想到的。

在对比文件 1 的基础上结合本领域常规技术手段以获得该权利要求所要求保护的技术方案，对所属技术领域的技术人员来说是显而易见的，因此该权利要求所要求保护的技术方案不具备突出的实质性特点和显著的进步，因而不具第 22 条第 3 款规定的创造性。

6. **权利要求 15 不符合专利法第 22 条第 3 款的规定**

权利要求 15 对其引用的权利要求作了进一步限定，对比文件 1 中进一步公开了少量血液可以进入采样通道 2308(相当于样品路径)，采样通道 2308 最初被阀 2310(相当于阻力塞)关闭(相当于该阻力塞被配置为在接收到流体样品的第一部分并将污染物容纳在所述污染物容纳储库期间，抑制所述流体样品的第一部分的至少一部分和污染物进入所述样品路径)。

当释放阀 2310 时，并且在进一步的真空力或其他力的作用下，后续量的血液将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308 朝向出口端口 2304 并至收集装置。

因此，当其引用的权利要求不具备创造性时，权利要求 15 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

7. 权利要求 16-20 不符合专利法第 22 条第 3 款的规定

权利要求 16-20 对其引用的权利要求作了进一步限定。在对比文件 1 的基础上根据需要，设置外壳，该外壳容纳和/或限定所述入口、所述出口、所述样品路径和所述污染物容纳储库中的一个或多个是本领域技术人员有能力选择的；

对比文件 1 中记载了隔离室 2306 包括在隔离室 2306 的距入口端口 2302 最远的远端处的疏水塞 2312，从出

口端口 2304(例如从真空采血管等)施加的真空或其他牵引力将血液吸入入口端口 2302 并直接吸入隔离室 2306，其中血液的初始等分试样将接触疏水塞 2312 并导致血液的初始等分部分返回到隔离室 2306 中并被隔离在那里(相当于透气的流阻器包括与所述流体样品的第一部分接触时密封的材料)；

在对比文件 1 的基础上，根据需要可以选择污染物容纳储库包括曲折路径；

对比文件 1 中记载了当释放阀 2308 时，并且在进一步的真空力或其他力的作用下(相当于施加后续压差)，后续量的血液将流入入口端口 2302，绕过隔离室 2306，并且流入并穿过采样通道 2308(相当于每个压差由所述流体收集装置提供的真空压力提供)；因此对比文件 1 公开了权利要求 5 的附加技术特征；

对比文件 1 中已经公开了采样通道 2308 最初被阀 2310(相当于阻力塞)关闭；在对比文件 1 的基础上，关于阻力塞的设置方式是根据需要可以选择的，具体的阻力塞包括被后续第一压差可刺穿的膜，阻力塞还包括刺穿构件，该刺穿构件被配置为当后续第一压差施加在所述膜的相对侧上时刺穿所述膜是可以选择的设置方式。

因此，当其引用的权利要求不具备创造性时，权利要求 16-20 不具有突出的实质性特点和显著的进步，不符合专利法第 22 条第 3 款有关创造性的规定。

基于上述理由，本申请的独立权利要求以及从属权利要求都不具备创造性，同时说明书中也没有记载其他任何可以授予专利权的实质性内容，因而即使申请人对权利要求进行重新组合和/或根据说明书记载的内容作进一步的限定，本申请也不具备被授予专利权的前景。如果申请人不能在本通知书规定的答复期限内提出表明本申请具有创造性的充分理由，本申请将被驳回。

在第一次审查意见通知书答复期限届满前（已提交答复意见的除外）主动申请撤回的，可以退还 50%的专利申请实质审查费。审查员电话 0371-87791927，或审查值班电话 0371-87792282 代为转达。

审查员姓名:李媛媛
审查员代码:30110854

纸件申请，回函请寄：100088 北京市海淀区蓟门桥西土城路 6 号 国家知识产权局专利局受理处收
电子申请，应当通过电子专利申请系统以电子文件形式提交相关文件。除另有规定外，以纸件等其他形式提交的文件视为未提交。

国 家 知 识 产 权 局

检 索 报 告

申请号：2020800006660	申请日：2020 年 04 月 01 日	首次检索
申请人：酷睿有限公司	最早的优先权日：2019 年 04 月 01 日	
权利要求项数：20	说明书段数：95	

审查员确定的 IPC 分类号：G01N1/10,G01N1/02,A61B5/15

检索记录信息：US2018271425A1: 参考国际检索报告以及美局通知书

EP3324845A1: 参考同族检索报告

US2014112841A1: 参考同族检索报告

WO2019232196A1: 参考同族检索报告

CN104107054A: CNTXT 语义检索,语义基准:2020800006660

CN104981203A: CNTXT 语义检索,语义基准:CN213588280U

CN1717280A: 425 CNTXT, (G01N1/IC) and (((阻隔 or 阻塞 or 流阻 or 阻力塞) and ((流体 or 血 or 样品) s 污染)) and (真空 or 压差 or 负压))

相 关 专 利 文 献

类型	国别以及代码[11] 给出的文献号	代码[43]或[45] 给出的日期	IPC 分类号	相关的段落 和/或图号	涉及的权 利要求
X	US2018271425A1	2018-09-27	A61B5/15	说明书第 0141-0149 段，说明书附图 23A-23B	1-20
A	EP3324845A1	2018-05-30	A61M39/06	全文	1-20
A	US2014112841A1	2014-04-24	B01L3/00	全文	1-20
L	WO2019232196A1	2019-12-05	A61B5/15	全文	1-20

A	CN104107054A	2014-10-22	A61B5/151	全文	1-20
A	CN104981203A	2015-10-14	A61B5/155	全文	1-20
A	CN1717280A	2006-01-04	B01L3/00	全文	1-20

相 关 非 专 利 文 献					
类型	书名（包括版本号和卷号）	出版日期	作者姓名和出版者名称	相关页数	涉及的权利要求
类型	期刊或文摘名称 （包括卷号和期号）	发行日期	作者姓名和文章标题	相关页数	涉及的权利要求
类型	网址	网络发布日 或公开日	作者姓名和网页标题	相关部分	涉及的权利要求

表格填写说明事项：

1. 审查员实际检索领域的 IPC 分类号应当填写到大组和/或小组所在的分类位置。
2. 期刊或其它定期出版物的名称可以使用符合一般公认的国际惯例的缩写名称。
3. 相关文件的类型说明：

   X：单独影响权利要求的新颖性或创造性的文件；

   Y：与本检索报告中其他 Y 类文件组合后影响权利要求的创造性的文件；

   A：背景技术文件，即反映权利要求的部分技术特征或者有关的现有技术的文件；

   R：任何单位或个人在申请日向专利局提交的、属于同样的发明创造的专利或专利申请文件。

   P：中间文件，其公开日在申请的申请日与所要求的优先权日之间的文件，或者会导致需要核实该申请优先权的文件；

E：单独影响权利要求新颖性的抵触申请文件；

T：申请日或优先权日当天或之后公布的，可以对所要求保护发明的理论或原理提供清楚解释的文件，或者可显示出所要求保护发明的推理或事实不成立的文件；

L：除 X、Y、A、R、P、E 和 T 类文件之外的文件。

审 查 员：李媛媛　　审查部门：专利审查协作河南中心

2023 年 09 月 25 日

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/838,017	04/01/2020	Bobby E. ROGERS	069366-0572158_KUR7001US	1044

27500 7590 04/25/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
PORTILLO, JAIRO H	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
04/25/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 16/838,017	Applicant(s) ROGERS et al.	
	Examiner JAIRO H PORTILLO	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 1/18/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) 13 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-12 and 14-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 6/16/2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

CLAIM INTERPRETATION

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Use of the word "means" (or "step for") in a claim with functional language creates a rebuttable presumption that the claim element is to be treated in accordance with 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph). The presumption that 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph) is invoked is rebutted when the function is recited with sufficient structure, material, or acts within the claim itself to entirely perform the recited function.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step for") in a claim creates a rebuttable presumption that the claim element **is not** to be treated in accordance with 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph). The presumption that 35 U.S.C. 112(f) (pre-AIA 35 U.S.C. 112, sixth paragraph) is not invoked is rebutted when the claim element recites function but fails to recite sufficiently definite structure, material or acts to perform that function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Such claim limitations is/are:

- (Claim 12) "a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film."
- (Claim 20) "a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film."

A review of the specification shows that the following appears to be the corresponding structure described in the specification for the 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph limitation:

- (Claim 12) "a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film.": As identified by the Specification, the following is recognized as the corresponding structure to the piercing member: "The piercing member 704 can include a spike, pin, blade, shard, or the like, and can be held substantially in the center of the opening to the sampling path, as shown in FIG. 9A, by a holding mechanism as shown in FIG. 9B." Or equivalents thereof.
- (Claim 20) "a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film.": As identified by the Specification, the following is recognized as the corresponding structure to the piercing member: "The piercing member 704 can include a spike, pin, blade, shard, or the like, and can be held substantially in the center of the opening to the sampling path, as shown in FIG. 9A, by a holding mechanism as shown in FIG. 9B." Or equivalents thereof.

If applicant wishes to provide explanation or dispute the examiner's interpretation of the corresponding structure, applicant must identify the corresponding structure with reference to the specification by page and line number, and to the drawing, if any, by reference characters in response to this Office action.

If applicant does not intend to have the claim limitation(s) treated under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112 , sixth paragraph, applicant may amend the claim(s) so that it/they will clearly not invoke 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites/recite sufficient structure, material, or acts for

performing the claimed function to preclude application of 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

For more information, see MPEP § 2173 *et seq.* and *Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, 76 FR 7162, 7167 (Feb. 9, 2011).

Claim Rejections - 35 USC § 102

In the event the determination of the status of the application as subject to AIA 35 U.S.C. 102 and 103 (or as subject to pre-AIA 35 U.S.C. 102 and 103) is incorrect, any correction of the statutory basis for the rejection will not be considered a new ground of rejection if the prior art relied upon, and the rationale supporting the rejection, would be the same under either status.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-3, 5-8, 10, and 14-17 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by **Rogers et al (US 2017/0020428) ("Rogers").**

Regarding Claim 1, while Rogers teaches a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants (Abstract, [0124] Figs. 23A and 23B), the fluid sample optimization device comprising:

an inlet configured to connect with the fluid source ([0124] inlet port 2302);

an outlet configured to connect with the fluid collection device ([0124] outlet port 2304);

a sample path connected between the inlet and the outlet ([0124] sample path/sampling channel 2308); and

a contaminant containment reservoir connected between the inlet and the outlet (Figs. 23A and 23B, [0124] sequestration chamber 2306), the contaminant containment reservoir having an air permeable fluid resistor proximate the outlet (Figs. 23A and 23B, hydrophobic plug 2312), the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet ([0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.).

Regarding Claim 2, Rogers teaches the fluid sample optimization device in accordance with claim 1, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir (*See Claim 1 Rejection,* the tubing of the blood sequestration device 2300 acts as a housing).

Regarding Claim 3, Rogers teaches the fluid sample optimization device in accordance with claim 1, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (*See Claim 1 Rejection).*

Regarding Claim 5, Rogers teaches the fluid sample optimization device in accordance with claim 1, wherein each pressure differential is provided by a vacuum pressure provided by the fluid collection device (*See Claim 1 Rejection,* [0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there.).

Regarding Claim 6, Rogers teaches a fluid sample optimization device for optimizing a fluid sample collected by a fluid collection device from a fluid source, a first portion of the fluid sample potentially having contaminants (Abstract, [0124] Figs. 23A and 23B), the fluid sample optimization device comprising:

an inlet configured to connect with the fluid source ([0124] inlet port 2302);

an outlet configured to connect with the fluid collection device ([0124] outlet port 2304 connected to a blood sample collection device);

a sample path connected between the inlet and the outlet ([0124] sample path/sampling channel 2308), the sample path further having a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path ([0124] valve 2310. Examiner notes that the patent publication has the valve written as 2308, but the language of paragraph [0124] and the Figures heavily imply the valve should be understood as corresponding to reference character 2310); and

a contaminant containment reservoir connected between the inlet and the outlet (Figs. 23A and 23B, [0124] sequestration chamber 2306), the contaminant containment reservoir further having an air permeable fluid resistor proximate the outlet (Figs. 23A and 23B, hydrophobic plug 2312), the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the

fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet ([0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.).

Regarding Claim 7, Rogers teaches the fluid sample optimization device in accordance with claim 6, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir (*See Claim 6 Rejection*, the tubing of the blood sequestration device 2300 acts as a housing).

Regarding Claim 8, Rogers teaches the fluid sample optimization device in accordance with claim 6, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (*See Claim 6 Rejection*).

Regarding Claim 10, Rogers teaches the fluid sample optimization device in accordance with claim 6, wherein each pressure differential is provided by a vacuum pressure provided by the fluid collection device (*See Claim 1 Rejection,* [0124] "A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial

aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there.).

Regarding Claim 14, Rogers teaches a fluid sample optimization device for optimizing a fluid sample, a first portion of the fluid sample potentially having contaminants, the fluid sample optimization device comprising:

an inlet ([0124] inlet port 2302);

an outlet ([0124] outlet port 2304);

a sample path connected between the inlet and the outlet ([0124] sample path/sampling channel 2308); and

a contaminant containment reservoir connected between the inlet and the outlet (Figs. 23A and 23B, [0124] sequestration chamber 2306), the contaminant containment reservoir having an air permeable fluid resistor proximate the outlet (Figs. 23A and 23B, hydrophobic plug 2312), the contaminant containment reservoir being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet when subsequent pressure differentials are applied between the inlet and the outlet ([0124] “A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port

2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.).

Regarding Claim 15, Rogers teaches the fluid sample optimization device in accordance with claim 14, wherein the sample path further includes a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample and the contaminants from entering the sample path during receipt of the first portion of the fluid sample and containment of the contaminants in the contaminant containment reservoir (*See Claim 14 Rejection*, the valve is a resistive plug).

Regarding Claim 16, Rogers teaches the fluid sample optimization device in accordance with claim 14, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the contaminant containment reservoir (*See Claim 14 Rejection*, the tubing of the blood sequestration device 2300 acts as a housing).

Regarding Claim 17, Rogers teaches the fluid sample optimization device in accordance with claim 14, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample (*See Claim 14 Rejection*).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 4, 9, and 18 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Rogers.**

Regarding Claim 4, while Rogers teaches the fluid sample optimization device in accordance with claim 1, and Rogers teaches in a separate embodiment that a contaminant containment reservoir includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to configure the contaminant containment reservoir of Rogers with a tortuous path as Rogers teaches that a tortuous path has a sealing function ([0065]) which would be useful for containing contaminants.

Regarding Claim 9, while Rogers teaches the fluid sample optimization device in accordance with claim 6, and Rogers teaches in a separate embodiment that a contaminant containment reservoir includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to configure the contaminant containment reservoir of Rogers with a tortuous path as Rogers teaches that a tortuous path has a sealing function ([0065]) which would be useful for containing contaminants.

Regarding Claim 18, while Rogers teaches the fluid sample optimization device in accordance with claim 14, and Rogers teaches in a separate embodiment that a contaminant containment reservoir includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to configure the contaminant containment reservoir of Rogers with a tortuous path as Rogers teaches that a tortuous path has a sealing function ([0065]) which would be useful for containing contaminants.

Claim(s) 11-12 and 19-20 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Rogers** in view of **Davis et al (US 2007/0031283) ("Davis").**

Regarding Claim 11, while Rogers teaches the fluid sample optimization device in accordance with claim 6, wherein the resistive plug includes a valve (*See Claim 6 Rejection*), Rogers fail to teach the resistive plug includes a film that is pierceable by a first of the subsequent pressure differentials.

However Davis teaches a medical sampling device (Abstract) comprising a valve composition of a film that is pierceable to allow fluid flow ([0278], [0280]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to substitute the pinching valve of Rogers for a needle-pierceable membrane valve of Davis as a simple substitution of one form of controlling fluid flow for another to obtain predictable results of sample optimization by denying the initial aliquot of blood. Further, the pierceable nature of Davis' film would support that it is pierceable by a pressure differential.

Regarding Claim 12, Rogers and Davis teach the fluid sample optimization device in accordance with claim 11, wherein the resistive plug further includes a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film (*See Claim 11 Rejection*, a piercing instrument is configured to pierce the film).

Regarding Claim 19, while Rogers teaches fluid sample optimization device in accordance with claim 15, wherein the resistive plug includes a valve (*See Claim 15 Rejection*), Rogers fail to teach the resistive plug includes a film that is pierceable by a first of the subsequent pressure differentials.

However Davis teaches a medical sampling device (Abstract) comprising a valve composition of a film that is pierceable to allow fluid flow ([0278], [0280]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to substitute the pinching valve of Rogers for a needle-pierceable

membrane valve of Davis as a simple substitution of one form of controlling fluid flow for another to obtain predictable results of sample optimization by denying the initial aliquot of blood. Further, the pierceable nature of Davis' film would support that it is pierceable by a pressure differential.

Regarding Claim 20, Rogers and Davis teach the fluid sample optimization device in accordance with claim 19, wherein the resistive plug further includes a piercing member configured to pierce the film when the first of the subsequent pressure differentials is exerted on an opposite side of the film (*See Claim 20 Rejection*, a piercing instrument is configured to pierce the film).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAIRO H PORTILLO whose telephone number is (571)272-1073. The examiner can normally be reached M-F 9:00 am - 5:15 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about

filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAIRO H. PORTILLO/
Examiner
Art Unit 3791

/NATHAN J JENNESS/
Primary Examiner, Art Unit 3792
20 April 2023

Notice of References Cited	Application/Control No. 16/838,017	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner JAIRO H PORTILLO	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20070031283-A1	02-2007	Davis; Charles Quentin	A61B5/15087	422/400
*	B	US-20170020428-A1	01-2017	Rogers; Bobby E.	A61B5/15003	1/1
	C					
	D					
	E					
	F					
	G					
	H					
	I					
	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	16838017
Filing Date	2020-04-01
First Named Inventor	Bobby E. ROGERS
Art Unit	1798
Examiner Name	
Attorney Docket Number	KURIN7US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

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U.S.PATENT APPLICATION PUBLICATIONS Remove

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140112841	A1	2014-04-24	Schoen et al.	
	2	20180271425	A1	2018-09-27	Rogers et al.	

If you wish to add additional U.S. Published Application citation information please click the Add button. Add

FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	1378602	GB	A	1974-12-27	Ayers		
	2	2019055487	WO	A1	2019-03-21	Magnolia Medical Technologies, Inc.		

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16838017
	Filing Date	2020-04-01
	First Named Inventor	Bobby E. ROGERS
	Art Unit	1798
	Examiner Name	
	Attorney Docket Number	KURIN7US

	3	2019232196	WO	A1	2019-12-05	Magnolia Medical Technologies, Inc.		

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	International Search Report and Written Opinion dated 16 July 2020 for PCT application no. PCT/US2020/026276.	

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EXAMINER SIGNATURE

Examiner Signature	/JAIRO H PORTILLO/	Date Considered	04/19/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16838017
	Filing Date	2020-04-01
	First Named Inventor	Bobby E. ROGERS
	Art Unit	1798
	Examiner Name	
	Attorney Docket Number	KURIN7US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/JSN/	Date (YYYY-MM-DD)	2020-07-31
Name/Print	James S. Nolan	Registration Number	53393

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/838,017	04/01/2020	Bobby E. ROGERS	069366-0572158_KUR7001US	1044

27500 7590 04/16/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
PORTILLO, JAIRO H	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
04/16/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 16/838,017	Applicant(s) ROGERS et al.	
	Examiner JAIRO H PORTILLO	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 4/05/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-9,14 and 16-18 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-9,14 and 16-18 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/05/2024 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 1-3, 6-8, 14, and 16-17 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Bullington et al (US 2019/0365303) ("Bullington").**

Regarding Claim 1, while Bullington teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet configured to connect with the fluid source ([0135] Figs. 9 and 10, inlet 512);

an outlet configured to connect with the fluid collection device ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), the sample path further having a resistive plug ([0141] Figs, 9 and 10, barrier 574); and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574, pierceable by the piercing member); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 2, Bullington teaches the device in accordance with claim 1, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 1 Rejection,* housing of fluid control device 500).

Regarding Claim 3, Bullington teaches the device in accordance with claim 1, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Regarding Claim 6, Bullington teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet configured to connect with the fluid source ([0135] Figs. 9 and 10, inlet 512);

an outlet configured to connect with the fluid collection device ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), the sample path further having a resistive plug that is configured to inhibit at least a part of a first portion of the fluid sample from entering the sample path ([0141] Figs, 9 and 10, barrier 574 acts as resistive plug); and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber further having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet, after piercing, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 7, Bullington teaches the device in accordance with claim 6, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 6 Rejection,* housing of fluid control device 500).

Regarding Claim 8, Bullington teaches the device in accordance with claim 6, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Regarding Claim 14, Bullington teaches a device for optimizing a fluid sample (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet ([0135] Figs. 9 and 10, inlet 512);

an outlet ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet),

wherein the sample path further includes a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample from entering the sample path during receipt of the first portion of the fluid sample in the chamber ([0141] Figs. 9 and 10, barrier 574 acts as resistive plug),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 16, Bullington teaches the device in accordance with claim 14, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 14 Rejection,* housing of fluid control device 500).

Regarding Claim 17, Bullington teaches the device in accordance with claim 14, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Claim(s) 4, 9, and 18 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Bullington** in view of **Rogers et al (US 2017/0020428) ("Rogers").**

Regarding Claim 4, while Bullington teaches the device in accordance with claim 1, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Regarding Claim 9, while Bullington teaches the device in accordance with claim 6, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Regarding Claim 18, while Bullington teaches the device in accordance with claim 14, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Response to Arguments

Applicant's amendments filed 4/05/2024 with respect to the 35 USC 103 rejection have been fully considered, and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bullington.

Applicant's arguments filed 4/05/2024 with respect to the 35 USC 103 rejection have been fully considered, but are not persuasive.

Applicant argues that Bullington teaches the opposite of the amended claim by having the needle move to puncture the membrane, rather than the membrane moving to be punctured by the piercing member. Redesigning Bullington to meet the claim language is not obvious as it would require a substantial redesign and change in the operation of Bullington's device. Examiner respectfully disagrees. Changing Bullington to meet the claim limitations merely requires a reversal of which membrane flexes upon receipt of the fluid sample. This does not require a change in operation as the system would still guide a first portion of the sample to a sequestration chamber, leading to a membrane flexing to enable a piercing action, the piercing action allowing the subsequent portion of the fluid sample to flow to the outlet. Further, a

substantial redesign is not needed as the only change required would be which membrane has the flexing property (barrier 574 instead of diaphragm 576).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAIRO H PORTILLO whose telephone number is (571)272-1073. The examiner can normally be reached M-F 9:00 am - 5:15 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAIRO H. PORTILLO/
Examiner
Art Unit 3791

/PUYA AGAHI/
Primary Examiner, Art Unit 3791

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16838017
Filing Date	2020-04-01
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	PORTILLO, JAIRO H
Attorney Docket Number	069366-0572158_KUR7001US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4416291		1983-11-22	KAUFMAN JOSEPH	
	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
	7	11660030		2023-05-30	BULLINGTON GREGORY J	
	8	11259727		2022-03-01	BULLINGTON GREGORY J	

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	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
	12	11612340		2023-03-28	BULLINGTON GREGORY J	
	13	11234626		2022-02-01	BULLINGTON GREGORY J	
	14	10624977		2020-04-21	BULLINGTON GREGORY J	
	15	11653863		2023-05-23	BULLINGTON GREGORY J	
	16	11419531		2022-08-23	BULLINGTON GREGORY J	
	17	11786155		2023-10-17	BULLINGTON GREGORY J	
	18	11789017		2023-10-17	BULLINGTON GREGORY J	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
	2	20220151527		2022-05-19	BULLINGTON GREGORY J	
	3	20200289039		2020-09-17	BULLINGTON GREGORY J	
	4	20210275068		2021-09-09	MIAZGA JAY M	
	5	20220304664		2022-09-29	HAMMER JEREMY	
	6	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	S5825146	JP		1983-02-15	BECTON DICKINSON CO		☒

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	Art Unit	3791
	Examiner Name	PORTILLO, JAIRO H
	Attorney Docket Number	069366-0572158_KUR7001US

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	2	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	3	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐
	4	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
	5	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐

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EXAMINER SIGNATURE

Examiner Signature	/JAIRO H PORTILLO/	Date Considered	04/10/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Examiner Name	PORTILLO, JAIRO H
	Attorney Docket Number	069366-0572158_KUR7001US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-05
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 09/29/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/29/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 17/893,079	**Applicant(s)** ROGERS et al.	
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (FITF) Status** Yes

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 September 2023 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☑ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires ____ months from the mailing date of the final rejection.
   b) ☑ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection.The current period for reply expires ____ months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____ (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s):(a)☐ will not be entered, or (b)☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☑ Other: See Continuation Sheet.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed:_____.
    Claim(s) objected to:_____.
    Claim(s) rejected:1-4,6-7 and 32-41.
    Claim(s) withdrawn from consideration:_____.

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791

Continuation of REQUEST FOR RECONSIDERATION/OTHER 14. Other: Applicant contends that Cinqualbre et al does not disclose a housing “that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel” because the test tubes are removable from the body of the device, as well as being external to the device. It is submitted that applicant is reading limitations into the claims. The term “houses” and “defines” is not limited to structural “enclosure.” The claims do not require that the chamber resides “completely within the housing.”
https://www.merriam-webster.com/dictionary/housing defines the term as simply “something that covers or protects, such as a support, e.g. frame, for mechanical parts.” It is submitted that this reading of the term “ houses” is a broad but reasonable interpretation to one of ordinary skill in the art. The term “defines” is even broader than “houses” and requires/implies even less structure. Therefore, it is submitted that because housing 1 structurally provides the recesses 4 in which test tubes 5 are disposed, the housing absolutely “houses” and “defines” the chamber (defined as test tube), in addition to the inlet, outlet, and sampling channel, as broadly as has been claimed. Though applicant contends that Cinqualbre et al is not a “blood separation device,” said term does not imply any particular structure or function that the prior art cannot support, as broadly as has been claimed. Therefore, the rejection is maintained.
In regard to the drawing objections and 112 rejections, it is submitted that the junction needs to be shown with element numbers in Figure 24, which provides for the other structures of the invention as claimed. Providing said drawing would obviate the 112 rejection.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 07/19/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
07/19/2023	ELECTRONIC

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Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/893,079	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 05/22/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-7 and 32-41 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-7 and 32-41 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 8/22/02022 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the amendment filed 5/22/2023. Claims 1-4, 6-7, and 32-41 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "junction" in **Claims 3-4 and 40-41** must be shown *with element numbers* or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the

filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as

otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 40-41 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims recite a junction connecting the inlet port, sampling channel, and the chamber. However, as the instant invention appears to be drawn to the embodiment in Figure 24 and said junction has not been identified in Figure 24 per the drawing objection above, it is unclear that applicant has proper support for the embodiment of Figure 24 with the moving part having a first and second position along with said junction as claimed. If support exists for said junction, applicant is requested to point out portions of the disclosure showing said support.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 1-4, 6-7, 32, 34-38, and 40-41 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al (US Pat No. 3848581) in view of Eldridge (US Pat No. 4207870).

In regard to Claim 1, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood, thus bypassing the first test tube/chamber as defined; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

2. Eldridge discloses the material is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

3. Cinqualbre et al disclose a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

4. Cinqualbre et al disclose wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

6. Cinqualbre et al disclose wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

7. Cinqualbre et al disclose the moving part 11 as defined further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled, the user can close the valve 11 to move it into the closed position so that the next test tube in the series can be

filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

32. Cinqualbre et al disclose wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

In regard to Claim 34, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

35. Eldridge discloses the device in accordance with claim 34, wherein the air permeable blood barrier is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

36. Cinqualbre et al disclose the device in accordance with claim 34, wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling

channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

37. Cinqualbre et al disclose the device in accordance with claim 36, the moving part further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled with blood, the user can close the valve 11 to move it into closed position so that the next test tube in the series can be filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

38. Cinqualbre et al disclose the device in accordance with claim 36, wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

40. Cinqualbre et al disclose the device in accordance with claim 34, further comprising a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

41. Cinqualbre et al disclose the device in accordance with claim 40, wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

Claim(s) 33 and 39 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al in view of Eldridge, further in view of Vaillancouert (US Pat No. 6126643).

Cinqualbre et al in view of Eldridge disclose the inventio above but do not expressly disclose a locking mechanism configured to maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Vaillancouert teach that it is well-known in the art to provide an analogous blood sampling device comprising a locking mechanism 24 that enables plunger 21 to be releasably locked relative to barrel 11 so that blood is selectively introduced into the syringe, best see n in Figure 4-5 (Col.4: 63-Col.5: 53). Vaillancouert also teaches that other suitable releasable locking means may also be used to secure the plunger 21 relative to the barrel 11 (Col.5: 8-9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the invention of Cinqualbre et al in view of Eldridge such that there is a locking mechanism configured to selectively maintain the moving part in the first position until the chamber is filled, as taught by Vaillancouert, to effectively prevent the moving part (valve 11 of Cinqualbre et al) from prematurely closing the window 12 before blood sufficiently fills chamber 5 (defined as first test tube on left), which when combined with the user, would thus provide force to overcome the locking mechanism to enable movement of the moving part to the second position as desired. It is noted that the disclosure does not provide any detail into how force would overcome the locking mechanism other than as broadly as has been claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 3, and 20-21 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a

housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 and 8-9 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Response to Arguments

Applicant's arguments with respect to claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

The previous Drawing objections and 112 rejections are moot in light of applicant's amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner
Art Unit 3791

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 1

Notice of Allowance

(Divisional)

Application Serial No.:	2021-214177
Drafting Date:	June 16, 2023
Examiner:	Naoya TAKAGI 3611 2Q00
Title of the Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
Number of Claims:	20
Applicant(s):	KURIN, INC.
Agent:	MURAKOSHI, Satoshi

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.
Certificated: June 19, 2023
Administrative Official of Ministry of Economy, Trade and Industry, Takashi SATO

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

- Type of Application: Divisional Application
- Cited References: Yes
- Grace Period under Patent Act Article 30: No
- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 3/E

Reference Information

Application Serial No.: 2021-214177

- FI

  A61B 5/15 200

- Search Fields (IPC, DB Name):

  A61B 5/15-5/157

- References Cited :

  Japanese Patent Application Publication No.2013-240628 (JP,A)
  Japanese Patent Application Publication No.2016-504075 (JP,A)
  International Patent Application Publication No.2014/058945 (WO,A1)
  US Patent Application Publication No.2005/0245885 (US,A1)

- Non-patent literatures:

特許査定

（分割）

特許出願の番号	特願２０２１－２１４１７７
起案日	令和　５年　６月１６日
特許庁審査官	▲高▼木　尚哉　３６１１　２Ｑ００
発明の名称	流体分流デバイス、及び流体分流サンプリングシステム
請求項の数	２０
特許出願人	クリン　インコーポレイテッド
代理人	村越　智史（ほか　４名）

この出願については、拒絶の理由を発見しないから、特許査定をします。

上記はファイルに記録されている事項と相違ないことを認証する。
認証日　令和 5年 6月19日　経済産業事務官　佐藤　隆

注意：この書面を受け取った日から３０日以内に特許料の納付が必要です。

・出願種別　分割
・参考文献　有
・特許法第３０条適用　無
・発明の名称の変更　無

・菌寄託

参考情報

特許出願の番号　特願２０２１－２１４１７７

・ＦＩ

Ａ６１Ｂ　５／１５　２００

・調査した分野（ＩＰＣ，ＤＢ名）

Ａ６１Ｂ　５／１５－５／１５７

・参考特許文献

特開２０１３－２４０６２８	（ＪＰ，Ａ）
特表２０１６－５０４０７５	（ＪＰ，Ａ）
国際公開第２０１４／０５８９４５	（WO，Ａ１）
米国特許出願公開第２００５／０２４５８８５	（ＵＳ，Ａ１）

・参考図書雑誌

Europäisches Patentamt
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Questions about this communication?
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Primary Examiner
Name: Nielsen, Michael
Tel: +49 30 259 01 - 554

Carroll, Christopher P.
Burns & Levinson London LLP
4-12 Regent Street, 4th Floor
London SW1Y 4PE
ROYAUME UNI

Application No.	Ref.	Date
22 181 212.6 - 1122	KUR-19212-P-EP	28.09.2023
Applicant: Kurin, Inc.		

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and in sofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the Examining Division requesting that you correct this deficiency (R. 137(4) EPC).

In case you withdraw the application within the above-mentioned period, the examination fee will be refunded at a rate of 50% (Art. 11(b) RFees).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).

Registered Letter

Nielsen, Michael
Primary Examiner
For the Examining Division

Enclosure(s): 3 page/s reasons (EPO Form 2906)

The examination is being carried out on the **following application documents**

Description, Pages

1, 2, 4-46	as originally filed	
3, 3a, 3b	filed in electronic form on	19-05-2023

Claims, Numbers

1-8	filed in electronic form on	19-05-2023

Drawings, Sheets

1/69-69/69	as originally filed

1). The applicants arguments with regard to neither of the documents cited hinting to "a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, **the chamber including a material that is air permeable and blood impermeable**" are agreed upon.

Applicants arguments with regard support for the claims on file, their novelty and inventiveness are likewise agreed upon.

Therefore:

2). The applicant should **bring the description into conformity** with the claims of the present divisional application (Article 84 EPC). In particular should features that are present in the independent claim not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment", "in one implementation" and so forth, but be clearly identified as forming part of the invention. T**his applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. **recitation of superseded claims and subject-matter be removed or adapted** to the wording of the claims on file.

Anything referred to as "**embodiment**" or "**implementation**" and which is not covered by the claims on file should be **excised or clearly referred to as examples not covered by the invention**. This throughout the description and drawings.

- The technical field of the invention (Rule 42(1)(a) EPC; Guidelines F-II.4.2) must correspond to the amended set of claims.

- The summary of the invention (Rule 42(1)(c) EPC; Guidelines F-II.4.5) must correspond to the amended set of claims. Where appropriate, statements such as "The invention is set out in the appended set of claims" or "The invention is as defined in claim X" may be used instead of repeating the claims verbatim.
- **Embodiments which are no longer covered by the claims must be** deleted, unless they can reasonably be considered to be useful for highlighting specific aspects of the amended subject-matter. If this is the case, they must be clearly marked as not being part of the present invention (T 1808/06 and Guidelines F-IV, 4.3)]:
  - Any combinations of features which do not fall under the scope of the amended independent claims must be clearly marked as not being part of the present invention.
  - Statements such as "The following examples/aspects/embodiments X, Y, Z are not according to the invention and are present for illustration purposes only" may be used **at the start of the description or in the list of figures**.
- The technical features of the independent claims may not be presented as optional in the description. Where they precede a feature of an independent claim, terms such as "for example", "may", "can", "exemplary", "optionally", "preferably" and the like must be removed.
- The **"claim-like" clauses** in paragraphs [0014] to [0023] and at pages 43 to 46 **must be deleted prior to grant**. Claim-like clauses are clauses present in the description which use claim language such as "according to the preceding clause" or "characterised in that" (Guidelines F-IV, 4.4). Claim-like clauses include examples, embodiments or aspects which are presented as claim-like clauses. The simple conversion of these clauses into separate optional features will not be admitted either.

3). The unit inches expressed in paragraphs [0099], [00115] and [00156] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex, 2). The present expression should, however, be retained in parentheses after the replacement expression.

4). Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Articles 76(1) and 123(2) EPC).

5). Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Articles 76(1) and 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

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NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 04/20/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER
ABOUELELA, MAY A

ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 04/20/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/094,692	11/10/2020	Bobby E. ROGERS	069366-0572169_KUR4C01US	8012

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD BARRIER WITH CLOSURE MECHANISM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	07/20/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 04/20/2023
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/094,692	11/10/2020	Bobby E. ROGERS	069366-0572169_KUR4C01US	8012

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH ONE-WAY AIR VALVE AND AIR-PERMEABLE BLOOD BARRIER WITH CLOSURE MECHANISM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	07/20/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-573000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via Patent Center or EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/094,692	11/10/2020	Bobby E. ROGERS	069366-0572169_KUR4C01US	8012

27500 7590 04/20/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 04/20/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/094,692	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 04/04/2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are See Continuation Sheet . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Continuation of 3. The allowed claim(s) is/are: 1,3-8,10-14,16-18 and 20-47

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 04/10/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Allowable Subject Matter

3. Claims 1, 3-8, 10-14, 16-18 and 20-47 are allowed.

4. The following is an examiner's statement of reasons for allowance: the most pertinent art Cuppy et al (US 5,749,857) teaches a blood sampling device, comprising inlet and outlet port, a chamber connected to the inlet port; a sampling channel connected to the outlet; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

The prior art failed to teach, disclose and/or fairly suggest the chamber connected with the inlet port via a junction, and the sampling channel having a proximal end connected with the inlet port via the junction and a distal end connected to the outlet port, the sampling channel being configured to convey subsequent portions of blood to the outlet port after the first portion of blood has entered the chamber.

The other pertinent prior art Patton et al (US 2008/0145933) teaches the chamber connected with the inlet port via a junction, and the sampling channel having a

proximal end connected with the inlet port via the junction and a distal end connected to the outlet port, the sampling channel being configured to convey subsequent portions of blood to the outlet port after the first portion of blood has entered the chamber, but failed to teach and/or suggest a housing that houses and defines the inlet port, the junction, the outlet port, the chamber, and the sampling channel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is

available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17094692
Filing Date	2020-11-10
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	ABOUELELA, MAY A
Attorney Docket Number	069366-0572169_KUR4C01US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	1							

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17094692
	Filing Date	2020-11-10
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572169_KUR4C01US

	1	Weinbaum, Fredric I., et al. "Doing it right the first time: quality improvement and the contaminant blood culture." Journal of Clinical Microbiology 35.3 (1997): 563-565.	
	2	Weinstein, Melvin P. "Blood culture contamination: persisting problems and partial progress." Journal of clinical microbiology 41.6 (2003): 2275-2278.	
	3	Weinstein, Melvin P. "Current blood culture methods and systems: clinical concepts, technology, and interpretation of results." Clinical infectious diseases 23.1 (1996): 40-46.	
	4	Weinstein, Melvin P., et al. "The clinical significance of positive blood cultures in the 1990s: a prospective comprehensive evaluation of the microbiology, epidemiology, and outcome of bacteremia and fungemia in adults." Clinical Infectious Diseases 24.4 (1997): 584-602.	
	5	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	
	6	Zimmon, David S. et al. "Effect of portal venous blood flow diversion on portal pressure." The Journal of Clinical Investigation 65.6 (1980): 1388-1397.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	04/11/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

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	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572169_KUR4C01US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-04-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Privacy Act Statement

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	ABOUELELA, MAY A
Attorney Docket Number	069366-0572169_KUR4C01US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3382865		1968-05-14	WORRALL JR ASHTON L	
	2	3494352		1970-02-10	RUSSO RONALD D	
	3	3604410		1971-09-14	WHITACRE GARY L	
	4	3648684		1972-03-14	BARNWELL CLEORA W	
	5	3817240		1974-06-18	AYRES W	
	6	3835835		1974-09-17	THOMPSON R	
	7	3848579		1974-11-19	VILLA REAL A	
	8	3859998		1975-01-14	THOMAS JOSEPH JOHN	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572169_KUR4C01US

	9	3945380		1976-03-23	DABNEY WILLIAM C	
	10	4056101		1977-11-01	GEISSLER ULRICH C	
	11	4150089		1979-04-17	LINET MICHAEL S	
	12	4193400		1980-03-18	LOVELESS JAMES C	
	13	4257416		1981-03-24	PRAGER DAVID	
	14	4349035		1982-09-14	THOMAS JOSEPH J	
	15	4373535		1983-02-15	MARTELL MICHAEL D	
	16	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
	17	4673386		1987-06-16	GORDON MARK G	
	18	4690154		1987-09-01	WOODFORD TIMOTHY	
	19	4813433		1989-03-21	DOWNEY JOHN M	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

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	Attorney Docket Number	069366-0572169_KUR4C01US

	20	4904240		1990-02-27	HOOVER ROCKLIN L	
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	Attorney Docket Number	069366-0572169_KUR4C01US

	42	Patton, Richard G., et al. "Innovation for reducing blood culture contamination: initial specimen diversion technique." Journal of clinical microbiology 48.12 (2010): 4501-4503.	
	43	Perez, P., et al. "Multivariate analysis of determinants of bacterial contamination of whole-blood donations." Vox Sanguinis 82.2 (2002): 55-60.	
	44	Quilici, Nathalie, et al. "Differential quantitative blood cultures in the diagnosis of catheter-related sepsis in intensive care units." Clinical infectious diseases 25.5 (1997): 1066-1070.	
	45	Retractable Techs., Inc. v. Becton Dickinson & Co., CA No. 2:07-CV-250, Claim Construction Order (E.D. Tex., Jan. 20, 2009). 20 pages.	
	46	Sheppard, Chelsea A., et al. "Bacterial contamination of platelets for transfusion: recent advances and issues." Laboratory Medicine 36.12 (2005): 767-770.	
	47	Sheppard, et al., Bacterial Contamination of Platelets for Transfusion: Recent Advances and Issues, LABMEDICINE, Vol. 36, No. 12, Dec. 2005 ("Sheppard 2005").	
	48	Shulman, Gerald. "Quality of processed blood for autotransfusion." JOURNAL OF EXTRACORPOREAL TECHNOLOGY 32.1 (2000): 11-19.	
	49	Tang, Menglin, et al. "Closed blood conservation device for reducing catheter-related infections in children after cardiac surgery." Critical Care Nurse 34.5 (2014): 53-60.	
	50	Van Zundert, Adrien. "New closed IV catheter system." Acta Anæsthesiologica Belgica 56.3 (2005): 283-285.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	04/11/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17094692
	Filing Date	2020-11-10
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572169_KUR4C01US

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17094692
	Filing Date	2020-11-10
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	ABOUELELA, MAY A
	Attorney Docket Number	069366-0572169_KUR4C01US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-04-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,088	07/24/2024	Bobby E. ROGERS	069366-0580418_KUR2C06US	2051

27500 7590 08/29/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER
CENTRAL, DOCKET

ART UNIT	PAPER NUMBER
OPAP	

NOTIFICATION DATE	DELIVERY MODE
08/29/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 18/783,088	**Applicant(s)** ROGERS et al.	
	Examiner CHERYL P GIBSON BAYLOR	**Art Unit** OPET	**AIA (FITF) Status** Yes

1. THE REQUEST FILED 24 July 2024 IS **GRANTED** .

The above-identified application has met the requirements for prioritized examination

A. ☑ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;

B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;

C. filing a **request for continued examination** ;

D. filing a notice of appeal;

E. filing a request for suspension of action;

F. mailing of a notice of allowance;

G. mailing of a final Office action;

H. completion of examination as defined in 37 CFR 41.102; or

I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET	

TO: Docket_IP@pillsburylaw.com
FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Fri Aug 30 05:00:05 EDT 2024

Dear Patent Center Customer:

Correspondence Address:

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean,VIRGINIA,22102
UNITED STATES

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Application	Document	Mailroom Date	Attorney Docket No.
18783088	TRACK1.GRANT	08/29/2024	069366-0580418_KUR2C06US

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Sincerely,

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,088	07/24/2024	Bobby E. ROGERS	069366-0580418_KUR2C06US	2051

27500 7590 09/17/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/17/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 18/783,088	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 07/24/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-26 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-9,11-22 and 24-26 is/are rejected.

8) ☑ Claim(s) 10 and 23 is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 07/24/2024 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 08/26/2024. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 11 is objected to because of the following informalities: the phrase "a sample collection device" in line 2 should be amended to read –the blood sample collection device--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1, 6-9, 11, 12, 14, 19-22, 24 and 25 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Patton et al (US 2008/0145933).

As to claims 1 and 14, Patton discloses a device (blood sampling device 500, par.38-40, fig.5) comprising:

an inlet port for receiving a blood sample (inlet/opening connecting needle 508 to input tubing 514, par.38-40, fig.5);

an outlet port (needle 510, fig.5);

a chamber (tubing 516 and reservoir 504, par.38-40, fig.5) comprising a flexible material (flexible material of tubing 516 and reservoir 504), wherein the chamber is connected with the inlet port (516 and 504 are connected to inlet of tubing 514, as best seen in fig.5) and configured to collect a first portion of the blood sample (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, par.40, fig.5) when under a drawing force applied from the outlet port from a blood sample collection device (pre vacuumed effect of vessel 506 withdraws blood, first needle 508 can be inserted into a patient to procure a blood sample. In FIG. 5, the first needle 508 is shown inserted into a vein 520. The second needle 510 is shown inserted into the one or more sample vessels 506 that have been vacuum-sealed. The vacuum in each of the one or more sample vessels 506 causes blood to pass from the vein 520 to the diversion mechanism 512, par.40); and

a sampling channel (tubings 514 and 518 connected with inlet of tubing 214, par.38-40, as best seen in fig.4) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port (which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, ar.38-40, fig.5).

As to claims 6 and 19, Patton discloses the device, further comprising a valve (diversion mechanism 512 having valve 60, par.38-41, fig.5) configured to initially close off the sampling channel (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 7 and 20, Patton discloses the device, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40).

As to claims 8 and 21, Patton discloses the device, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at

which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, as best seen from fig.5 the subsequent blood will bypass reservoir 504 and flows straight from inlet of 502 to tubings 514 and 518).

As to claims 9 and 22, Patton discloses the device, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber (diversion mechanism 512 can be initially adjusted to divert blood to the one or more pre-sample reservoirs 504 until the one or more pre-sample reservoirs 504 are filled, or a desired amount of blood has been withdrawn, at which point the diversion mechanism 512 can be adjusted to divert the flow of blood to the one or more sample vessels 506, par.40, fig.5).

As to claims 11 and 24, Patton discloses the device, further comprising a patient needle (patient needle 508, par.38-40, fig.5) and a sample collection device (sample vessel 506, par.38-40, fig.5).

As to claims 12 and 25, Patton discloses the device, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (the data suggests that fewer false positive test results for the presence of microbes in blood are obtained over conventional methods when initially-drawn volumes of blood are not used in microbial testing, par.54).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 2-5 and 15-18 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933) in view of Flaherty et al (US 2006/0009713).

As to claims 2-5 and 15-18, Patton discloses the invention substantially above, wherein a housing of the diverting mechanism is separate from a blood impermeable membrane, but failed to explicitly teach a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample, and causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port, and wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

However, Flaherty discloses an analogous blood sampling device, wherein the blood sampling chamber comprises (liquid impenetrable, air-permeable membrane 45, par.39, fig.8-10), wherein blood flows into the blood collection chamber 39, air is displaced from the blood collection chamber 39, through the membrane 45 and air opening or openings 46, respectively. This facilitates the substantially continual and unhindered flow of blood from the patient 106 and into the blood collection chamber 39

to collect the desired quantity of blood into the blood collection chamber 39 (par.40, fig.8-10).

Since blood impermeable membrane is well-known in the art, so it would have been obvious to one having an ordinary skill in the art before the effective filing date of the invention to include a blood impermeable membrane in reservoir 504 taught by Patton's invention, as blood impermeable membrane 45 taught by Flaherty's invention to facilitate the continual and unhindered flow of blood from the patient and into the blood collection chamber, as taught by Flaherty's invention (par.40).

6. Claim(s) 13 and 26 is/are rejected under 35 U.S.C. 103 as being obvious over Patton et al (US 2008/0145933).

As to claims 13 and 26, Patton discloses the volume of blood withdrawn into the one or more pre-sample reservoirs 504 is at least equal to the collective volumes of the first needle 508, the flexible, sterile input tubing 516, the diversion mechanism 512, and the first sterile output tubing 516 (par.40), but failed to explicitly teach he chamber has a volume of less than 1.5 cubic centimeters. However, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to allow reservoir 504 to collect blood volume less than 1.5 cubic centimeters, since it has been that discovering the optimum value of a result of effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215(CCPA 1980).

Allowable Subject Matter

7. Claims 10 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For

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/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/783,088	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 5

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20080319346-A1	2008-12-25	Crawford; Jamieson	A61B5/150656	600/576
*	B	US-4412548-A	1983-11-01	Hoch; Louis	A61B5/150213	600/577
*	C	US-5222502-A	1993-06-29	Kurose; Katsutoshi	A61B5/150732	600/584
*	D	US-5520193-A	1996-05-28	Suzuki; Issei	A61B5/1545	604/126
*	E	US-20100057004-A1	2010-03-04	Christensen; Kelly D.	A61M25/0606	604/122
*	F	US-20070088279-A1	2007-04-19	Shue; Ming-Jeng	A61M25/0693	604/168.01
*	G	US-20080145933-A1	2008-06-19	Patton; Richard G.	A61B10/0051	435/379
*	H	US-20040054333-A1	2004-03-18	Theeuwes, Felix	A61M5/14276	604/248
*	I	US-9022951-B2	2015-05-05	Bullington; Gregory	A61B5/150221	600/576
*	J	US-6569117-B1	2003-05-27	Ziv; David	A61M39/02	604/246
*	K	US-3741197-A	1973-06-26	Sanz; Manuel C.	A61B5/150267	600/583
*	L	US-20100010372-A1	2010-01-14	BROWN; LEROY R.	A61B5/15003	600/573
*	M	US-8603009-B2	2013-12-10	Tan; Alvin Chee Leong	A61B5/150251	600/573

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*	B	US-20080167577-A1	2008-07-10	Weilbacher; Eugene E.	A61B5/1545	600/576
*	C	US-20080086085-A1	2008-04-10	Brown; Leroy R.	A61B5/150389	604/122
*	D	US-9877675-B2	2018-01-30	Baid; Rishi	A61B5/150389	1/1
*	E	US-4444203-A	1984-04-24	Engelman; Allan	A61B5/150496	600/576
*	F	US-20070083162-A1	2007-04-12	O'Reagan; James	A61M39/26	604/167.03
*	G	US-6398743-B1	2002-06-04	Halseth; Thor R.	A61B5/15003	604/164.12
*	H	US-9022950-B2	2015-05-05	Bullington; Gregory	A61B5/150251	600/576
*	I	US-9155495-B2	2015-10-13	Bullington; Gregory J.	A61B5/150389	1/1
*	J	US-20160008579-A1	2016-01-14	Burkholz; Jonathan Karl	A61M5/158	604/164.08
*	K	US-20120016266-A1	2012-01-19	Burkholz; Jonathan Karl	A61B5/150992	600/581
*	L	US-4436098-A	1984-03-13	Kaufman; Joseph	A61B5/1545	604/199
*	M	US-4154229-A	1979-05-15	Nugent; Edward L.	A61B5/154	600/577

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*	B	US-8568371-B2	2013-10-29	Siopes; William	A61M39/06	251/903
*	C	US-8540663-B2	2013-09-24	Davey; Christopher T.	A61M25/0029	604/93.01
*	D	US-8523826-B2	2013-09-03	Layton, Jr.; Russell K.	A61M39/16	604/533
*	E	US-20160174888-A1	2016-06-23	Berthier; Erwin	A61B5/150503	600/573
*	F	US-8197420-B2	2012-06-12	Patton; Richard G.	A61B10/0045	600/573
*	G	US-4057050-A	1977-11-08	Sarstedt; Walter	A61B5/150351	604/125
*	H	US-20050240161-A1	2005-10-27	Crawford, Jamieson William McLean	A61B5/150816	604/264
*	I	US-20040147855-A1	2004-07-29	Marsden, Stewart	A61B5/150496	600/576
*	J	US-8864684-B2	2014-10-21	Bullington; Gregory J.	A61B10/0048	600/576
*	K	US-8535241-B2	2013-09-17	Bullington; Gregory	A61B5/150251	604/249
*	L	US-20130317391-A1	2013-11-28	Bullington; Gregory J.	A61B5/15003	600/578
*	M	US-20050004524-A1	2005-01-06	Newby, C. Mark	A61B5/150648	604/164.08

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*	B	US-5749857-A	1998-05-12	Cuppy; Michael J.	A61M25/0606	604/161
*	C	US-9060724-B2	2015-06-23	Bullington; Gregory J.	A61B5/1405	1/1
*	D	US-9204864-B2	2015-12-08	Bullington; Gregory J.	A61B10/0096	1/1
*	E	US-20020004647-A1	2002-01-10	Leong, Alvin Tan Chee	A61B5/15003	604/168.01
*	F	US-3817240-A	1974-06-18	Ayres; Waldemar A.	A61B5/150221	600/584
*	G	US-3874367-A	1975-04-01	Ayres; Waldemar A.	A61B5/15003	600/577
*	H	US-3886930-A	1975-06-03	Ryan; George R.	A61B5/150351	600/584
*	I	US-4106497-A	1978-08-15	Percarpio; Edward P.	A61B5/150389	600/579
*	J	US-4207870-A	1980-06-17	Eldridge; William N.	A61B5/150732	604/167.03
*	K	US-20150359473-A1	2015-12-17	Garrett; Chad	A61B5/157	600/309
*	L	US-20150314105-A1	2015-11-05	GASPARYAN; Levon	A61M5/427	604/117
*	M	US-20160073937-A1	2016-03-17	Burkholz; Jonathan Karl	A61B5/150251	604/524

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*	A	US-20060009713-A1	2006-01-12	Flaherty; Patrice	A61B5/154	600/576
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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/783,088	ROGERS et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	Date	Examiner
A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068	09/16/2024	MA

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner

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Search Notes		
Search Notes	Date	Examiner
text search, inventor name search, class/subclass search	09/16/2024	MA

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/16/2024								
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5200325		1993-04-06	BLATT JOEL M	
	2	5432084		1995-07-11	BRUBAKER DANIEL B	
	3	5972294		1999-10-26	SMITH JOHN L	
	4	6187347		2001-02-13	PATTERSON JAMES A	
	5	6599474		2003-07-29	EVTODIENKO VLADIMIR	
	6	8197420		2012-06-12	PATTON RICHARD G	
	7	8535241		2013-09-17	BULLINGTON GREGORY	
	8	9060724		2015-06-23	BULLINGTON GREGORY J	

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	9	9155495		2015-10-13	BULLINGTON GREGORY J	
	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
	18	9877675		2018-01-30	BAID RISHI	
	19	4444203		1984-04-24	ENGELMAN ALLAN	

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	20	6398743		2002-06-04	HALSETH THOR R	
	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
	24	8568371		2013-10-29	SIOPES WILLIAM	
	25	8540663		2013-09-24	DAVEY CHRISTOPHER T	
	26	8523826		2013-09-03	LAYTON JR RUSSELL K	
	27	4057050		1977-11-08	SARSTEDT WALTER	
	28	8864684		2014-10-21	BULLINGTON GREGORY J	
	29	5749857		1998-05-12	CUPPY MICHAEL J	
	30	9204864		2015-12-08	BULLINGTON GREGORY J	

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	31	3874367		1975-04-01	AYRES WALDEMAR A	
	32	3886930		1975-06-03	RYAN GEORGE R	
	33	4106497		1978-08-15	PERCARPIO EDWARD P	
	34	4154229		1979-05-15	NUGENT EDWARD L	
	35	4980297		1990-12-25	HAYNES JOHN L	
	36	9820682		2017-11-21	ROGERS BOBBY E	
	37	10010282		2018-07-03	ROGERS BOBBY E	
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	39	11185266		2021-11-30	ROGERS BOBBY E	
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	42	3817240		1974-06-18	AYRES W	
	43	3648684		1972-03-14	BARNWELL CLEORA W	
	44	4056101		1977-11-01	GEISSLER ULRICH C	
	45	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
	46	8070725		2011-12-06	CHRISTENSEN KELLY D	
	47	4349035		1982-09-14	THOMAS JOSEPH J	
	48	4813433		1989-03-21	DOWNEY JOHN M	
	49	5401262		1995-03-28	KARWOSKI THEODORE	
	50	3859998		1975-01-14	THOMAS JOSEPH JOHN	
	51	4373535		1983-02-15	MARTELL MICHAEL D	
	52	4690154		1987-09-01	WOODFORD TIMOTHY	

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	53	5097842		1992-03-24	BONN GINA B	
	54	5865803		1999-02-02	MAJOR MIKLOS	
	55	5873841		1999-02-23	BRANNON JAMES K	
	56	6013037		2000-01-11	BRANNON JAMES K	
	57	6913580		2005-07-05	STONE BENJAMIN CURTIS	
	58	11213232		2022-01-04	IVOSEVIC MILAN	
	59	6626884		2003-09-30	DILLON JAGMOHANBIR SINGH	
	60	4904240		1990-02-27	HOOVER ROCKLIN L	
	61	4673386		1987-06-16	GORDON MARK G	
	62	7461671		2008-12-09	EHWALD RUDOLF	
	63	6506182		2003-01-14	ESTABROOK BRIAN K	

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	64	3382865		1968-05-14	WORRALL JR ASHTON L	
	65	3848579		1974-11-19	VILLA REAL A	
	66	6106509		2000-08-22	LOUBSER PAUL G	
	67	3494352		1970-02-10	RUSSO RONALD D	
	68	6224561		2001-05-01	SWENDSON DAVID L	
	69	7055401		2006-06-06	PRYBELLA JOHN R	
	70	5135489		1992-08-04	JEPSON STEVEN C	
	71	5811658		1998-09-22	VAN DRIEL MICHAEL R	
	72	3604410		1971-09-14	WHITACRE GARY L	
	73	5772608		1998-06-30	DHAS V VARAPRABHU	
	74	4150089		1979-04-17	LINET MICHAEL S	

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	75	4257416		1981-03-24	PRAGER DAVID	
	76	4193400		1980-03-18	LOVELESS JAMES C	
	77	6843775		2005-01-18	HYUN DONGCHUL D	
	78	7666166		2010-02-23	EMMERT MICHAEL	
	79	7479131		2009-01-20	MATHIAS JEAN-MARIE	
	80	8377040		2013-02-19	BURKHOLZ JONATHAN KARL	
	81	5417673		1995-05-23	GORDON MARK G	
	82	6638252		2003-10-28	MOULTON WILLIAM G	
	83	3945380		1976-03-23	DABNEY WILLIAM C	
	84	5100394		1992-03-31	DUDAR THOMAS E	
	85	8827958		2014-09-09	BIERMAN STEVEN F	

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	86	8574203		2013-11-05	STOUT MARTY L	
	87	6860871		2005-03-01	KURACINA THOMAS C	
	88	6945948		2005-09-20	BAINBRIDGE MARLENE	
	89	7306736		2007-12-11	COLLINS GREGORY R	
	90	5691486		1997-11-25	BEHRINGER BRUCE E	
	91	5980830		1999-11-09	SAVAGE DOUGLAS ROBERT	
	92	5045185		1991-09-03	OHNAKA YUKIHIRO	
	93	5632906		1997-05-27	ISHIDA NOBORU	
	94	6695004		2004-02-24	RAYBUCK JOHN L	
	95	6733433		2004-05-11	FELL CLAUDE	
	96	7241281		2007-07-10	COELHO PHILIP H	

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	97	8349254		2013-01-08	HOSHINO YOSHITERU	
	98	5439450		1995-08-08	HAEDT LORI E	
	99	6905483		2005-06-14	NEWBY C MARK	
	100	5431811		1995-07-11	TUSINI ANDREA	
	101	6736783		2004-05-18	BLAKE KEVIN R	
	102	7052603		2006-05-30	SCHICK KARL G	
	103	3835835		1974-09-17	THOMPSON R	
	104	4416291		1983-11-22	KAUFMAN JOSEPH	
	105	10299713		2019-05-28	PATTON RICHARD G	
	106	10265007		2019-04-23	BULLINGTON GREGORY	
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	Attorney Docket Number	069366-0580418_KUR2C06US

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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	2	104981203	CN		2015-10-14	MAGNOLIA MEDICAL TECHNOLOGIES INC		☒
	3	1717280	CN		2006-01-04	SECR DEFENCE		☒

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	4	2015150742	WO		2015-10-08	UNIV HULL		☒
	5	0448795	EP		1991-02-10	BECTON DICKINSON CO		☒
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	1	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, vol. 39, No. 3., pp. 321-323, Mar. 1963.	☐
	2	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	3	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	4	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
	5	Notice of Allowance mailed 09-14-2023; Attorney Docket No. 069366-0574152_KUR2D02IL. 90 pages.	☐
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	7	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	8	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐
	9	Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. No. 202080000666.0 (pages 1-28).	☐
	10	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
	11	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
	12	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐
	13	Office Action (Non-Final Rejection) dated 01/25/2024 for IL App. 302893 (pages 1-3).	☐
	14	Li, Yiwen, et al. "Direct labeling and visualization of blood vessels with lipophilic carbocyanine dye DiI." Nature protocols 3.11 (2008): 1703-1708.	☐
	15	Abbott Point of Care, Cartridge and Test Information, Art: 714258-010; Rev. Date: 15-Aug-16,1-6 pages.	☐
	16	NCCLS. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth dition. H3-A5, vol. 23, No. 32. Replaces H3-A4; vol. 18, No. 7. 1-52 pages. http://demo.nextlab.ir/Organization/Documents/CLSI-Standards/CLSI-H3-A5.aspx.	☐
	17	Perez, P., et al. "Multivariate analysis of determinants of bacterial contamination of whole-blood donations." Vox Sanguinis 82.2 (2002): 55-60.	☐

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	18	Sheppard, et al., Bacterial Contamination of Platelets for Transfusion: Recent Advances and Issues, LABMEDICINE, vol. 36, No. 12, Dec. 2005 ("Sheppard 2005").	☐
	19	Office Action (Non-Final Rejection) dated 04/25/2023 for US App. 16838017 (pages 1-20).	☐
	20	Office Action (Final Rejection) dated 01/29/2024 for US App. 16838017 (pages 1-44).	☐
	21	"Membrane Definition & Meaning," Merriam-Webster, Merriam-Webster, 22 Apr. 2009, www.merriam-webster.com/ dictionary/ membrane. (Year: 2009).	☐
	22	Office Action (Advisory Action) dated 02/09/2024 for US App. 16838017 (pages 1-6).	☐
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	27	Second Office Action (Non-Final Rejection dated 04/28/2024 for CN App. 202080000666.0 (pages 1-11).	☐
	28	European Patent Office, Extended European Search Report for European Patent Application 21818838.1-1122, dated April 22, 2024, 11 pages.	☐

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	29	Australian Patent Office, Examination Report No. 1 for for Australian Patent Application 2021202622, dated March 18, 2022, 3 pages.	☐
	30	Office Action (Final Rejection) dated 08/25/2023 for US Application No. 18113710 (pages 1-50).	☐
	31	European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated July 26, 2023, pages 1-8.	☐
	32	Notice of Allowance mailed 04-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
	33	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
	34	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐
	35	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
	36	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
	37	Advisory Action dated 09/29/2023 for US Application 17893079, pages 1-24.	☐
	38	European Patent Office, Examination Report for European Patent Application 22181212.6-1122, dated September 28, 2023, pages 1-5.	☐
	39	European Patent Office, Extended European Search Report for European Patent Application 20781928.5-1122 dated October 28, 2022, pages 1-10.	☐

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	40	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐
	41	International Search Report and Written Opinion dated 19 March 2020 for PCT application no. PCT/US2020/023617. pages.	☐
	42	International Search Report and Written Opinion dated 28 September 2021 for PCT application no. PCT/ US2021/035294. 7 pages.	☐
	43	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
	44	Australian Patent Office, Australian Examination Report No. 1 for Application No. 2021120 622 dated March 18, 2022, 3 pages.	☐
	45	Notice of Allowance mailed 03-01-2023; Attorney Docket No. 069366-0572419_KUR2D01AU. 3 pages.	☐
	46	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
	47	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
	48	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Bibliographic Data

Application No: 18/783,088

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/ Examiner's Signature | Initials

Title: BLOOD SAMPLE OPTIMIZATION DEVICE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/24/2024	600	3791	069366-0580418_KUR2C06US
RULE			

APPLICANTS

Kurin, Inc., San Diego, CA, UNITED STATES

INVENTORS

Bobby E. ROGERS, Park City, UT, UNITED STATES

Gino KANG, Irvine, CA, UNITED STATES

John DETLOFF, San Diego, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 18494622 10/25/2023

18494622 is a CON of 18113710 02/24/2023 PAT 11832944

18113710 is a CON of 17538990 11/30/2021 PAT 11963769

17538990 is a CON of 16208559 12/04/2018 PAT 11185266

16208559 is a CON of 15994559 05/31/2018 PAT 10143412

15994559 is a CON of 15140448 04/27/2016 PAT 10010282

15140448 has PRO of 62318194 04/04/2016

15140448 has PRO of 62238636 10/07/2015

15140448 has PRO of 62196797 07/24/2015

FOREIGN APPLICATIONS

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PE2E SEARCH - Search History (Prior Art)

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L105	19	("2009/0312711").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L106	11	("2007/0106220").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L107	288967	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L108	6321	L107 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L109	121	L108 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:17 PM
L110	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:31 PM
L111	6	L110 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:31 PM
L113	71	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:31 PM
L114	0	("15140443").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2018/07/24

			USOCR)				01:38 PM
L115	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:38 PM
L116	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:40 PM
L117	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 01:56 PM
L118	854	L117 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:56 PM
L119	91	L118 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:57 PM
L120	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:06 PM
L121	1074	L120 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L122	80	L121 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L123	301210	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L124	6556	L123 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L125	3664	L124 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L126	12749	"19" and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L127	117	L125 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L128	1348	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:16 PM
L129	75	L128 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:17 PM
L130	1	("20120291564").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:21 PM
L131	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:25 PM
L132	18	L131 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:25 PM
L133	98	("20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054333" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:44 PM

		"20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6626884" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7744573" | "8197420" | "8231546" | "8337418").PN. OR ("8535241").URPN.					
L134	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:47 PM
L135	23	("4166450").PN. OR ("4412548").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L136	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L137	4	("2007/0088279").URPN.	(USPAT)	OR	ON	ON	2018/07/24 02:48 PM
L138	1	(14/990763).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:58 PM
L139	9	(blood and sequest$5 and junction and first	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 03:07 PM

		and portion and sampl$4).clm.					
L140	1	(15/287421).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/25 09:39 PM
L141	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/26 11:56 AM
L142	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:24 PM
L143	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:25 PM
L144	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"20080145933"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 05:53 PM
L145	272	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian")) OR (("GARRETT") near3 ("Chad"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/11/07 05:57 PM
L146	9	L145 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 05:58 PM
L147	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"200801459	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 06:26 PM

		33"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.					
L148	5	L147 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 06:29 PM
L149	6	("2010/0057004").URPN.	(USPAT)	OR	ON	ON	2019/11/07 06:40 PM
L150	0	L149 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:20 PM
L151	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:21 PM
L152	4	L151 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L153	1766	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:21 PM
L154	13	L153 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L155	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:22 PM
L156	48	L155 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:22 PM
L157	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L158	17	L157 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:43 PM
L159	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L160	6	L159 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L161	333030	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L162	6981	L161 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L163	139	L162 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L164	117	L163 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:45 PM
L165	1	L146 and (enclos$3	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07

		near4 mechanism)					07:51 PM
L166	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/08 04:57 PM
L167	1	(15/139716).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/11 12:09 PM
L168	1	(15/520430).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 11:02 AM
L169	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:11 PM
L170	1	("20120253321").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:13 PM
L171	1	(15/861959).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:14 PM
L172	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 02:17 PM
L173	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:14 PM
L174	1	("20080167577").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:19 PM
L175	4	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2019/12/09 03:30 PM
L176	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:31 PM
L177	39	(US-20040073171-$ or US-20160174888-$ or US-20050240161-$ or US-20040147855-$ or US-20130317391-$ or US-20050004524-$ or US-20030105414-$ or US-20020004647-$ or US-20100057004-$ or US-20070088279-$ or US-20080145933-$ or US-20040054333-$ or US-20100010372-$ or US-20080319346-$ or US-20080167577-$).did. or (US-9138572-$ or US-8568371-$ or US-8540663-$ or US-8523826-$ or US-8197420-$ or US-4057050-$ or US-8864684-$ or US-8535241-$ or US-5749857-$ or US-9060724-$ or US-9204864-$ or US-3817240-$ or US-3874367-$ or US-3886930-$ or US-4106497-$ or US-4154229-$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:37 PM

		4207870-$ or US-4412548-$ or US-5222502-$ or US-5520193-$ or US-9022951-$ or US-6569117-$ or US-3741197-$ or US-8603009-$).did.					
L178	8	("20040054333"|"8197420"|"9855001"|"9861306"|"10045724"|"10028687"|"8337418"|"10028689").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:42 PM
L179	100	("20020002349" | "20020183651" | "20030055381" | "20040010228" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047").PN. OR ("8197420").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 03:43 PM
L180	70	L179 and (blood near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 03:43 PM
L181	43	L180 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 03:44 PM
L182	270	((("BULLINGTON")	(US-PGPUB; USPAT;	OR	ON	ON	2019/12/09

		near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	USOCR; EPO; JPO; DERWENT)				04:13 PM
L183	335813	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L184	7259	L183 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L185	325	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 04:33 PM
L186	594	L184 and (flash$6 and seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L187	476	L186 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L188	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:14 PM
L189	1123	L188 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L190	1013	L189 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L191	10	L190 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:16 PM
L192	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:23 PM
L193	1143	L192 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L194	1038	L193 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L195	3	L194 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L196	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:24 PM
L197	618	L196 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L198	557	L197 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L199	1	(15/854273).APP.	(US-PGPUB; USPAT;	OR	OFF	OFF	2019/12/09

			USOCR)				05:25 PM
L200	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:31 PM
L201	219	L200 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L202	199	L201 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L203	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:36 PM
L204	44	L203 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:37 PM
L205	1	(15/508871).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/10 11:58 AM
L206	342199	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/03/16 12:53 PM
L207	4239	L206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:53 PM
L208	146	L207 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:54 PM
L209	101	L208 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:55 PM
L210	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:38 PM
L211	1123	L210 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:38 PM
L212	1013	L211 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L213	22	L212 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L214	108	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 01:46 PM

		"20050245869" | "20050245870" | "20050245879" | "20050245885" | "20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" | "5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.					

L215	26	L214 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:47 PM
L216	27	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:47 PM
L217	23	("2003/0105414").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:48 PM
L218	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:52 PM
L219	1143	L218 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L220	25	L219 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L221	353695	((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:54 PM
L222	3643	L221 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L223	1926	L222 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L224	785	L223 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:56 PM
L225	7046	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 02:32 PM
L226	14	L225 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:35 PM
L227	1352	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:36 PM
L228	135	L227 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L229	19	L228 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L230	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:47 PM
L231	3	L230 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:47 PM
L232	19	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/03/16 02:48 PM
L233	795	(600/576).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16

							02:58 PM
L234	71	L233 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:58 PM
L235	57	L234 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:59 PM
L236	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:12 PM
L237	11	L236 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:12 PM
L238	45	("20040054333"|"20050240161"|"4412548"|"5749857"|"8197420"|"9855001"|"9861306"|"20020004647"|"20100057004"|"3741197"|"20040073171"|"3874367"|"4057050"|"4106497"|"8197420"|"8535241"|"8540663"|"8603009"|"8864684"|"10045724"|"3817240"|"10028687"|"20030105414"|"5222502"|"5520193"|"6569117"|"8568371"|"20040147855"|"20070088279"|"20080145933"|"20100010372"|"3886930"|"8523826"|"9060724"|"9204864"|"8337418"|"20050004524"|"20080167577"|"20080319346"|"20130317391"|"4154229"|"9022951"|"10028689"|"20160174888"|"4207870"|"9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:13 PM
L239	6	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2020/03/16 03:13 PM
L240	118	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 03:15 PM
L241	6	("2008/0167577").URPN.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 03:15 PM
L242	274	((("BULLINGTON") near3 ("Gregory")) OR	(US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	ON	ON	2020/03/16 03:25 PM

		(("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	DERWENT)				
L243	61	L242 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:25 PM
L244	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:47 PM
L245	0	(14/502498).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:11 PM
L246	1	("20110082383").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L247	1	("8150506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L252	1	(15/057214).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/17 11:28 AM
L253	348964	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L254	7453	L253 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L255	155	L254 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:23 PM
L256	77	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:35 PM
L257	343953	(blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:40 PM
L258	11	L256 and (blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:41 PM
L259	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:50 PM
L260	121	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:19 PM
L261	32	L260 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:20 PM

L262	1	("3648684").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L263	1	("4056101").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L264	329	(600/577).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/06/10 06:39 PM
L265	11	L264 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:39 PM
L266	29	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/06/10 06:40 PM
L267	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:40 PM
L268	72	L267 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:40 PM
L269	1767	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:44 PM
L270	31	L269 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:45 PM
L271	77	("4676249" | "4787891" | "4850960" | "4874382" | "4886067" | "4886500" | "4900307" | "4904242" | "4917102" | "4950252" | "4955862" | "5046508" | "5116353" | "5125718" | "5129884" | "5163911" | "5217435" | "5290244" | "5295974" | "5314503" | "5318585" | "5330432" | "5360410" | "5366441" | "5376075" | "5395337" | "5531692" | "5695475" | "5695479" | "5702367" | "5735813" | "5749857" | "5788654" | "5800395" | "5846226" | "5871470" | "5882342" | "5919172" | "5935108" | "5935113" | "5989220" | "6050976" | "6077244" | "6099504" | "6126641" | "6162195").PN. OR ("6398743").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:46 PM
L272	18	L271 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:46 PM
L273	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:48 PM
L274	7050	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:49 PM

L275	14	L274 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:49 PM
L276	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:51 PM
L277	7	L276 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:51 PM
L278	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:52 PM
L279	135	L278 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:52 PM
L280	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 07:08 PM
L281	3	L280 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 07:08 PM
L282	20	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/06/10 07:08 PM
L286	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 08:56 PM
L287	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:16 PM
L288	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:17 PM
L289	100	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/03/01 09:17 PM
L290	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:36 PM
L291	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:39 PM
L292	180	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/03/02 12:19 PM
L293	11	L292 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 12:20 PM
L294	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:47 PM
L295	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:49 PM
L296	1	("20020048170").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:36 PM
L297	1	("20040174525").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:49 PM
L298	1	("10045704").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2021/03/02

			USOCR)				03:09 PM
L299	27321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/03/02 03:17 PM
L300	4594	L299 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:27 PM
L301	3762	L300 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:28 PM
L302	257	L301 and (air near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L303	420	L301 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L304	1	("20110167658").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:30 PM
L305	5	("2015/0306288").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:15 PM
L306	1	(16/208559).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 04:32 PM
L307	2	("2009/0043225").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:49 PM
L308	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/03/02 05:00 PM
L309	1363	L308 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:00 PM
L310	73	L309 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L311	73	L310 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L312	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:34 PM
L313	711	L312 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L314	58	L313 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L315	58	L314 and	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02

		@ad<"20150724"					05:34 PM
L316	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:42 PM
L317	277	L316 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:42 PM
L318	20	L317 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:43 PM
L319	336	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/03/02 05:44 PM
L320	210	L319 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L321	196	L320 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L322	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:48 PM
L323	1208	L322 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L324	73	L323 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L325	73	L324 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:49 PM
L326	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:59 PM
L327	271	L326 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L328	10	L327 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L329	268	L327 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L330	182	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/07/08 02:22 PM
L331	27660	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/07/08 03:27 PM

		A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.					
L332	4684	L331 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:28 PM
L333	3769	L332 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L334	579	L333 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L335	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:54 PM
L336	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:56 PM
L337	337	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:19 PM
L338	211	L337 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L339	196	L338 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L340	37	L339 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L341	221	("20010021827" | "20020004650" | "20020055716" | "20020072715" | "20020103464" | "20020103465" | "20020107488" | "20020151856" | "20020193748" | "20030028171" | "20030036730" | "20030050608" | "20030055385" | "20030078544" | "20030093009" | "20030105414" | "20030114797" | "20030120222" | "20030176842" | "20030181873" | "20030191438" | "20030199827" | "20030216687" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"20030220614" | "20030229315" | "20030229316" | "20040024370" | "20040059302" | "20040092872" | "20040102740" | "20040111068" | "20040193120" | "20040204681" | "20040210197" | "20050004524" | "20050059936" | "20050065482" | "20050124944" | "20050165353" | "20050187493" | "20050228345" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" | "20050283093" | "20060015073" | "20060036217" | "20060036219" | "20060079847" | "20060129064" | "20060189934" | "20060189936" | "20060224122" | "20060270947" | "20060276756" | "20070021724" | "20070027430" | "20070106220" | "20070106224" | "20070167914" | "20070282275" | "20080015513" | "20080086085" | "20080177202" | "20080221528" | "20080269691" | "20080306452" | "20080319345" | "20080319346" | "20090204026" | "20090227896" | "20100063455" | "20100191189" | "20100262038" | "20110118674" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4813426" |				

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L344	41	("2735430" | "2798487" | "3187749" | "3240209" | "3585984" | "3817240" | "4166450" | "4207870" | "4295477" | "4312362").PN. OR ("4436098").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:22 PM
L345	163	L341 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:22 PM
L346	163	L345 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:23 PM
L347	22	("2005/0283093").URPN.	(USPAT)	OR	ON	ON	2021/07/08 04:23 PM
L348	163	L345 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L349	163	L348 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L350	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/08 04:37 PM
L351	1363	L350 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:37 PM
L352	1346	L351 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L353	136	L352 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L354	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:41 PM
L355	711	L354 and ((blood or fluid$4) near4 (sequest$5 or sampl$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM

		or flash$4 or collect$4))					
L356	699	L355 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L357	123	L356 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L358	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:44 PM
L359	277	L358 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L360	260	L359 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L361	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:46 PM
L362	1208	L361 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:46 PM
L363	1194	L362 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L364	1194	L363 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L366	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:05 PM
L367	319	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/02/02 03:14 PM
L368	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:35 PM
L369	190	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 03:36 PM
L370	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:41 PM
L371	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L372	1	("9060725").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L373	1	("9060724").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:43 PM
L374	1	("9022950").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L375	1	("9022951").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L376	1	("10292633").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2022/02/02

			USOCR)				03:46 PM
L377	1	("10433779").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:47 PM
L378	1	("10436554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:48 PM
L379	1	("10736554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L380	1	("10912506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L381	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L382	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:50 PM
L383	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:51 PM
L384	276	(600/579).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:52 PM
L385	204	L384 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 03:53 PM
L386	37427	(A61B5/150221 or A61B5/15003 or A61B5/150236 or A61B5/150244 or A61B5/150251 or A61B5/150389 or A61B5/150503 or A61B5/150992 or A61B5/153 or A61B5/155 or A61B10/0048 or A61B10/0051 or A61B10/007 or A61B2010/0061 or A61B2010/0077 or A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 04:35 PM
L387	7279	L386 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L388	4442	L387 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L389	874	L388 and (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:38 PM
L390	26	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:52 PM
L391	44	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:59 PM
L392	385	L386 and ((blood or fluid) near4 (seal$4 near4 (member or	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM

		mechanism$4 or vent$4 or elastic$4)))					
L393	171	L392 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L394	355	(604/103).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 05:52 PM
L395	7	L394 and ((blood or fluid) near4 (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:52 PM
L396	1	(16/328127).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/03 12:00 PM
L397	0	"1020130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L398	8	"20130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L399	14	"2013021595"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:18 PM
L400	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/04 07:10 PM
L401	1	(15/746656).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/05 11:48 AM
L402	0	(17/388440).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/07 09:34 AM
L403	1	("20050048465").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/07 09:34 AM
L404	196	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:08 PM
L405	16	L404 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L406	16	L404 and ((blood or chamber) near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L407	16	L406 and (junct$4 or bypass$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L408	16	L406 and junct$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L409	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:54 PM

		A61B5/150572 or A61B5/154 or A61B5/15074).cpc.					
L410	4525	L409 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:55 PM
L411	3810	L410 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:56 PM
L412	820	L411 and ((vent$4 or open$4 or apertur$4) near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:57 PM
L413	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 05:51 PM
L414	4603	L413 and ((blood or fluid$4 or chamber) same (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:51 PM
L415	511	L414 and ((junct$4 or bypass$4 or divert$4) near4 (blood or fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:52 PM
L416	355	L415 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:53 PM
L417	1	(16/819033).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:10 PM
L418	1	(17/094692).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L419	1	(17/538990).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L420	1	("11311219").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:27 PM
L421	1	("11185266").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:30 PM
L422	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:31 PM
L423	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:32 PM
L424	252	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS,	OR	OFF	OFF	2022/10/13 01:41 PM

			IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L425	38	424 AND (closur$4 OR enclos$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:42 PM
L426	42781	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/10/13 01:47 PM
L427	5205	426 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:50 PM
L428	4803	427 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 01:51 PM
L429	519	428 AND ((closur$4 OR enclos$4 OR pug$4) near5 (vent OR open$4 OR air))	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 01:54 PM
L430	169	"5749857"	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
L431	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:14 PM
L432	346	427 AND ((junct$4 OR bypass$4 OR divert$4) near4 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:18 PM
L433	186	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/10/13 02:32 PM

		| "5400798").pn. OR ("5749857").urpn. AND (PGPB | USPT | USOC).dbnm.					
L434	124	433 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4 OR optimiz$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/10/13 02:34 PM
L435	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/13 02:34 PM
L436	1	17/138056	(US-PGPUB; USPAT)	OR	ON	ON	2022/10/19 11:35 AM
L437	253	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/11/16 03:25 PM
L438	39	437 AND (closur$4 OR enclos$4)	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 03:25 PM
L439	35391	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/154 OR A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/11/16 03:46 PM
L440	4100	439 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:48 PM
L441	3875	440 AND ((blood OR fluid$4 OR urine) SAME (sequest$5 OR sampl$4 OR flash$4 OR collect$4 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:49 PM

		optimiz$5))					
L442	368	441 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 03:50 PM
L443	7	"10827964"	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 04:13 PM
L444	1	16/819033	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 04:48 PM
L445	359	"4207870"	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 05:07 PM
L446	1	("4207870").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2022/11/16 05:07 PM
L447	3814	440 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flash$4 OR collect$4 OR optimiz$5))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:17 PM
L448	366	447 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:17 PM
L449	89	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 01:13 PM
L450	24	449 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:14 PM
L451	24	449 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:14 PM
L452	6634	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 01:32 PM
L453	5326	452 AND @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:32 PM
L454	4928	453 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:32 PM

		OR collect$4 OR optimiz$5 OR flash$4))					
L455	371	454 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 01:33 PM
L456	11	("2016/0361006").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:03 PM
L457	1	17/094692	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:11 PM
L458	49	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"20160008579"|"20160174888"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"4436098"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:18 PM
L459	13	458 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:18 PM
L460	155	("2707953" | "2992974" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3635798" | "3648684" | "3848579" | "3890203" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4425235" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:21 PM

		| "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5454786" | "5485854" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6328726" | "6364890" | "6387086" | "6403381" | "6520948" | "6626884" | "6692479" | "6716187" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7384416" | "7744573" | "8197420" | "8231546" | "8337418" | "8535241" | "8647286" | "8864684" | "8876734" | "20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054283" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "20100152681" | "20120095367" | "20120215131" | "20130079604" | "20130116599" | "20130317391" | "20140081172").pn. OR ("9060724").urpn. AND (PGPB | USPT | USOC).dbnm.					
L461	31	("2008/0145933").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2023/04/11 03:30 PM
L462	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 03:46 PM
L463	13	459 AND ((junct$4 OR bypass$4 OR divert$4) near5 (blood OR fluid OR urine))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:47 PM

L464	4994	453 AND ((blood OR fluid$4 OR urine OR semen) SAME (sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:58 PM
L465	968	464 AND ((junct$4 OR bypass$4 OR diver$5) SAME (blood OR fluid OR urine OR semen))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 03:59 PM
L466	707	465 AND housing	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:50 PM
L467	2911	464 AND ((blood OR fluid$4 OR urine OR semen) near5 (first OR second OR subsequent$4 OR bypass))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L468	2954	464 AND ((blood OR fluid$4 OR urine OR semen) near5 (first OR second OR subsequent$4 OR convey$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L469	2891	464 AND ((blood OR fluid$4 OR urine OR semen) near5 (first OR second OR subsequent$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:52 PM
L470	790	469 AND ((junct$4 OR bypass$4 OR diver$5) SAME (blood OR fluid OR urine OR semen))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/04/11 04:53 PM
L471	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 12:35 PM
L472	164	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2023/05/08 02:18 PM
L473	1	("4207870").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:23 PM
L474	1	("10827964").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08

							03:31 PM
L475	1	("11311219").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:32 PM
L476	1	"17094692"	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:34 PM
L477	2	"17730118"	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:34 PM
L478	1	("10012828").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:36 PM
L479	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 03:36 PM
L480	48138	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/05/08 03:59 PM
L481	5081	480 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 04:15 PM
L482	3947	481 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 04:17 PM
L483	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 04:17 PM
L484	1069	482 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 04:32 PM
L485	203	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").pn. OR ("5749857").urpn. AND	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/05/08 04:51 PM

		(PGPB | USPT | USOC).dbnm.					
L486	606	484 AND ((pressure OR vacuum) near5 (draw OR forc$4 OR withdraw OR flow$4)) SAME (blood OR fluid)	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 05:32 PM
L487	24	("2010/0057004").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/05/08 05:35 PM
L488	3	487 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/05/08 05:55 PM
L489	49	((US-20080319346-A1 OR US-20100057004-A1 OR US-20070088279-A1 OR US-20080145933-A1 OR US-20040054333-A1 OR US-20100010372-A1 OR US-20080167577-A1 OR US-20080086085-A1 OR US-20070083162-A1 OR US-20160008579-A1 OR US-20120016266-A1 OR US-20130317391-A1 OR US-20160174888-A1 OR US-20050240161-A1 OR US-20040147855-A1 OR US-20040073171-A1 OR US-20050004524-A1 OR US-20030105414-A1 OR US-20020004647-A1).did. AND PGPB.dbnm.) OR ((US-4412548-A OR US-5222502-A OR US-5520193-A OR US-9022951-B2 OR US-6569117-B1 OR US-3741197-A OR US-8603009-B2 OR US-4207870-A OR US-9877675-B2 OR US-4444203-A OR US-6398743-B1 OR US-9022950-B2 OR US-9155495-B2 OR US-4436098-A OR US-9138572-B2 OR US-8568371-B2 OR US-	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/05/08 06:07 PM

		8523826-B2 OR US-8197420-B2 OR US-4057050-A OR US-8864684-B2 OR US-8535241-B2 OR US-5749857-A OR US-9060724-B2 OR US-9204864-B2 OR US-3817240-A OR US-3874367-A OR US-3886930-A OR US-4106497-A OR US-4154229-A).did. AND USPT.dbnm.)					
L490	25	489 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:07 PM
L491	204	482 AND (hous$4 SAME (inlet AND outlet AND channel))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:29 PM
L492	118	491 AND (hous$4 near5 ((top OR upper) AND (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:33 PM
L493	1	489 AND (hous$4 near5 ((top OR upper) AND (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L494	0	489 AND (hous$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L495	27	492 AND (hous$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:39 PM
L496	172	484 AND (hous$4 near5 ((top OR upper) SAME (lower OR bottom)))	(US-PGPUB; USPAT)	OR	ON	ON	2023/05/08 06:41 PM
L497	113	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/07/05 01:58 PM
L498	26	497 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 01:58 PM

L499	4	15/855439	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 03:12 PM
L500	48306	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/07/05 03:36 PM
L501	5081	500 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 03:36 PM
L502	3947	501 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 03:37 PM
L503	1069	502 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 03:37 PM
L504	3871	501 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:18 PM
L505	3030	501 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4 OR allow$4)) SAME (channel$4 OR chamber OR junct$4 OR inlet OR outlet OR path$4 OR contain$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:20 PM
L506	921	503 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4 OR allow$4)) SAME (channel$4 OR chamber OR junct$4 OR inlet OR outlet OR path$4 OR contain$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/07/05 05:20 PM
L507	1	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05

							06:04 PM
L508	1	16/961875	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 08:21 PM
L509	7	"20070148624"	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 01:02 PM
L510	43469	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO)	OR	ON	ON	2023/08/31 01:28 PM
L511	5081	510 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L512	3947	511 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L513	2653	512 AND ((blood OR fluid$4 OR urine) near5(divert$4 OR direct$4 OR flow$4 OR bypass$4 OR allow$4)) SAME (channel$4 OR chamber OR junct$4 OR inlet OR outlet OR path$4 OR contain$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/31 01:32 PM
L514	921	513 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 01:33 PM
L515	1	18/113710	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:05 PM
L516	372	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2023/11/20 02:30 PM
L517	172	516 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:41 PM

		sampl$4 OR flush$4 OR collect$4 OR optimiz$5 OR flash$4 OR divert$4 OR bypass$4))					
L518	165	516 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR divert$4 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:42 PM
L519	165	516 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 02:42 PM
L520	1	("11395612").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:43 PM
L521	1	("11395611").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:45 PM
L522	1	("10292633").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:46 PM
L523	1	("9022950").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:52 PM
L524	11	"10736554"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L525	1	("10736554").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L526	1	("10912506").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:55 PM
L527	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:56 PM
L528	1	("9820682").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 02:58 PM
L529	67080	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/11/20 03:05 PM
L530	1791	529 AND ((blood OR fluid$4 OR urine)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/11/20 03:05 PM

		near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))					
L531	322	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism) near5 rotat$4	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:07 PM
L532	420	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 rotat$4	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:07 PM
L533	0	("2021/0128037").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/20 03:39 PM
L534	1267	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR hous$4 OR container)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:56 PM
L535	1142	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 03:56 PM
L536	1	17/863605	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 04:48 PM
L537	1	("10292633").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 05:19 PM
L538	505	530 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (multiple OR pluarlit$4 OR first OR second) near5 (lumen OR channel OR path$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/20 05:25 PM
L539	8	"20080077183"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 01:29 PM
L540	1	15/933356	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 01:47 PM
L541	7	("20060074354"|"20080077183"|"20100131454"|"20140228714"|"20150196247"|"20200129380"|"9974476").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:08 PM
L542	6	541 AND (suck$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:09 PM
L543	146297	(A61B5/4542 OR A61B5/7242 OR A61B5/7246 OR	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY,	OR	ON	ON	2023/11/21 02:17 PM

		A61B5/7257 OR A61B5/7267 OR A61B5/7282 OR A61B2503/045 OR A61B2562/0247 OR A61B5/038 OR A61B5/002).cpc.	CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L544	16368	543 AND @ad<"20170322"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:17 PM
L545	15	544 AND (determin$4 OR measur$4 OR detect$4 OR process$4) near5(suck$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:18 PM
L546	120	544 AND (determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5((suck$4 OR feed$4) near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:20 PM
L547	15	544 AND (determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5((suck$4) near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:20 PM
L548	1868	(determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5(suck$4 near5 pressure)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:27 PM
L549	1387	548 AND @ad<"20170322"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:27 PM
L550	48	(determin$4 OR measur$4 OR detect$4 OR process$4 OR estimat$4) near5(suck$4 near5 pressure) AND (nutrit$4 SAME feed$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:34 PM
L551	39	550 AND (baseline OR threshold OR predetermin$4)	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:35 PM
L552	16	"20150011874"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 02:55 PM
L553	5	"20140288398"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21

							02:55 PM
L554	6	"20140120531"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:01 PM
L555	1	("9060724").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:45 PM
L556	1	("10433779").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:49 PM
L557	12	"10736554"	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:50 PM
L558	1	("10912506").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 03:54 PM
L559	0	18/381369	(US-PGPUB; USPAT)	OR	ON	ON	2023/11/21 05:01 PM
L560	21	(Artificial Intelligence) More like doc: US-10912506-B2 Text: (US-20200359951-A1 OR US-11395611-B2 OR US-20220071533-A1 OR US-20180116577-A1 OR US-11395612-B2 OR US-20220079482-A1 OR US-10736554-B2 OR US-10433779-B2 OR US-20150351679-A1 OR US-20140155781-A1 OR US-9060724-B2 OR US-20150011910-A1 OR US-9022951-B2 OR US-20210361206-A1 OR US-20150011911-A1 OR US-9022950-B2 OR US-20150257691-A1 OR US-20200060595-A1 OR US-10292633-B2 OR US-20230172502-A1).did.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/11/21 07:16 PM
L561	0	("10912506").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/21 07:16 PM
L562	273	("2707953" | "2992974" | "3013557" | "3098016" | "3382865" | "3405706" | "3467095" | "3494351" | "3494352" | "3577980" | "3604410" | "3635798" | "3648684" | "3730168" | "3741197" | "3777773" | "3803810" | "3817240" | "3834372" | "3835835" | "3848579" | "3848581"	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2023/11/21 07:16 PM

		| "3874367" | "3886930" | "3890203" | "3890968" | "3937211" | "3945380" | "3978846" | "4056101" | "4057050" | "4063460" | "4077395" | "4106497" | "4133863" | "4150089" | "4154229" | "4166450" | "4190426" | "4193400" | "4207870" | "4212308" | "4238207" | "4257416" | "4275730" | "4298358" | "4340067" | "4340068" | "4349035" | "4370987" | "4398544" | "4412548" | "4416290" | "4425235" | "4444203" | "4459997" | "4509534" | "4608996" | "4654027" | "4657027" | "4657160" | "4673386" | "4676256" | "4679571" | "4705497" | "4714461" | "4772273" | "4865583" | "4879098" | "4886072" | "4890627" | "4904240" | "4980297" | "4988339" | "5009847" | "5027827" | "5032116" | "5045185" | "5066284" | "5084034" | "5097842" | "5100394" | "5108927" | "5116323" | "5122129" | "5135489" | "5222502" | "5269317" | "5330464" | "5417673" | "5431811" | "5439450" | "5450856" | "5466228" | "5472605" | "5485854" | "5507299" | "5520193" | "5575777" | "5603700" | "5632906" | "5649912" | "5691486" | "5749857" | "5772608" | "5811658" | "5824001" | "5865812" | "5871699" | "5911705" | "5961472" | "5971956" | "5980830" | "6001307" | "6010633" | "6106509" | "6210909" | "6224561" | "6325975" | "6328726" | "6364890" | "6387086" | "6403381" | "6506182" | "6520948" | "6569117" | "6626884" | "6638252" | "6648835" | "6692479" | "6695004" | "6716187" | "6733433" | "6736783" | "6746420" | "6843775" | "6860871" | "6905483"					

		| "6913580" | "6945948" | "7044941" | "7052603" | "7055401" | "7087047" | "7141097" | "7241281" | "7306736" | "7314452" | "7316662" | "7335188" | "7384416" | "7461671" | "7479131" | "7614857" | "7615033" | "7618407" | "7648491" | "7666166" | "7744573" | "7766879" | "8070725" | "8197420" | "8231546" | "8337418" | "8349254" | "8377040" | "8382712" | "8383044" | "8412300" | "8523826" | "8535241" | "8540663" | "8568371" | "8574203" | "8603009" | "8647286" | "8795198" | "8827958" | "8864684" | "8876734" | "9022950" | "9022951" | "D731643" | "9060724" | "9060725" | "9138572" | "9149576" | "9155495" | "9204864" | "9314201" | "9855001" | "9855002" | "9855386" | "9861306" | "9872645" | "9877675" | "9895092" | "9950084" | "9999383" | "10028687" | "10028689" | "10045724" | "10251590" | "10736554" | "20010039058" | "20020002349" | "20020004647" | "20020183651" | "20020193751" | "20030013991" | "20030055381" | "20030069543" | "20030105414" | "20030208151" | "20040009542" | "20040010228" | "20040054283" | "20040054333" | "20040127816" | "20040147855" | "20050004524" | "20050148993" | "20050161112" | "20050199077" | "20050240161" | "20050245885" |				

		"20050273019" | "20050281713" | "20060251622" | "20060287639" | "20070088279" | "20070100250" | "20070119508" | "20070287948" | "20080086085" | "20080108954" | "20080167577" | "20080185056" | "20080319346" | "20090050213" | "20090306601" | "20100010372" | "20100042048" | "20100057004" | "20100094171" | "20100152681" | "20100268118" | "20110306899" | "20120035540" | "20120265099" | "20120265128" | "20140066880" | "20150018715" | "20150342510" | "20150351679" | "20160174888" | "20160213294" | "20170071519" | "20180160958" | "20180353117" | "20190076074" | "20190175087" | "20200060595" | "20200060596").pn. OR ("10912506").urpn. AND (PGPB | USPT | USOC).dbnm.					
L563	303	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/01/08 02:52 PM

L564	26	563 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 02:55 PM
L565	33645	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/01/08 03:06 PM
L566	5091	565 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:09 PM
L567	1014	566 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:09 PM
L568	828	567 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve OR junct$4) near5 (chamber OR reservoir OR container OR hous$4 OR inlet OR outlet OR channel OR port)	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 03:15 PM
L569	51	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"20150314105"|"20150359473"|"20160008579"|"20160174888"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"443609	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 03:40 PM

		8"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.					
L570	35	569 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/01/08 03:40 PM
L571	353	567 AND (air near5 (filter$4 OR material$4 OR membrane OR permeab$4 OR vent$4))	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:09 PM
L572	3	17/538990	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:12 PM
L573	1	17/110651	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:28 PM
L574	16	"20150011874"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:23 PM
L575	5	"20140288398"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:26 PM
L576	7	"20140120531"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 05:27 PM
L577	2	"20140135604"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:26 PM
L578	1	("10624616").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L579	7	"20090118628"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L580	1	("10687811").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:27 PM
L581	2	"20060287603"	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/09 02:41 PM
L582	1	18/494622	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:48 PM
L583	1	("11832944").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:49 PM
L584	21	"20100057004"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 05:51 PM
L585	24	"20080167577"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:00 PM
L586	1	("11963769").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:26 PM
L587	1	("11185266").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16

							06:26 PM
L588	1	("10143412").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:27 PM
L589	1	("10010282").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:28 PM
L590	122	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/09/16 06:52 PM
L591	25	590 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container) AND (blood near5 impermeable)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 06:54 PM
L592	50925	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/09/16 07:03 PM
L593	5094	592 AND @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/16 07:03 PM
L594	1015	593 AND ((blood OR fluid$4 OR urine) near5(sequest$5 OR flush$4 OR optimiz$5 OR flash$4 OR diver$5 OR bypass$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/16 07:04 PM
L595	6	594 AND (blood near5 (filter OR impermeabl$4 OR membrane)) WITH (facilitat$4 OR caus$4) near5 (withdraw$4 OR draw$4 OR sampl$4 OR collect$4)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:06 PM
L596	0	594 AND (blood near5 (filter OR impermeabl$4 OR membrane)) WITH (facilitat$4 near5 (withdraw$4 OR draw$4 OR sampl$4 OR	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:07 PM

		collect$4))					
L597	2	594 AND (blood near5 (filter OR impermeabl$4 OR membrane)) SAME (facilitat$4 near5 (withdraw$4 OR draw$4 OR sampl$4 OR collect$4))	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:08 PM
L598	66	593 AND (flow$4 OR control$4 OR divert$4 OR mechanism OR valve) near5 (chamber OR reservoir OR container) AND (blood near5 impermeable)	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:20 PM
L599	0	18/783088	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/16 07:35 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N94	1	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:15 PM
N112	3	(port and sequest$5 and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:39 PM
N248	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N249	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow$4 and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N250	495	(blood and fluid$4 and allow$4 and initial$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N251	107	(blood and fluid$4 and allow$4 and initial$4 and subsequent$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N283	9	((blood or fluid$4) and sequestrat$4 and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N284	530	((blood or fluid$4) and chamber and sampl$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM

		and vent$4 and air$4).clm.					
N285	84	((blood or fluid$4) and chamber and cap and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:32 PM
N365	6	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:49 PM
N366	9	(blood AND fluid$4 AND inlet AND outlet AND junct$4 AND inhibit$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:31 PM
N367	84	((blood OR fluid$4) AND chamber AND sampl$4 AND junction AND (inhibit$4 OR prevent$4)).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/11/16 05:36 PM
N368	25	(blood AND chamber AND sampl$4 AND junction AND inlet AND outlet AND port AND first).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:48 PM
N369	4	(blood AND chamber AND sampl$4 AND junction AND inlet AND outlet AND port AND first AND hous$4 AND subsequent).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:49 PM
N370	64902	"465" AND housing	(US-PGPUB; USPAT)	OR	ON	ON	2023/04/11 04:50 PM
N371	6	(inlet AND outlet AND junct$4 AND channel AND sampl$4 AND fluid$4 AND vent AND air AND permeab$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:51 PM
N372	167	(inlet AND outlet AND junct$4 AND channel AND sampl$4 AND fluid$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:52 PM
N373	23	(inlet AND outlet AND junct$4 AND channel AND sampl$4 AND fluid$4 AND bypass$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/07/05 05:53 PM
N374	33	(inlet AND outlet AND chamber AND blood AND sampl$4 AND bypass).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:35 PM
N375	18	(inlet AND outlet AND chamber AND blood	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/31 02:36 PM

		AND sampl$4 AND bypass AND air AND permeable).clm.					
N376	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl$4 AND bypass AND air AND permeable AND junct$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:24 PM
N377	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl$4 AND bypass AND air AND permeable AND junct$4 AND channel).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:25 PM
N378	14	(inlet AND outlet AND chamber AND (blood OR fluid OR urine) AND sampl$4 AND bypass AND air AND permeable AND junct$4 AND channel AND vent).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/01/08 04:25 PM

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18783088
Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580418_KUR2C06US

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PC 6.1.24

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783088
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580418_KUR2C06US

	1	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
	2	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
	3	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
	4	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
	5	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
	6	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	7	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
	8	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
	9	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
	10	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐
	11	Office Action (Non-Final Rejection) mailed 04/16/2024 for Application No. 16838017, pages 1-19.	☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783088
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580418_KUR2C06US

	12	Second Office Action dated 04/28/2024 for CN Application No. 202080000666.0, pages 1-28.	☐
	13	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	14	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	15	European Patent Office, Examination Report for European Patent Application 21818838.1, dated April 22, 2024, pages 1-11.	☐
	16	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐
	17	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	☐

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	09/16/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783088
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580418_KUR2C06US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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Tue Sep 17 14:00:06 EDT 2024

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Application	Document	Mailroom Date	Attorney Docket No.
18783088	CTNF	09/17/2024	069366-0580418_KUR2C06US
18783088	892	09/17/2024	069366-0580418_KUR2C06US
18783088	1449	09/17/2024	069366-0580418_KUR2C06US
18783088	1449	09/17/2024	069366-0580418_KUR2C06US
18783088	1449	09/17/2024	069366-0580418_KUR2C06US

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/783,088	**09/25/2024 09:41:32 PM Z ET**	**069366-0580418_KUR2C06US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	2051	FILED BY	Trent Tercenio
PATENT CENTER #	67326575	FILING DATE	07/24/2024
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 8

DOCUMENT		PAGES	DESCRIPTION	SIZE (KB)
069366-0580418_KUR2C06US-Response-to-Non-Final-Office-Action-rcvd-17SEP2024-4874-9518-6150-v1.pdf		9	-	140 KB
069366-0580418_KUR2C06US-Response-to-Non-Final-Office-Action-rcvd-17SEP2024-4874-9518-6150-v1-A....pdf	(1-1)	1	Amendment/Request for Reconsideration-After Non-Final Rejection	94 KB
069366-0580418_KUR2C06US-Response-to-Non-Final-	(2-6)	5	Claims	124 KB

Office-Action-rcvd-17SEP2024-4874-9518-6150-v1-CLM.pdf				
069366-0580418_KUR2C06US-Response-to-Non-Final-Office-Action-rcvd-17SEP2024-4874-9518-6150-v1-REM.pdf	(7-9)	3	Applicant Arguments/Remarks Made in an Amendment	100 KB
069366-0580418_KUR2C06US_Transmittal-Letter.pdf		1	Transmittal Letter	493 KB
069366-0580418_KUR2C06US_PTO_IDS-Form.pdf		4	Information Disclosure Statement (IDS) Form (SB08)	1272 KB
069366-0580418_KUR2C06US-NPL-002.pdf		50	Non Patent Literature	3306 KB
069366-0580418_KUR2C06US-NPL-001.pdf		62	Non Patent Literature	3562 KB
069366-0580418_KUR2C06US-NPL-003.pdf		73	Non Patent Literature	4530 KB

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DOCUMENT	MESSAGE DIGEST(SHA-512)
069366-0580418_KUR2C06US-Response-to-Non-Final-Office-Action-rcvd-17SEP2024-4874-9518-6150-v1.pdf	9D76EFE733A9406719EE4E4AED578276E29D2F35E5CB0F24583A7CB5F2862536C20E9D143EC3D89E8C8B22AB87F317C3B76F1EAFF23D9D9B42655AB9917D6E5A
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9518-6150-v1-CLM.pdf	
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069366-0580418_KUR2C06US_PTO_IDS-Form.pdf	022828611CF6F97EAAC04971B9B26B806E02AB44416EC35DE649B4842574568D28A27363175A5C2D92A6E95E727E1DC815CD0B7D136DF78AE7BDF01392133119
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069366-0580418_KUR2C06US-NPL-001.pdf	DBC4BFCA135CF575267F942413789F9095A4AAA652053FC8877E140BFE0216587BFC67846BB824B8C9D98A2DD2644EC02C8F901068A0E770302791974FC64588
069366-0580418_KUR2C06US-NPL-003.pdf	168A56A7A06C6D112C1FF2E37985B2142A36AF4E973CA63EC5D2E5A854272E847E165ADF7F6A25D8E5F60BA05363C817ABDF70C132DB78D2412C99AA1BD94B54

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/730,118	04/26/2022	Bobby E. ROGERS	069366-0572186_KUR3C01US	1667

27500 7590 09/23/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
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EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
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NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 17/730,118	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

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Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 4/26/2022.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 4/26/2022 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as

otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No claim elements are interpreted under 112(f).

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the junction of Claim 1 (referred to element 3007 in the specification 00160, which is not shown), the vent of Claim 1 (referred to as element 3010 in the spec 00161, which is not shown), and the air vent (Claim 1) must be shown with reference numbers in the claimed embodiment of Figure 30 or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or

"New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "3012" has been used to designate both fulcrum (0166 – published spec) and semi permeable barrier (0166 – published spec). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "3017" and "2\3008" have both been used to designate "the seal" (0166 – published spec), while "3008" has also been used to designate the sequestration chamber (0166 – published spec). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement

Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 1 is objected to because of the following informalities: "insludes" should be "includes."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

The recitation of "and includes one or more air vents" is indefinite because it is unclear if the air vents are part of the wall or the air permeable blood barrier. It is assumed the air vents are part of the wall, however, clarification is requested.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to

examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-5, or 7, 9, 10, 11, 12 of U.S. Patent No. 10827964 in view of Eldridge et al (US Pat No. 4207870).

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a blood sequestration device comprising; an inlet port; an outlet port; a sequestration chamber connected with the inlet port, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents (aperture in claim 3, 10 of Patent), the vent further including a cap that at least partially covers the wall and a one-way seal (flexible sheet, plug in claim 3, 10 of Patent)

abutting (claim 3, 12 of Patent) the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port, and a distal end connected with the outlet port; the sequestration chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

However, the patent doesn't expressly disclose the sequestration chamber connected to the inlet port via a junction. Eldridge et al teach that it is well-known in the art to provide an analogous blood sequestration device comprising inlet port (in hub 10 where cannula 14 is connected Col.2: 50-55), outlet port (cannula 18 in hub 12, Col.2: 50-55), sequestration chamber (28 and 30, Col.2: 63-65), the sequestration chamber connected to the inlet port via a junction (valve 20, Col.2: 57-6), and proximal end of sampling channel (32, Col.3: 52-54) connected to the inlet port via the junction, best seen in Figure 1 and 3, as an effective manner of connecting the inlet port to the sequestration chamber for controlled blood flow in the desired direction. Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the invention of the Patent such that the sequestration chamber is connected to the inlet port via a junction as taught by Eldridge, to provide an effective manner of connecting the two for controlled blood flow in the desired direction.

Claim 1 is rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 8, or 15 of U.S. Patent No. 11311219 (Parent case of instant application) in view of Fischel (US Pub No. 20110306899).

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a blood sequestration device comprising; an inlet port; an outlet port; a sequestration chamber connected with the inlet port via the junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port; the sequestration chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

However, the Patent does not disclose one or more air vents. Fischel teach that it is well-known in the art to provide an analogous blood collection device comprising both an air permeable blood barrier 160 (0043 – "member 160 may be constructed out of any material which is capable of substantially preventing blood from passing through it while permitting air to vent through it") as well as one or more air vents 336 that leads to ambient, best seen in Figure 16, as an effective configuration for the desired blood flow

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/730,118	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20110306899-A1	2011-12-15	BROWN; LEROY R.	A61B5/150572	600/581
	B					
	C					
	D					
	E					
	F					
	G					
	H					
	I					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
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	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in YYYY-MM-DD format are publication dates. Classifications may be US or foreign.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17730118
Filing Date	2022-04-26
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572186_KUR3C01US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

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	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572186_KUR3C01US

	1	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	☐
	2	European Patent Office; Communication pursuant to Article 94(3) EPC, dated Oct. 31, 2018; 11 pages.	☐
	3	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	☐
	4	Japanese Patent Office, Notice of Reasons for Rejection dated Jun. 15, 2021, Application No. JP 2019-534792, 6 pages.	☐
	5	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application No. JP2018-523384, dated Jul. 23, 2019, 5 pages.	☐

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EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/17/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17730118
	Filing Date	2022-04-26
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572186_KUR3C01US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

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Filing Date	2022-04-26
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572186_KUR3C01US

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17730118
	Filing Date	2022-04-26
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572186_KUR3C01US

	1	BD Diagnostics, "Venous Blood Collection, BD Vacutainer Passive Shielding Blood Collection Needle " literature (2005) 2 pages.	
	2	Barnard, Dorothy R., et al. "Fibronectin (cold insoluble globulin) in the neonate," The Journal of Pediatrics, Vol. 102, Issue 3, March 1983, Pages 453-455.	
	3	Mayer, G.A. "A Method for the Reliable Determination of Clotting Time in Whole Blood," Canadian Medical Association Journal, June 15, 1955, Vol. 72, Pages 927-929.	
	4	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	
	5	Pall Medical, "Leukotrap Filtration Systems for Whole Blood Derived Platelets, Leukotrap RC PL and Leukotrap PL Systems" literature, (2005) 8 pages.	
	6	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, Vol. 39, No. 3., pp. 321-323, March 1963.	
	7	Sheppard, et al., Bacterial Contamination of Platelets for Transfusion: Recent Advances and Issues, LABMEDICINE, Vol. 36, No. 12, Dec. 2005 ("Sheppard 2005").	

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Examiner Signature	/H Q NGUYEN/	Date Considered	09/17/2024

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	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572186_KUR3C01US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-17
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	17730118
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First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572186_KUR3C01US

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	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572186_KUR3C01US

	1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

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Examiner Signature	/H Q NGUYEN/	Date Considered	09/17/2024

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	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572186_KUR3C01US

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

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☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6126643		2000-10-03	VAILLANCOUERT VINCENT L	
	2	9764891		2017-09-19	AVILES VICTOR M	
	3	5147329		1992-09-15	BRANNON JAMES K	
	4	5518005		1996-05-21	BRANNON JAMES K	
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	1	20150314105		2015-11-05	GASPARYAN LEVON	

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	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572186_KUR3C01US

	2	20150359473		2015-12-17	GARRETT CHAD	
	3	20160262677		2016-09-15	EBETSBERGER FRANZ	
	4	20160325085		2016-11-10	CHELAK TODD	
	5	20070031283		2007-02-08	DAVIS CHARLES Q	
	6	20190365303		2019-12-05	BULLINGTON GREGORY J	
	7	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
	8	20190175087		2019-06-13	BULLINGTON GREGORY J	
	9	20210145336		2021-05-20	ROGERS BOBBY E	
	10	20060009713		2006-01-12	FLAHERTY PATRICE	

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	1	S5643474	JP		1981-10-12			☐
	2	1996005875	WO		1996-02-29	BAXTER INT		☒
	3	104107054	CN		2014-10-22	BECTON DICKINSON CO		☒
	4	104981203	CN		2015-10-14	MAGNOLIA MEDICAL TECHNOLOGIES INC		☒
	5	1717280	CN		2006-01-04	SECR DEFENCE		☒
	6	2015150742	WO		2015-10-08	UNIV HULL		☒

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	1	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	2	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
	3	Notice of Allowance mailed 09-14-2023; Attorney Docket No. 069366-0574152_KUR2D02IL. 90 pages.	☐

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	4	Office Action (Non-Final Rejection) dated 10/04/2023 for US App. No. 17538990 (pages 1-47)	☐
	5	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	6	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
	7	Notice of Allowance mailed 01-17-2024; Attorney Docket No. 069366-0572201_KUR2C03US. 16 pages.	☐
	8	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐
	9	Office Action (Non-Final Rejection) dated 01/25/2024 for IL App. 302893 (pages 1-3).	☐
	10	Office Action (Non-Final Rejection) dated 04/25/2023 for US App. 16838017 (pages 1-20).	☐
	11	Office Action (Final Rejection) dated 01/29/2024 for US App. 16838017 (pages 1-44).	☐
	12	"Membrane Definition & Meaning," Merriam-Webster, Merriam-Webster, 22 Apr. 2009, www.merriam-webster.com/ dictionary/ membrane. (Year: 2009).	☐
	13	Office Action (Advisory Action) dated 02/09/2024 for US App. 16838017 (pages 1-6).	☐
	14	Office Action (Non-Final Rejection) dated 04/16/2024 for US App. 16838017 (pages 1-19).	☐

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	15	Office Action (Non-Final Rejection) dated 05/21/2024 for IL App. 286812 (pages 1-3).	☐
	16	First Office Action (Non-Final Rejection) dated 01/16/2024 for JP App. 2021-558648 (pages 1-6).	☐
	17	First Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. 202080000666.0 (pages 1-11).	☐
	18	Second Office Action (Non-Final Rejection dated 04/28/2024 for CN App. 202080000666.0 (pages 1-11).	☐
	19	European Patent Office, Extended European Search Report for European Patent Application 21818838.1-1122, dated April 22, 2024, 11 pages.	☐
	20	Australian Patent Office, Examination Report No. 1 for for Australian Patent Application 2021202622, dated March 18, 2022, 3 pages.	☐
	21	European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated July 26, 2023, pages 1-8.	☐
	22	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
	23	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐
	24	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
	25	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐

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	Attorney Docket Number	069366-0572186_KUR3C01US

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	Filing Date	2022-04-26
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572186_KUR3C01US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572186_KUR3C01US

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2]	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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	2	2009131273A	JP		2009-06-18	CSL BEHRING GMBH		☒
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That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-17
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17730118
Filing Date	2022-04-26
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572186_KUR3C01US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3848581		1974-11-19	CINQUALBRE P	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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FOREIGN PATENT DOCUMENTS Remove

Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	S5825146	JP		1983-02-15	BECTON DICKINSON CO		☒

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

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	1		☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/17/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572186_KUR3C01US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-23
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

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Application Number	17730118
Filing Date	2022-04-26
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572186_KUR3C01US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4416291		1983-11-22	KAUFMAN JOSEPH	
	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
	7	11660030		2023-05-30	BULLINGTON GREGORY J	
	8	11259727		2022-03-01	BULLINGTON GREGORY J	

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	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
	12	11612340		2023-03-28	BULLINGTON GREGORY J	
	13	11234626		2022-02-01	BULLINGTON GREGORY J	
	14	10624977		2020-04-21	BULLINGTON GREGORY J	
	15	11653863		2023-05-23	BULLINGTON GREGORY J	
	16	11419531		2022-08-23	BULLINGTON GREGORY J	
	17	11786155		2023-10-17	BULLINGTON GREGORY J	
	18	11789017		2023-10-17	BULLINGTON GREGORY J	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
	2	20220151527		2022-05-19	BULLINGTON GREGORY J	
	3	20200289039		2020-09-17	BULLINGTON GREGORY J	
	4	20210275068		2021-09-09	MIAZGA JAY M	
	5	20220304664		2022-09-29	HAMMER JEREMY	
	6	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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	Attorney Docket Number	069366-0572186_KUR3C01US

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	2	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/17/2024

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	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
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	Attorney Docket Number	069366-0572186_KUR3C01US

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☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-02-06
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18783088
Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	May A. Abouelela
Attorney Docket Number	069366-0580418_KUR2C06US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4312362		1982-01-26	KAUFMAN JOSEPH	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140163419		2014-06-12	BULLINGTON GREGORY J	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

PC 6.1.24

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783088
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	May A. Abouelela
	Attorney Docket Number	069366-0580418_KUR2C06US

	1	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	2	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
	3	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PC 6.1.24

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	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	May A. Abouelela
	Attorney Docket Number	069366-0580418_KUR2C06US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-09-25
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

PC 6.1.24

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 09/17/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/17/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	**Application No.** 17/893,079	**Applicant(s)** ROGERS et al.	
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (FITF) Status** Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 01/19/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-7 and 32-41 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-7 and 32-41 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 8/22/02022 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/19/2024 has been entered.

Claims 1-4, 6-7, and 32-41 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "junction" in **Claims 3-4 and 40-41** must be shown *with element numbers* or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element

(also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under

35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 40-41 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims recite a junction connecting the inlet port, sampling channel, and the chamber. However, as the instant invention appears to be drawn to the embodiment in Figure 24 and said junction has not been identified in Figure 24 per the drawing objection above, it is unclear that applicant has proper support for the embodiment of Figure 24 with the moving part having a first and second position along with said junction as claimed. If support exists for said junction, applicant is requested to point out portions of the disclosure showing said support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-4, 6-7, 32, 34-38, and 40-41 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claim 1, Percarpio discloses a device comprising:

an inlet port (corresponding to location of needle 22) for receiving a blood sample, best seen in Figure 3 (Col.2: 58-Col.3: 23);

an outlet port 42, 44 (central passageway, opening -- Col.2: 58-Col.3: 23) – Figure 3;

a chamber (one channel) 92 connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample ("by capturing the blood within the indicator area including channels 92, there is no danger of contamination of blood being collected into chamber 32 and ultimately into an evacuated container through the passageway interconnected with rear needle 50" – Col.4: 16-39) – Figure 3,

the chamber including a material 90 that is air permeable (due to vents) and blood impermeable ("film of water expansible material 90… Three spaced channels 92 are formed in the film to provide air passageways for facilitating venting of the assembly and flow of blood into the indicator area where film 90 is located. The number of channels is a matter of choice. Thereafter, expansion of the film due to contact with the liquid closes channels 92 and locks the blood into the area of the location of the film" – Col.4: 16-39) – Figure 3;

a sampling channel 28 (extends through valve 78) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through

the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4; and

a housing (defined by hub 26 and adapter 40) that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 3.

2. (Previously Presented) The device in accordance with claim 1, wherein the material is configured to seal upon contact with the first portion of the blood sample (Col.4: 16-39; Col.5: 1-47).

3. (Previously Presented) The device in accordance with claim 1, further comprising a junction 32 connecting the inlet port (corresponding to location of needle 22) and the sampling channel 28 and the chamber 92, best seen in Figure 3.

4. (Previously Presented) The device in accordance with claim 3, wherein the junction 32 is configured to convey the subsequent portion of the blood sample to the outlet port 42, 44 while bypassing the chamber 92 (Col.4: 16-39; Col.5: 1-47).

6. (Previously Presented) The device in accordance with claim 1, wherein the device is configured with a moving part – 78 check valve with flaps 82, 84 – that is movable from a first position (closed) to a second position (open) to allow blood to bypass the chamber 92 and go through the sampling channel 28 – "The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through

the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes" (Col.5: 1-47), best seen in Figure 2 and 4.

7. (Previously Presented) The device in accordance with claim 6, the moving part 78, 82, 84 further configured to move from the first position to the second position after the first portion of blood flows into the chamber 92 – "tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes" (Col.5: 1-47).

32. (Previously Presented) The device in accordance with claim 6, wherein the moving part 78, 82, 84 is an inner chamber housing, best seen in Figure 3-4.

In regard to Claim 34, Percarpio discloses a device comprising:

an inlet port (corresponding to location of needle 22) for receiving a blood sample, best seen in Figure 3 (Col.2: 58-Col.3: 23);

an outlet port 42, 44 (central passageway, opening -- Col.2: 58-Col.3: 23) – Figure 3;

a chamber (one channel) 92 connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample ("by capturing the blood within the indicator area including channels 92, there is no danger of contamination of blood being

collected into chamber 32 and ultimately into an evacuated container through the passageway interconnected with rear needle 50" – Col.4: 16-39) – Figure 3,

the chamber including an air permeable blood barrier due to vents ("Three spaced channels 92 are formed in the film to provide air passageways for facilitating venting of the assembly and flow of blood into the indicator area where film 90 is located. The number of channels is a matter of choice – Col.4: 16-39) – Figure 3;

a sampling channel 28 (extends through valve 78) connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port – after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4; and

a housing (defined by hub 26 and adapter 40) that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 3.

35. (Previously Presented) The device in accordance with claim 34, wherein the air permeable blood barrier is configured to seal upon contact with the first portion of the blood sample (Col.4: 16-39; Col.5: 1-47).

36. (Previously Presented) The device in accordance with claim 34, wherein the device is configured with a moving part – 78 check valve with flaps 82, 84 – that is movable from a first position (closed) to a second position (open) to allow blood to bypass the chamber 92 and go through the sampling channel 28 – "The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes" (Col.5: 1-47), best seen in Figure 2 and 4.

37. (Previously Presented) The device in accordance with claim 36, the moving part 78, 82, 84 further configured to move from the first position to the second position after the first portion of blood flows into the chamber 92 -- after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4.

38. (Previously Presented) The device in accordance with claim 36, wherein the moving part 78, 82, 84 is an inner chamber housing, best seen in Figure 3-4.

40. (Previously Presented) The device in accordance with claim 34, further comprising a junction 32 connecting the inlet port (corresponding to location of needle 22) and the sampling channel 28 and the chamber 92, best seen in Figure 3.

41. (Previously Presented) The device in accordance with claim 40, wherein the junction 32 is configured to convey the subsequent portion of the blood sample to the outlet port 42, 44 while bypassing the chamber 92, best seen in Figure 3-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 33 and 39 is/are rejected under 35 U.S.C. 103 as being unpatentable over Percarpio in view of Kaufman (US Pat No. 4312362).

Percarpio discloses the invention above but do not expressly disclose the device further comprising a locking mechanism configured to maintain the moving part in the first until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Kaufman teach that it is well-known in the art to provide a blood sampling device comprising a locking mechanism that maintain the moving part 26 in the first position (so that hole 48 is free) which allows air to escape (similar to in Percarpio), and then providing force to overcome the locking mechanism to enable movement of the moving part to the second position (to free hole 49), which enables collection of the blood into evacuated tube 16 when said tube is connected also similarly to Percarpio, best seen in Figure 2 and 7 (Col.6: 44-Col.7: 50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention of filing to modify Percarpio such that the device further comprising a locking

mechanism configured to maintain the moving part in the first until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position as taught by Kaufman to effectively maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the

examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood

sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air

permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 3, and 20-21 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an

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Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 and 8-9 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Response to Arguments

Applicant's arguments with respect to claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

Regarding the Drawing objections and 112(a) rejection, it is submitted that the mention of "a pathway" to the sampling channel 2422 in paragraph 0142 does not necessarily indicate a junction as recited in claims 3-4 and 40-41. As previously noted, Figure 24 does not clearly show said structure, the specification does not describe said structure in relation to said embodiment, and the specific reference to a junction in Figure 17A is not relevant as said figure does not apply to the instant embodiment. Therefore, said objections and rejections are maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/893,079	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	Page 1 of 1

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*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-4312362-A	1982-01-26	Kaufman; Joseph	A61B5/15003	600/584
	B					
	C					
	D					
	E					
	F					
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*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Country	Name	CPC Classification
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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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First Named Inventor	Gino KANG
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572192_KUR3C02US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	3848581		1974-11-19	CINQUALBRE P	

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	1	S5825146	JP		1983-02-15	BECTON DICKINSON CO		☒

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☒ A certification statement is not submitted herewith.

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A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-23
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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	1	European Patent Office; Communication pursuant to Article 94(3) EPC, dated Oct. 31, 2018; 11 pages.	☐
	2	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	☐
	3	Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.	☐
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	6	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application No. JP2018-523384, dated Jul. 23, 2019, 5 pages.	☐

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	2	9764891		2017-09-19	AVILES VICTOR M	
	3	5147329		1992-09-15	BRANNON JAMES K	
	4	5518005		1996-05-21	BRANNON JAMES K	
	5	62845767		2019-05-09	BREWER MICHAEL	

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	1	20150314105		2015-11-05	GASPARYAN LEVON	

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	2	20150359473		2015-12-17	GARRETT CHAD	
	3	20160262677		2016-09-15	EBETSBERGER FRANZ	
	4	20160325085		2016-11-10	CHELAK TODD	
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	7	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
	8	20190175087		2019-06-13	BULLINGTON GREGORY J	
	9	20210145336		2021-05-20	ROGERS BOBBY E	
	10	20060009713		2006-01-12	FLAHERTY PATRICE	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17893079
	Filing Date	2022-08-22
	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

	1	S5643474	JP		1981-10-12	TORAY INDUSTRIES		☐
	2	1996005875	WO		1996-02-29	BAXTER INT		☒
	3	104107054	CN		2014-10-22	BECTON DICKINSON CO		☒
	4	104981203	CN		2015-10-14	MAGNOLIA MEDICAL TECHNOLOGIES INC		☒
	5	1717280	CN		2006-01-04	SECR DEFENCE		☒
	6	2015150742	WO		2015-10-08	UNIV HULL		☒

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	1	Office Action (Non-Final Rejection) dated 04/25/2023 for US App. 16838017 (pages 1-20).	☐
	2	Office Action (Final Rejection) dated 01/29/2024 for US App. 16838017 (pages 1-44).	☐
	3	"Membrane Definition & Meaning," Merriam-Webster, Merriam-Webster, 22 Apr. 2009, www.merriam-webster.com/dictionary/ membrane. (Year: 2009).	☐

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	4	Office Action (Advisory Action) dated 02/09/2024 for US App. 16838017 (pages 1-6).	☐
	5	Office Action (Non-Final Rejection) dated 04/16/2024 for US App. 16838017 (pages 1-19).	☐
	6	Office Action (Non-Final Rejection) dated 05/21/2024 for IL App. 286812 (pages 1-3).	☐
	7	First Office Action (Non-Final Rejection) dated 01/16/2024 for JP App. 2021-558648 (pages 1-6).	☐
	8	First Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. 202080000666.0 (pages 1-11).	☐
	9	Second Office Action (Non-Final Rejection dated 04/28/2024 for CN App. 202080000666.0 (pages 1-11).	☐
	10	European Patent Office, Extended European Search Report for European Patent Application 21818838.1-1122, dated April 22, 2024, 11 pages.	☐
	11	Australian Patent Office, Examination Report No. 1 for for Australian Patent Application 2021202622, dated March 18, 2022, 3 pages.	☐
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	13	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
	14	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐

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	15	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
	16	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
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	20	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐
	21	International Search Report and Written Opinion dated 19 March 2020 for PCT application no. PCT/US2020/023617. pages.	☐
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	23	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
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	26	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
	27	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
	28	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
	29	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐
	30	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐
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	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

	37	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
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	46	Notice of Allowance mailed 09-14-2023; Attorney Docket No. 069366-0574152_KUR2D02IL. 90 pages.	☐
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	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

	48	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	49	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	☐
	50	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	☐

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Examiner Signature	/H Q NGUYEN/	Date Considered	09/06/2024

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	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

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☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	17893079
Filing Date	2022-08-22
First Named Inventor	Gino KANG
Art Unit	3791
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Attorney Docket Number	069366-0572192_KUR3C02US

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	1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

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EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/06/2024

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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CERTIFICATION STATEMENT

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

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Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	17893079
	Filing Date	2022-08-22
	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4416291		1983-11-22	KAUFMAN JOSEPH	
	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
	7	11660030		2023-05-30	BULLINGTON GREGORY J	
	8	11259727		2022-03-01	BULLINGTON GREGORY J	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17893079
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	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
	12	11612340		2023-03-28	BULLINGTON GREGORY J	
	13	11234626		2022-02-01	BULLINGTON GREGORY J	
	14	10624977		2020-04-21	BULLINGTON GREGORY J	
	15	11653863		2023-05-23	BULLINGTON GREGORY J	
	16	11419531		2022-08-23	BULLINGTON GREGORY J	
	17	11786155		2023-10-17	BULLINGTON GREGORY J	
	18	11789017		2023-10-17	BULLINGTON GREGORY J	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
	2	20220151527		2022-05-19	BULLINGTON GREGORY J	
	3	20200289039		2020-09-17	BULLINGTON GREGORY J	
	4	20210275068		2021-09-09	MIAZGA JAY M	
	5	20220304664		2022-09-29	HAMMER JEREMY	
	6	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	2	Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. No. 202080000666.0 (pages 1-28).	☐

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EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/06/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17893079
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	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-01-19
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al.

Confirmation No: 2051

Application No.: 18/783,088

Art Unit: 3791

Filed: July 24, 2024

Examiner: May A. Abouelela

For: BLOOD SAMPLE OPTIMIZATION DEVICE

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NON-FINAL OFFICE ACTION

Dear Examiner Abouelela:

This reply is responsive to the Non-Final Office Action mailed September 17, 2024, in the above-referenced matter (hereinafter "the Office Action"). Reconsideration and allowance of the application is requested in view of the following:

Listing of Claims beginning on page 2.

Remarks beginning on page 7.

LISTING OF CLAIMS

This listing of claims replaces all prior versions of claims in the application:

1. (Currently Amended) A device comprising:

an inlet port for receiving a blood sample;

an outlet port;

a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device; ~~and~~

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port; and

a housing that defines the inlet port, the sampling channel, and the outlet port.

2. (Original) The device in accordance with claim 1, wherein a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

3. (Original) The device in accordance with claim 1, wherein a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port.

4. (Currently Amended) The device in accordance with claim 2, ~~further comprising a housing,~~ wherein the housing is separate from the blood impermeable membrane.

5. (Original) The device in accordance with claim 1, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber to contact a material that is blood impermeable.

6. (Original) The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel.

7. (Original) The device in accordance with claim 1, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber.

8. (Original) The device in accordance with claim 1, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood sample is in the chamber and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port.

9. (Original) The device in accordance with claim 6, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood sample is collected in the chamber.

10. (Cancelled)

11. (Currently Amended) The device in accordance with claim 1, further comprising a patient needle and [[a]] <u>the blood</u> sample collection device.

12. (Original) The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered.

13. (Original) The device in accordance with claim 1, wherein the chamber has a volume of less than 1.5 cubic centimeters.

14. (Currently Amended) A device comprising:

an inlet port for receiving blood;

an outlet port;

a chamber comprising a flexible material, the chamber connected with the inlet port and configured to collect a first portion of the blood when under a drawing force applied from the outlet port; ~~and~~

a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood to the outlet port; and

a housing that defines the inlet port, the sampling channel, and the outlet port.

15. (Original) The device in accordance with claim 14, wherein the flexible material is a blood impermeable membrane configured to facilitate the chamber collecting the first portion of the blood.

16. (Original) The device in accordance with claim 14, wherein the flexible material is a blood impermeable membrane causes the first portion of the blood to back up into the chamber following application of the drawing force applied from the outlet port.

17. (Currently Amended) The device in accordance with claim 15, ~~further comprising a housing,~~ wherein the housing is separate from the blood impermeable membrane.

18. (Original) The device in accordance with claim 14, wherein the device is configured such that, when the drawing force is applied at the outlet port, the first portion of the blood is drawn into the chamber to contact a material that is blood impermeable.

19. (Original) The device in accordance with claim 14, further comprising a valve configured to initially close off the sampling channel.

20. (Original) The device in accordance with claim 14, further comprising a valve configured to initially close off the sampling channel until the first portion of the blood is in the chamber.

21. (Original) The device in accordance with claim 14, further comprising a valve that is configured to initially close off the sampling channel until the first portion of the blood is in the chamber and is further configured such that, upon release, follow-on amounts of the blood will bypass the chamber and flow through the sampling channel toward the outlet port.

22. (Original) The device in accordance with claim 19, wherein the valve is configured to pinch, shunt, bend or otherwise close off the sampling channel before the first portion of the blood is collected in the chamber.

23. (Cancelled)

24. (Original) The device in accordance with claim 14, further comprising a patient needle and a sample collection device.

25. (Original) The device in accordance with claim 14, the chamber having a volume sufficient to collect the first portion of the blood that is more prone to contamination and also to minimize an amount of blood to be sequestered.

26. (Original) The device in accordance with claim 14, wherein the chamber has a volume of less than 1.5 cubic centimeters.

REMARKS

Claim Summary: Prior to this response, Claims 1-26 were pending. Claims 1, 4, 11, 14, and 17 are amended and Claims 10 and 23 are canceled. After entry of this response, Claims 1-9, 11-22, and 24-26 will be pending. No new matter is added with this amendment. Reconsideration and allowance of the current application are requested in light of the following remarks.

Summary of Rejections: The Office has objected to Claims 10-23. The Office rejects Claims 1, 6-9, 11, 12, 14, 19-22, 24 and 25 under 35 U.S.C. §102(a)(1) as allegedly being anticipated by Patton, et al. (U.S. 2008/145933), hereinafter "Patton;" rejects Claims 2-5 and 15-18 as allegedly being unpatentable under 35 U.S.C. §103 over Patton in view of Flaherty, et al. (U.S. 2006/0009713), hereinafter "Flaherty;" and rejects Claims 13 and 26 as allegedly being unpatentable under 35 U.S.C. §103 over Patton.

No Change in Scope of Claims: The Office is respectfully reminded that the scope of at least one claim has remained unchanged in this Response. If new grounds of rejection for an unchanged claim are presented in a subsequent action, per MPEP§706.07(a), that subsequent action cannot properly be made final.

Request for Interview: The present response is believed to be sufficient to overcome the pending rejections. However, if this paper is not deemed sufficient to result in a notice of allowance, or if any remaining issues can be more efficiently handled by telephone, the Examiner is respectfully requested to contact the undersigned by either phone or e-mail to schedule an interview at a mutually convenient time.

Claim objections

Claim 11 was objected to as allegedly containing informalities. Claim 11 has been amended to correspond with the blood sample collection device recited in Claim 1. As such, Applicant respectfully requests that the objection is withdrawn.

Allowable Subject Matter

The Office Action objects to Claims 10 and 23 as being dependent upon a rejected base claim but allowable if rewritten in independent form, including all the limitations of the base claim and any intervening claims.

With this response, independent Claims 1 and 14 are amended to incorporate the features of allowable Claims 10 and 23, respectively. Each of the additional pending claims depend from this allowable independent claims and thus the application is now in condition for allowance.

Applicant also wishes to reiterate that the instant response is intended to place the application in condition for allowance. **If there are any issues that prevent the next action from being a notice of allowance, Applicant respectfully requests that the Examiner contact the Applicant** to schedule an interview to address any outstanding issues prior to a subsequent office action.

Continuation application

Applicant believes that independent Claims 1 and 14, prior to the present amendment, were allowable over the cited art and is filing an additional Track 1 continuation application to continue pursuing those claims.

CONCLUSION

On the basis of the foregoing remarks and/or amendments, allowance of the pending claims is respectfully requested. It is believed that all the pending rejections have been addressed in this paper. However, failure to address a specific rejection, issue or comment, does not signify agreement with or concession of that rejection, issue or comment. In addition, because any arguments made above are not intended to be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper.

No additional fees are believed to be due, however the Commissioner is authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account 033975, Reference No. 069366-0580418_KUR2C06US. If there are any questions regarding this submission, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,
PILLSBURY WINTHROP SHAW PITTMAN LLP

Date: September 25, 2024 By: /Ben Hudson/
Benjamin F. Hudson, Ph.D.
Reg. No. 71,474

PO BOX 10500
McLean, Virginia 22102
Telephone: (858) 509-4000
Customer No. 27500

UNITED STATES
PATENT AND TRADEMARK OFFICE

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/783,088	**09/25/2024 09:41:32 PM Z ET**	**069366-0580418_KUR2C06US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	2051	FILED BY	Trent Tercenio
PATENT CENTER #	67326575	AUTHORIZED BY	Benjamin Hudson
CUSTOMER #	27500	FILING DATE	07/24/2024
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Bobby E. ROGERS

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 033975	**E20249OL41596003**	**Trent Tercenio**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2806	SUBMISSION OF AN INFORMATION DISCLOSURE STATEMENT	104.00	1	104.00
			TOTAL AMOUNT:	**$104.00**

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C.

371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,173	07/24/2024	Bobby E. ROGERS	069366-0580420_KUR3C03US	1561

27500 7590 09/24/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/24/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	**Application No.** 18/783,173	**Applicant(s)** ROGERS et al.	
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (FITF) Status** Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 7/24/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-30 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-30 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 7/24/2024 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, valve to close off the sampling channel along with the moving part that moves from a first position to a second position to allow travel to the sampling channel of **Claims 10-12 and 25-27** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the

applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term “means” or “step” or a term used as a substitute for “means” that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No claim elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-12 and 25-27 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 10-12 and 25-27 recite a valve to initially close off the sampling channel. This appears to be disclosed in the embodiment of Figure 23A-E. However, the independent claims recite an embodiment with a moving part configured to be movable from a first position to a

second position to allow the blood sample to flow to the sampling channel (and bypass the chamber), which appears disclosed in the embodiment Figure 24A-D.

However, the embodiment in Figure 23 does not disclose said moving part *in addition* to the valve to allow the bypass as claimed. Therefore, it appears that said claims improperly mix embodiments, which constitutes new matter. However, if an embodiment which contains both structures exists, applicant is requested to point out the portions of the specification disclosing such. Also see Drawing Objection above.

The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 12, 22, and 27 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

In regard to Claim 7 and 22, the recitation of blood impermeable membrane causes the first portion of the blood sample “to back up” into the chamber is indefinite because it is unclear what specific meaning or function this is meant to convey. In the rejection that follows it is assumed to be normal fluid flow. Clarification is requested.

In regard to Claim 12 and 27, the recitation of "otherwise close off the outlet" is indefinite because it is unclear what mechanisms are included in said limitation to close off the outlet, which are also supported by the disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-5, 13-20, and 28-30 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Bullington et al (US Pub No. 20140163419).

In regard to Claims 1 and 16, Bullington et al disclose a device comprising:

an inlet port 405 for receiving a blood sample, best seen in Figure 12 (0081, 0089);

an outlet port 475 (proximal end of lumen 475), best seen in Figure 13-15 (0085);

a chamber 480 connected with the inlet port, and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device 451, best seen in Figure 14 (0079, 0091-0092 – "a bodily-fluid is drawn through the port 405, the first lumen 432 defined by the flow control mechanism 430, and the first lumen 406 defined by the diverter 409 and into the fluid reservoir 480. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes and/or other external contaminants");

a sampling channel 433 connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port, best seen in Figure 15 (0095); and

a moving part 430, 431, 435 (flow control mechanism first member 431 controlled by member 435), moving part also defined by plunger 476 (0084 – Figure 13-15),

configured to be movable from a first position to a second position to allow the blood sample to flow to the sampling channel –

in the first position, moving member 435 rotates first member 431 such that lumen 433 (sampling channel) is fluidically isolated, due to lumen 432 of the flow control mechanism aligned with the inlet port 405, which leads through lumen 406 in diverter 409 and into chamber 480 – thus the inlet port 405 is in fluid communication with the chamber 480, best seen in Figure 14 (0081, 0092);

in the second position, moving member 435 rotates first member 431 such that lumen 433 is aligned with inlet port 405 such that "a desired amount of bodily-fluid is drawn through the port 405, the second lumen 433 of the flow control mechanism 430, the second lumen 407 of the diverter 409, and the lumen 475 [defining the outlet port] defined by the shunt tube 471 and into the second reservoir 490. Moreover, the bodily-fluid disposed within the second reservoir 490 is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the first reservoir 480," best seen in Figure 15 (0082, 0083, 0095, 0097) – thus creates a pathway from the inlet port 405 to the outlet port 475.

2, 17. The device in accordance with claim 1, wherein the first position allows the collection of the first portion of the blood sample in the chamber 480, best seen in Figure 14.

3, 18. The device in accordance with claim 1, wherein the moving part 430, 431, 435 is configured to move from the first position to the second position after the first portion of the blood sample flows into the chamber 480 – sample flow into the chamber 480 occurs first, best seen in Figure 14, followed by moving member 435 rotating first member 431 such that lumen 433 is aligned with inlet port 405 is aligned with the outlet port 475, into second reservoir 490, best seen in Figure 15 (0082, 0083, 0095, 0097).

4, 19. The device in accordance with claim 1, the device further comprising a locking mechanism 474 configured to maintain the moving part 476 in the first position (Figure 14) until the chamber 480 is filled with the first portion of the blood sample – protrusion 474 enables proximal movement of plunger 476 to create chamber 480 for the first portion of the blood sample, best seen in Figure 13-14 (0085, 0091, 0096).

5, 20. The device in accordance with claim 1, wherein the moving part 430, 431, 476 is an inner chamber housing, best seen in Figure 13-15.

13, 28. The device in accordance with claim 1, further comprising a patient needle – "a user can engage the transfer device 400 to couple the port 405 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle, a cannula assembly, a trocar (which in some cases is used to insert a catheter into a patient), or the like" (0089) and

a sample collection device – "with the desired amount of bodily-fluid disposed within the second fluid reservoir 490, the transfer device 400 can be removed from the portion of the patient and disposed above or in a container (e.g., a vile, a test tube, a petri dish, a culture medium, a test apparatus, or the like) such that a portion of the second amount of bodily-fluid can be tested" (0099).

14, 29. The device in accordance with claim 1, the chamber having a volume sufficient to collect the first portion of the blood sample that is more prone to contamination and also to minimize an amount of blood to be sequestered (0092).

15, 30. The device in accordance with claim 1, wherein the chamber 480 has a volume of less than 1.5 cubic centimeters, e.g. 0.1 mL (0094).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 6-12 and 21-27 is/are rejected under 35 U.S.C. 103 as being unpatentable over Bullington et al as applied to claim 1 above, and further in view of Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claims 6-9 and 21-24, Bullington et al disclose the invention above but do not expressly disclose a blood impermeable membrane is configured to facilitate the chamber collecting the first portion of the blood sample.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a

chamber to collect a first portion of the blood sample (indicator area), and a sampling channel 28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a housing 40, 56 separate from the blood impermeable membrane 90, best seen in Figure 3-4, as an effective configuration for the location of said blood impermeable membrane.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the of filing to modify Bullington et al to include a blood impermeable membrane causes the first portion of the blood sample to back up into the chamber following application of the drawing force applied from the outlet port as taught by Percarpio by enabling necessary venting of air from the device during the desired flow of blood such that, when the drawing force is applied at the outlet port, the first portion of the blood sample is drawn into the chamber in the manner taught by Bullington et al to contact a material that is blood impermeable to enable the venting of air, wherein the blood impermeable membrane is separate from the housing, as taught by Percarpio as an effective configuration for said blood impermeable membrane.

In regard to Claims 10-12 and 25-27, Bullington et al disclose the invention above but do not expressly disclose a valve configured to initially close off the sampling channel.

Percarpio teach that it is well-known in the art to provide an analogous blood sampling device comprising an inlet port 22 for receiving a blood sample, an outlet port 42, 44, a chamber to collect a first portion of the blood sample (indicator area), and a sampling channel

28 connecting the inlet and the outlet, including a blood impermeable membrane 90 to enable necessary venting of air for the desired flow of the blood first to the chamber before directing it to the outlet (Col.4: 16-39). Percarpio teach a valve 78 (check valve) that is configured to initially close off access to the outlet until the first portion of the blood sample is in the chamber, best seen in Figure 3, and is further configured such that, upon release, follow-on amounts of the blood sample will bypass the chamber and flow through the sampling channel toward the outlet port, best seen in Figure 4 (Col.3: 61-Col.4: 15, 64-Col.5: 47). Percarpio also teach the valve is configured to pinch, shunt, bend or otherwise close off the outlet before the first portion of the blood sample is collected in the chamber, best seen in Figure 3-4 (Col.3: 61-Col.4: 15, 64-Col.5: 47).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify Bullington et al to include a valve to pinch, shunt, bend or otherwise close off the outlet in the manner above as taught by Percarpio to effectively seal off the outlet before the blood is properly in the chamber of Bullington et al, wherein it would have been obvious to a skilled artisan to place the valve such that it closes off the sampling channel and not just the outlet, to effectively block the flow of blood upstream before it reaches the outlet, prior to being drawn into the chamber as taught by Bullington et al, as well as Percarpio.

Also see 112 rejection above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 18/783,173	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-20140163419-A1	2014-06-12	Bullington; Gregory J.	A61B5/153	600/575
	B					
	C					
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	E					
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18783173
Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580420_KUR3C03US

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	1	Meissner, George F. , et al., "The Standard Clotting Time, A Method Based on the Use of Whole Venous Blood in Capillary Tubes," The American Journal of Clinical Pathology, vol. 39, No. 3., pp. 321-323, Mar. 1963.	☐
	2	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	3	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	4	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐
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	Attorney Docket Number	069366-0580420_KUR3C03US

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	Attorney Docket Number	069366-0580420_KUR3C03US

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	30	Office Action (Final Rejection) dated 08/25/2023 for US Application No. 18113710 (pages 1-50).	☐
	31	European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated July 26, 2023, pages 1-8.	☐
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	33	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
	34	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐
	35	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
	36	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
	37	Advisory Action dated 09/29/2023 for US Application 17893079, pages 1-24.	☐
	38	European Patent Office, Examination Report for European Patent Application 22181212.6-1122, dated September 28, 2023, pages 1-5.	☐
	39	European Patent Office, Extended European Search Report for European Patent Application 20781928.5-1122 dated October 28, 2022, pages 1-10.	☐
	40	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐

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	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580420_KUR3C03US

	41	International Search Report and Written Opinion dated 19 March 2020 for PCT application no. PCT/US2020/023617. pages.	☐
	42	International Search Report and Written Opinion dated 28 September 2021 for PCT application no. PCT/ US2021/035294. 7 pages.	☐
	43	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
	44	Australian Patent Office, Australian Examination Report No. 1 for Application No. 2021120 622 dated March 18, 2022, 3 pages.	☐
	45	Notice of Allowance mailed 03-01-2023; Attorney Docket No. 069366-0572419_KUR2D01AU. 3 pages.	☐
	46	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
	47	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
	48	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
	49	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐
	50	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐

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	Attorney Docket Number	069366-0580420_KUR3C03US

EXAMINER SIGNATURE			
Examiner Signature	/H Q NGUYEN/	Date Considered	09/09/2024

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CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

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SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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Doc description: Information Disclosure Statement (IDS) Filed

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Application Number	18783173
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First Named Inventor	Bobby E. ROGERS
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Examiner Name	DOCKET CENTRAL
Attorney Docket Number	069366-0580420_KUR3C03US

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	1	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
	2	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
	3	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
	4	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
	5	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
	6	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	7	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
	8	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
	9	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
	10	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐
	11	Office Action (Non-Final Rejection) mailed 04/16/2024 for Application No. 16838017, pages 1-19.	☐

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	12	Second Office Action dated 04/28/2024 for CN Application No. 202080000666.0, pages 1-28.	☐
	13	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	14	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	15	European Patent Office, Examination Report for European Patent Application 21818838.1, dated April 22, 2024, pages 1-11.	☐
	16	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐
	17	Ziegler, R., et al. "Controlled Clinical Laboratory Comparison of Two Supplemented Aerobic and Anaerobic Media Used in Automated Blood Culture Systems to Detect Bloodstream Infections," Journal of Clinical Microbiology, Mar. 1998, p. 657-661.	☐
	18	Pall Medical, "Leukotrap Filtration Systems for Whole Blood Derived Platelets, Leukotrap RC PL and Leukotrap PL Systems" literature, (2005) 8 pages.	☐

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Examiner Signature	/H Q NGUYEN/	Date Considered	09/09/2024

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

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Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	5200325		1993-04-06	BLATT JOEL M	
	2	5432084		1995-07-11	BRUBAKER DANIEL B	
	3	5972294		1999-10-26	SMITH JOHN L	
	4	6187347		2001-02-13	PATTERSON JAMES A	
	5	6599474		2003-07-29	EVTODIENKO VLADIMIR	
	6	8197420		2012-06-12	PATTON RICHARD G	
	7	8535241		2013-09-17	BULLINGTON GREGORY	
	8	9060724		2015-06-23	BULLINGTON GREGORY J	

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	Art Unit	OPAP
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	Attorney Docket Number	069366-0580420_KUR3C03US

	9	9155495		2015-10-13	BULLINGTON GREGORY J	
	10	4412548		1983-11-01	HOCH LOUIS	
	11	5222502		1993-06-29	KUROSE KATSUTOSHI	
	12	5520193		1996-05-28	SUZUKI ISSEI	
	13	9022951		2015-05-05	BULLINGTON GREGORY	
	14	6569117		2003-05-27	ZIV DAVID	
	15	3741197		1973-06-26	SANZ M	
	16	8603009		2013-12-10	TAN ALVIN CHEE LEONG	
	17	4207870		1980-06-17	ELDRIDGE WILLIAM N	
	18	9877675		2018-01-30	BAID RISHI	
	19	4444203		1984-04-24	ENGELMAN ALLAN	

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	20	6398743		2002-06-04	HALSETH THOR R	
	21	9022950		2015-05-05	BULLINGTON GREGORY	
	22	4436098		1984-03-13	KAUFMAN JOSEPH	
	23	9138572		2015-09-22	ZEYTOONIAN PAUL	
	24	8568371		2013-10-29	SIOPES WILLIAM	
	25	8540663		2013-09-24	DAVEY CHRISTOPHER T	
	26	8523826		2013-09-03	LAYTON JR RUSSELL K	
	27	4057050		1977-11-08	SARSTEDT WALTER	
	28	8864684		2014-10-21	BULLINGTON GREGORY J	
	29	5749857		1998-05-12	CUPPY MICHAEL J	
	30	9204864		2015-12-08	BULLINGTON GREGORY J	

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	31	3874367		1975-04-01	AYRES WALDEMAR A	
	32	3886930		1975-06-03	RYAN GEORGE R	
	33	4106497		1978-08-15	PERCARPIO EDWARD P	
	34	4154229		1979-05-15	NUGENT EDWARD L	
	35	4980297		1990-12-25	HAYNES JOHN L	
	36	9820682		2017-11-21	ROGERS BOBBY E	
	37	10010282		2018-07-03	ROGERS BOBBY E	
	38	10143412		2018-12-04	ROGERS BOBBY E	
	39	11185266		2021-11-30	ROGERS BOBBY E	
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	Attorney Docket Number	069366-0580420_KUR3C03US

	42	3817240		1974-06-18	AYRES W	
	43	3648684		1972-03-14	BARNWELL CLEORA W	
	44	4056101		1977-11-01	GEISSLER ULRICH C	
	45	4416290		1983-11-22	LUTKOWSKI LAWRENCE	
	46	8070725		2011-12-06	CHRISTENSEN KELLY D	
	47	4349035		1982-09-14	THOMAS JOSEPH J	
	48	4813433		1989-03-21	DOWNEY JOHN M	
	49	5401262		1995-03-28	KARWOSKI THEODORE	
	50	3859998		1975-01-14	THOMAS JOSEPH JOHN	
	51	4373535		1983-02-15	MARTELL MICHAEL D	
	52	4690154		1987-09-01	WOODFORD TIMOTHY	

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	53	5097842		1992-03-24	BONN GINA B	
	54	5865803		1999-02-02	MAJOR MIKLOS	
	55	5873841		1999-02-23	BRANNON JAMES K	
	56	6013037		2000-01-11	BRANNON JAMES K	
	57	6913580		2005-07-05	STONE BENJAMIN CURTIS	
	58	11213232		2022-01-04	IVOSEVIC MILAN	
	59	6626884		2003-09-30	DILLON JAGMOHANBIR SINGH	
	60	4904240		1990-02-27	HOOVER ROCKLIN L	
	61	4673386		1987-06-16	GORDON MARK G	
	62	7461671		2008-12-09	EHWALD RUDOLF	
	63	6506182		2003-01-14	ESTABROOK BRIAN K	

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	64	3382865		1968-05-14	WORRALL JR ASHTON L	
	65	3848579		1974-11-19	VILLA REAL A	
	66	6106509		2000-08-22	LOUBSER PAUL G	
	67	3494352		1970-02-10	RUSSO RONALD D	
	68	6224561		2001-05-01	SWENDSON DAVID L	
	69	7055401		2006-06-06	PRYBELLA JOHN R	
	70	5135489		1992-08-04	JEPSON STEVEN C	
	71	5811658		1998-09-22	VAN DRIEL MICHAEL R	
	72	3604410		1971-09-14	WHITACRE GARY L	
	73	5772608		1998-06-30	DHAS V VARAPRABHU	
	74	4150089		1979-04-17	LINET MICHAEL S	

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	75	4257416		1981-03-24	PRAGER DAVID	
	76	4193400		1980-03-18	LOVELESS JAMES C	
	77	6843775		2005-01-18	HYUN DONGCHUL D	
	78	7666166		2010-02-23	EMMERT MICHAEL	
	79	7479131		2009-01-20	MATHIAS JEAN-MARIE	
	80	8377040		2013-02-19	BURKHOLZ JONATHAN KARL	
	81	5417673		1995-05-23	GORDON MARK G	
	82	6638252		2003-10-28	MOULTON WILLIAM G	
	83	3945380		1976-03-23	DABNEY WILLIAM C	
	84	5100394		1992-03-31	DUDAR THOMAS E	
	85	8827958		2014-09-09	BIERMAN STEVEN F	

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	86	8574203		2013-11-05	STOUT MARTY L	
	87	6860871		2005-03-01	KURACINA THOMAS C	
	88	6945948		2005-09-20	BAINBRIDGE MARLENE	
	89	7306736		2007-12-11	COLLINS GREGORY R	
	90	5691486		1997-11-25	BEHRINGER BRUCE E	
	91	5980830		1999-11-09	SAVAGE DOUGLAS ROBERT	
	92	5045185		1991-09-03	OHNAKA YUKIHIRO	
	93	5632906		1997-05-27	ISHIDA NOBORU	
	94	6695004		2004-02-24	RAYBUCK JOHN L	
	95	6733433		2004-05-11	FELL CLAUDE	
	96	7241281		2007-07-10	COELHO PHILIP H	

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	97	8349254		2013-01-08	HOSHINO YOSHITERU	
	98	5439450		1995-08-08	HAEDT LORI E	
	99	6905483		2005-06-14	NEWBY C MARK	
	100	5431811		1995-07-11	TUSINI ANDREA	
	101	6736783		2004-05-18	BLAKE KEVIN R	
	102	7052603		2006-05-30	SCHICK KARL G	
	103	3835835		1974-09-17	THOMPSON R	
	104	4416291		1983-11-22	KAUFMAN JOSEPH	
	105	10299713		2019-05-28	PATTON RICHARD G	
	106	10265007		2019-04-23	BULLINGTON GREGORY	
	107	11395612		2022-07-26	BULLINGTON GREGORY J	

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	108	10881343		2021-01-05	BULLINGTON GREGORY J	
	109	10596315		2020-03-24	BULLINGTON GREGORY J	
	110	11660030		2023-05-30	BULLINGTON GREGORY J	
	111	11259727		2022-03-01	BULLINGTON GREGORY J	
	112	11737693		2023-08-29	BULLINGTON GREGORY J	
	113	11439332		2022-09-13	BULLINGTON GREGORY J	
	114	11589843		2023-02-28	BULLINGTON GREGORY J	
	115	11612340		2023-03-28	BULLINGTON GREGORY J	
	116	11234626		2022-02-01	BULLINGTON GREGORY J	
	117	10624977		2020-04-21	BULLINGTON GREGORY J	
	118	11653863		2023-05-23	BULLINGTON GREGORY J	

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	119	11419531		2022-08-23	BULLINGTON GREGORY J	
	120	11786155		2023-10-17	BULLINGTON GREGORY J	
	121	11789017		2023-10-17	BULLINGTON GREGORY J	
	122	3848581		1974-11-19	CINQUALBRE P	
	123	6126643		2000-10-03	VAILLANCOUERT VINCENT L	
	124	9764891		2017-09-19	AVILES VICTOR M	
	125	5147329		1992-09-15	BRANNON JAMES K	
	126	5518005		1996-05-21	BRANNON JAMES K	
	127	62845767		2019-05-09	BREWER MICHAEL	

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	1	20010044615		2001-11-22	AMANO YOSHIKAZU	
	2	20030082074		2003-05-01	JURIK FRANKLIN A	
	3	20030185707		2003-10-02	IWAKI YOSHIHIDE	
	4	20040116830		2004-06-17	TRUDEAU WILLIAM M	
	5	20090299253		2009-12-03	HURSEY FRANCIS X	
	6	20130158506		2013-06-20	HARRIS ADRIENNE ROSE	
	7	20150246352		2015-09-03	BULLINGTON GREGORY J	
	8	20150342510		2015-12-03	BULLINGTON GREGORY J	
	9	20160361006		2016-12-15	BULLINGTON GREGORY J	
	10	20170065733		2017-03-09	BULLINGTON GREGORY J	
	11	20180140240		2018-05-24	BULLINGTON GREGORY J	

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	12	20140112841		2014-04-24	SCHOEN CHRISTIAN	
	13	20180271425		2018-09-27	ROGERS BOBBY E	
	14	20080319346		2008-12-25	CRAWFORD JAMIESON	
	15	20100057004		2010-03-04	CHRISTENSEN KELLY D	
	16	20070088279		2007-04-19	SHUE MING-JENG	
	17	20080145933		2008-06-19	PATTON RICHARD G	
	18	20040054333		2004-03-18	THEEUWES FELIX	
	19	20100010372		2010-01-14	BROWN LEROY R	
	20	20080167577		2008-07-10	WEILBACHER EUGENE E	
	21	20080086085		2008-04-10	BROWN LEROY R	
	22	20070083162		2007-04-12	OREAGAN JAMES	

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	23	20160008579		2016-01-14	BURKHOLZ JONATHAN KARL	
	24	20120016266		2012-01-19	BURKHOLZ JONATHAN KARL	
	25	20130317391		2013-11-28	BULLINGTON GREGORY J	
	26	20160174888		2016-06-23	BERTHIER ERWIN	
	27	20050240161		2005-10-27	CRAWFORD JAMIESON W M	
	28	20040147855		2004-07-29	MARSDEN STEWART	
	29	20040073171		2004-04-15	ROGERS BOBBY E	
	30	20050004524		2005-01-06	NEWBY C MARK	
	31	20030105414		2003-06-05	LEONG ALVIN TAN CHEE	
	32	20020004647		2002-01-10	LEONG ALVIN TAN CHEE	
	33	20140155781		2014-06-05	BULLINGTON GREGORY J	

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	34	20030208151		2003-11-06	KRAUS MENACHEM	
	35	20090227953		2009-09-10	TAN CHEE LEONG	
	36	20170020428		2017-01-26	ROGERS BOBBY E	
	37	20170020427		2017-01-26	ROGERS BOBBY E	
	38	20050005635		2005-01-13	LE METAIS MARC	
	39	20050007524		2005-01-13	LUO FANG-CHEN	
	40	20140039348		2014-02-06	BULLINGTON GREGORY J	
	41	20140107564		2014-04-17	BULLINGTON GREGORY J	
	42	20140155782		2014-06-05	BULLINGTON GREGORY J	
	43	20140276578		2014-09-18	BULLINGTON GREGORY J	
	44	20160017488		2016-01-21	KOBAYASHI MASAYUKI	

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	45	20180177445		2018-06-28	ROGERS BOBBY E	
	46	20180353117		2018-12-13	BULLINGTON GREGORY J	
	47	20190159711		2019-05-30	ROGERS BOBBY E	
	48	20050245885		2005-11-03	BROWN LEROY	
	49	20110306899		2011-12-15	BROWN LEROY R	
	50	20130116599		2013-05-09	BULLINGTON GREGORY J	
	51	20050273019		2005-12-08	CONWAY HUGH	
	52	20150351678		2015-12-10	BULLINGTON GREGORY	
	53	20220160271		2022-05-26	IVOSEVIC MILAN	
	54	20050161112		2005-07-28	EHWALD RUDOLF	
	55	20070119508		2007-05-31	WEST RICHARD L	

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	56	20220304600		2022-09-29	HAMMER JEREMY	
	57	20220151525		2022-05-19	BULLINGTON GREGORY J	
	58	20220151527		2022-05-19	BULLINGTON GREGORY J	
	59	20200289039		2020-09-17	BULLINGTON GREGORY J	
	60	20210275068		2021-09-09	MIAZGA JAY M	
	61	20220304664		2022-09-29	HAMMER JEREMY	
	62	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	
	63	20150314105		2015-11-05	GASPARYAN LEVON	
	64	20150359473		2015-12-17	GARRETT CHAD	
	65	20160262677		2016-09-15	EBETSBERGER FRANZ	
	66	20160325085		2016-11-10	CHELAK TODD	

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	67	20070031283		2007-02-08	DAVIS CHARLES Q	
	68	20190365303		2019-12-05	BULLINGTON GREGORY J	
	69	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
	70	20190175087		2019-06-13	BULLINGTON GREGORY J	
	71	20210145336		2021-05-20	ROGERS BOBBY E	
	72	20060009713		2006-01-12	FLAHERTY PATRICE	

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	2	2009131273A	JP		2009-06-18	CSL BEHRING GMBH		☒
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	4	2013082301A1	WO		2013-06-06	TELEFLEX MEDICAL INC		☐
	5	1378602A	GB		1974-12-27	BECTON DICKINSON CO		☐
	6	2019055487A1	WO		2019-03-21	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐
	7	2019232196A1	WO		2019-12-05	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐
	8	1665986	EP		2006-06-07	BECTON DICKINSON CO		☐
	9	2011162772A1	WO		2011-12-29	CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC		☐
	10	2993646	CA		2017-02-02	KURIN INC		☐
	11	3324845A1	EP		2018-05-30	KURIN INC		☐
	12	3562397A1	EP		2019-11-06	KURIN INC		☐
	13	3622890A1	EP		2020-03-18	KURIN INC		☐
	14	5789869B2	JP		2015-10-07	TOHO ENGINEERING KK,		☒

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	15	5867238B2	JP		2016-02-24	FUJITSU LTD,		☒
	16	6643474B2	JP		2020-02-12	クリン インコーポレイテッド		☒
	17	6734490	JP		2020-08-05	クリン インコーポレイテッド		☒
	18	2001000424	JP		2001-01-09	NISSHO KK		☒
	19	2012016496A	JP		2012-01-26	TERUMO CORP		☒
	20	2016504075	JP		2016-02-12	マグノリア メディカル テクノロジーズ , インコーポレイテッド		☒
	21	2019534792A	JP		2019-12-05	プライメタルズ・テクノロジーズ・オーストリア・ゲーエムベーハー		☒
	22	H09504726A	JP		1997-05-13	BAXTER INT		☒
	23	9605875A1	WO		1996-02-29	BAXTER INT		☐
	24	2013181352A1	WO		2013-12-05	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐
	25	2014058945	WO		2014-04-17	BULLINGTON GREGORY J		☐

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	26	2017019552A1	WO		2017-02-02	KURIN INC		☐
	27	2018125929A1	WO		2018-07-05	KURIN INC		☐
	28	S5825146A	JP		1983-02-15	BECTON DICKINSON CO		☒
	29	S5867238A	JP		1983-04-21	BECTON DICKINSON CO		☒
	30	5643474	JP		2014-12-17	ヴェロシス，インク．		☒
	31	5825146B2	JP		2015-12-02	JVC KENWOOD CORP,		☒
	32	2020000340A	JP		2020-01-09	TOSHO INC		☒
	33	2013240628	JP		2013-12-05	COVIDIEN LP		☒
	34	H02224742	JP		1990-09-06	SPACELABS INC		☒
	35	S5789869	JP		1982-06-04	BECTON DICKINSON CO		☒
	36	2005349196	JP		2005-12-22	BECTON DICKINSON CO		☒

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	37	10243129	DE		2004-04-01	RITTER GMBH		☒
	38	7203008	DE		1972-05-10	IMMUNO AG FUER CHEM-MED PROD		☒
	39	10038026	DE		2001-02-22	ZIERDEN PETER		☒
	40	29913417	DE		2000-12-28	ZIERDEN PETER		☒
	41	10134913	DE		2003-02-20	HIBERNA AG		☒
	42	10134913C2	DE		2003-06-26	HIBERNA AG		☒
	43	2541494	DE		1977-03-31	GUERRA LUIS A		☒
	44	2008101025	WO		2008-08-21	EDWARDS LIFESCIENCES CORP		☐
	45	0448795A2	EP		1991-10-02	BECTON DICKINSON CO		☐
	46	2007033319A1	WO		2007-03-22	EDWARDS LIFESCIENCES CORP		☐
	47	199216144	WO		1992-10-01	GOLDSPILL PTY. LTD.		☐

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783173
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580420_KUR3C03US

	48	S5643474	JP		1981-10-12	TORAY INDUSTRIES		☐
	49	H08257018	JP		1996-10-08	NISSHO KK		☒
	50	1996005875	WO		1996-02-29	BAXTER INT		☒

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	International Search Report and Written Opinion dated Nov. 5, 2015, for PCT application No. PCT/US2015/035870. 6 pages.	☐
	2	International Search Report and Written Opinion dated 16 July 2020 for PCT application no. PCT/US2020/026276. 9 pages.	☐
	3	Bullington, et al., Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in U.S. Appl. No. 62/517,681, dated Jun. 9, 2017, 131 pages.	☐
	4	Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.	☐
	5	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	☐
	6	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	☐

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	Attorney Docket Number	069366-0580420_KUR3C03US

	7	European Patent Office; Communication pursuant to Article 94(3) EPC, dated Oct. 31, 2018; 11 pages.	☐
	8	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	☐
	9	International Search Report and Written Opinion dated Jun. 19, 2020, for PCT application No. PCTUS2020/023617. 12 pages.	☐
	10	European Patent Office, International Search Report and Written Opinion for PCT/US16/43709, dated Oct. 19, 2016, 14 pages.	☐
	11	International Search Report/Written Opinion for PCT/US17/68569 dated Apr. 25, 2018. 9 pages.	☐
	12	Japanese Patent Office, Notice of Reasons for Rejection dated Jun. 15, 2021, Application No. JP 2019-534792, 6 pages.	☐
	13	Japanese Patent Office, Notice of Reasons for Rejection for JP Application No. JP 2020-118498 date Aug. 10, 2021.	☐
	14	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application No. JP2018-523384, dated Jul. 23, 2019, 5 pages.	☐
	15	European Patent Office, International Search Report/Written Opinion for PCT/US17/068569 dated Apr. 25, 2018, 9 pages.	☐
	16	International Search Report and Written Opinion for PCT/US16/43709, Dated October 19,2016. 13 pages.	☐
	17	Retractable Techs., Inc. v. Becton Dickinson & Co., CA No. 2:07-CV-250, Claim Construction Order (E.D. Tex., Jan. 20, 2009). 20 pages.	☐

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	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580420_KUR3C03US

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	19	De Korte, Dirk, et al. “Diversion of first blood volume results in a reduction of bacterial contamination for whole-blood collections.” Vox sanguinis 83.1 (2002): 13-16.	☐
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	21	Van Zundert, Adrien. “New closed IV catheter system.” Acta Anæsthesiologica Belgica 56.3 (2005): 283-285.	☐
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	23	Page, Catherine, et al. "Blood conservation devices in critical care: a narrative review." Annals of intensive care 3 [2013): 1-6.	☐
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	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580420_KUR3C03US

	29	Norberg, Alonna, et al. “Contamination rates of blood cultures obtained by dedicated phlebotomy vs intravenous catheter.” Jama 289.6 (2003): 726-729.	☐
	30	Quilici, Nathalie, et al. “Differential quantitative blood cultures in the diagnosis of catheter-related sepsis in intensive care units.” Clinical infectious diseases 25.5 (1997): 1066-1070.	☐
	31	Napolitano, Marcello, et al. “Quality control of bacterial contamination of blood components: the feasibility of diversion system testing.” Blood Transfus 2 (2004): 231-232.	☐
	32	De Korte, Dirk, et al. “Effects of skin disinfection method, deviation bag, and bacterial screening on clinical safety of platelet transfusions in the Netherlands.” Transfusion 46.3 (2006): 476-485.	☐
	33	Liumbruno, Giancarlo Maria, et al. “Reduction of the risk of bacterial contamination of blood components through diversion of the first part of the donation of blood and blood components.” Blood Transfusion 7.2 (2009): 86.	☐
	34	Challiner, A., et al. “Venous/arterial blood management protection system.” Anaesthesia 47.2 (1992): 169-169.	☐
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	36	Palavecino, Elizabeth L., et al. "Detecting bacterial contamination in platelet products." Clinical laboratory 52.9-10 [2006): 443-456.	☐
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	38	Shulman, Gerald. “Quality of processed blood for autotransfusion.” Journal of Extracorporeal Technology 32.1 (2000): 11-19.	☐
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	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580420_KUR3C03US

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	45	Lifesciences, Edwards. “Conservation. Safety. Simplicity. Edwards VAMP and VAMP Jr. Systems.” (2002). 4 pages.	☐
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	48	Mayer, G.A. "A Method for the Reliable Determination of Clotting Time in Whole Blood," Canadian Medical Association Journal, June 15, 1955, Vol. 72, Pages 927-929.	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/09/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580420_KUR3C03US

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	DOCKET CENTRAL
	Attorney Docket Number	069366-0580420_KUR3C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application Number	18/783,088
	Filing Date	07/24/2024
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Client Number	069366
Page 1 of 1	**Matter Number**	0580418_KUR2C06US

GENERAL

Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention, nor is it intended to constitute an admission that such information is "analogous prior art".

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING

In accordance with 37 CFR 1.97(c), this Information Disclosure Statement is being filed after the period specified in 37 CFR 1.97(b) and before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(c) and is accompanied by the fee set forth in 37 CFR 1.17(p).

FEE

This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(c), and is not accompanied by one of the certification statements of 37 CFR 1.97(e). Therefore, this Information Disclosure Statement is subject to the $104 (small entity) fee set forth in 37 CFR 1.17(p).

ADDITIONAL COMMENTS

SIGNATURE

Signature	/Benjamin F. Hudson/	**Date**	2024-09-25
Name	Benjamin F. Hudson	**Registration Number**	71,474

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 18/783,088	Filing Date 07/24/2024	☐ To be Mailed

ENTITY: ☐ LARGE ☑ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $40 =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*		x $192 =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).				
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))					
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT	09/25/2024	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 24	Minus	** 26	= 0		x $40 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	*** 3	= 0		x $192 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

AMENDMENT		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/POLIN ANG/
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The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.	

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 10/10/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 10/10/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,088	07/24/2024	Bobby E. ROGERS	069366-0580418_KUR2C06US	2051

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION DEVICE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	01/10/2025

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 10/10/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,088	07/24/2024	Bobby E. ROGERS	069366-0580418_KUR2C06US	2051

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION DEVICE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	01/10/2025

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-577000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via the USPTO patent electronic filing system ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,088	07/24/2024	Bobby E. ROGERS	069366-0580418_KUR2C06US	2051

27500 7590 10/10/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 10/10/2024

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/ owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 18/783,088	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 09/25/2024.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-9,11-22 and 24-26 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information , please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 09/25/2024. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Allowable Subject Matter

3. Claims 1-9, 11-22 and 24-26 are allowed.

4. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Patton et al (US 2008/0145933) teaches a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and configured to collect a first portion of the blood sample when under a drawing force applied from the outlet port from a blood sample collection device; and a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port.

The prior art does not teach, disclose and/or fairly suggest a housing that defines the inlet port, the sampling channel, and the outlet port.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197

(toll-free). If you would like assistance from a USPTO Customer Service

Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/783,088	ROGERS et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	09/16/2024	09/30/2024							
1	1	✓	=							
2	2	✓	=							
3	3	✓	=							
4	4	✓	=							
5	5	✓	=							
6	6	✓	=							
7	7	✓	=							
8	8	✓	=							
9	9	✓	=							
	10	O	-							
10	11	✓	=							
11	12	✓	=							
12	13	✓	=							
13	14	✓	=							
14	15	✓	=							
15	16	✓	=							
16	17	✓	=							
17	18	✓	=							
18	19	✓	=							
19	20	✓	=							
20	21	✓	=							
21	22	✓	=							
	23	O	-							
22	24	✓	=							
23	25	✓	=							
24	26	✓	=							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/783,088	ROGERS et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068	09/16/2024	MA
updated as above	09/30/2024	MA

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
text search, inventor name search, class/subclass search	09/16/2024	MA
updated as above	09/30/2024	MA

Interference Search			
US Class/CPC Symbol	**US Subclass/CPC Group**	**Date**	**Examiner**
as above		09/30/2024	MA

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/783,088	ROGERS et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

CPC						
Symbol					**Type**	**Version**
A61B	/	5	/	150992	F	2013-01-01
A61M	/	39	/	04	I	2013-01-01
A61B	/	5	/	150221	I	2013-01-01
A61B	/	5	/	15003	I	2013-01-01
A61B	/	5	/	150213	I	2013-01-01
A61B	/	5	/	150389	I	2013-01-01
A61B	/	5	/	150473	I	2013-01-01
A61B	/	5	/	150572	I	2013-01-01
A61B	/	5	/	154	I	2013-01-01
A61B	/	5	/	153	I	2013-01-01
A61M	/	39	/	0693	I	2013-01-01
A61M	/	2039	/	0202	A	2013-01-01
A61M	/	2039	/	068	A	2013-01-01
A61M	/	2039	/	0633	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

Use images from artifact folder? ◉ Yes ○ No

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 24	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791 (Primary Examiner)	02 October 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/783,088	ROGERS et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B	/	5	/	00	

NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					

Use images from artifact folder? (•) Yes ( ) No

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 24	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791 (Primary Examiner)	02 October 2024 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	18/783,088	ROGERS et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1		10	18	19										
2	2	10	11	19	20										
3	3	11	12	20	21										
4	4	12	13	21	22										
5	5	13	14		23										
6	6	14	15	22	24										
7	7	15	16	22	25										
8	8	16	17	24	26										
9	9	17	18												

Use images from artifact folder? ◉ Yes ○ No

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	24	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	02 October 2024	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Bibliographic Data

Application No: 18/783,088

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☑ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/ (Examiner's Signature) | M.A.A (Initials)

Title: BLOOD SAMPLE OPTIMIZATION DEVICE

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/24/2024 RULE	600	3791	069366-0580418_KUR2C06US

APPLICANTS

Kurin, Inc., San Diego, CA, UNITED STATES

INVENTORS

Bobby E. ROGERS, Park City, UT, UNITED STATES

Gino KANG, Irvine, CA, UNITED STATES

John DETLOFF, San Diego, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 18494622 10/25/2023

18494622 is a CON of 18113710 02/24/2023 PAT 11832944

18113710 is a CON of 17538990 11/30/2021 PAT 11963769

17538990 is a CON of 16208559 12/04/2018 PAT 11185266

16208559 is a CON of 15994559 05/31/2018 PAT 10143412

15994559 is a CON of 15140448 04/27/2016 PAT 10010282

15140448 has PRO of 62318194 04/04/2016

15140448 has PRO of 62238636 10/07/2015

15140448 has PRO of 62196797 07/24/2015

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

08/06/2024

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102
UNITED STATES

FILING FEE RECEIVED

$2,640

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	18783088
Filing Date	2024-07-24
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	May A. Abouelela
Attorney Docket Number	069366-0580418_KUR2C06US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4312362		1982-01-26	KAUFMAN JOSEPH	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20140163419		2014-06-12	BULLINGTON GREGORY J	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1							☐

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NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]

PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783088
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	May A. Abouelela
	Attorney Docket Number	069366-0580418_KUR2C06US

	1	Office Action (Non-Final Rejection) dated 9/24/2024 for U.S. Application No. 18/783,173 ; Attorney Docket No. 069366-0580420_KUR3C03US (pages 1-62).	☐
	2	Office Action (Non-Final Rejection) dated 9/17/2024 for U.S. Application No. 17/893,079 ; Attorney Docket No. 069366-0572192_KUR3C02US (pages 1-50).	☐
	3	Office Action (Non-Final Rejection) dated 9/23/2024 for U.S. Application No. 17/730,118 ; Attorney Docket No. 069366-0572186_KUR3C01US (pages 1-73).	☐

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	09/30/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

PC 6.1.24

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18783088
	Filing Date	2024-07-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	May A. Abouelela
	Attorney Docket Number	069366-0580418_KUR2C06US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97(e) to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-09-25
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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PE2E SEARCH - Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
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L100	13	L99 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:50 PM
L101	255	("1779451" | "2004050" | "2700385" | "2836942" | "2854976" | "2953243" | "3021942" | "3073307" | "3074542" | "3255873" | "3294231" | "3323523" | "3329146" | "3333682" | "3367488" | "3382865" | "3485239" | "3537452" | "3585984" | "3610240" | "3658061" | "3664879" | "3817240" | "3828775" | "3859998" | "3874367" | "3886930" | "3890971" | "3904033" | "3934722" | "3968876" | "4106497" | "4108175" | "4113090" | "4139009" | "4154229" | "4166450" | "4175008" | "4193400" | "4207870" | "4269186" | "4300678" | "4312362" | "4317445" | "4340068" | "4375849" | "4398544" | "4409990" | "4412548" | "4416290" | "4416291" | "4418703"	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/01/09 04:51 PM

		| "4430082" | "4436098" | "4444203" | "4592744" | "4634428" | "4643722" | "4659330" | "4664249" | "4664654" | "4671408" | "4679571" | "4681567" | "4695274" | "4702738" | "4723943" | "4728320" | "4728321" | "4731059" | "4735311" | "4735618" | "4737144" | "4738663" | "4743233" | "4746008" | "4747836" | "4747837" | "4772272" | "4778453" | "4781697" | "4782841" | "4788986" | "4790828" | "4793484" | "4795432" | "4795443" | "4801295" | "4804372" | "4813426" | "4816022" | "4816024" | "4819659" | "4820277" | "4826490" | "4826491" | "4838871" | "4842587" | "4844089" | "4846796" | "4850968" | "4850976" | "4850977" | "4850978" | "4850994" | "4850996" | "4858607" | "4863434" | "4863435" | "4863436" | "4865592" | "4867746" | "4872552" | "4874383" | "4874384" | "4883469" | "4886072" | "4886503" | "4888001" | "4892107" | "4892521" | "4894052" | "4900309" | "4909791" | "4909792").PN. OR ("4921096" | "4927018" | "4944397" | "4966591" | "4971068" | "4976699" | "4982842" | "5011475" | "5011479" | "5030207" | "5032116" | "5033476" | "5055102" | "5069225" | "5078693" | "5078698" | "5092845" | "5112327" | "5116325" | "5120319" | "5122121" | "5135509" | "5137518" | "5139489" | "5151089" | "5154285" | "5181523" | "5188611" | "5197954" | "5201794" | "5207653" | "5217025" | "5222502" | "5232454" | "5232455" | "5242411" | "5242417" | "5277311" | "5290246" | "5295969" | "5303713" | "5306259"					

		| "5312369" | "5401251" | "5405332" | "5423765" | "5450856" | "5462534" | "5485854" | "5486163" | "5490841" | "5496281" | "5509907" | "5520193" | "5533984" | "5542932" | "5584816" | "5599313" | "5599318" | "5603699" | "5632732" | "5643219" | "5662617" | "5665075" | "5669889" | "5693022" | "5697914" | "5702369" | "5733265" | "5755701" | "5807351" | "5830190" | "5836920" | "5885249" | "5893844" | "5913846" | "5984895" | "5993426" | "6059737" | "6077244" | "6077253" | "6080137" | "6096006" | "6110160" | "6120482" | "6156010" | "6190370" | "6261263" | "6511439" | "6533760" | "6964658" | "7160267" | "RE31086").PN. OR ("7615033").URPN.					
L102	215	L101 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 04:51 PM
L103	1347	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:11 PM
L104	17	L103 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L105	19	("2009/0312711").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L106	11	("2007/0106220").URPN.	(USPAT)	OR	OFF	OFF	2018/01/09 05:11 PM
L107	288967	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L108	6321	L107 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/01/09 05:16 PM
L109	121	L108 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:17 PM
L110	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/01/09 05:31 PM
L111	6	L110 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:31 PM
L113	71	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:31 PM
L114	0	("15140443").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2018/07/24

			USOCR)				01:38 PM
L115	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:38 PM
L116	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 01:40 PM
L117	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 01:56 PM
L118	854	L117 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:56 PM
L119	91	L118 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 01:57 PM
L120	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:06 PM
L121	1074	L120 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L122	80	L121 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:06 PM
L123	301210	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L124	6556	L123 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2018/07/24 02:11 PM
L125	3664	L124 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L126	12749	"19" and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L127	117	L125 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:12 PM
L128	1348	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:16 PM
L129	75	L128 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:17 PM
L130	1	("20120291564").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:21 PM
L131	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 02:25 PM
L132	18	L131 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/07/24 02:25 PM
L133	98	("20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054333" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:44 PM

		"20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6626884" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7744573" | "8197420" | "8231546" | "8337418").PN. OR ("8535241").URPN.					
L134	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:47 PM
L135	23	("4166450").PN. OR ("4412548").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L136	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2018/07/24 02:48 PM
L137	4	("2007/0088279").URPN.	(USPAT)	OR	ON	ON	2018/07/24 02:48 PM
L138	1	(14/990763).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/24 02:58 PM
L139	9	(blood and sequest$5 and junction and first	(US-PGPUB; USPAT)	OR	ON	ON	2018/07/24 03:07 PM

		and portion and sampl$4).clm.					
L140	1	(15/287421).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/25 09:39 PM
L141	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2018/07/26 11:56 AM
L142	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:24 PM
L143	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 03:25 PM
L144	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"20080145933"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 05:53 PM
L145	272	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian")) OR (("GARRETT") near3 ("Chad"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2019/11/07 05:57 PM
L146	9	L145 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 05:58 PM
L147	34	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20070088279"|"200801459	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 06:26 PM

		33"|"20100057004"|"20130317391"|"20160174888"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"5222502"|"5520193"|"5749857"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8864684"|"9022951"|"9060724"|"9138572"|"9204864").PN.					
L148	5	L147 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 06:29 PM
L149	6	("2010/0057004").URPN.	(USPAT)	OR	ON	ON	2019/11/07 06:40 PM
L150	0	L149 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:20 PM
L151	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:21 PM
L152	4	L151 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L153	1766	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:21 PM
L154	13	L153 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:21 PM
L155	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/07 07:22 PM
L156	48	L155 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:22 PM
L157	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L158	17	L157 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:43 PM
L159	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/11/07 07:43 PM
L160	6	L159 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L161	333030	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L162	6981	L161 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/11/07 07:44 PM
L163	139	L162 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:44 PM
L164	117	L163 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07 07:45 PM
L165	1	L146 and (enclos$3	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/11/07

		near4 mechanism)					07:51 PM
L166	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/08 04:57 PM
L167	1	(15/139716).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/11 12:09 PM
L168	1	(15/520430).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 11:02 AM
L169	1	("7637875").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:11 PM
L170	1	("20120253321").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:13 PM
L171	1	(15/861959).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/11/12 12:14 PM
L172	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 02:17 PM
L173	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:14 PM
L174	1	("20080167577").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:19 PM
L175	4	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2019/12/09 03:30 PM
L176	1	("8197420").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 03:31 PM
L177	39	(US-20040073171-$ or US-20160174888-$ or US-20050240161-$ or US-20040147855-$ or US-20130317391-$ or US-20050004524-$ or US-20030105414-$ or US-20020004647-$ or US-20100057004-$ or US-20070088279-$ or US-20080145933-$ or US-20040054333-$ or US-20100010372-$ or US-20080319346-$ or US-20080167577-$).did. or (US-9138572-$ or US-8568371-$ or US-8540663-$ or US-8523826-$ or US-8197420-$ or US-4057050-$ or US-8864684-$ or US-8535241-$ or US-5749857-$ or US-9060724-$ or US-9204864-$ or US-3817240-$ or US-3874367-$ or US-3886930-$ or US-4106497-$ or US-4154229-$ or US-	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:37 PM

		4207870-$ or US-4412548-$ or US-5222502-$ or US-5520193-$ or US-9022951-$ or US-6569117-$ or US-3741197-$ or US-8603009-$).did.					
L178	8	("20040054333"|"8197420"|"9855001"|"9861306"|"10045724"|"10028687"|"8337418"|"10028689").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 03:42 PM
L179	100	("20020002349" | "20020183651" | "20030055381" | "20040010228" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047").PN. OR ("8197420").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 03:43 PM
L180	70	L179 and (blood near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 03:43 PM
L181	43	L180 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 03:44 PM
L182	270	((("BULLINGTON")	(US-PGPUB; USPAT;	OR	ON	ON	2019/12/09

		near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	USOCR; EPO; JPO; DERWENT)				04:13 PM
L183	335813	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L184	7259	L183 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2019/12/09 04:22 PM
L185	325	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2019/12/09 04:33 PM
L186	594	L184 and (flash$6 and seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L187	476	L186 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 04:40 PM
L188	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:14 PM
L189	1123	L188 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L190	1013	L189 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:15 PM
L191	10	L190 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:16 PM
L192	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:23 PM
L193	1143	L192 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L194	1038	L193 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L195	3	L194 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:23 PM
L196	811	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/09 05:24 PM
L197	618	L196 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L198	557	L197 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:24 PM
L199	1	(15/854273).APP.	(US-PGPUB; USPAT;	OR	OFF	OFF	2019/12/09

			USOCR)				05:25 PM
L200	1351	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:31 PM
L201	219	L200 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L202	199	L201 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:33 PM
L203	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2019/12/09 05:36 PM
L204	44	L203 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2019/12/09 05:37 PM
L205	1	(15/508871).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2019/12/10 11:58 AM
L206	342199	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/03/16 12:53 PM
L207	4239	L206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:53 PM
L208	146	L207 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:54 PM
L209	101	L208 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 12:55 PM
L210	1735	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:38 PM
L211	1123	L210 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:38 PM
L212	1013	L211 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L213	22	L212 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:39 PM
L214	108	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 01:46 PM

		"20050245869" | "20050245870" | "20050245879" | "20050245885" | "20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" | "5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.					

L215	26	L214 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:47 PM
L216	27	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:47 PM
L217	23	("2003/0105414").URPN.	(USPAT)	OR	ON	ON	2020/03/16 01:48 PM
L218	1258	(600/583).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 01:52 PM
L219	1143	L218 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L220	25	L219 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:52 PM
L221	353695	((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:54 PM
L222	3643	L221 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L223	1926	L222 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:55 PM
L224	785	L223 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 01:56 PM
L225	7046	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 02:32 PM
L226	14	L225 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:35 PM
L227	1352	(604/164.01).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:36 PM
L228	135	L227 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L229	19	L228 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:36 PM
L230	448	(435/294.1).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 02:47 PM
L231	3	L230 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:47 PM
L232	19	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/03/16 02:48 PM
L233	795	(600/576).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16

							02:58 PM
L234	71	L233 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:58 PM
L235	57	L234 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 02:59 PM
L236	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:12 PM
L237	11	L236 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:12 PM
L238	45	("20040054333"|"20050240161"|"4412548"|"5749857"|"8197420"|"9855001"|"9861306"|"20020004647"|"20100057004"|"3741197"|"20040073171"|"3874367"|"4057050"|"4106497"|"8197420"|"8535241"|"8540663"|"8603009"|"8864684"|"10045724"|"3817240"|"10028687"|"20030105414"|"5222502"|"5520193"|"6569117"|"8568371"|"20040147855"|"20070088279"|"20080145933"|"20100010372"|"3886930"|"8523826"|"9060724"|"9204864"|"8337418"|"20050004524"|"20080167577"|"20080319346"|"20130317391"|"4154229"|"9022951"|"10028689"|"20160174888"|"4207870"|"9138572").PN.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:13 PM
L239	6	("2008/0167577").URPN.	(USPAT)	OR	ON	ON	2020/03/16 03:13 PM
L240	118	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/03/16 03:15 PM
L241	6	("2008/0167577").URPN.	(US-PGPUB; USPAT)	OR	ON	ON	2020/03/16 03:15 PM
L242	274	((("BULLINGTON") near3 ("Gregory")) OR	(US-PGPUB; USPAT; USOCR; EPO; JPO;	OR	ON	ON	2020/03/16 03:25 PM

		(("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	DERWENT)				
L243	61	L242 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:25 PM
L244	1	(15/854273).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 03:47 PM
L245	0	(14/502498).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:11 PM
L246	1	("20110082383").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L247	1	("8150506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/16 04:24 PM
L252	1	(15/057214).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/03/17 11:28 AM
L253	348964	(blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L254	7453	L253 AND ((A61B10/0096 OR A61B5/150022).CPC.)	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2020/06/10 05:22 PM
L255	155	L254 and ((vent$4 near4 air) and flash$6)	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:23 PM
L256	77	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:35 PM
L257	343953	(blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:40 PM
L258	11	L256 and (blood same (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 05:41 PM
L259	1	("5749857").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 05:50 PM
L260	121	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:19 PM
L261	32	L260 and (blood near4 (sequest$5 or sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:20 PM

L262	1	("3648684").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L263	1	("4056101").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:38 PM
L264	329	(600/577).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2020/06/10 06:39 PM
L265	11	L264 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:39 PM
L266	29	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2020/06/10 06:40 PM
L267	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:40 PM
L268	72	L267 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:40 PM
L269	1767	(600/573).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:44 PM
L270	31	L269 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:45 PM
L271	77	("4676249" | "4787891" | "4850960" | "4874382" | "4886067" | "4886500" | "4900307" | "4904242" | "4917102" | "4950252" | "4955862" | "5046508" | "5116353" | "5125718" | "5129884" | "5163911" | "5217435" | "5290244" | "5295974" | "5314503" | "5318585" | "5330432" | "5360410" | "5366441" | "5376075" | "5395337" | "5531692" | "5695475" | "5695479" | "5702367" | "5735813" | "5749857" | "5788654" | "5800395" | "5846226" | "5871470" | "5882342" | "5919172" | "5935108" | "5935113" | "5989220" | "6050976" | "6077244" | "6099504" | "6126641" | "6162195").PN. OR ("6398743").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2020/06/10 06:46 PM
L272	18	L271 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:46 PM
L273	1	(15/893518).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:48 PM
L274	7050	(600/300).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:49 PM

L275	14	L274 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:49 PM
L276	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:51 PM
L277	7	L276 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:51 PM
L278	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 06:52 PM
L279	135	L278 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:52 PM
L280	499	(435/294.1).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 07:08 PM
L281	3	L280 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 07:08 PM
L282	20	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2020/06/10 07:08 PM
L286	1	("10045704").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2020/06/10 08:56 PM
L287	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:16 PM
L288	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:17 PM
L289	100	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2021/03/01 09:17 PM
L290	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:36 PM
L291	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/01 09:39 PM
L292	180	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/03/02 12:19 PM
L293	11	L292 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 12:20 PM
L294	2	(15/140443).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:47 PM
L295	1	(15/855439).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 12:49 PM
L296	1	("20020048170").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:36 PM
L297	1	("20040174525").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 01:49 PM
L298	1	("10045704").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2021/03/02

			USOCR)				03:09 PM
L299	27321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/03/02 03:17 PM
L300	4594	L299 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:27 PM
L301	3762	L300 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:28 PM
L302	257	L301 and (air near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L303	420	L301 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 03:29 PM
L304	1	("20110167658").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 03:30 PM
L305	5	("2015/0306288").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:15 PM
L306	1	(16/208559).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 04:32 PM
L307	2	("2009/0043225").URPN.	(USPAT)	OR	ON	ON	2021/03/02 04:49 PM
L308	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/03/02 05:00 PM
L309	1363	L308 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:00 PM
L310	73	L309 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L311	73	L310 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:01 PM
L312	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:34 PM
L313	711	L312 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L314	58	L313 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:34 PM
L315	58	L314 and	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02

		@ad<"20150724"					05:34 PM
L316	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:42 PM
L317	277	L316 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:42 PM
L318	20	L317 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:43 PM
L319	336	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/03/02 05:44 PM
L320	210	L319 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L321	196	L320 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:44 PM
L322	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:48 PM
L323	1208	L322 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L324	73	L323 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:48 PM
L325	73	L324 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 05:49 PM
L326	1368	(604/164.01).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/03/02 05:59 PM
L327	271	L326 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L328	10	L327 and ((air or gas$4) near4 permeab$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L329	268	L327 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/03/02 06:00 PM
L330	182	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2021/07/08 02:22 PM
L331	27660	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2021/07/08 03:27 PM

		A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.					
L332	4684	L331 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:28 PM
L333	3769	L332 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L334	579	L333 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 03:29 PM
L335	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:54 PM
L336	1	("4207870").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 03:56 PM
L337	337	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:19 PM
L338	211	L337 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L339	196	L338 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L340	37	L339 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:19 PM
L341	221	("20010021827" | "20020004650" | "20020055716" | "20020072715" | "20020103464" | "20020103465" | "20020107488" | "20020151856" | "20020193748" | "20030028171" | "20030036730" | "20030050608" | "20030055385" | "20030078544" | "20030093009" | "20030105414" | "20030114797" | "20030120222" | "20030176842" | "20030181873" | "20030191438" | "20030199827" | "20030216687" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"20030220614" | "20030229315" | "20030229316" | "20040024370" | "20040059302" | "20040092872" | "20040102740" | "20040111068" | "20040193120" | "20040204681" | "20040210197" | "20050004524" | "20050059936" | "20050065482" | "20050124944" | "20050165353" | "20050187493" | "20050228345" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" | "20050283093" | "20060015073" | "20060036217" | "20060036219" | "20060079847" | "20060129064" | "20060189934" | "20060189936" | "20060224122" | "20060270947" | "20060276756" | "20070021724" | "20070027430" | "20070106220" | "20070106224" | "20070167914" | "20070282275" | "20080015513" | "20080086085" | "20080177202" | "20080221528" | "20080269691" | "20080306452" | "20080319345" | "20080319346" | "20090204026" | "20090227896" | "20100063455" | "20100191189" | "20100262038" | "20110118674" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4813426" |				

		"4840619" | "4887998" | "4894055" | "4900307" | "4923477" | "4994046" | "5015241" | "5195985" | "5215534" | "5219333" | "5222502" | "5242417" | "5246428" | "5256153").PN. OR ("5295970" | "5295975" | "5303713" | "5312372" | "5318547" | "5336199" | "5344408" | "5348544" | "5356392" | "5389085" | "5403286" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5549558" | "5595566" | "5599313" | "5607402" | "5662617" | "5665075" | "5669889" | "5672161" | "5676658" | "5681295" | "5685855" | "5687740" | "5688241" | "5695474" | "5702369" | "5704920" | "5718239" | "5733265" | "5755522" | "5769826" | "5795336" | "5879337" | "5893845" | "5910130" | "5921964" | "5957892" | "5984899" | "6149629" | "6171284" | "6183445" | "6224576" | "6254575" | "6261263" | "6261265" | "6298541" | "6344032" | "6419658" | "6436086" | "6440104" | "6471677" | "6475191" | "6485469" | "6524277" | "6533760" | "6554807" | "6575939" | "6592556" | "6623456" | "6623461" | "6635032" | "6641555" | "6648855" | "6648856" | "6659983" | "6695819" | "6699217" | "6712792" | "6716199" | "6761704" | "6773419" | "6780169" | "6805689" | "6811545" | "6835190" | "6837877" | "6846302" | "6860872" | "6869415" | "6905483" | "6918891" | "6958054" | "6974423" | "6984223" | "6997913" | "7001363" | "7083600" | "7101355" | "7128726" | "7147624" | "7160267" | "7163526" | "7201740" | "7211065" | "7223258"				

		| "7226432" | "7361159" | "7396343" | "7428773" | "7524308" | "7537581" | "7670320" | "7727190" | "7766879" | "7938808" | "8066679" | "8282605" | "8795198" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287" | "RE35539" | "RE43473").PN. OR ("9615783").URPN.					
L342	115	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245879" | "20050245885" | "20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.					
L343	148	("20020193748" | "20030105414" | "20030229315" | "20040059302" | "20040092872" | "20050004524" | "20050187493" | "20050245868" | "20050245869" | "20050245870" | "20050245885" | "20060036219" | "20070106220" | "20070167914" | "20080086085" | "20080177202" | "4106497" | "4207870" | "4305406" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5672161" |	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:21 PM

		"5676658" | "5702369" | "5704920" | "5755522" | "5984899" | "6149629" | "6261263" | "6298541" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "D422700" | "D442280").PN. OR ("7766879").URPN.					
L344	41	("2735430" | "2798487" | "3187749" | "3240209" | "3585984" | "3817240" | "4166450" | "4207870" | "4295477" | "4312362").PN. OR ("4436098").URPN.	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2021/07/08 04:22 PM
L345	163	L341 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:22 PM
L346	163	L345 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:23 PM
L347	22	("2005/0283093").URPN.	(USPAT)	OR	ON	ON	2021/07/08 04:23 PM
L348	163	L345 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L349	163	L348 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:27 PM
L350	1736	(600/573).CCLS.	(US-PGPUB; USPAT)	OR	ON	ON	2021/07/08 04:37 PM
L351	1363	L350 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:37 PM
L352	1346	L351 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L353	136	L352 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:38 PM
L354	812	(600/576).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:41 PM
L355	711	L354 and ((blood or fluid$4) near4 (sequest$5 or sampl$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM

		or flash$4 or collect$4))					
L356	699	L355 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L357	123	L356 and (vent$4 near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:41 PM
L358	371	(600/577).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:44 PM
L359	277	L358 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L360	260	L359 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:45 PM
L361	1259	(600/583).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2021/07/08 04:46 PM
L362	1208	L361 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:46 PM
L363	1194	L362 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L364	1194	L363 and @ad<"20150724"	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:47 PM
L366	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:05 PM
L367	319	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/02/02 03:14 PM
L368	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:35 PM
L369	190	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 03:36 PM
L370	2	(15/140448).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:41 PM
L371	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L372	1	("9060725").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:42 PM
L373	1	("9060724").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:43 PM
L374	1	("9022950").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L375	1	("9022951").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:45 PM
L376	1	("10292633").PN.	(US-PGPUB; USPAT;	OR	OFF	OFF	2022/02/02

			USOCR)				03:46 PM
L377	1	("10433779").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:47 PM
L378	1	("10436554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:48 PM
L379	1	("10736554").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L380	1	("10912506").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L381	1	("10010282").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:49 PM
L382	1	(16/376745).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:50 PM
L383	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:51 PM
L384	276	(600/579).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 03:52 PM
L385	204	L384 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 03:53 PM
L386	37427	(A61B5/150221 or A61B5/15003 or A61B5/150236 or A61B5/150244 or A61B5/150251 or A61B5/150389 or A61B5/150503 or A61B5/150992 or A61B5/153 or A61B5/155 or A61B10/0048 or A61B10/0051 or A61B10/007 or A61B2010/0061 or A61B2010/0077 or A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/02/02 04:35 PM
L387	7279	L386 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L388	4442	L387 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:36 PM
L389	874	L388 and (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 04:38 PM
L390	26	("2008/0145933").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:52 PM
L391	44	("2008/0319346").URPN.	(USPAT)	OR	ON	ON	2022/02/02 04:59 PM
L392	385	L386 and ((blood or fluid) near4 (seal$4 near4 (member or	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM

		mechanism$4 or vent$4 or elastic$4)))					
L393	171	L392 and @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:28 PM
L394	355	(604/103).CCLS.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/02 05:52 PM
L395	7	L394 and ((blood or fluid) near4 (seal$4 near4 (member or mechanism$4 or vent$4 or elastic$4)))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/02/02 05:52 PM
L396	1	(16/328127).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/03 12:00 PM
L397	0	"1020130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L398	8	"20130062845"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:17 PM
L399	14	"2013021595"	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/02/04 04:18 PM
L400	2	(14/055232).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/04 07:10 PM
L401	1	(15/746656).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/05 11:48 AM
L402	0	(17/388440).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/02/07 09:34 AM
L403	1	("20050048465").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2022/02/07 09:34 AM
L404	196	(("ROGERS") near3 ("Bobby")).INV.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:08 PM
L405	16	L404 and (blood near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L406	16	L404 and ((blood or chamber) near4 sequest$5)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:08 PM
L407	16	L406 and (junct$4 or bypass$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L408	16	L406 and junct$4	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:09 PM
L409	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 03:54 PM

		A61B5/150572 or A61B5/154 or A61B5/15074).cpc.					
L410	4525	L409 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:55 PM
L411	3810	L410 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:56 PM
L412	820	L411 and ((vent$4 or open$4 or apertur$4) near4 air)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 03:57 PM
L413	22445	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150221 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/15074).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2022/05/18 05:51 PM
L414	4603	L413 and ((blood or fluid$4 or chamber) same (sequest$5 or sampl$4 or flash$4 or collect$4 or flush$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:51 PM
L415	511	L414 and ((junct$4 or bypass$4 or divert$4) near4 (blood or fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:52 PM
L416	355	L415 and @ad<"20170210"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/05/18 05:53 PM
L417	1	(16/819033).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:10 PM
L418	1	(17/094692).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L419	1	(17/538990).APP.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:25 PM
L420	1	("11311219").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:27 PM
L421	1	("11185266").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:30 PM
L422	1	("10143412").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:31 PM
L423	1	("9820682").PN.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2022/05/18 06:32 PM
L424	331	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2022/06/06 03:44 PM

L425	8944	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:17 PM
L426	58747	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2022/06/06 05:17 PM
L427	7420	426 AND ((blood OR fluid$4) near4 (sequest$5 OR sampl$4 OR flash$4 OR collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:18 PM
L428	4441	427 AND @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:18 PM
L429	846	428 AND (seal$4 near4 (member OR mechanism$4 OR vent$4 OR elastic$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:20 PM
L430	2	"17525682"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:46 PM
L431	547	426 AND (((blood OR fluid$4) near4 (sequest$5 OR bypass$4 OR flash$4)) AND seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:50 PM
L432	231	431 AND @ad<"20120530"	(US-PGPUB; USPAT)	OR	OFF	OFF	2022/06/06 05:50 PM
L433	1	18/113710	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/22 02:58 PM
L434	209	(("ROGERS") near3	(US-PGPUB; USPAT;	OR	OFF	OFF	2023/08/22

		("Bobby")).INV.	USOCR; FPRS; EPO; JPO; DERWENT)				03:09 PM
L435	21	434 AND (((blood OR fluid$4) near4 (sequest$5 OR bypass$4 OR flash$4)) AND seal$4)	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 03:09 PM
L436	9	"20100057004"	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/22 03:11 PM
L437	49165	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR A61M2039/0202 OR A61M2039/0633 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/08/22 03:49 PM
L438	33727	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/154 OR A61B5/153 OR A61M39/0693 OR A61M39/04 OR A61B5/150221 OR A61M2039/0633 OR A61M2039/0202 OR A61M2039/068 OR A61B5/150251).cpc.	(US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2023/08/22 03:51 PM
L439	36143	438 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2023/08/22 03:52 PM

L440	3944	439 AND ((blood OR fluid$4) near4 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 03:52 PM
L441	1473	440 AND (seal$4 near4 (member OR mechanism$4 OR vent$4 OR elastic$4 OR filter$4 OR material$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 03:53 PM
L442	8	"20080167577"	(US-PGPUB; USPAT)	OR	ON	ON	2023/08/22 04:42 PM
L443	115	440 AND (seal$4 near4(expos$4 OR contact$4) near5 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 04:58 PM
L444	116	440 AND (seal$4 near4(expos$4 OR contact$4 OR absorb$4) near5 (blood OR fluid))	(US-PGPUB; USPAT)	OR	OFF	OFF	2023/08/22 04:59 PM
L445	1	18/317558	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 02:44 PM
L446	303	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/05/06 02:45 PM
L447	127	446 AND ((blood OR fluid$4) near4 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 02:54 PM
L448	122	447 AND (((vent$4 OR open$5 OR hole OR aperture) near5 air) sam (clos$4 OR plug$4 OR cap$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 02:56 PM
L449	3	17/094692	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 03:07 PM

L450	46753	(A61B5/150213 OR A61B5/15003 OR A61B5/150221 OR A61B5/150251 OR A61B5/150732 OR A61B5/15074 OR A61B5/150992 OR A61B5/153 OR A61B5/150389 OR A61B5/150503).cpc.	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO, RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/05/06 03:08 PM
L451	37283	450 AND @ad<"20170210"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/05/06 03:09 PM
L452	4944	451 AND ((blood OR fluid$4) near5 (sequest$5 OR sampl$4 OR flash$4 OR collect$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 03:14 PM
L453	511	452 AND (((vent$4 OR open$5 OR hole OR aperture) near5 air) SAME (clos$4 OR plug$4 OR cap$4 OR seal$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 03:15 PM
L454	1	("5749857").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 03:25 PM
L455	233	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").pn. OR	(US-PGPUB; USPAT; USOCR)	OR	ON	ON	2024/05/06 03:37 PM

		("5749857").urpn. AND (PGPB | USPT | USOC).dbnm.					
L456	228	455 AND @ad<"20170210"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/05/06 03:37 PM
L457	14	456 AND (((vent$4 OR open$5 OR hole OR aperture) near5 air) SAME (clos$4 OR plug$4 OR cap$4 OR seal$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 03:37 PM
L458	8	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 03:57 PM
L459	387	452 AND (((vent$4 OR open$5 OR hole OR aperture) near5 air) near5 (chamber OR hous$4 OR contain$4 OR tub$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 04:01 PM
L460	601	452 AND (air near5 (displac$4 OR mov$4 OR substit$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 04:22 PM
L461	346	452 AND (air near5 (displac$4 OR substit$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/05/06 04:22 PM
L462	1	17/250875	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 04:58 PM
L463	1	("5376100").pn.	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:06 PM
L464	19	"20140276233"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:07 PM
L465	13	"20120101508"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:08 PM
L466	2	"20070179473"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:09 PM
L467	6	"20060073538"	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/06 07:56 PM
L468	1	18/079528	(US-PGPUB; USPAT)	OR	ON	ON	2024/05/07 01:22 PM

L469	9	"20080145933"	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 02:35 PM
L470	122	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	(US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT)	OR	ON	ON	2024/09/30 02:39 PM
L471	34	470 AND ((blood OR fluid$4) near4 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 02:40 PM
L472	53	("20020004647"|"20030105414"|"20040054333"|"20040073171"|"20040147855"|"20050004524"|"20050240161"|"20060009713"|"20070083162"|"20070088279"|"20080086085"|"20080145933"|"20080167577"|"20080319346"|"20100010372"|"20100057004"|"20120016266"|"20130317391"|"20150314105"|"20150359473"|"20160008579"|"20160073937"|"20160174888"|"3741197"|"3817240"|"3874367"|"3886930"|"4057050"|"4106497"|"4154229"|"4207870"|"4412548"|"4436098"|"4444203"|"5222502"|"5520193"|"5749857"|"6398743"|"6569117"|"8197420"|"8523826"|"8535241"|"8540663"|"8568371"|"8603009"|"8864684"|"9022950"|"9022951"|"9060724"|"9138572"|"9155495"|"9204864"|"9877675").PN.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 02:50 PM
L473	50987	(A61B5/150992 OR A61B5/15003 OR A61B5/150213 OR A61B5/150221 OR A61B5/150389 OR A61B5/150473 OR A61B5/150572 OR A61B5/153 OR A61B5/154 OR A61M39/04 OR A61M39/0693 OR	(US-PGPUB; USPAT; USOCR; FIT (AU, AP, AT, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, OA, RU, SU, WO, MC, MD, MY, NL, NO, NZ, PH, PL, PT, RO,	OR	ON	ON	2024/09/30 02:57 PM

		A61M2039/0202 OR A61M2039/0633 OR A61M2039/068).cpc.	RS, SE, SG, SI, SK, TH, TN, TR, TW, UA, VN); FPRS; EPO; JPO; DERWENT; IBM_TDB)				
L474	203	455 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/09/30 02:58 PM
L475	36038	473 AND @ad<"20150724"	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	OFF	OFF	2024/09/30 02:59 PM
L476	22627	475 AND ((collect$4 OR sampl$4 OR draw$4 OR withdraw$4) near5 (blood OR fluid))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/09/30 03:02 PM
L477	499	476 AND ((blood OR fluid$4) NEAR (sequest$5 OR	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 03:02 PM

		bypass$4 OR flash$4 OR subsequent$4))					
L478	0	18/783088	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 03:24 PM
L479	3918	475 AND ((blood OR fluid$4) near5 (sequest$5 OR bypass$4 OR flash$4 OR collect$4 OR sampl$4))	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 03:27 PM
L480	648	479 AND ((pump$4 OR vacuum) near5 (draw$4 OR withdraw$4 OR forc$4) near5 blood)	(US-PGPUB; USPAT)	OR	OFF	OFF	2024/09/30 03:30 PM
L481	7	("2014/0309557").urpn. AND (PGPB | USPT | USOC).dbnm.	(US-PGPUB; USPAT; USOCR)	OR	OFF	OFF	2024/09/30 03:56 PM
L482	0	476 AND (blood near5 (impereamble OR impenetrat$4))	(US-PGPUB; USPAT; USOCR; FIT (AP, AT, AU, BE, BG, BR, BY, CA, CH, CN, CS, CU, CZ, DD, DE, DK, EA, EE, EP, ES, FI, FR, GB, HR, HU, ID, IE, IL, IS, IT, JP, KR, LT, LU, LV, MA, MC, MD, MY, NL, NO, NZ, OA, PH, PL, PT, RO, RS, RU, SE, SG, SI, SK, SU, TH, TN, TR, TW, UA, VN, WO); FPRS; EPO; JPO; DERWENT; IBM_TDB)	OR	ON	ON	2024/09/30 04:07 PM

PE2E SEARCH - Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	British Equivalents	Time Stamp
N94	1	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2017/09/28 04:15 PM
N112	3	(port and sequest$5 and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2018/01/09 05:39 PM
N248	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow and initial$4 and sequest$5).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM
N249	4	(blood and fluid$4 and inlet and outlet and port	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:30 PM

		and reservoir and allow$4 and initial$4 and sequest$5).clm.					
N250	495	(blood and fluid$4 and allow$4 and initial$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N251	107	(blood and fluid$4 and allow$4 and initial$4 and subsequent$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/03/16 03:31 PM
N283	9	((blood or fluid$4) and sequestrat$4 and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N284	530	((blood or fluid$4) and chamber and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:31 PM
N285	84	((blood or fluid$4) and chamber and cap and sampl$4 and vent$4 and air$4).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2020/06/10 06:32 PM
N365	6	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	(US-PGPUB; USPAT)	OR	OFF	OFF	2021/07/08 04:49 PM
N366	0	(blood AND seal$4 AND sampl$4 AND state AND transfrer$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 03:50 PM
N367	41	(blood AND seal$4 AND bypass$4 AND transfer$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 03:51 PM
N368	396	(blood AND seal$4 AND sampl$4 AND transfer$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:13 PM
N369	172	(blood AND seal$4 AND sampl$4 AND transfer$4 AND volume).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:13 PM
N370	5	(blood AND seal$4 AND sampl$4 AND transfer$4 AND volume AND bypass$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:14 PM
N371	8944	(A61B5/150221 OR A61B5/15003 OR A61B5/150236 OR A61B5/150244 OR A61B5/150251 OR A61B5/150389 OR A61B5/150503 OR A61B5/150992 OR A61B5/153 OR	(US-PGPUB; USPAT)	OR	ON	ON	2022/06/06 05:16 PM

		A61B5/155 OR A61B10/0048 OR A61B10/0051 OR A61B10/007 OR A61B2010/0061 OR A61B2010/0077 OR A61B2010/008).cpc.					
N372	22	(chamber AND inlet AND outlet AND channel AND forc$4 AND draw$4 AND blood).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 04:09 PM
N373	8	(chamber AND inlet AND outlet AND channel AND forc$4 AND draw$4 AND blood AND hous$4).clm.	(US-PGPUB; USPAT)	OR	ON	ON	2024/09/30 04:10 PM

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 10/10/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
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McLean, VA 22102

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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,088	07/24/2024	Bobby E. ROGERS	069366-0580418_KUR2C06US	2051

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION DEVICE

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	01/10/2025

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-577000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Pillsbury Winthrop Shaw Pittman LLP
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: Kurin, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): San Diego, CA

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. Fees submitted: ☒ Issue Fee ☐ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

☒ Electronic Payment via the USPTO patent electronic filing system ☐ Enclosed check ☐ Non-electronic payment by credit card (Attach form PTO-2038)

☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. 033975

5. **Change in Entity Status** (from status indicated above)

☐ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

☐ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

☐ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /Ben Hudson/ Date October 10, 2024

Typed or printed name Benjamin F. Hudson Registration No. 71474

UNITED STATES
PATENT AND TRADEMARK OFFICE

P.O. Box 1450
Alexandria, VA 22313 - 1450
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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/783,088	**10/10/2024 02:06:12 PM Z ET**	**069366-0580418_KUR2C06US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	2051	FILED BY	Trent Tercenio
PATENT CENTER #	67516325	FILING DATE	07/24/2024
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. ROGERS
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 2

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
069366-0580418_KUR2C06US-Issue-Fee-Payment.pdf	1	Issue Fee Payment (PTO-85B)	1202 KB
069366-0580418_KUR2C06US-Comments-on-Reasons-for-Allowance.pdf	2	Miscellaneous Incoming Letter	785 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
069366-0580418_KUR2C06US-Issue-	E1B34F1CA544F1512A33051093EF39428ABCBE4AF534A960E2632933A6619FCC133A7CCC53D889D507F1F08F85BD163D0E

Fee-Payment.pdf	BE24219A64A53EFE1F162C9AD3218F
069366-0580418_KUR2C06US-Comments-on-Reasons-for-Allowance.pdf	68DA0D5D39A05BD811D5F6F6F0632D811B53D3D8473BA25A9B31E11646B1D8A68B69A049CB180417CAEDD626E552258FB4B30855C49A094CAB54F6EBBABEC6A9

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If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Bobby E. Rogers, et al.

Confirmation No: 2051

Application No.: 18/783,088

Art Unit: 3791

Filed: July 24, 2024

Examiner: May A. Abouelela

For: BLOOD SAMPLE OPTIMIZATION DEVICE

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COMMENTS ON EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

Applicant thanks Examiner Abouelela for the Notice of Allowance and the Examiner's efforts in examining the above-referenced application.

Applicant received the Examiner's "Statement Of Reasons For Allowance" (hereafter the "Statement") along with the Notice and wishes to note that entry of this Statement should not be construed as Applicant necessarily agreeing with or acquiescing to the reasons stated therein.

Applicant recognizes that, in accordance with MPEP § 1302.14, the Statement need not set forth all of the details as to why claims are allowed and, respectfully, Applicant does not concede that the Statement contains the only reasons for which the pending claims are allowable. Each of the claims stands on its own merits and is patentable because of the combination it recites and not because of the presence or absence of any one particular element.

CONCLUSION

It is believed that no fees are due in connection with the filing of this paper. In the event that it is determined that fees are due, however, the Commissioner is hereby authorized to charge any fees that may be due, or credit any overpayment of same, to Deposit Account 033975, Reference No. 069366-0580418_KUR2C06US.

Respectfully submitted,
PILLSBURY WINTHROP SHAW PITTMAN LLP

Date: October 10, 2024

By: /Ben Hudson/
Benjamin F. Hudson, Ph.D.
Reg. No. 71,474

PO Box 10500
McLean, Virginia 22102
Telephone: (858) 509-4000
Customer No. 27500

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PATENT AND TRADEMARK OFFICE

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/783,088	**10/10/2024 02:06:12 PM Z ET**	**069366-0580418_KUR2C06US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	2051	FILED BY	Trent Tercenio
PATENT CENTER #	67516325	AUTHORIZED BY	Benjamin Hudson
CUSTOMER #	27500	FILING DATE	07/24/2024
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Bobby E. ROGERS

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 033975	**E202400E06295322**	**Trent Tercenio**

PRE-AUTHORIZED ACCOUNT	PRE-AUTHORIZED CATEGORY
033975	**37 CFR 1.16 (National application filing, search, and examination fees); 37 CFR 1.17 (Patent application and reexamination processing fees); 37 CFR 1.19 (Document supply fees); 37 CFR 1.20 (Post Issuance fees); 37 CFR 1.21 (Miscellaneous fees and charges)**

FEE CODE	DESCRIPTION	ITEM PRICE($)	QUANTITY	ITEM TOTAL($)
2501	UTILITY ISSUE FEE	480.00	1	480.00
			TOTAL AMOUNT:	**$480.00**

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Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,088	11/12/2024	12138052	069366-0580418_KUR2C06US	2051

27500 7590 10/23/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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P.O BOX 10500
McLean, VA 22102

ISSUE NOTIFICATION

The projected patent number and issue date are specified above. The patent will issue electronically. The electronically issued patent is the official patent grant pursuant to 35 U.S.C. § 153. The patent may be accessed on or after the issue date through Patent Center at https://patentcenter.uspto.gov/. The patent will be available in both the public and the private sides of Patent Center. Further assistance in electronically accessing the patent, or about Patent Center, is available by calling the Patent Electronic Business Center at 1-888-217-9197.

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Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Center (https://patentcenter.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional inventors):

Bobby E. ROGERS, Park City, UT;
Gino KANG, Irvine, CA;
John DETLOFF, San Diego, CA;

APPLICANT(s) (Please see PATENT CENTER site https://patentcenter.uspto.gov for additional applicants):

Kurin, Inc., San Diego, CA;

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FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Thu Oct 10 05:00:19 EDT 2024

Dear Patent Center Customer:

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Application	Document	Mailroom Date	Attorney Docket No.
18783088	NOA	10/10/2024	069366-0580418_KUR2C06US
18783088	1449	10/10/2024	069366-0580418_KUR2C06US

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SUBJECT: USPTO: Patent Electronic System - Correspondence Notification for Customer Number 27500

Thu Oct 24 05:00:27 EDT 2024

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Application	Document	Mailroom Date	Attorney Docket No.
18783088	ISSUE.NTF	10/23/2024	069366-0580418_KUR2C06US

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/783,088	07/24/2024	Bobby E. ROGERS	069366-0580418_KUR2C06US	2051

27500 7590 11/12/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
11/12/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

APPLICATION NO.	ISSUE DATE	PATENT NO.
18/783,088	12-Nov-2024	12138052

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
McLean, VA 22102

EGRANT NOTIFICATION

Your electronic patent grant (eGrant) is now available, which can be accessed via Patent Center at https://patentcenter.uspto.gov

The electronic patent grant is the official patent grant under 35 U.S.C. 153. For more information, please visit https://www.uspto.gov/electronicgrants

TO: Docket_IP@pillsburylaw.com
FROM: noreply@uspto.gov
CC: patentcenter_eofficeaction@uspto.gov
SUBJECT: USPTO: Patent Electronic System - eGrant Notification for Customer Number 27500

Tue Nov 12 06:25:46 EST 2024

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Application	Patent	Document	Mailroom Date	Attorney Docket No.
18783088	12138052	EGRANT.NTF	11/12/2024	069366-0580418_KUR2C06US

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
18/783,088	07/24/2024	Bobby E. ROGERS	069366-0580418_KUR2C06US

CONFIRMATION NO. 2051

27500
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

PUBLICATION NOTICE

Date Mailed: 11/14/2024

Title:BLOOD SAMPLE OPTIMIZATION DEVICE

Publication No.US-2024-0374186-A1
Publication Date:11/14/2024

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be viewed using the USPTO's publicly available Searchable Databases via the Patent Public Search tool at www.uspto.gov. The direct link to access the Patent Public Search tool is currently https://ppubs.uspto.gov/pubwebapp/static/pages/ppubsbasic.html.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through Patent Center, the USPTO's electronic patent application filing and management system. The direct link to access this status information is currently https://patentcenter.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of Patent Center.

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18783088	NTC.PUB	11/14/2024	069366-0580418_KUR2C06US

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