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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/931,333	04/20/2021	10980934	130670-80103	7421
86738	7590	03/31/2021		
MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston, MA 02110				

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

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 Application Information Retrieval (PAIR) WEB site (<http://pair.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 Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Michael Ragusa, Hingham, MA;
Haemonetics Corporation, Boston, MA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

Document Description: Issue Fee Payment (PTO-85B)

Issue Fee Transmittal Form

Application Number	Filing Date	First Named Inventor	Atty. Docket No.	Confirmation No.
16931333	16-Jul-2020	Michael Ragusa	130670-80103	7421

TITLE OF INVENTION :

SYSTEM AND METHOD FOR COLLECTING PLASMA

Entity Status	Application Type	Art Unit	Class - Subclass	EXAMINER
Regular Undiscounted	Utility under 35 USC 111(a)	3799	006040	LESLIE DEAK
Issue Fee Due	Publication Due	Total Fee(s) Due	Date Due	Prev. Paid Fee
\$1200	\$0	\$1200	05-May-2021	\$0

1.Change of Correspondence Address and/or Indication Of Fee Address (37 CFR 1.33 & 1.363)

Current Correspondence Address:	Current Indicated Fee Address :
86738 MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston MA 02110 UNITED STATES 617-449-6500 ~~doctet@mccarter.com~~	
☐ Change of correspondence address requested, system generated AIA/122-EFS form attached	☐ Fee Address indication requested, system generated SB/47-EFS form attached

2.Entity Status**Change in Entity Status**

Applicant certifying micro entity status; system generated Micro Entity certification form attached. See 37 CFR 1.29.

Note: Absent a valid certification of micro entity status, issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment. If this box is checked, you will be prompted to choose a micro entity status on the gross income basis (37 CFR 1.29(a)) or the institution of higher education basis (37 CFR 1.29(d)), and make the applicable certification online.



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.



Document Description: Issue Fee Payment (PTO-85B)

3.The Following Fee(s) Are Submitted:☒ Issue Fee☐ I authorize USPTO to apply my previously paid issue fee to the current fees due☐ Publication Fee☐ The Director is hereby authorized to apply my previously paid issue fee to the current fee due and to charge deficient fees to Deposit Account Number _____☐ Advance Order - # of copies _____

If **in addition to** the payment of the issue fee amount submitted with this form, there are any discrepancies in any amount(s) due, the Director is authorized to charge any deficiency, or credit any overpayment, to Deposit Account Number 50-4876.

☒ The **issue fee must be submitted** with this form. **If payment of the issue fee does not accompany this form, checking this box and providing a deposit account number will NOT be effective to satisfy full payment of the fee(s) due.**

4.Firm and/or Attorney Names To Be Printed**NOTE: If no name is listed, no name will be printed**

For printing on the patent front page, list to be displayed as entered

1. McCarter & English, LLP

2. Jonathan C. Lovely

3.

5.Assignee Name(s) and Residence Data To Be Printed

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

Name	City	State	Country	Category
HAEMONETICS CORPORATION	Boston	MASSACHUSETTS	united states	corporation

6.Signature

I certify, in accordance with 37 CFR 1.4(d)(4) that I am an attorney or agent registered to practice before the Patent and Trademark Office who has filed and has been granted power of attorney in this application. I also certify that this Fee(s) Transmittal form is being transmitted to the USPTO via EFS-WEB on the date indicated below.

Signature	/Jonathan C. Lovely/	Date	03-18-2021
Name	Jonathan C. Lovely	Registration Number	60821

Electronic Patent Application Fee Transmittal				
Application Number:		16931333		
Filing Date:		16-Jul-2020		
Title of Invention:		SYSTEM AND METHOD FOR COLLECTING PLASMA		
First Named Inventor/Applicant Name:		Michael Ragusa		
Filer:		Jonathan Lovely		
Attorney Docket Number:		130670-80103		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY APPL ISSUE FEE	1501	1	1200	1200
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				1200

Electronic Acknowledgement Receipt	
EFS ID:	42214879
Application Number:	16931333
International Application Number:	
Confirmation Number:	7421
Title of Invention:	SYSTEM AND METHOD FOR COLLECTING PLASMA
First Named Inventor/Applicant Name:	Michael Ragusa
Customer Number:	86738
Filer:	Jonathan Lovely
Filer Authorized By:	
Attorney Docket Number:	130670-80103
Receipt Date:	18-MAR-2021
Filing Date:	16-JUL-2020
Time Stamp:	14:55:35
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$1200
RAM confirmation Number	E20213HE55322217
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Web85b.pdf	46314	no	2
			5752c4e48ba3666cee3ef66cc044a536dcae dd29		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	31989	no	2
			5cd15aa401c3121819a1796d1f5dd71e965a d55a		
Warnings:					
Information:					
Total Files Size (in bytes):			78303		
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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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NOTICE OF ALLOWANCE AND FEE(S) DUE

86738 7590 02/05/2021
MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston, MA 02110

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3799

DATE MAILED: 02/05/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/931,333	07/16/2020	Michael Ragusa	130670-80103	7421

TITLE OF INVENTION: SYSTEM AND METHOD FOR COLLECTING PLASMA

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	05/05/2021

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.

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 and an extra copy of the form should be submitted. 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 including the Patent, advance orders and notification of maintenance fees 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.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

86738 7590 02/05/2021
MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston, MA 02110

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.
16/931,333	07/16/2020	Michael Ragusa	130670-80103	7421

TITLE OF INVENTION: SYSTEM AND METHOD FOR COLLECTING PLASMA

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$1200	\$0.00	\$0.00	\$1200	05/05/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
DEAK, LESLIE R	3799	604-006040

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/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 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,

1 _____

(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.

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. _____



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/931,333	07/16/2020	Michael Ragusa	130670-80103	7421
86738	7590	02/05/2021	EXAMINER	
MCCARTER & ENGLISH, LLP BOSTON			DEAK, LESLIE R	
265 Franklin Street			ART UNIT	
Boston, MA 02110			PAPER NUMBER	
			3799	
DATE MAILED: 02/05/2021				

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. 16/931,333	Applicant(s) Ragusa, Michael	
	Examiner LESLIE R DEAK	Art Unit 3799	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 TD and arguments filed 8 January 2021.
☐ 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 1-30 . 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)	5. ☐ Examiner's Amendment/Comment
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.	6. ☐ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.	7. ☐ Other _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____.	

/LESLIE R DEAK/ Primary Examiner, Art Unit 3799	
--	--

<i>Search Notes</i> 	Application/Control No. 16/931,333	Applicant(s)/Patent Under Reexamination Ragusa, Michael
	Examiner LESLIE R DEAK	Art Unit 3799

CPC - Searched*		
Symbol	Date	Examiner
(A61M1/024 OR A61M1/029 OR A61M1/3672 OR A61M1/3693 OR A61M1/38 OR A61M2202/0415 OR A61M2230/207 OR G01N15/05 OR G01N2015/055 OR G01N15/042 OR G01N33/86).CPC.	10/28/2019	LRD
A61M1/029 A61M1/3672 A61M1/3693 A61M1/38 A61M2202/0415 A61M2230/207	11/05/2020	LRD

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.

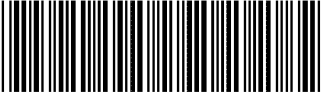
Search Notes		
Search Notes	Date	Examiner
inventor name search, EAST BRS search, consulted foreign search report	10/28/2019	LRD
updated prior searches, consulted primary examiners	02/27/2020	LRD
updated prior searches	05/05/2020	LRD
consulted parent case, updated searches, ODP	11/06/2020	LRD
consulted parent, copending cases, ODP	11/10/2020	LRD
consulted parent cases, interview notes	02/01/2021	LRD

/LESLIE R DEAK/ Primary Examiner, Art Unit 3799	
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<i>Search Notes</i> 	Application/Control No. 16/931,333	Applicant(s)/Patent Under Reexamination Ragusa, Michael
	Examiner LESLIE R DEAK	Art Unit 3799

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
	N/A	05/05/2020	LRD

/LESLIE R DEAK/ Primary Examiner, Art Unit 3799	
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Issue Classification 	Application/Control No. 16/931,333	Applicant(s)/Patent Under Reexamination Ragusa, Michael
	Examiner LESLIE R DEAK	Art Unit 3799

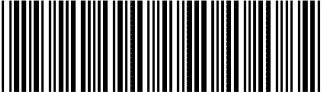
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A61M	/	1	/	3672	A	2013-01-01
A61M	/	1	/	3693	A	2013-01-01
A61M	/	2202	/	0415	A	2013-01-01
A61M	/	1	/	3496	A	2013-01-01
A61M	/	2205	/	3379	A	2013-01-01
A61M	/	2205	/	3393	A	2013-01-01
A61M	/	2205	/	3306	A	2013-01-01
A61M	/	1	/	3626	A	2013-01-01
A61M	/	2230	/	207	A	2013-01-01

CPC Combination Sets				
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NONE (Assistant Examiner) (Date)		Total Claims Allowed: 30	
/LESLIE R DEAK/ Primary Examiner, Art Unit 3799 (Primary Examiner) (Date)		01 February 2021 O.G. Print Claim(s) 1	O.G. Print Figure 5

U.S. Patent and Trademark Office

Part of Paper No.: 20210201

Issue Classification 	Application/Control No. 16/931,333	Applicant(s)/Patent Under Reexamination Ragusa, Michael
	Examiner LESLIE R DEAK	Art Unit 3799

INTERNATIONAL CLASSIFICATION			
CLAIMED			
A61M1/38		1	 38
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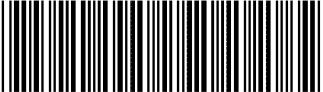
US ORIGINAL CLASSIFICATION	
CLASS	SUBCLASS

CROSS REFERENCES(S)						
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NONE		Total Claims Allowed:	
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/LESLIE R DEAK/ Primary Examiner, Art Unit 3799	01 February 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	5

U.S. Patent and Trademark Office

Part of Paper No.: 20210201

Issue Classification 	Application/Control No. 16/931,333	Applicant(s)/Patent Under Reexamination Ragusa, Michael
	Examiner LESLIE R DEAK	Art Unit 3799

☒ 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

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 30	
/LESLIE R DEAK/ Primary Examiner, Art Unit 3799 (Primary Examiner) _____ (Date) 01 February 2021		O.G. Print Claim(s) 1	O.G. Print Figure 5

U.S. Patent and Trademark Office

Part of Paper No.: 20210201

EAST Search History**EAST Search History (Prior Art)**

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Bibliographic Data

Application No: 16/931,333

Foreign Priority claimed: ☐ Yes ☒ No

35 USC 119 (a-d) conditions met: ☐ Yes ☒ No ☐ Met After Allowance

Verified and Acknowledged:

/LESLIE R DEAK/

Examiner's Signature

Initials

Title:

SYSTEM AND METHOD FOR COLLECTING PLASMA

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
07/16/2020	604	3799	130670-80103
RULE			

APPLICANTS

Haemonetics Corporation, Boston, MA,

INVENTORS

Michael Ragusa, Hingham, MA, UNITED STATES

CONTINUING DATA

This application is a CON of 15793339 10/25/2017 PAT 10792416

15793339 is a CIP of 15608183 05/30/2017 PAT 10758652

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

07/27/2020

STATE OR COUNTRY

UNITED STATES

ADDRESS

MCCARTER & ENGLISH, LLP BOSTON

265 Franklin Street

Boston, MA 02110

UNITED STATES

FILING FEE RECEIVED

\$7,320

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.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875				Application or Docket Number 16/931,333		Filing Date 07/16/2020		☐ To be Mailed		
ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO										
APPLICATION AS FILED - PART I										
		(Column 1)	(Column 2)							
FOR		NUMBER FILED	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), (l), 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(j))		minus 20 =	*		x \$100 =					
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 =	*		x \$460 =					
☐ 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										
		(Column 1)	(Column 2)		(Column 3)					
AMENDMENT	01/08/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)			
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	Independent (37 CFR 1.16(h))	* 4	Minus	*** 4	= 0	x \$480 =	0			
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	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
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	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".						/DEBRA A SAVOY/				
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Docket No.: 130670-80103
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Utility Application of:
Haemonetics Corporation

Application No.: 16/931,333

Confirmation No.: 7421

Filed: July 16, 2020

Art Unit: 3799

For: SYSTEM AND METHOD FOR COLLECTING
PLASMA

Examiner: L. R. Deak

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION UNDER 37 C.F.R. § 1.111

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

In response to the Office Action dated November 17, 2020, please amend the above-identified U.S. patent application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS

The following **Listing of Claims** will replace all prior versions, and listing, of claims in the application.

Listing of Claims

1. (Original) A method for collecting plasma comprising:
 - (a) determining the weight and height of a donor;
 - (b) determining the hematocrit of the donor;
 - (c) calculating a donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor;
 - (d) calculating a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma;
 - (e) withdrawing whole blood from the donor through a venous-access device and a first line, the first line connected to a blood component separation device;
 - (f) introducing anticoagulant into the withdrawn whole blood through an anticoagulant line;
 - (g) separating the withdrawn whole blood into a plasma component and at least a second blood component;
 - (h) collecting the plasma component from the blood component separation device and into a plasma collection container;
 - (i) continuing steps (e) through (h) until the target plasma volume to collect is reached in the plasma collection container.
2. (Original) A method according to claim 1, further comprising:
 - calculating a volume of anticoagulant to be collected with the plasma component in the plasma collection container, the volume of anticoagulant to be collected with the plasma component based, at least in part, on the hematocrit of the donor.
3. (Original) A method according to claim 2, wherein the target plasma volume to collect is a target volume of pure plasma to collect plus the calculated volume of anticoagulant to be collected.

4. (Original) A method according to claim 2, wherein the target plasma volume to collect is a target volume of pure plasma to collect in the plasma collection container, the target volume of pure plasma to collect based, at least in part, upon the volume of anticoagulant to be collected with the plasma component in the plasma collection container.

5. (Original) A method according to claim 1, further comprising:

calculating the donor's body mass index based, at least in part on the weight and height of the donor, the donor plasma volume calculated based, at least in part, on the donor's body mass index.

6. (Original) A method according to claim 1, wherein the target plasma volume to collect is calculated before withdrawing whole blood.

7. (Original) A method according to claim 1, wherein the target percentage of plasma is between 26.5 and 29.5 percent of the donor's plasma volume.

8. (Currently Amended) A system for collecting plasma comprising:

a venous-access device for drawing whole blood from a ~~subject~~ donor and returning blood components to the donor;

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container;

a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump;

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to control the operation of the blood component separation device and the first pump, the controller configured to calculate (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, (2) a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target

percentage of plasma, and (3) a volume of plasma component collected within the plasma collection container, the controller configured to stop the first pump when the calculated volume of plasma component collected within the plasma collection container equals the target plasma volume to collect.

9. (Original) A system according to claim 8, wherein the controller is further configured to calculate a volume of anticoagulant to be collected with the plasma component in the plasma collection container, the volume of anticoagulant to be collected with the plasma component based, at least in part, on the hematocrit of the donor.

10. (Original) A system according to claim 9, wherein the target plasma volume to collect is a target volume of pure plasma to collect plus the calculated volume of anticoagulant to be collected.

11. (Original) A system according to claim 9, wherein the target plasma volume to collect is a target volume of pure plasma to collect within the plasma collection container, the target volume of pure plasma to collect based, at least in part, upon the volume of anticoagulant to be collected with the plasma component in the plasma collection container, the controller configured to stop the first pump when the volume of pure plasma collected within the plasma collection container equals the target plasma collection volume.

12. (Original) A system according to claim 8, wherein the controller is further configured to calculate the donor's body mass index based, at least in part on the weight and height of the donor, the donor plasma volume calculated based, at least in part, on the donor's body mass index.

13. (Original) A system according to claim 8, wherein the target plasma volume to collect is calculated before withdrawing whole blood.

14. (Original) A system according to claim 8, wherein the target percentage of plasma is between 26.5 and 29.5 percent of the donor's plasma volume.

15. (Original) A method for programming a blood processing device comprising:

- (a) receiving, in a control system, a weight and height of a donor;
- (b) receiving, in a control system, a hematocrit of the donor;

(c) calculating, using the control system, a donor plasma volume, the control system calculating the donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor;

(d) calculating, using the control system, a target plasma volume to collect, the control system calculating the target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma;

(e) determining a target collection volume based, at least in part, on the calculated target plasma volume to collect; and

(f) programming a controller of a blood processing device with a blood processing end point, the blood processing end point being based, at least in part, on the target collection volume.

16. (Original) A method according to claim 15, further comprising:

calculating, using the control system, a volume of anticoagulant to be collected with a plasma component in a plasma collection container, the control system calculating the volume of anticoagulant to be collected with the plasma component based, at least in part, on the hematocrit of the donor.

17. (Original) A method according to claim 16, wherein the target plasma volume to collect is a target volume of pure plasma to collect, the target volume of pure plasma to collect based, at least in part, upon the volume of anticoagulant to be collected with the plasma component.

18. (Original) A method according to claim 17, wherein the target collection volume is the target volume of pure plasma to collect.

19. (Original) A method according to claim 17, wherein the target collection volume is the target volume of pure plasma to collect plus the calculated volume of anticoagulant to be collected in the plasma collection container.

20. (Original) A method according to claim 15, further comprising:

calculating, using the control system, the donor's body mass index based, at least in part on the weight and height of the donor, the control system calculating the donor plasma volume based, at least in part, on the donor's body mass index.

21. (Original) A method according to claim 15, wherein the blood processing end point is when the target collection volume has been collected within a plasma collection container of the blood processing device.

22. (Original) A method according to claim 15, wherein the control system includes the controller.

23. (Original) A system for collecting plasma comprising:

a blood processing device including:

a venous-access device for drawing whole blood from a donor and returning blood components to the donor,

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container,

a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump, and

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to (1) calculate a donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor, (2) calculate a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, and (3) calculate a target collection volume based, at least in part, on the calculated target plasma volume to collect.

24. (Original) The system according to claim 23, wherein the blood processing device is configured to stop the blood draw pump when the target collection volume is collected within the plasma collection container.

25. (Original) The system according to claim 23, wherein the controller is part of the blood processing device.

26. (Original) The system according to 23, wherein the controller is further configured to program the blood processing device with a blood processing end point based, at least in part, on the target collection volume.

27. (Original) A system according to claim 26, wherein the blood processing end point is when the target collection volume has been collected within the plasma collection container.

28. (Original) A system according to claim 23, wherein the target plasma volume to collect is a target volume of pure plasma to collect in the plasma collection container, the target volume of pure plasma to collect based, at least in part, upon a volume of anticoagulant to be collected with the plasma component in the plasma collection container.

29. (Original) A system according to claim 28, wherein the target collection volume is the target volume of pure plasma to collect and/or the target volume of pure plasma to collect plus the volume of anticoagulant to be collected in the plasma container.

30. (Original) A system according to claim 23, wherein the controller is further configured to calculate the donor's body mass index based, at least in part on the weight and height of the donor, the donor plasma volume based, at least in part, on the donor's body mass index.

REMARKS

Applicants would like to thank the examiner for the review of the present application. Applicants request reconsideration of the pending claims in view of the following remarks. Applicant has amended claim 8 herewith such that the claim consistently uses the term “donor.” Claims 1-30 are currently pending in the application.

Examiner Interview Summary

Applicant would like to thank Examiner Deak for the telephone interview on December 11, 2020. During the interview, Examiner Deak and Applicant’s counsel discussed the present application and the related pending application U.S. 16/866,078 (Attorney Docket No. 130670-08005). With respect to this application, Examiner Deak, and Applicant’s counsel discussed the pending claims, the Office Action dated November 17, 2020 and the cited prior art (e.g., U.S. Application No. 2003/012881 to Ryan, hereinafter “Ryan”). In particular, Applicant’s counsel and Examiner Deak discussed the double patenting rejection raised within the office action. During the discussion, Examiner Deak agreed to withdraw the double patenting rejection over U.S. Patent No. 10,758,562 and co-pending application 16/866,0778 and noted the double patenting rejection should be over U.S. Patent No. 10,792,416. Applicant’s counsel indicated that Applicant will file a terminal disclaimer with respect to U.S. Patent No. 10,792,416 with the response.

With regard to the prior art rejections, Applicant’s counsel explained, among other things, (1) the reason why the present claims calculate the donor plasma volume and then take a percentage of the donor plasma volume to calculate a target plasma volume to collect and (2) that Ryan doesn’t calculate a total plasma volume and, therefore, cannot then calculate the target plasma volume based on the total plasma volume. Additionally, Applicant’s counsel explained that Ryan does not/cannot determine the total plasma volume because they don’t look at height (e.g., it is not included in the list of donor factors in paragraph [0014]) and, therefore, cannot calculate BMI. In the response, Examiner Deak asked Applicant to clarify that the “at least in part” language within the claims does not omit the use of one or more of the cited parameters in the calculation, but rather allows additional parameters as part of the calculations. Examiner Deak indicated that, based on our

discussion and if we include the above in the response, the response should result in a notice of allowance.

Double Patenting

The office action originally rejected claims 1-3, 8-17 and 23-30 on the grounds of nonstatutory double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 10,758,652. Additionally, the office action provisionally rejected claims 1-3, 8-17 and 23-30 on the grounds of nonstatutory double patenting as being unpatentable over claims 1-3, 8-17 and 23-30 of copending application no. 16/866,078. As discussed during the examiner interview on December 11, 2020, the examiner has withdrawn the double patenting rejection based on U.S. Patent No. 10,758,652 and U.S. Application No. 16/866,078 and issued a new double patenting rejection with respect to U.S. Patent No. 10,792,416. To expedite prosecution, Applicant files herewith a terminal disclaimer with respect to U.S. Patent No. 10,792,416. Accordingly, Applicant believes that this rejection is now moot.

35 USC § 102

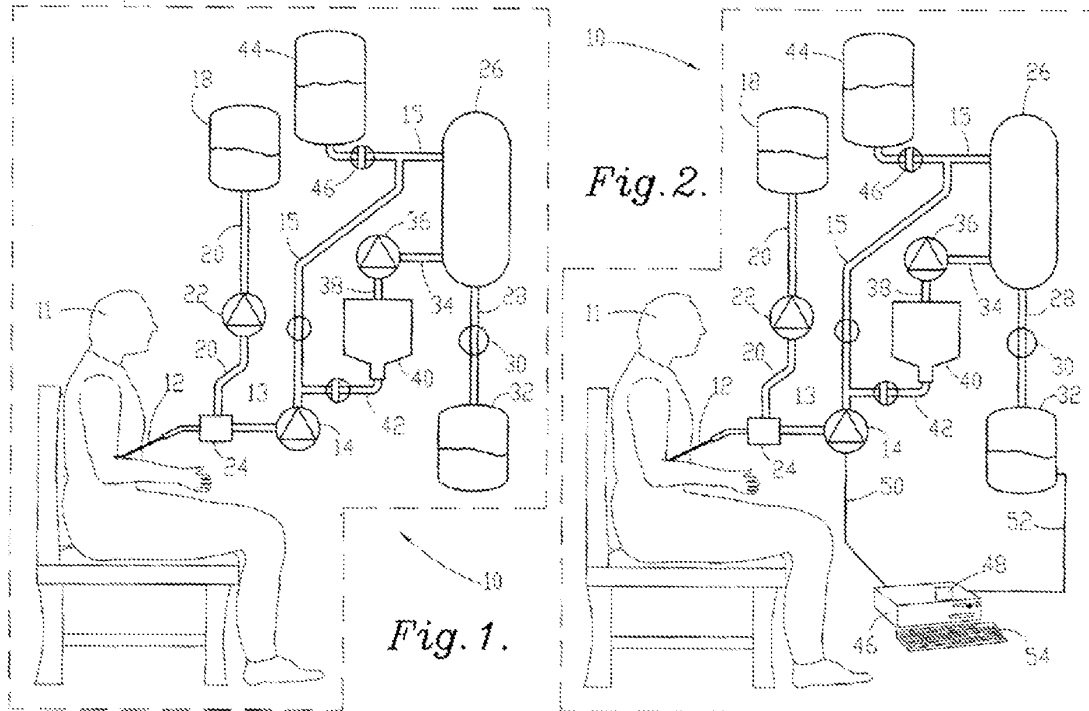
Claims 8-14 and 23-30 are rejected under 35 U.S.C. 102(a)(1) and (a)(2) as being anticipated by U.S. 2003/0125881 to Ryan.

Claim 8 defines, in relevant part, a system for collecting plasma that includes a venous-access device for drawing whole blood from a subject and returning blood components to the donor, a blood component separation device for separating the drawn blood into a plasma component and a second blood component, a first line and an anticoagulant line. The blood component separation device has an outlet and is configured to send the plasma component to a plasma collection container. The first line is fluidly connected to the venous-access device, transports drawn whole blood to the blood component separation device, and returns fluid within the blood component separation device to the donor. The flow through the first line is controlled by a first pump. The anticoagulant line is connected to an anticoagulant source and introduces anticoagulant into the drawn whole blood. The system also has a controller that controls the operation of the blood

component separation device and the first pump. The controller calculates (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, (2) a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, and (3) a volume of plasma component collected within the plasma collection container. The controller stops the first pump when the calculated volume of plasma component collected within the plasma collection container equals the target plasma volume to collect.

Applicant would like to note that, as discussed during the examiner interview dated December 11, 2020, the phrase “based, at least in part,…” within claim 8 (and the other independent claims) means that the related calculation uses at least all of the criteria listed and may use additional criteria. The language is not meant to imply that only a subset of the listed criteria is used. For example, with respect to the donor plasma volume, the claimed controller (or method step) uses the weight, height and hematocrit of the donor, and perhaps additional criteria.

Ryan fails to teach or suggest the claimed system. Rather, Ryan teaches a method and apparatus for collecting a plasma portion and that withdraws donor-weight specific plasma and blood volumes. Ryan’s plasmapheresis system 10 includes a controller 46 that is in communicative control of a whole blood pump 14 as a function of either the volume of blood pumped by pump 14 or the volume of plasma contained in plasma reservoir 32 (e.g., as determined by the weight of the plasma reservoir 32 or by volume using optical sensors). The data from the scale or from the optical sensor is transmitted to the controller 46 and a processor 48 which monitor the amount of plasma collected. During operation, a donor 11 is weighed on a conventional scale, and the donor-specific body weight of the donor is obtained. Ryan then provides the processor 48 with the donor-specific body weight and the processor 48 calculates a particular plasma volume to be extracted from the donor based upon the donor-specific body weight and a selected standard of milliliters of plasma per pound of body weight. Ryan continues processing whole blood and collecting plasma until the calculated plasma volume is collected as determined by the number of revolutions of the pump 14 or the “actual” volume of plasma collected in the plasma reservoir 32 as measured by the weight of the reservoir 32 or the optical sensor.



The office action suggests that Ryan's controller/processor 46/48 constitutes the claimed controller and that Ryan's controller/processor 46/48 performs the calculations of claim 8 (e.g., (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, and (2) a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma). Applicant respectfully disagrees. As a preliminary matter, Applicant would like to note that Ryan fails to teach or suggest calculating a donor plasma volume based on the weight, height, and hematocrit of the donor. Rather, as discussed above, Ryan merely calculates a total collection volume based on the weight of the donor -- for example, Ryan's collection volume is 5.8mL X the weight of the donor. Ryan does not calculate the donor plasma volume and then calculate a target plasma to collected based on a percentage of the total donor plasma volume.

During the examiner interview dated December 11, 2020, Examiner Deak pointed to paragraph [0014] of Ryan as possibly teaching the donor plasma volume calculation. However, this paragraph merely states “The determination of the amount of plasma which can be derived from an individual donor is calculated based on the donor’s body weight, hematocrit, and the amount of anticoagulant in the procedure.” It is not clear what Ryan means by “amount plasma that can be derived from an individual donor” but it does not appear to refer to the donor’s total plasma volume (how much plasma the donor has) – it appears to refer to how much plasma may be collected from the donor. In fact, as discussed during the Examiner Interview dated December 11, 2020, because Ryan does not use the donor’s height, Ryan cannot calculate the donor’s total plasma volume and use the donor’s Body Mass Index (e.g., claim 12).

Accordingly, claim 8 is allowable over Ryan. Moreover, claims 9-14 which depend from claim 8 are also allowable over Ryan

In a manner similar to claim 8, claim 23 teaches a system for collecting plasma with a controller that calculates (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, and (2) a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma. Therefore, claim 23 is allowable over Ryan for at least the same reasons as discussed above for claim 8. Moreover, claims 24-30 which depend from claim 23 are allowable over Ryan for at least the same reasons.

35 USC § 103

Claims 1-7 and 15-22 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. 2003/0125881 to Ryan in view of U.S. Patent No. 7,270,645 (Langley et al., hereinafter “Langley”).

In a manner similar to claim 8, claims 1 and 15 teach methods that calculate (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, and a (2) a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma. Therefore, claims 1 and 15 are allowable over

Ryan for at least the same reasons as discussed above for claim 8. Moreover, claims 2-7 and 16-22 which depend from claims 1 and 15 are allowable over Ryan for at least the same reasons.

Additionally, Langley fails to teach or suggest the deficiencies of Ryan. In particular, Langley teaches an apparatus for producing blood component products that uses two on-line yield determination techniques to determine the yield for the harvested blood components. One is a predetermined yield prediction technique and the second is a predetermined yield monitoring technique, each of which are individually calibrated in relation to a predetermined off-line yield determination technique. The predetermined yield prediction and monitoring techniques each provide the yield for the harvested blood components and each is then utilized to provide a determined yield. When the harvested blood components are packaged, the determined yield may be associated therewith, thereby providing a blood component product.

Langley provides several yield calculation/predictions. However, nowhere does Langley teach or suggest calculating (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, and a (2) a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma. Rather, at best, Langley suggests that the plasma volume may be based solely on weight (e.g., 600 mL if the donor weighs more than 175 pounds or 500 mL if the donor weighs less than 175 pounds) or may just be a percentage of the blood volume – Langley does not calculate the donor's plasma volume based on the weight, height and hematocrit and then calculate the target plasma volume to collected based on the calculated donor plasma volume and a target percentage of plasma. Accordingly, claims 1 and 15 are allowable over Ryan and Langley, alone or in combination with one another. Moreover, claims 2-7 and 16-22, which depend from claims 1 and 15 are allowable over the combination of Ryan and Langley for at least the same reasons.

CONCLUSION

It is believed that the application is now in order for allowance and Applicant respectfully requests that a notice of allowance be issued. Applicant does not believe that any extension of time is required. However, if an extension of time is required, please charge the associated fee and any

Application No. 16/931,333
Amendment dated January 8, 2021
Reply to Office Action of November 17, 2020

Docket No.: 130670-80103

additional fees required by this paper or credit any overpayment to deposit account number 50-4876. Applicants also request that the examiner contact applicant's attorney, Jonathan C. Lovely, if it will assist in processing this application through issuance.

Dated: January 8, 2021

Respectfully submitted,
Electronic signature: /Jonathan C. Lovely, Reg.
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Attorney/Agent For Applicant

Electronic Acknowledgement Receipt	
EFS ID:	41590123
Application Number:	16931333
International Application Number:	
Confirmation Number:	7421
Title of Invention:	SYSTEM AND METHOD FOR COLLECTING PLASMA
First Named Inventor/Applicant Name:	Michael Ragusa
Customer Number:	86738
Filer:	Jonathan Lovely
Filer Authorized By:	
Attorney Docket Number:	130670-80103
Receipt Date:	08-JAN-2021
Filing Date:	16-JUL-2020
Time Stamp:	10:53:20
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Response_to_Non-Final_Office_Action_due_217.pdf	726775	yes	14
			45409e56acee5515a362b5c88063e3ca231d1b32		

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	14
Warnings:			
Information:			
Total Files Size (in bytes):		726775	
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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.			

Doc Code: DIST.E.FILE Document Description: Electronic Terminal Disclaimer - Filed		PTO/SB/26 U.S. Patent and Trademark Office Department of Commerce
Electronic Petition Request	TERMINAL DISCLAIMER TO OBTAIN A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	
Application Number	16931333	
Filing Date	16-Jul-2020	
First Named Inventor	Michael Ragusa	
Attorney Docket Number	130670-80103	
Title of Invention	SYSTEM AND METHOD FOR COLLECTING PLASMA	
☒ Filing of terminal disclaimer does not obviate requirement for response under 37 CFR 1.111 to outstanding Office Action ☒ This electronic Terminal Disclaimer is not being used for a Joint Research Agreement.		
Owner	Percent Interest	
Haemonetics Corporation	100%	
The owner(s) with percent interest listed above in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of prior patent number(s) 10792416 as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns. In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the prior patent, "as the term of said prior patent is presently shortened by any terminal disclaimer," in the event that said prior patent later: - expires for failure to pay a maintenance fee; - is held unenforceable; - is found invalid by a court of competent jurisdiction; - is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321; - has all claims canceled by a reexamination certificate; - is reissued; or - is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer. ☒ Terminal disclaimer fee under 37 CFR 1.20(d) is included with Electronic Terminal Disclaimer request.		

☐ I certify, in accordance with 37 CFR 1.4(d)(4), that the terminal disclaimer fee under 37 CFR 1.20(d) required for this terminal disclaimer has already been paid in the above-identified application.	
Applicant claims the following fee status: ☐ Small Entity ☐ Micro Entity ☒ Regular Undiscounted	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.	
THIS PORTION MUST BE COMPLETED BY THE SIGNATORY OR SIGNATORIES I certify, in accordance with 37 CFR 1.4(d)(4) that I am: ☒ An attorney or agent registered to practice before the Patent and Trademark Office who is of record in this application Registration Number <u>60821</u> ☐ A sole inventor ☐ A joint inventor; I certify that I am authorized to sign this submission on behalf of all of the inventors as evidenced by the power of attorney in the application ☐ A joint inventor; all of whom are signing this request	
Signature	/Jonathan C. Lovely/
Name	Jonathan C. Lovely

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
 Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

Electronic Patent Application Fee Transmittal				
Application Number:		16931333		
Filing Date:		16-Jul-2020		
Title of Invention:		SYSTEM AND METHOD FOR COLLECTING PLASMA		
First Named Inventor/Applicant Name:		Michael Ragusa		
Filer:		Jonathan Lovely		
Attorney Docket Number:		130670-80103		
Filed as Large Entity				
Filing Fees for Utility under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
STATUTORY OR TERMINAL DISCLAIMER	1814	1	170	170
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				170

Doc Code: DISQ.E.FILE

Document Description: Electronic Terminal Disclaimer – Approved

Application No.: 16931333

Filing Date: 16-Jul-2020

Applicant/Patent under Reexamination: Ragusa

Electronic Terminal Disclaimer filed on January 8, 2021

☒ APPROVED

This patent is subject to a terminal disclaimer

☐ DISAPPROVED

Approved/Disapproved by: Electronic Terminal Disclaimer automatically approved by EFS-Web

U.S. Patent and Trademark Office

Electronic Acknowledgement Receipt	
EFS ID:	41590053
Application Number:	16931333
International Application Number:	
Confirmation Number:	7421
Title of Invention:	SYSTEM AND METHOD FOR COLLECTING PLASMA
First Named Inventor/Applicant Name:	Michael Ragusa
Customer Number:	86738
Filer:	Jonathan Lovely
Filer Authorized By:	
Attorney Docket Number:	130670-80103
Receipt Date:	08-JAN-2021
Filing Date:	16-JUL-2020
Time Stamp:	10:49:56
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$170
RAM confirmation Number	E202118A49534060
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer-Filed (Electronic)	eTerminal-Disclaimer.pdf	33274	no	2
			5156dc6eff77977ba08e191f77cd1e7f3822e814		
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30146	no	2
			cacdc2f246c2ebdcaa175b7e2b6d8ecb2097569d		
Warnings:					
Information:					
Total Files Size (in bytes):			63420		
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/931,333	07/16/2020	Michael Ragusa	130670-80103	7421
86738	7590	12/16/2020		
MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston, MA 02110			EXAMINER DEAK, LESLIE R	
			ART UNIT 3799	PAPER NUMBER
			NOTIFICATION DATE 12/16/2020	DELIVERY MODE 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@mccarter.com

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Discussed double patenting rejection. Examiner agrees to withdrawn double patenting rejection over copending case 16/866,078 and its parent, US 10,758,562. Applicant will file a Terminal Disclaimer over this application's parent case, US 10,792,416.

With regard to the prior art rejection, Ryan in para 14 doesn't use height for donor calculations, so can't use BMI and can't calculate total plasma volume, only the amount that can be derived from pt. Examiner noted Applicant should define "at least in part" from the claims as not omitting the use of the claimed parameters in calculations, but allowing additional parameters as part of the calculations.

Applicant will submit formal arguments pointing out the above, which Examiner thinks will overcome the Ryan reference.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/931,333	07/16/2020	Michael Ragusa	130670-80103	7421
86738	7590	11/17/2020		
MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston, MA 02110			EXAMINER DEAK, LESLIE R	
			ART UNIT 3799	PAPER NUMBER
			NOTIFICATION DATE 11/17/2020	DELIVERY MODE 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@mccarter.com

DETAILED ACTION

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.

Double Patenting

2. 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.

3. Claims 1-3, 8-17, 23-30, are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 10,758,652. Although the claims at issue are not identical, they are not patentably distinct from each other. With regard to claims 1-3, the steps of the patented method are substantially similar to the instantly claimed method—using various patient parameters to calculate a volume of pure plasma to be collected, and performing apheresis to collect the target volume. It is unclear how the methods differ from one another in a practical or patentable way, other than the variables used and the order of the steps of the method. With regard to claims 8 and 23, the elements of the apparatus are the same, but are recited in a functionally different manner. With regard to claims 15-17, the programming method claimed by Applicant is realized in the execution of the steps performed in the

patented method. That is, if the patented method performs the steps that are “programmed” into a processing device, the method of programming is already known as a part of the patented method.

With regard to claims 9-14 and 24-30, Applicant is setting forth the intended use of the claimed apparatus, which does not add patentable weight to the structural limitations of the apparatus.

4. Claims 1-3, 8-17, 23-30 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-3, 8-17, 23-30 of copending Application No. 16/866,078 (reference application). Although the claims at issue are not identical, they are not patentably distinct from each other because the instant claims and the copending claims each recite steps of collecting variable parameters from a patient, calculating fluid volumes to generate a desired collection value, and performing apheresis to arrive at the desired volume. Using different variables to arrive at the same outcome is within the skill of a worker in the art.

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

Claim Rejections - 35 USC § 102

5. 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.

(a)(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case maybe, names another inventor and was effectively filed before the effective filing date of the claimed invention.

6. Claims 8-14 and 23-30 are rejected under 35 U.S.C. 102(a)(1) and (a)(2) as being anticipated by US 2003/0125881 to Ryan.

In the specification and figures, Ryan teaches the apparatus as claimed by Applicant. With regard to claims 8 and 23, Ryan discloses a venous access device 12, a blood component separation device 26, plasma container 32, a blood draw line connected to venous access 12, a blood pump 14, an anticoagulant line 20, and a controller 46/48 that calculates a percentage of anticoagulant in the collected plasma, and a volume of plasma collected, and an appropriate time to stop blood pump 14 (see FIG 2, Table 2, ¶1022).

With regard to claims 9-14 and 24-30, Applicant is setting forth the intended use of the claimed apparatus, which does not add patentable weight to the structural limitations of the apparatus.

Claim Rejections - 35 USC § 103

7. 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.

8. Claims 1-7, 15-22 are rejected under 35 U.S.C. 103 as being unpatentable over US 2003/0125881 to Ryan in view of US 7,270,645 to Langley et al.

In the specification and figures, Ryan teaches the method substantially as claimed by Applicant. With regard to claims 1-4, 6, and 7, Ryan teaches a method for collecting plasma comprising the steps of using donor weight, donor hematocrit and amount/ratio of anticoagulant used to determine a target amount of plasma that can be collected from a patient (see ¶0014). Once that determination is made, the method includes the steps of drawing blood from a patient, adding anticoagulant, separating the blood, collecting the plasma, and repeating those steps until a target plasma volume is reached (see ¶011, 0012, 0022, 0023). Ryan does not teach using a patient's height as a variable nor that the steps of the method are performed in the same order as set forth by Applicant, but does teach using many of the same variables as those used by Applicant (donor weight, hematocrit, amount of anticoagulant) to generate the same result (target plasma volume).

Langley discloses an apparatus and method for producing blood component products including using the height and weight of a donor to make fluid calculations to generate a desired collection yield (see at least column 14, lines 4-22). Langley's disclosure indicates that using a patient's weight to calculate a desired yield is well known in the art. Accordingly, it would have been obvious to a person having ordinary skill in the art at the time of filing to use both height and weight as disclosed by Langley in the calculations performed by Ryan, in order to provide a desired yield, as taught by Langley.

With regard to claims 15-18, 21, and 22, the programming method claimed by Applicant is realized in the execution of the steps performed in the disclosed method. That is, if the disclosed method performs the steps that are “programmed” into a processing device, the method of programming is already known as a part of the disclosed method.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday-Friday, 9am to 5:30pm.

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, Tom Sweet can be reached on 571-272-4761. 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 <https://ppair-my.uspto.gov/pair/PrivatePair>. Should you have questions on access to the Private

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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.

**/LESLIE R DEAK/
Primary Examiner, Art Unit 3799
9 November 2020**

<i>Notice of References Cited</i>	Application/Control No. 16/931,333		Applicant(s)/Patent Under Reexamination Ragusa, Michael	
	Examiner LESLIE R DEAK		Art Unit 3799	Page 1 of 1

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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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*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.

<i>Search Notes</i> 	Application/Control No. 16/931,333	Applicant(s)/Patent Under Reexamination Ragusa, Michael
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CPC - Searched*		
Symbol	Date	Examiner
(A61M1/024 OR A61M1/029 OR A61M1/3672 OR A61M1/3693 OR A61M1/38 OR A61M2202/0415 OR A61M2230/207 OR G01N15/05 OR G01N2015/055 OR G01N15/042 OR G01N33/86).CPC.	10/28/2019	LRD
A61M1/029 A61M1/3672 A61M1/3693 A61M1/38 A61M2202/0415 A61M2230/207	11/05/2020	LRD

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
inventor name search, EAST BRS search, consulted foreign search report	10/28/2019	LRD
updated prior searches, consulted primary examiners	02/27/2020	LRD
updated prior searches	05/05/2020	LRD
consulted parent case, updated searches, ODP	11/06/2020	LRD
consulted parent, copending cases, ODP	11/10/2020	LRD

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<i>Search Notes</i> 	Application/Control No. 16/931,333	Applicant(s)/Patent Under Reexamination Ragusa, Michael
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Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
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Doc description: Information Disclosure Statement (IDS) Filed

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Filing Date	
	First Named Inventor	Michael Ragusa
	Art Unit	N/A
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	130670-80103

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156	6743192	B1	2004-06-01	Sakota et al.	
157	7115205	B2	2006-10-03	Robinson et al.	
158	7186231	B2	2007-03-06	Takagi et al.	
159	7270645	B2	2007-09-18	Langley et al.	
160	7704454	B1	2010-04-27	Langley et al.	
161	8628489	B2	2014-01-14	Pages et al.	
162	8702637	B2	2014-04-22	Pages et al.	

**INFORMATION DISCLOSURE
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Application Number	
Filing Date	
First Named Inventor	Michael Ragusa
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	130670-80103

163	8759094	B2	2014-06-24	Ranby
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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	20010000185	A1	2001-04-05	Keller et al.	
	2	20010027156	A1	2001-10-04	Egozy et al.	
	3	20020043492	A1	2002-04-18	Bischof	
	4	20020062100	A1	2002-05-23	Pierce et al.	
	5	20020120227	A1	2002-08-29	Childers et al.	
	6	20030055375	A1	2003-03-20	Holst et al.	
	7	20030066807	A1	2003-04-10	Suzuki	
	8	20030125881	A1	2003-07-03	Ryan	

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Examiner Name	Not Yet Assigned	
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9	20030175150	A1	2003-09-18	Grimm	
10	20040186409	A1	2004-09-23	Cavalcanti et al.	
11	20050209522	A1	2005-09-22	Tadokoro et al.	
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13	20060058167	A1	2006-03-16	Ragusa et al.	
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15	20070112289	A1	2007-05-17	Cavalcanti et al.	
16	20080146993	A1	2008-06-19	Krishna	
17	20120175313	A1	2012-07-12	Barry, JR. et al.	
18	20140039373	A1	2014-02-06	Ragusa et al.	
19	20140356851	A1	2014-12-04	Pages et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		
	First Named Inventor	Michael Ragusa	
	Art Unit	N/A	
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number	130670-80103	

	20	20180344910	A1	2018-12-06	Ragusa	
	21	20180344921	A1	2018-12-06	Ragusa	

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	1	2735985	CN	Y	2005-10-26	Shanghai Dahua Medical Apparatus Co., Ltd		☒
	2	0128683	EP	A2	1984-12-19	Baxter Travenol Laboratories, Inc		☐
	3	0171749	EP	A1	1986-02-19	Terumo Corp		☐
	4	0208061	EP	A1	1987-01-14	Biotest Pharma GmbH		☐
	5	257755	EP	A1	1988-03-02	Haemonetics Corp		☐
	6	0578086	EP	A1	1994-01-12	Terumo Corp		☐
	7	619145	EP	A2	1994-10-12	Electromedics, Inc		☐

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First Named Inventor	Michael Ragusa	
Art Unit	N/A	
Examiner Name	Not Yet Assigned	
Attorney Docket Number	130670-80103	

8	0654277	EP	A1	1995-05-24	Cobe Laboratories, Inc	☐
9	664159	EP	A1	1995-07-26	Haemonetics Corp	☐
10	799645	EP	A1	1997-10-08	Haemonetics Corp	☐
11	0885619	EP	A1	1998-12-23	Terumo Corp	☐
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14	1374927	EP	A1	2004-01-02	Terumo Corp	☐
15	2258898	FR	A1	1975-08-22	Heraeus Christ Gmbh,dt	☐
16	2047110	GB	A	1980-11-26	Hogman, C F	☐
17	S59-006952	JP		1984-01-14	Hitachi Koki KK	☒
18	S59-069166	JP		1984-04-19	Nikkiso Co Ltd.	☒

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19	H02-052665	JP		1990-02-22	Nissho KK		☒
20	H03-131268	JP		1991-06-04	Fresenius AG		☒
21	H07-075746	JP		1995-03-20	Electromedics Inc.		☒
22	H08-131539	JP		1996-05-28	Terumo Corp.		☒
23	H09-192215	JP		1997-07-29	Nakane Takaharu		☒
24	2002-291872	JP	A	2002-10-08	Terumo Corp		☒
25	2008-506424	JP	A	2008-03-06			☒
26	660718	SU	A1	1979-05-05	Sp K B Biofizicheskoy Apparatu		☐
27	762982	SU	A1	1980-09-15	Sp K B Biofizicheskoy Apparatu		☐
28	1146098	SU	A1	1985-03-23	Sp K B Biofiz App		☐
29	1985/02561	WO	A1	1985-06-20	Baxter Travenol Laboratories, Inc		☐

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Attorney Docket Number	130670-80103	

30	1990/00059	WO	A1	1990-01-11	Sirchia, Girolamo	☐
31	1990/07383	WO	A1	1990-07-12	Haemonetics Corp	☐
32	1994/06535	WO	A1	1994-03-31	Fischel, Halbert	☐
33	1996/11747	WO	A2	1996-04-25	Transfusion, Technologies Corporation	☐
34	1996/33023	WO	A1	1996-10-24	Cobe Laboratories, Inc	☐
35	2002/05059	WO	A2	2002-01-17	Baxter Int	☐
36	2007/041716	WO	A1	2007-04-12	Gambro, Inc	☐

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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
	1	Haemonetics Nomogram - Male, 2 pages, May 1990.	
	2	LEMMENS et al., Estimating blood volume in obese and morbidly obese patients. Obes Surg. 2006 Jun;16(6):773-6.	

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Attorney Docket Number	130670-80103	

3	NADLER et al., Prediction of blood volume in normal human adults. Surgery. 1962 Feb;51(2):224-32.
4	WINTERS, Complications of donor apheresis. J Clin Apher. 2006 Jul;21(2):132-41.
5	International Search Report and Written Opinion for Application No. PCT/US2018/033826, dated August 3, 2018, 10 pages.
6	International Search Report and Written Opinion for Application No. PCT/US2018/57528, dated January 7, 2019 17 pages.

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Examiner Signature	/LESLIE R DEAK/ (11/10/2020)	Date Considered	
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Application Number	
Filing Date	
First Named Inventor	Michael Ragusa
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	130670-80103

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	/Jonathan C. Lovely, Reg. No. 60,821/	Date (YYYY-MM-DD)	2020-07-16
Name/Print	Jonathan C. Lovely	Registration Number	60,821

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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EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	2	("20180344910").PN.	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2019/10/28 11:36
S2	1	((A61M1/029 and A61M1/3672 and A61M1/3693 and A61M1/38 and A61M2202/0415 and A61M2230/207).CPC.)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2019/10/28 11:37
S3	1	((A61M1/029 and A61M1/3672 and A61M1/3693 and A61M1/38 and A61M2202/0415).CPC.)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2019/10/28 11:37
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S6	2	"20030125881"	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2019/10/28 12:16
S7	27	2009/0215602	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2019/10/28 12:17
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S9	2	S1 AND ((A61M1/024 OR A61M1/029 OR A61M1/3672 OR A61M1/3693 OR A61M1/38 OR A61M2202/0415 OR A61M2230/207 OR G01N15/05 OR G01N2015/055 OR G01N15/042 OR G01N33/86).CPC.)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2019/10/28 12:25
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S13	1	"l10" and (hematocrit with anticoagulant)	US-PGPUB; USPAT; USOCR; DERWENT	OR	OFF	2019/10/28 12:30
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S31	51	S30 and height	US-PGPUB; USPAT; USOCR	OR	OFF	2020/11/09 15:20

11/10/2020 3:05:38 PM

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/931,333	07/16/2020	Michael Ragusa	130670-80103

CONFIRMATION NO. 7421

86738
MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston, MA 02110

PUBLICATION NOTICE



Title:SYSTEM AND METHOD FOR COLLECTING PLASMA

Publication No.US-2020-0345924-A1

Publication Date:11/05/2020

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 accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/931,333	07/16/2020	Michael Ragusa	130670-80103	7421
86738	7590	08/24/2020	EXAMINER	
MCCARTER & ENGLISH, LLP BOSTON 265 Franklin Street Boston, MA 02110				
			ART UNIT	PAPER NUMBER
			3799	
			NOTIFICATION DATE	DELIVERY MODE
			08/24/2020	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@mccarter.com

<i>Decision Granting Request for Prioritized Examination (Track I)</i>	Application No. 16/931,333	Applicant(s) Ragusa, Michael	
	Examiner TERRI S JOHNSON	Art Unit OPET	AIA (FITF) Status Yes
1. THE REQUEST FILED <u>16 July 2020</u> 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 <u>petition for extension of time</u> to extend the time period for filing a reply; B. filing an <u>amendment to amend the application to contain more than four independent claims, more than thirty total claims</u>, or a multiple dependent claim; C. filing a <u>request for continued examination</u> ; 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 TERRI JOHNSON at (571)272-2991. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.			
/TERRI S JOHNSON/ Paralegal Specialist, OPET			

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 16/931,333				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	300			
SEARCH FEE (37 CFR 1.16(k), (j), or (m))	N/A	N/A	N/A			N/A	660			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760			
TOTAL CLAIMS (37 CFR 1.16(i))	30	minus 20 = *	10			x 100 =	1000			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4	minus 3 = *	1			x 460 =	460			
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).						0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL		TOTAL	3180			
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.										



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY DOCKET NO	TOT CLAIMS	IND CLAIMS
16/931,333	07/16/2020	3799	3180	130670-80103	30	4

CONFIRMATION NO. 7421

UPDATED FILING RECEIPT



0000000118838072

86738

MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston, MA 02110

Date Mailed: 07/31/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Michael Ragusa, Hingham, MA;

Applicant(s)

Haemonetics Corporation, Boston, MA;

Power of Attorney: The patent practitioners associated with Customer Number 86738

Domestic Priority data as claimed by applicant

This application is a CON of 15/793,339 10/25/2017
which is a CIP of 15/608,183 05/30/2017

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 07/27/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/931,333**

Projected Publication Date: 11/05/2020

Non-Publication Request: No

Early Publication Request: No
Title

SYSTEM AND METHOD FOR COLLECTING PLASMA

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

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Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

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Docket No.: 130670-80103
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Utility Application of:
Michael Ragusa

Application No.: 16/931,333

Confirmation No.: 7421

Filed: July 16, 2020

Art Unit: 3799

For: SYSTEM AND METHOD FOR COLLECTING
PLASMA

Examiner: Not Yet Assigned

MS Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION
AND PRELIMINARY AMENDMENT**

Dear Sir:

In response to the Notice to File Missing Parts of Application – Filing Date Granted mailed July 28, 2020, Applicant respectfully submits a Preliminary Amendment in compliance with 37 CFR 1.102.

The Preliminary Amendment submitted herewith is intended to cancel the second claim 29 and to reduce the total claims in excess of thirty in order to bring this application in compliance with the requirements of a prioritized examination application under 37 CFR 1.102 and MPEP 708.02(b)(e)(1).

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 8 of this paper.

AMENDMENTS TO THE CLAIMS

The following Listing of Claims will replace all prior versions, and listing, of claims in the application.

Listing of Claims

1. (Original) A method for collecting plasma comprising:

- (a) determining the weight and height of a donor;
- (b) determining the hematocrit of the donor;
- (c) calculating a donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor;
- (d) calculating a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma;
- (e) withdrawing whole blood from the donor through a venous-access device and a first line, the first line connected to a blood component separation device;
- (f) introducing anticoagulant into the withdrawn whole blood through an anticoagulant line;
- (g) separating the withdrawn whole blood into a plasma component and at least a second blood component;
- (h) collecting the plasma component from the blood component separation device and into a plasma collection container;
- (i) continuing steps (e) through (h) until the target plasma volume to collect is reached in the plasma collection container.

2. (Original) A method according to claim 1, further comprising:

calculating a volume of anticoagulant to be collected with the plasma component in the plasma collection container, the volume of anticoagulant to be collected with the plasma component based, at least in part, on the hematocrit of the donor.

3. (Original) A method according to claim 2, wherein the target plasma volume to collect is a target volume of pure plasma to collect plus the calculated volume of anticoagulant to be collected.
4. (Original) A method according to claim 2, wherein the target plasma volume to collect is a target volume of pure plasma to collect in the plasma collection container, the target volume of pure plasma to collect based, at least in part, upon the volume of anticoagulant to be collected with the plasma component in the plasma collection container.
5. (Original) A method according to claim 1, further comprising:

calculating the donor's body mass index based, at least in part on the weight and height of the donor, the donor plasma volume calculated based, at least in part, on the donor's body mass index.
6. (Original) A method according to claim 1, wherein the target plasma volume to collect is calculated before withdrawing whole blood.
7. (Original) A method according to claim 1, wherein the target percentage of plasma is between 26.5 and 29.5 percent of the donor's plasma volume.
8. (Original) A system for collecting plasma comprising:

a venous-access device for drawing whole blood from a subject and returning blood components to the donor;

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container;

a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump;

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to control the operation of the blood component separation device and the first pump, the controller configured to calculate (1) a donor plasma volume based, at least in part, on a

weight and height of the donor and a hematocrit of the donor, (2) a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, and (3) a volume of plasma component collected within the plasma collection container, the controller configured to stop the first pump when the calculated volume of plasma component collected within the plasma collection container equals the target plasma volume to collect.

9. (Original) A system according to claim 8, wherein the controller is further configured to calculate a volume of anticoagulant to be collected with the plasma component in the plasma collection container, the volume of anticoagulant to be collected with the plasma component based, at least in part, on the hematocrit of the donor.

10. (Original) A system according to claim 9, wherein the target plasma volume to collect is a target volume of pure plasma to collect plus the calculated volume of anticoagulant to be collected.

11. (Original) A system according to claim 9, wherein the target plasma volume to collect is a target volume of pure plasma to collect within the plasma collection container, the target volume of pure plasma to collect based, at least in part, upon the volume of anticoagulant to be collected with the plasma component in the plasma collection container, the controller configured to stop the first pump when the volume of pure plasma collected within the plasma collection container equals the target plasma collection volume.

12. (Original) A system according to claim 8, wherein the controller is further configured to calculate the donor's body mass index based, at least in part on the weight and height of the donor, the donor plasma volume calculated based, at least in part, on the donor's body mass index.

13. (Original) A system according to claim 8, wherein the target plasma volume to collect is calculated before withdrawing whole blood.

14. (Original) A system according to claim 8, wherein the target percentage of plasma is between 26.5 and 29.5 percent of the donor's plasma volume.

15. (Original) A method for programming a blood processing device comprising:

- (a) receiving, in a control system, a weight and height of a donor;
- (b) receiving, in a control system, a hematocrit of the donor;

(c) calculating, using the control system, a donor plasma volume, the control system calculating the donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor;

(d) calculating, using the control system, a target plasma volume to collect, the control system calculating the target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma;

(e) determining a target collection volume based, at least in part, on the calculated target plasma volume to collect; and

(f) programming a controller of a blood processing device with a blood processing end point, the blood processing end point being based, at least in part, on the target collection volume.

16. (Original) A method according to claim 15, further comprising:

calculating, using the control system, a volume of anticoagulant to be collected with a plasma component in a plasma collection container, the control system calculating the volume of anticoagulant to be collected with the plasma component based, at least in part, on the hematocrit of the donor.

17. (Original) A method according to claim 16, wherein the target plasma volume to collect is a target volume of pure plasma to collect, the target volume of pure plasma to collect based, at least in part, upon the volume of anticoagulant to be collected with the plasma component.

18. (Original) A method according to claim 17, wherein the target collection volume is the target volume of pure plasma to collect.

19. (Original) A method according to claim 17, wherein the target collection volume is the target volume of pure plasma to collect plus the calculated volume of anticoagulant to be collected in the plasma collection container.

20. (Original) A method according to claim 15, further comprising:

calculating, using the control system, the donor's body mass index based, at least in part on the weight and height of the donor, the control system calculating the donor plasma volume based, at least in part, on the donor's body mass index.

21. (Original) A method according to claim 15, wherein the blood processing end point is when the target collection volume has been collected within a plasma collection container of the blood processing device.

22. (Original) A method according to claim 15, wherein the control system includes the controller.

23. (Original) A system for collecting plasma comprising:

a blood processing device including:

a venous-access device for drawing whole blood from a donor and returning blood components to the donor,

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container,

a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump, and

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to (1) calculate a donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor, (2) calculate a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, and (3) calculate a target collection volume based, at least in part, on the calculated target plasma volume to collect.

24. (Original) The system according to claim 23, wherein the blood processing device is configured to stop the blood draw pump when the target collection volume is collected within the plasma collection container.

25. (Original) The system according to claim 23, wherein the controller is part of the blood processing device.

26. (Original) The system according to 23, wherein the controller is further configured to program the blood processing device with a blood processing end point based, at least in part, on the target collection volume.

27. (Original) A system according to claim 26, wherein the blood processing end point is when the target collection volume has been collected within the plasma collection container.

28. (Original) A system according to claim 23, wherein the target plasma volume to collect is a target volume of pure plasma to collect in the plasma collection container, the target volume of pure plasma to collect based, at least in part, upon a volume of anticoagulant to be collected with the plasma component in the plasma collection container.

29. (Original) A system according to claim 28, wherein the target collection volume is the target volume of pure plasma to collect and/or the target volume of pure plasma to collect plus the volume of anticoagulant to be collected in the plasma container.

~~29. (Cancelled) A system according to claim 23, wherein the blood processing end point is when the target collection volume has been collected within the plasma collection container.~~

30. (Original) A system according to claim 23, wherein the controller is further configured to calculate the donor's body mass index based, at least in part on the weight and height of the donor, the donor plasma volume based, at least in part, on the donor's body mass index.

REMARKS

Please enter this preliminary amendment. After filing of the present application and upon receipt of the Notice to File Missing Parts dated July 28, 2020, Applicant noticed that the application was inadvertently filed with two claim 29s, bringing the total number of claims to 31. Applicant has canceled the second claim 29 herewith. Applicant respectfully requests the examiner to consider claims 1-30 included herewith upon examination of this present application.

The present application was filed with a Track 1 Request for Prioritized Examination. With the submission of the corrected claim set, the present application has no more than 4 independent claims and 30 total claims. Accordingly, the present application meets the requirements for Track 1 Prioritized Examination and Applicant requests that the Track 1 Request filed with the present application be granted.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-4876, under Order No. 130670-80103 from which the undersigned is authorized to draw. Applicant also requests that the examiner contact applicant's attorney, Jonathan Lovely, if it will assist in processing this application through issuance.

Dated: July 29, 2020

Respectfully submitted,

Electronic signature: /Jonathan C. Lovely, Reg. No. 60,821/

Jonathan C. Lovely

Registration No.: 60,821

MCCARTER & ENGLISH, LLP

265 Franklin Street

Boston, Massachusetts 02110

(617) 449-6556

(617) 607-9200 (Fax)

Attorney/Agent For Applicant

Electronic Acknowledgement Receipt	
EFS ID:	40136856
Application Number:	16931333
International Application Number:	
Confirmation Number:	7421
Title of Invention:	SYSTEM AND METHOD FOR COLLECTING PLASMA
First Named Inventor/Applicant Name:	Michael Ragusa
Customer Number:	86738
Filer:	Jonathan Lovely
Filer Authorized By:	
Attorney Docket Number:	130670-80103
Receipt Date:	29-JUL-2020
Filing Date:	16-JUL-2020
Time Stamp:	15:13:05
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		07292020_Response_to_Notice_to_File_Missing_Parts__Preliminary_Amendment_.pdf	40588	yes	8
			9d796679bbdc286416b8592c31a0d35fcd049897		

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Applicant Response to Pre-Exam Formalities Notice	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	8
Warnings:			
Information:			
Total Files Size (in bytes):		40588	
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. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a 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. <u>National Stage of an International Application under 35 U.S.C. 371</u> 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. <u>New International Application Filed with the USPTO as a Receiving Office</u> 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 NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY DOCKET NO	TOT CLAIMS	IND CLAIMS
16/931,333	07/16/2020	3781	3180	130670-80103	31	4

CONFIRMATION NO. 7421

FILING RECEIPT



0000000118738235

86738
MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston, MA 02110

Date Mailed: 07/28/2020

Receipt is acknowledged of this non-provisional utility patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF FIRST INVENTOR, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection.

Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please submit a written request for a corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections provided that the request is grantable.

Inventor(s)

Michael Ragusa, Hingham, MA;

Applicant(s)

Haemonetics Corporation, Boston, MA;

Power of Attorney: The patent practitioners associated with Customer Number 86738

Domestic Priority data as claimed by applicant

This application is a CON of 15/793,339 10/25/2017
which is a CIP of 15/608,183 05/30/2017

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see <http://www.uspto.gov> for more information.) - None.

Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 07/27/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/931,333**

Projected Publication Date: 11/05/2020

Non-Publication Request: No

Early Publication Request: No
Title

SYSTEM AND METHOD FOR COLLECTING PLASMA

Preliminary Class

604

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

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Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

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This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

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NOT GRANTED

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875						Application or Docket Number 16/931,333				
APPLICATION AS FILED - PART I										
(Column 1)		(Column 2)		SMALL ENTITY		OTHER THAN SMALL ENTITY				
FOR	NUMBER FILED	NUMBER EXTRA	RATE(\$)	FEE(\$)		RATE(\$)	FEE(\$)			
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	300			
SEARCH FEE (37 CFR 1.16(k), (j), or (m))	N/A	N/A	N/A			N/A	660			
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	760			
TOTAL CLAIMS (37 CFR 1.16(i))	31	minus 20 = *	11			x 100 =	1100			
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4	minus 3 = *	1			x 460 =	460			
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).						0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.				TOTAL		TOTAL	3280			
APPLICATION AS AMENDED - PART II										
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OTHER THAN SMALL ENTITY		
AMENDMENT A		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
AMENDMENT B		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE(\$)	ADDITIONAL FEE(\$)		RATE(\$)	ADDITIONAL FEE(\$)
	Total (37 CFR 1.16(i))	*	Minus	**	=	x	=		x	=
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x	=		x	=
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))									
						TOTAL ADD'L FEE			TOTAL ADD'L FEE	
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.										



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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/931,333	07/16/2020	Michael Ragusa	130670-80103

CONFIRMATION NO. 7421

FORMALITIES LETTER

86738
MCCARTER & ENGLISH, LLP BOSTON
265 Franklin Street
Boston, MA 02110



Date Mailed: 07/28/2020

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing.

Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- Additional claim fees of \$ **100** as an undiscounted entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. No entity status discount is in effect. If applicant is qualified for small entity status, a written assertion of small entity status must be submitted to establish small entity status. (See 37 CFR 1.27). If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- \$ **1100** for 11 total claims over 20.
- \$(**1000**) previous unapplied payment amount.
- \$ **100** TOTAL FEE BALANCE DUE.

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

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Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice".
<https://portal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/fasrat/

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA/82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	Not Yet Assigned		
Filing Date	Concurrently Herewith		
First Named Inventor	Michael Ragusa		
Title	SYSTEM AND METHOD FOR COLLECTING PLASMA		
Art Unit	N/A		
Examiner Name	Not Yet Assigned		
Attorney Docket Number	130670-80103		
SIGNATURE of Applicant or Patent Practitioner			
Signature	/Jonathan C. Lovely, Reg. No. 60,821/	Date (Optional)	July 16, 2020
Name	Jonathan C. Lovely	Registration Number	60,821
Title (if Applicant is a juristic entity)			
Applicant Name (if Applicant is a juristic entity)			
NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.			
☐	*Total of <u>1</u> forms are submitted.		

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☒ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above:

OR

86738

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☒ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name

Address

City

State

Zip

Country

Telephone

Email

I am the Applicant (If the Applicant is a juristic entity, list the Applicant name in the box):

Haemonetics Corporation

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☒ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature

Date (Optional)

Name

John F. Perillo

Title

Vice President, Associate General Counsel and Chief Intellectual Property Officer, Haemonetics Corporation

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☐ Total of forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 1.11 and 1.14. This collection is estimated to take 3 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 1480, Alexandria, VA 22313-1480.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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		
	Filing Date		
	First Named Inventor	Michael Ragusa	
	Art Unit	N/A	
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number	130670-80103	

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	1025059		1912-04-30	Hatton et al.	
	2	1611725		1926-12-21	Degerth et al.	
	3	2087778		1937-07-20	Nelin	
	4	2661150		1953-12-01	Abbott, Jr.	
	5	2750107		1956-06-12	More	
	6	2792172		1957-05-14	Tait	
	7	3096283		1963-07-02	Hein	
	8	3145713		1964-08-25	Latham, Jr.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		
	First Named Inventor	Michael Ragusa	
	Art Unit		N/A
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number		130670-80103

	9	3239136		1966-03-08	Hein	
	10	3244362		1966-04-05	Hein	
	11	3244363		1966-04-05	Hein	
	12	3409213		1968-11-05	Latham, Jr.	
	13	3456875		1969-07-22	Hein	
	14	3489145		1970-01-13	Judson et al.	
	15	3565330		1971-02-23	Latham, Jr.	
	16	3655058		1972-04-11	Novak	
	17	3737096		1973-06-05	Jones et al.	
	18	3774840		1973-11-27	Boatright	
	19	3987961		1976-10-26	Sinn et al.	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		
	First Named Inventor	Michael Ragusa	
	Art Unit	N/A	
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number	130670-80103	

	20	4007871		1977-02-15	Jones et al.	
	21	4010894		1977-03-08	Kellogg et al.	
	22	4014497		1977-03-29	Spiewok et al.	
	23	4040965		1977-08-09	Kohlheb	
	24	4056224		1977-11-01	Lolachi	
	25	4082217		1978-04-04	Westberg	
	26	4086924		1978-05-02	Latham, Jr.	
	27	4140268		1979-02-20	Lacour	
	28	4142670		1979-03-06	Ishimaru et al.	
	29	4151844		1979-05-01	Cullis et al.	
	30	4197847		1980-04-15	Djerassi	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number		
	Filing Date		
	First Named Inventor	Michael Ragusa	
	Art Unit	N/A	
	Examiner Name	Not Yet Assigned	
	Attorney Docket Number	130670-80103	

	31	4285464		1981-08-25	Latham, Jr.	
	32	4300717		1981-11-17	Latham, Jr.	
	33	4303193		1981-12-01	Latham, Jr.	
	34	4321921		1982-03-30	Laszczower	
	35	4387848		1983-06-14	Kellogg et al.	
	36	4425114		1984-01-10	Schoendorfer et al.	
	37	4430072		1984-02-07	Kellogg et al.	
	38	4447221		1984-05-08	Mulzet	
	39	4457747		1984-07-03	Tu	
	40	4464167		1984-08-07	Schoendorfer et al.	
	41	4466888		1984-08-21	Verkaart	

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	5	257755	EP	A1	1988-03-02	Haemonetics Corp		☐
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	32	1994/06535	WO	A1	1994-03-31	Fischel, Halbert		☐
	33	1996/11747	WO	A2	1996-04-25	Transfusion, Technologies Corporation		☐
	34	1996/33023	WO	A1	1996-10-24	Cobe Laboratories, Inc		☐
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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.

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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	/Jonathan C. Lovely, Reg. No. 60,821/	Date (YYYY-MM-DD)	2020-07-16
Name/Print	Jonathan C. Lovely	Registration Number	60,821

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UTILITY PATENT APPLICATION TRANSMITTAL		Attorney Docket No. 130670-80103	
		First Named Inventor Michael Ragusa	
		Title	SYSTEM AND METHOD FOR COLLECTING PLASMA
<i>(Only for new nonprovisional applications under 37 CFR 1.53(b))</i>		Priority Mail Express® Label No.	

APPLICATION ELEMENTS <i>See MPEP chapter 600 concerning utility patent application contents.</i>	ADDRESS TO: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
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1. ☐ Fee Transmittal Form (PTO/SB/17 or equivalent) 2. ☐ Applicant asserts small entity status. See 37 CFR 1.27 3. ☐ Applicant certifies micro entity status. See 37 CFR 1.29. Applicant must attach form PTO/SB/15A or B or equivalent. 4. ☒ Specification [Total Pages <u>32</u>] Both the claims and abstract must start on a new page. <i>(See MPEP § 608.01(a) for information on the preferred arrangement)</i> 5. ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets <u>5</u>] 6. ☐ Inventor's Oath or Declaration [Total Pages <u>1</u>] <i>(including substitute statements under 37 CFR 1.64 and assignments serving as an oath or declaration under 37 CFR 1.63(e))</i> a. ☐ Newly executed (original or copy) b. ☒ A copy from a prior application (37 CFR 1.63(d)) 7. ☒ Application Data Sheet * See note below. See 37 CFR 1.76 (PTO/AIA/14 or equivalent) 8. ☐ CD-ROM or CD-R in duplicate, large table, or Computer Program (Appendix) ☐ Landscape Table on CD 9. Nucleotide and/or Amino Acid Sequence Submission <i>(if applicable, items a. – c. are required)</i> a. ☐ Computer Readable Form (CRF) b. ☐ Specification Sequence Listing on: i. ☐ CD-ROM or CD-R (2 copies); or ii. ☐ Paper c. ☐ Statements verifying identity of above copies	ACCOMPANYING APPLICATION PAPERS 10. ☐ Assignment Papers (cover sheet & document(s)) Name of Assignee 11. ☐ 37 CFR 3.73(c) Statement <i>(when there is an assignee)</i> ☒ Power of Attorney 12. ☐ English Translation Document <i>(if applicable)</i> 13. ☒ Information Disclosure Statement (PTO/SB/08 or PTO-1449) ☐ Copies of citations attached 14. ☐ Preliminary Amendment 15. ☐ Return Receipt Postcard <i>(MPEP § 503) (Should be specifically itemized)</i> 16. ☐ Certified Copy of Priority Document(s) <i>(if foreign priority is claimed)</i> 17. ☐ Nonpublication Request Under 35 U.S.C. 122(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent. 18. ☒ Other: 1. INFORMATION DISCLOSURE STATEMENT – TRANSMITTAL LETTER 2. CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e)
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***Note:** (1) Benefit claims under 37 CFR 1.78 and foreign priority claims under 1.55 **must** be included in an Application Data Sheet (ADS).
 (2) For applications filed under 35 U.S.C. 111, the application must contain an ADS specifying the applicant if the applicant is an assignee, person to whom the inventor is under an obligation to assign, or person who otherwise shows sufficient proprietary interest in the matter. See 37 CFR 1.46(b).

19. CORRESPONDENCE ADDRESS			
☒ The address associated with Customer Number: <u>86738</u> OR ☐ Correspondence address below			
Name			
Address			
City	State	Zip Code	
Country	Telephone	Email	
Signature	/Jonathan C. Lovely, Reg. No. 60,821/		Date
Name (Print/Type)	Jonathan C. Lovely		Registration No. (Attorney/Agent)
			July 16, 2020 60,821

Electronic Patent Application Fee Transmittal				
Application Number:				
Filing Date:				
Title of Invention:		SYSTEM AND METHOD FOR COLLECTING PLASMA		
First Named Inventor/Applicant Name:		Michael Ragusa		
Filer:		Jonathan Lovely/Tricia Troup		
Attorney Docket Number:		130670-80103		
Filed as Large Entity				
Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	300	300
UTILITY SEARCH FEE	1111	1	660	660
UTILITY EXAMINATION FEE	1311	1	760	760
REQUEST FOR PRIORITIZED EXAMINATION	1817	1	4000	4000
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	10	100	1000
INDEPENDENT CLAIMS IN EXCESS OF 3	1201	1	460	460

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous-Filing:				
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				7320

Electronic Acknowledgement Receipt	
EFS ID:	40023227
Application Number:	16931333
International Application Number:	
Confirmation Number:	7421
Title of Invention:	SYSTEM AND METHOD FOR COLLECTING PLASMA
First Named Inventor/Applicant Name:	Michael Ragusa
Customer Number:	86738
Filer:	Jonathan Lovely
Filer Authorized By:	
Attorney Docket Number:	130670-80103
Receipt Date:	16-JUL-2020
Filing Date:	
Time Stamp:	20:54:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	\$7320
RAM confirmation Number	E20207FK55072162
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	TrackOne Request	Certification_and_Request_for _Prioritized_Examination_Under_37_CFR_1102e.pdf	33742	no	1
			dea3cc6340b0b1645046c8143ba2018046c85ae9		
Warnings:					
Information:					
2	Oath or Declaration filed	Executed_Declaration_from_USSN_15793339.PDF	44219	no	1
			2d1e9814a88f79f27066b7f9d7d7c81ccc2af21b		
Warnings:					
Information:					
3	Application Data Sheet	Application_Data_Sheet_Fillable_PDF.PDF	1255638	no	8
			3b4abe671e8698158a8d9eef2121cb62b49503c5		
Warnings:					
Information:					
4		Application.pdf	117056	yes	32
			036288ca62c5de063cb21720c73b6f3c47a1fc15		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Specification		1	25	
	Claims		26	31	
	Abstract		32	32	
Warnings:					
Information:					
5	Drawings-only black and white line drawings	Figures.PDF	140972	no	5
			417f9009a2bdf6044427fd31c78e93c58890f348		

Warnings:					
Information:					
6	Transmittal Letter	Information_Disclosure_State ment_IDS.PDF	19185	no	2
			8eea3bcc0664e4a35b396d6568aaf8437405c887		
Warnings:					
Information:					
7	Information Disclosure Statement (IDS) Form (SB08)	Information_Disclosure_State ment_Fillable_PDF.PDF	1040254	no	24
			cf4184ecac7ef8128e2c5253999ab197f2bc a17		
Warnings:					
Information:					
8	Power of Attorney	130670-80103_- _POA_by_Applicant.pdf	242295	no	2
			75ade26c14f8436c4125c7cd2c6d7f38d2eb f178		
Warnings:					
Information:					
9	Transmittal of New Application	Utility_Patent_Application_Tra nsmittal.pdf	32512	no	1
			4f4e22da5e2a56b78b91e65778e4ff2472f1 4de0		
Warnings:					
Information:					
10	Fee Worksheet (SB06)	fee-info.pdf	43037	no	2
			9842b887f5868976ad2513fee548e61f0f60 c0ef		
Warnings:					
Information:					
Total Files Size (in bytes):			2968910		

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 a 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.

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)			
First Named Inventor:	Michael Ragusa	Nonprovisional Application Number (if known):	Not Yet Assigned
Title of Invention:	SYSTEM AND METHOD FOR COLLECTING PLASMA		
APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION. 1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently \$0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application. 2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed. 3. The applicable box is checked below: I. ☒ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1) i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web. ---OR--- (b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper. ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, <u>or</u> the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application. II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2) i. A request for continued examination has been filed with, or prior to, this form. ii. If the application is a utility application, this certification and request is being filed via EFS-Web. iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371. iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination. v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).			
Signature /Jonathan C. Lovely, Reg. No. 60,821/		Date July 16, 2020	
Name (Print/Typed) Jonathan C. Lovely		Practitioner Registration Number 60,821	
Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*			
☐ *Total of <u>1</u> forms are submitted.			

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**

Title of
Invention

SYSTEM AND METHOD FOR COLLECTING PLASMA

As the below named inventor, I hereby declare that:

This declaration ☐ The attached application, or
is directed to:

☒ United States application or PCT international application number 15/793,339
filed on 10/25/2017

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby state that I have reviewed and understand the contents of the above identified specification,

I acknowledge the duty to disclose all information known to me that is material to patentability in accordance with Title 37, Code of Federal Regulations § 1.56.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Michael Ragusa

Date (Optional): Oct 25, 2018

Signature: Michael J. Ragusa

Note: An application data sheet (PTO/AIA/14 or equivalent), including naming the entire inventive entity, must accompany this form. Use an additional PTO/SB/AIA/01 form for each additional inventor.

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	130670-80103
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR COLLECTING PLASMA		
The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76. This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.			

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor	1				Remove	
Legal Name						
Prefix	Given Name	Middle Name	Family Name	Suffix		
	Michael		Ragusa			
Residence Information (Select One) • US Residency Non US Residency Active US Military Service						
City	Hingham	State/Province	MA	Country of Residence	US	
Mailing Address of Inventor:						
Address 1	4 Willow Circle					
Address 2						
City	Hingham	State/Province	MA			
Postal Code	02043	Country	US			
All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the Add button.						

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).			
☐ An Address is being provided for the correspondence information of this application.			
Customer Number	86738		
Email Address	docket@mccarter.com	Add Email	Remove Email

Application Information:

Title of the Invention	SYSTEM AND METHOD FOR COLLECTING PLASMA		
Attorney Docket Number	130670-80103	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	5	Suggested Figure for Publication (if any)	

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	130670-80103
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR COLLECTING PLASMA		

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	☒ Customer Number	☐ US Patent Practitioner	☐ Limited Recognition (37 CFR 11.9)
Customer Number	86738		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.

When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15/793339	2017-10-25

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	130670-80103
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR COLLECTING PLASMA		
Prior Application Status	Pending	Remove	
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15/793339	Continuation in part of	15/608183	2017-05-30
Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the Add button.			Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)ⁱ the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Application Number	Country ⁱ	Filing Date (YYYY-MM-DD)	Access Code ^j (if applicable)	Remove
Additional Foreign Priority Data may be generated within this form by selecting the Add button.				Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.

NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	130670-80103
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR COLLECTING PLASMA		

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	130670-80103
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR COLLECTING PLASMA		

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.			
Applicant	1	Remove	
If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.			
		Clear	
☐ Assignee	Legal Representative under 35 U.S.C. 117		Joint Inventor
Person to whom the inventor is obligated to assign.		Person who shows sufficient proprietary interest	
If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:			
Name of the Deceased or Legally Incapacitated Inventor:			
If the Applicant is an Organization check here. ☒			
Organization Name	Haemonetics Corporation		
Mailing Address Information For Applicant:			
Address 1	125 Summer Street		
Address 2			
City	Boston	State/Province	MA
Country	US	Postal Code	02110
Phone Number		Fax Number	
Email Address			
Additional Applicant Data may be generated within this form by selecting the Add button. Add			

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	130670-80103
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR COLLECTING PLASMA		

Assignee 1				
Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.				
				Remove
If the Assignee or Non-Applicant Assignee is an Organization check here.				☐
Prefix	Given Name	Middle Name	Family Name	Suffix
Mailing Address Information For Assignee including Non-Applicant Assignee:				
Address 1				
Address 2				
City		State/Province		
Country i		Postal Code		
Phone Number		Fax Number		
Email Address				
Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button.				Add

Signature:

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	Jonathan C. Lovely, Reg. No. 60,821/		Date (YYYY-MM-DD)	2020-07-16
First Name	Jonathan	Last Name	Lovely	Registration Number
				60,821
Additional Signature may be generated within this form by selecting the Add button.				Add

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.

Application Data Sheet 37 CFR 1.76		Attorney Docket Number	130670-80103
		Application Number	
Title of Invention	SYSTEM AND METHOD FOR COLLECTING PLASMA		

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SYSTEM AND METHOD FOR COLLECTING PLASMA

Priority

[0001] This application is a continuation of and claims priority from co-pending U.S. Application No. 15/793,339, entitled “System and Method for Collecting Plasma,” filed October 25, 2017, attorney docket number 130670-80102 (formerly 1611/C86), and naming Michael Ragusa as inventor, the disclosure of which is incorporated herein, in its entirety, by reference.

[0002] U.S. Application No. 15/793,339 is a continuation-in-part of and claims priority to U.S. Patent Application No. 15/608,183, entitled “System and Method for Collecting Plasma,” filed May 30, 2017, attorney docket number 130670-08002 (formerly 1611/C80), and naming Michael Ragusa as inventor, the disclosure of which is incorporated herein, in its entirety, by reference.

Technical Field

[0003] The present invention relates to systems and methods for blood apheresis, and more particularly system and methods for collecting a plasma product.

Background Art

[0004] Apheresis is a procedure in which individual blood components can be separated and collected from whole blood temporarily withdrawn from a subject. Typically, whole blood is withdrawn through a needle inserted into a vein of the subjects arm and into a cell separator, such as a centrifugal bowl. Once the whole blood is separated into its various components, one or more of the components (e.g., plasma) can be removed from the centrifugal bowl. The remaining components can be returned to the subject along with optional compensation fluid to make up for the volume of the removed component. The process of drawing and returning continues until the quantity of the desired component has been collected, at which point the process is stopped. A central feature of apheresis systems is that the processed but unwanted components are returned to the donor. Separated blood components may include, for example, a high density component such as red blood cells, an

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intermediate density component such as platelets or white blood cells, and a lower density component such as plasma.

[0005] Many jurisdictions have regulations regarding the amount of whole blood and/or blood components that can be removed from a donor. For example, the U.S. Food and Drug Administration (“the FDA”) sets both an upper limit on the volume of plasma that may be collected (e.g., 800 ml for an adult weighing more than 175 pounds) as well as an upper limit on the total collection volume (e.g., 880 ml for an adult weighing more than 175 pounds). Prior art plasma collection systems are unable to determine the total volume of plasma that has been collected (e.g., because the product collected is a mixture of plasma and anticoagulant) and, therefore collect based on the total collection volume, even if the total volume of plasma that has been collected is below the limit prescribed by the FDA. Additionally, prior art collection systems do not tailor the amount of plasma collected to the individual (e.g., other than what weight group they fall into) and, therefore, the percentage of the patient’s plasma that is collected varies widely from patient to patient (e.g., only 23% percent of the plasma is collected for some patients and 29% - or greater – of the plasma is collected for others).

Summary of the Invention

[0006] In accordance with some embodiments of the present invention, a method for collecting plasma includes determining the weight and hematocrit of a donor, and inserting a venous-access device into the donor. Once the venous access device is inserted, the method may withdraw whole blood from the donor through the venous-access device and a draw line that is connected to a blood component separation device. The method may then introduce anticoagulant into the withdrawn whole blood through an anticoagulant line and separate, using the blood component separation device, the withdrawn whole blood into a plasma component and at least a second blood component. Once separated, the plasma component may be collected from the blood component separation device and into a plasma collection container. During processing, the method may calculate (1) a percentage of anticoagulant in the collected plasma component, and (2) a volume of pure plasma collected within the plasma collection container. The volume of pure plasma may be based, at least in part, on the

calculated percentage of anticoagulant in the collected plasma component. The method may continue the process (e.g., withdrawing whole blood, introducing anticoagulant into the whole blood, separating the blood, collecting the plasma, and calculating the percentage of anticoagulant and volume of pure plasma) until a target volume of pure plasma is collected within the plasma collection container.

[0007] In some embodiments, the method may determine a change in volume within an anticoagulant container, and the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the change in volume within the anticoagulant container. Additionally or alternatively, the method may determine a volume of anticoagulant introduced into the whole blood based on a number of rotations of an anticoagulant pump. In such embodiments, the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the number of rotations of the anticoagulant pump. The method may also determine a volume of anticoagulant within the blood component separation device, and the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the volume of anticoagulant within the blood component separation device.

[0008] In further embodiments, the method may monitor the volume and/or weight of the plasma component collected within the plasma collection container (e.g., using a weight sensor), and the calculated volume of pure plasma collected within the plasma collection device may be based, at least in part, on the monitored volume and/or weight of the collected plasma component. Additionally or alternatively, determining the hematocrit of the donor may include monitoring a volume of red blood cells collection within the blood separation device. In such embodiments, the determined hematocrit of the donor may be based, at least in part, on the monitored volume of red blood cells collected within the blood separation device and the volume of whole blood withdrawn from the donor.

[0009] The target volume of pure plasma may be based, at least in part, on the weight of the donor. The percentage of anticoagulant in the collected plasma component may include at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant that is added to the system during a priming step.

After collecting at least a portion of the target volume of pure plasma, the method may return the second blood component to the donor through a return line.

[0010] In accordance with additional embodiments, a system for collecting plasma includes a venous-access device for drawing whole blood from a subject and returning blood components to the subject, and a blood component separation device for separating the drawn blood into a plasma component and a second blood component. The blood component separation device has an outlet and is configured to send the plasma component to a plasma container. The system may also include a blood draw line fluidly connected to the venous-access device and an anticoagulant line connected to an anticoagulant source. The blood draw line transports drawn whole blood to the blood component separation device, and the flow through the blood draw line may be controlled by a blood draw pump. The anticoagulant line may introduce anticoagulant into the drawn whole blood.

[0011] Additionally, the system may include a controller that controls the operation of the centrifuge bowl. The controller may also calculate (1) a percentage of anticoagulant in the collected plasma component, and (2) a volume of pure plasma collected within the plasma container. The volume of pure plasma may be based, at least in part, upon the percentage of anticoagulant in the collected plasma component. The controller may stop the blood draw pump when a target volume of pure plasma (e.g., based, at least in part, on the weight of the donor) is collected within the plasma container. In some embodiments, the percentage of anticoagulant in the collected plasma component may be based, at least in part, on the volume of anticoagulant added to the drawn whole blood and the subject's hematocrit.

[0012] The system may also include an anticoagulant source weight sensor that measures the weight of the anticoagulant source. The controller may monitor the change in volume within the anticoagulant container based on the measured weight of the anticoagulant source, and the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the change in volume within the anticoagulant source. Additionally or alternatively, the controller may monitor the number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood. In such embodiments, the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the number of rotations of the anticoagulant pump.

[0013] In some embodiments, the system may include an optical sensor located on the blood component separation device. The optical sensor may monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device. The calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the volume of anticoagulant within the blood component separation device.

[0014] In additional embodiments, the system may also include a plasma container weight sensor that monitors a volume and/or weight of the plasma component collected within the plasma collection container. The calculated volume of pure plasma collected within the plasma collection container may be based, at least in part, on the monitored volume and/or weight of collected plasma component. The system may also have an optical sensor located on the blood component separation device. The optical sensor may monitor the volume of red blood cells collected within the blood separation device. The controller may then determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood separation device and the volume of whole blood withdrawn from the donor. The percentage of anticoagulant in the collected plasma component may include at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added to the system during a priming step.

[0015] In accordance with additional embodiments, a method for collecting plasma determines the weight, height, and hematocrit of a donor, and calculates a donor plasma volume based, at least in part, on the weight, height and hematocrit of the donor. The method then calculates a target plasma collection volume based, at least in part, on the calculated donor plasma volume and a target percentage of plasma (e.g., between 26.5 and 29.5 percent of the donor's plasma volume), and withdraws whole blood from the donor through the venous-access device and a first line that is connected to a blood component separation device. As the whole blood is withdrawn, the method may introduce anticoagulant into the withdrawn whole blood through an anticoagulant line.

[0016] The blood component separation device separates the withdrawn whole blood into a plasma component and at least a second blood component, and the method may collect

the plasma component from the blood component separation device and into a plasma collection container. During processing, the method may calculate a volume of pure plasma collected within the plasma collection container. The method continues the withdrawing, introduction of anticoagulant, separating, collecting, and calculating steps until the volume of pure plasma collected within the plasma collection container equals the target plasma collection volume.

[0017] In some embodiments, after collecting at least a portion of the target plasma collection volume, the method may return the contents of the blood component separation device to the donor through the first line. Additionally or alternatively, the method may calculate an intravascular deficit based, at least in part on, the volume of pure plasma collected and the volume of the contents of the blood component separation device that are returned to the donor. The method may also return a volume of saline to the donor to obtain a target intravascular deficit. The target intravascular deficit may be between -250 and 500 milliliters (e.g., it may be 0 milliliters or 250 milliliters). The donor plasma volume may be calculated based, at least in part, on the donor's body mass index that, in turn, is calculated based on the donor's weight and height.

[0018] In further embodiments, the method may include calculating a percentage of anticoagulant in the collected plasma component. In such embodiments, the volume of pure plasma may be based, at least in part, on the calculated percentage of anticoagulant in the collected plasma component. The calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on a change in volume within the anticoagulant container, the number of rotations of the anticoagulant pump, and/or the volume of anticoagulant within the blood component separation device. The method may determine the change in volume within the anticoagulant container, the volume of anticoagulant introduced into the whole blood, and/or the volume of anticoagulant within the blood component separation device. The percentage of anticoagulant in the collected plasma component may include at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

[0019] In some embodiments, the method may include monitoring a volume or and/or weight of the plasma component collected within the plasma collection container. In

such embodiments, the calculated volume of pure plasma collected within the plasma collection device may be based, at least in part, on the monitored volume and/or weight of collected plasma component. To determine the donor's hematocrit, the method may monitor the volume of red blood cells collected within the blood separation device. The hematocrit of the donor may be based, at least in part, on the monitored volume of red blood cells collected within the blood separation device and the volume of whole blood withdrawn from the donor.

[0020] In accordance with still further embodiments, a system for collecting plasma includes a venous-access device for drawing whole blood from a subject and returning blood components to the subject, and a blood component separation device for separating the drawn blood into a plasma component and a second blood component. The blood component separation device may have an outlet and may send the plasma component to a plasma container. The system may also have a first line and an anticoagulant line. The first line may be fluidly connected to the venous-access device and may (1) transport drawn whole blood to the blood component separation device and (2) return fluid within the blood component separation device to the subject. The flow through the first line may be controlled by a first pump. The anticoagulant line may be connected to an anticoagulant source and may introduce anticoagulant into the drawn whole blood.

[0021] The system may also include a controller that controls the operation of the centrifuge bowl and the first pump. The controller may calculate (1) a donor plasma volume, (2) a target plasma collection volume, and (3) a volume of pure plasma collected within the plasma container. The donor plasma volume may be based, at least in part, on a weight and height of the donor and a hematocrit of the donor. The target plasma collection volume may be based, at least in part, on the calculated donor plasma volume and a target percentage of plasma. The volume of pure plasma collected within the plasma container may be based, at least in part, upon a percentage of anticoagulant in the collected plasma component. The controller may stop the first pump when the calculated volume of pure plasma collected within the plasma collection container equals the target plasma collection volume.

[0022] In further embodiments, the controller may return, after collecting at least a portion of the target plasma collection volume, fluid remaining within the blood component

separation device via the first line. Additionally or alternatively, the controller may calculate an intravascular deficit based, at least in part on, the volume of pure plasma collected and the volume of the contents of the blood component separation device returned to the donor. The system may also include a saline line that fluidly connects to a saline source and the blood component separation device. The controller may return a volume of saline to the donor to obtain a target intravascular deficit (e.g., between -250 and 500 milliliters).

[0023] The controller may calculate the donor's body mass index based, at least in part, on the weight and height of the donor. The donor plasma volume may, in turn, be calculated based, at least in part, on the donor's body mass index. The target percentage of plasma may be between 26.5 and 29.5 percent (e.g., 28.5 percent) of the donor's plasma volume.

[0024] In additional embodiments, the controller may calculate the percentage of anticoagulant in the collected plasma component, for example, based on the volume of anticoagulant added to the drawn whole blood, and the subject's hematocrit. The system may also include an anticoagulant source weight sensor that measures the weight of the anticoagulant source. The controller may then monitor a change in volume within the anticoagulant container based on the measured weight of the anticoagulant source. The calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the change in volume within the anticoagulant source. Additionally or alternatively the controller may monitor a number of rotations of the anticoagulant pump to determine the volume of anticoagulant introduced into the whole blood. In such embodiments, the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the number of rotations of the anticoagulant pump.

[0025] The system may also include an optical sensor and/or a plasma container weight sensor. The optical sensor may be located on the blood component separation device and may monitor the contents of the blood component separation device to determine if a volume of anticoagulant remains within the blood component separation device. The calculated percentage of anticoagulant in the collected plasma may then be based, at least in part, on the volume of anticoagulant within the blood component separation device. The plasma container weight sensor may monitor a volume and/or weight of the plasma

component collected within the plasma container. The calculated volume of pure plasma collected within the plasma collection device may then be based, at least in part, on the monitored volume and/or weight of collected plasma component. The optical sensor may also monitor the volume of red blood cells collected within the blood separation device, and the controller may determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood separation device and the volume of whole blood withdrawn from the donor. The percentage of anticoagulant in the collected plasma component may include at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

Brief Description of the Drawings

[0026] The foregoing features of the invention will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

[0027] Fig. 1 schematically shows a perspective view of a blood processing system in accordance with some embodiments of the present invention.

[0028] Fig. 2 schematically shows a top view of the blood processing system of Figure 1, in accordance with some embodiments of the present invention;

[0029] Fig. 3 schematically shows a disposable set installed within the blood processing system of Figure 1, in accordance with some embodiments of the present invention.

[0030] Fig. 4 is a flowchart depicting a method of collecting plasma, in accordance with embodiments of the present invention.

[0031] Fig. 5 is a flowchart depicting an alternative method of collecting plasma, in accordance with further embodiments of the present invention.

Detailed Description of Specific Embodiments

[0032] Illustrative embodiments of the present invention provide blood processing systems and methods for collecting a target volume of pure plasma. The system and method calculate a percentage of anticoagulant collected within a plasma collection container (e.g.,

in addition to the plasma that is collected within the container) based on the amount of anticoagulant added to the system and the hematocrit of the donor. The system/method may then calculate the volume of pure plasma (e.g., plasma without anticoagulant) that has been collected within the container. Further embodiments may tailor the volume of plasma collected based on the donor's plasma volume and a target percentage of plasma to collect. Details of the illustrative embodiments are discussed below.

[0033] As shown in Figures 1 and 2, the blood processing system 100 includes a cabinet 110 that houses the main components of the system 100 (e.g., the non-disposable components). Within the cabinet 110, the system 100 may include a first/blood pump 232 that draws whole blood from a subject, and a second/anticoagulant pump 234 that pumps anticoagulant through the system 100 and into the drawn whole blood. Additionally, the system 100 may include a number of valves that may be opened and/or closed to control the fluid flow through the system 100. For example, the system 100 may include a donor valve 120 that may open and close to selectively prevent and allow fluid flow through a donor line 218 (e.g., an inlet line; Fig. 3), and a plasma valve 130 that selectively prevents and allows fluid flow through an outlet/plasma line 222 (Fig. 3). Some embodiments may also include a saline valve 135 that selectively prevents and allows saline to flow through a saline line 223.

[0034] To facilitate the connection and installation of a disposable set and to support the corresponding fluid containers, the system 100 may include an anticoagulant pole 150 on which the anticoagulant solution container 210 (Fig. 3) may be hung, and a saline pole 160 on which a saline solution container 217 (Fig. 3) may be hung (e.g., if the procedure being performed requires the use of saline). Additionally, in some applications, it may be necessary and/or desirable to filter the whole blood drawn from the subject for processing. To that end, the system 100 may include blood filter holder 170 in which the blood filter (located on the disposable set) may be placed.

[0035] As discussed in greater detail below, apheresis systems 100 in accordance with embodiments of the present invention withdraw whole blood from a subject through a venous access device 206 (Fig. 3) using the blood pump 232. As the system 100 withdraws the whole blood from the subject, the whole blood enters a blood component separation device 214, such as a Latham type centrifuge (other type of separation chambers and devices

may be used, such as, without limitation, an integral blow-molded centrifuge bowl, as described in U.S. Patent Nos. 4,983,158 and 4,943,273, which are hereby incorporated by reference). The blood component separation device 214 separates the whole blood into its constituent components (e.g., red blood cells, white blood cell, plasma, and platelets). Accordingly, to facilitate operation of the separation device 214, the system 100 may also include a well 180 in which the separation device 214 may be placed and in which the separation device 214 rotates (e.g., to generate the centrifugal forces required to separate the whole blood).

[0036] To allow the user/technician to monitor the system operation and control/set the various parameters of the procedure, the system 100 may include a user interface 190 (e.g., a touch screen device) that displays the operation parameters, any alarm messages, and buttons which the user/technician may depress to control the various parameters. Additional components of the blood processing system 100 are discussed in greater detail below (e.g., in relation to the system operation).

[0037] FIG. 3 is a schematic block diagram of the blood processing system 100 and a disposable collection set 200 (with an inlet disposable set 200A and an outlet disposable set 200B) that may be loaded onto/into the blood processing system 100, in accordance with the present invention. The collection set 200 includes a venous access device 206 (e.g., a phlebotomy needle) for withdrawing blood from a donor's arm 208, a container of anti-coagulant 210, a centrifugation bowl 214 (e.g., a blood component separation device), a saline container 217, and a final plasma collection bag 216. The blood/inlet line 218 couples the venous access device 206 to an inlet port 220 of the bowl 214, the plasma/outlet line 222 couples an outlet port 224 of the bowl 214 to the plasma collection bag 216, and a saline line 223 connects the outlet port 224 of the bowl 214 to the saline container 217. An anticoagulant line 225 connects the anti-coagulant container 210 to the inlet line 218. In addition to the components mentioned above and as shown in Figure 3, the blood processing system 100 includes a controller 226, a motor 228, and a centrifuge chuck 230. The controller 226 is operably coupled to the two pumps 232 and 234, and to the motor 228, which, in turn, drives the chuck 230. The controller 226 may be operably coupled to and in communication with the user interface 190.

[0038] In operation, the disposable collection set 200 (e.g., the inlet disposable set 200A and the outlet disposable set 200B) may be loaded onto/into the blood processing system 100 prior to blood processing. In particular, the blood/inlet line 218 is routed through the blood/first pump 232 and the anticoagulant line 225 from the anti-coagulant container 210 is routed through the anticoagulant/second pump 234. The centrifugation bowl 214 may then be securely loaded into the chuck 230. Once the bowl 214 is secured in place, the technician may install the outlet disposable set 200B. For example the technician may connect a bowl connector 300 to the outlet 224 of the bowl 214, install the plasma container 216 into the weight sensor 195, run the saline line 223 through valve 135, and run the plasma/outlet line 222 through valve 130 and the line sensor 185. Once the disposable set 200 is installed and the anticoagulant and saline containers 210/217 are connected, the system 100 is ready to begin blood processing.

[0039] Figure 4 is a flowchart depicting an exemplary method of collecting plasma in accordance with various embodiments of the present invention. Prior to connecting the donor to the blood processing device 100, it is beneficial (and perhaps necessary in some instances) to obtain/determine some information regarding the donor, namely, the donor's weight (Step 410) and hematocrit (Step 415). Not only does this information help determine if the individual is a viable donor and the volumes of blood components that may be withdrawn/collected (e.g., per the FDA guidelines), the hematocrit may be used during processing to help collect a target volume of plasma. The technician may obtain/determine the donor's weight by weighing the donor (e.g., on a scale). To obtain/determine the donor's hematocrit, the technician may draw a blood sample from the donor and test the sample of blood. Additionally or alternatively, as discussed in greater detail below, the system may determine the hematocrit during blood processing. For example, the blood processing device 100 may include a hematocrit sensor (not shown) that determines the hematocrit of the blood flowing into the blood processing device 100 and/or the system 100 may determine the hematocrit based on a volume of red blood cells collected within the bowl 214.

[0040] Once the lines 222/223 are in place and the technician has determined the donor's weight and/or hematocrit (if needed), the user/technician may insert the venous access device 206 into the donor's arm 208 (Step 420). Next, the controller 226 activates the

two pumps 232, 234 and the motor 228. Operation of the two pumps 232, 234 causes whole blood to be drawn from the donor (step 425), anticoagulant from container 210 to be introduced into the drawn whole blood (step 430), and the now anticoagulated whole blood to be delivered to the inlet port 220 of the bowl 214.

[0041] It should be noted that the anticoagulant line 225 may also include a bacteria filter (not shown) that prevents any bacteria in the anticoagulant source 210, the anticoagulant, or the anticoagulant line 225 from entering the system 100 and/or the subject. Additionally, the anticoagulant line 225 may include an air detector 140 that detects the presence of air within the anticoagulant. The presence of air bubbles within any of the system 100 lines can be problematic for the operation the system 100 and may also be harmful to the subject if the air bubbles enter the blood stream. Therefore, the air detector may be connected to an interlock that stops the flow within the anticoagulant line 225 in the event that an air bubble is detected (e.g., by stopping the anticoagulant pump 234), thereby preventing the air bubbles from entering the subject.

[0042] As the anti-coagulated whole blood is withdrawn from the subject and contained within the blood component separation device 214, the blood component separation device 214 separates the whole blood into several blood components (Step 435). For example, the blood component separation device 214 may separate the whole blood into a first, second, third, and, perhaps, fourth blood component. More specifically, the blood component separation device 214 (and the centrifugal forces created by rotation of the separation device 214) can separate the whole blood into plasma, platelets, red blood cells ("RBC"), and, perhaps, white blood cells ("WBC"). The higher density component, i.e., RBC, is forced to the outer wall of the bowl 214 while the lower density plasma lies nearer the core. A buffy coat is formed between the plasma and the RBC. The buffy coat is made up of an inner layer of platelets, a transitional layer of platelets and WBC and an outer layer of WBC. The plasma is the component closest to the outlet port and is the first fluid component displaced from the bowl 214 via the outlet port 224 as additional anticoagulated whole blood enters the bowl 214 through the inlet port 220.

[0043] As shown in Figure 3, the system 100 may also include an optical sensor 213 that may be applied to a shoulder portion of the bowl 214. The optical sensor monitors each

layer of the blood components as they gradually and coaxially advance toward the core from the outer wall of the bowl 214. The optical sensor 213 may be mounted in a position (e.g., within the well 180) at which it can detect the buffy coat and/or the red blood cells reaching a particular radius, and the steps of drawing the whole blood from the subject/donor and introducing the whole blood into the bowl 12 may be altered and/or terminated in response to the detection.

[0044] Additionally, in some embodiments, the optical sensor 213 may be used to determine the hematocrit of the donor during processing. For example, as the bowl 214 fills with red blood cells and the optical sensor 213 detects the layer of red blood cells, the system 100 (e.g., the controller) can determine the volume of red blood cells within bowl 214 based on the location of the red blood cell layer and the fixed/known bowl volume. The system 100 may then calculate the donor hematocrit based on the volume of red blood cells within the bowl and the volume of whole blood that has been processed to that point.

[0045] Once the blood component separation device 214 has separated the blood into the various components, one or more of the components can be removed from the blood component separation device 214. For instance, the plasma may be removed to a plasma container 216 (e.g., a plasma bottle) through line 222 (Step 440). As noted above, some embodiments of the system 100 may include a weight sensor 195 (Fig. 1) that measures the amount of plasma collected. The plasma collection process may continue until a target volume of pure plasma (discussed in greater detail below) is collected within the plasma collection container 216. Although not shown, if the blood processing system 100 and/or the disposable set 200 include platelet, red blood cell, and/or white blood cell bags, each of the bags/containers may include similar weight sensors (e.g., load cells).

[0046] In some embodiments, the system 100 may also include a line sensor 185 (mentioned above) that can determine the type of fluid (e.g., plasma, platelets, red blood cells etc.) exiting the blood component separation device 214. In particular, the line sensor 185 consists of an LED which emits light through the blood components leaving the bowl 214 and a photo detector which receives the light after it passes through the components. The amount of light received by the photo detector is correlated to the density of the fluid passing through the line. For example, if plasma is exiting the bowl 214, the line sensor 185 will be

able to detect when the plasma exiting the bowl 214 becomes cloudy with platelets (e.g., the fluid existing the bowl 214 is changing from plasma to platelets). The system 100 may then use this information to either stop the removal of blood components from the bowl 214, stop drawing whole blood from the subject, or redirect the flow by, for example, closing one valve an opening another.

[0047] It is important to note that during processing, the osmolarity of the red blood cells prevents the anticoagulant introduced into the whole blood from entering/remaining with the red blood cells (e.g., within the bowl 214). Rather, the anticoagulant mixes with the plasma component. Therefore, the anticoagulant exits the bowl 214 with the plasma and is collected within collection container 216 along with the plasma. In other words, the weight of the product measured by the weight sensor 195 is the weight of the plasma, as well as any anticoagulant that is mixed with the plasma – the weight provided by the weight sensor 195 is not the weight of pure plasma.

[0048] Additionally, whole blood contains a variable amount of plasma, as determined by the donor's hematocrit. The hematocrit for typical donors can vary from 38% to 54%, which means that for 100 ml of whole blood, the volume of plasma can vary from 36 to 62 ml. Furthermore, the amount of anticoagulant added to the withdrawn whole blood is fixed (e.g., it does not depend on the hematocrit of the donor), meaning that the percentage of anticoagulant in the collected plasma may vary from 9.7% to 12.7% for donor hematocrits between 38% to 54%, respectively. Therefore, not only does the volume measured by the weight sensor 195 include the volume of anticoagulant, that volume of anticoagulant may vary from donor to donor based on the hematocrit.

[0049] As mentioned above, some embodiments of the present invention continue the blood processing/separation procedure until a target volume of pure plasma (e.g., plasma only – without the volume of any anticoagulant mixed with the plasma included in the target volume) is collected within the plasma collection container 216. To that end, some embodiments of the present invention may calculate the volume of pure plasma within the plasma collection container 216. For example, the technician or the system 100 (e.g., the controller) may calculate the percentage of anticoagulant within the collected plasma (Step 455) (e.g., the plasma contained within the plasma collection container 216) based on the

amount of anticoagulant added/metered into the whole blood and the hematocrit of the donor. The technician and/or system can calculate the percentage of anticoagulant according to the following equation, where AC is the amount of anticoagulant added to the system 100. As noted above, because the osmolarity of the red blood cells prevents the anticoagulant from mixing with it, essentially all of the anticoagulant exits the bowl 214 and is collected within the plasma collection container 216 along with the plasma.

$$\%AC = \frac{1}{1 + (AC - 1)(1 - Hct_D)}$$

[0050] The amount of anticoagulant that is added to the system 100 can be determined in a number of ways. For example, the system 100 can base the amount of anticoagulant (e.g., the value of “AC” in the above equation) on the predetermined ratio of anticoagulant per unit of anticoagulated whole blood. In some embodiments, the value of “AC” may be the inverse of the predetermined ratio (e.g., “AC” would be 16 if the ratio of anticoagulant to anticoagulated whole blood was 1:16). Additionally or alternatively, the technician/system 100 can monitor the volume of anticoagulant added to the system. In such embodiments, the technician/system can monitor the volume of anticoagulant added to the system 100 based on the number of rotations of the anticoagulant pump (e.g., each rotation of the anticoagulant pump introduces a set volume of anticoagulant into the system 100) and/or based on the change in weight of the anticoagulant container 210 as measured by a weight sensor (discussed in greater detail below).

[0051] Once the technician/system 100 has calculated the percentage of anticoagulant within the plasma collection container 216, the technician/system 100 may then use this information to calculate the volume of pure plasma within the plasma collection container 216 (Step 465). For example, the technician/system 100 may determine the volume of anticoagulant within the container (based on the percentage of anticoagulant within the container 216) and subtract this volume from the total volume of fluid within the container 216 as measured by the weight sensor 195. The system 100 may continue to monitor the volume of pure plasma collected within the container 216 and continue processing whole blood (e.g., continue performing Steps 425, 430, 435, 440, 455, 460 and 465) until a target

volume of pure plasma is collected within the plasma collection container 216 (Step 470) (e.g., 800 mL for an adult donor weighing more than 175 pounds or other limit prescribed by the FDA or similar governing body).

[0052] Once the system 100 has collected the target volume of pure plasma within the plasma collection container 216, the system 100 can return the remaining components (e.g., the components remaining within the bowl 214) to the subject (Step 475). For example, when all the plasma has been removed and the bowl 214 is full of RBCs (and any other blood component not collected), the controller 226 stops the draw of whole blood from the subject and reverses the direction of the blood/first pump 232 to draw the RBCs (and other components) from the bowl 214 directly back to the subject. Alternatively, if the system 100 is so equipped, the system may return the components to the subject via a dedicated return line.

[0053] In addition to the non-collected blood components (e.g., the components remaining in the bowl 214), the system 100 may also return saline to the patient/subject. The saline may be used as a compensation fluid to make up for the volume of the blood component (e.g., plasma) that was removed and collected, and is not being returned to the patient. To that end, during the return step (e.g., Step 475), the saline valve 135 may be opened to allow saline from the saline container 217 to flow through the saline line 223 and into the bowl 214 (via outlet 224), where it can be returned to the patient/donor with or after the remaining blood components.

[0054] It should be noted that some embodiments may perform some additional and optional steps to help determine the volume of pure plasma within the plasma collection container 216. For example, as mentioned above, some embodiments may monitor the change in weight of the anticoagulant container 210 (e.g., as measured by a weight sensor/load cell on the anticoagulant container 210) (step 445). This measurement provides an indication of the volume of anticoagulant that has been added to the system 100, and may be used help determine the percentage of anticoagulant within the plasma collection container 216. Additionally or alternatively, some embodiments may similarly, monitor the change in weight and/or volume of the plasma and anticoagulant collected within the plasma collection container 216 (e.g., via weight sensor 195) (step 450). This measurement may be

used to calculate of the total volume of pure plasma collected within the plasma collection container 216 (e.g., to obtain the total weight from which to subtract the calculated volume of anticoagulant).

[0055] Some embodiments may also (optionally) monitor the volume of anticoagulant remaining in the bowl 214 (step 460) (e.g., anticoagulant that did not mix with the plasma and/or otherwise remained in the bowl). For example, the system 100 may utilize the optical sensor on the bowl 214 to determine whether any anticoagulant remains within the bowl 214. If it does, the method 400/system 100 may modify the calculation of the amount of pure plasma collected within the plasma collection container (e.g., either increase the calculated amount or decreased the calculated amount), based on the volume of anticoagulant remaining within the bowl 214.

[0056] The various embodiment of the present invention described above provide numerous benefits over prior art plasma collection systems. In particular, as noted above, prior art plasmapheresis devices end plasma collection based on a total volume of anticoagulated plasma (e.g., pure plasma plus the added anticoagulant). Although this is the easiest method because it requires only that the product collection container be weighed, the amount of true product – the pure plasma – is dependent on the donor's hematocrit. In other words, prior art systems will collect more plasma from low hematocrit donors than from high hematocrit donors because of the variation of the percentage of anticoagulant in the product. Various embodiments of the present invention address the issues of prior art systems by collecting a standard volume (e.g., a target volume) of pure plasma from each donor. As noted above, embodiments of the present invention accomplish this by using knowledge of the donor's hematocrit and the amount of anticoagulant collected within the plasma collection container 216 (e.g., by counting pump rotations and/or using scale/weight sensors, etc.) to determine the percentage of anticoagulant in the product. Additionally, by stopping the plasma collection process based on a volume of pure plasma collected, embodiments of the present invention are able to collect a greater volume of plasma as compared to prior art systems that stop based on a plasma/anticoagulant mixture.

[0057] Figure 5 shows an alternative method for collecting plasma, using the system (or similar system) shown within Figures 1-3, that bases the total volume of plasma to collect

on the individual donor (e.g., based on their height, weight, hematocrit, blood volume and/or plasma volume). In a manner similar to that described above for the method shown in Figure 4, prior to connecting the donor to the blood processing device 100, the system/method may obtain/determine some information regarding the donor, namely, the donor's weight and height (Step 505) and hematocrit (Step 510). For example, the technician may obtain/determine the donor's weight by weighing the donor (e.g., on a scale) and the donor's height by measuring the donor. To obtain/determine the donor's hematocrit (e.g., in a manner similar to that described above), the technician may test a blood sample or the system may determine the hematocrit during blood processing using a hematocrit sensor and/or based on the volume of red blood cells collected within the bowl 214.

[0058] Using the donor height and weight, and the hematocrit, the system 100/method 500 may calculate the donor's plasma volume (e.g., the volume of plasma within the donor's blood) (Step 515). For example, the system 100/method 500 may calculate the donor/subject's body mass index ("BMI") using the donor's height and weight (e.g., $BMI = \text{weight}/\text{height}^2$), and then the total blood volume within the donor/subject using the calculated BMI (e.g., see Lemmens et al., *Estimating Blood Volume in Obese and Morbidly Obese Patients*, Obesity Surgery, 2006:16, 773-776, the subject matter incorporated herein by reference). The total blood volume may be calculated using the following equation:

$$\text{[0059]} \text{ InBV} = \frac{70}{\sqrt{BMI_p/22}}$$

[0060] In the above equation, InBV is the indexed blood volume (e.g., the donor's total blood volume), BMI_p is the patient's BMI (e.g., kg/ m²), 22 is the BMI value (e.g., also in kg/m²) for an ideal body weight (IBW), and 70 is the total blood volume (in mL/kg) for a donor at their ideal weight (BMI = 22 kg/ m²). Once the system 100 has calculated the total blood volume within the donor/subject, the system 100 (e.g., the controller) may then determine/calculate the volume of plasma within the donor's blood (Step 515) based, for example, on the donor's hematocrit.

[0061] As mentioned above, the embodiment shown in Figure 5 bases the volume of plasma to collect on the individual donor. To that end, once the system 100/method 500 has

determined the donor's plasma volume, the system 100/method 500 may then calculate the target volume of plasma to collect (Step 520). For example, the system 100/method 500 may multiply the total plasma volume within the patient by a target percentage of plasma to collect to obtain the target plasma volume to collect (e.g., if the total plasma volume is 2700 ml and the target percentage to collect is 28.5%, then the target plasma volume to collect is 769.5 ml). The target percentage of plasma to collect may depend on the application and/or the donor, and may be input directly into the system 100 (e.g., using the user interface 190) or may be preset from the factory. In some embodiments, the target percentage may be between 26.5 and 30%, and preferably may be 28.5%. However, in other embodiments, the target percentage may be below 26.5% or above 30%.

[0062] Once the lines 222/223 are in place and the system 100/method 500 has calculated the target plasma volume, the user/technician may insert the venous access device 206 into the donor's arm 208 (Step 525). Next, in a manner similar to that described above for the method shown in Figure 4, the controller 226 activates the two pumps 232, 234 and the motor 228. Operation of the two pumps 232, 234 causes whole blood to be drawn from the donor (step 530), anticoagulant from container 210 to be introduced into the drawn whole blood (step 535), and the now anticoagulated whole blood to be delivered to the inlet port 220 of the bowl 214.

[0063] As the anti-coagulated whole blood is withdrawn from the subject and introduced into the blood component separation device 214, the blood component separation device 214 separates the whole blood into the respective blood components (e.g., into plasma, platelets, RBC, and, perhaps, WBC) (Step 540). As discussed above, the higher density component, i.e., RBC, is forced to the outer wall of the bowl 214 and the plasma is the component closest to the outlet port and, therefore, is the first fluid component displaced from the bowl 214 via the outlet port 224 as additional anticoagulated whole blood enters the bowl 214 through the inlet port 220. During separation and processing, the optical sensor 213 monitors each layer of the blood components as they gradually and coaxially advance toward the core from the outer wall of the bowl 214, and the steps of drawing the whole blood from the subject/donor and introducing the whole blood into the bowl 12 may be altered and/or terminated in response to the detection. Additionally, as discussed above, the optical sensor

213 may be used to determine the hematocrit of the donor during processing (e.g., if it is not known and/or determined prior to the start of processing).

[0064] Once the blood component separation device 214 has separated the blood into the various components, the plasma may be removed to a plasma container 216 (e.g., a plasma bottle) through line 222 (Step 545). As noted above, some embodiments of the system 100 may include a weight sensor 195 (Fig. 1) that measures the amount of plasma collected. The plasma collection process may continue until the target plasma collection volume (discussed in greater detail below) is collected within the plasma collection container 216. If equipped with the line sensor 185, the system 100 may then use the information from the sensor 185 to either stop the removal of blood components from the bowl 214, stop drawing whole blood from the subject, or redirect the flow by, for example, closing one valve and opening another.

[0065] As mentioned above, some embodiments of the present invention continue the blood processing/separation procedure until a target plasma collection volume is collected. In order to ensure that this volume does not include the volume of any anticoagulant collected within the container 216, the target plasma collection volume should only include the volume of pure plasma (e.g., plasma only – without the volume of any anticoagulant mixed with the plasma included in the target volume). To that end and in a manner similar to that described above, some embodiments of the present invention may calculate the volume of pure plasma within the plasma collection container 216. To determine the volume of pure plasma, the technician or the system 100 (e.g., the controller) may calculate the percentage of anticoagulant within the collected plasma (Step 560) (e.g., the plasma contained within the plasma collection container 216) based on the amount of anticoagulant added/metered into the whole blood and the hematocrit of the donor (see equation provided above). The amount of anticoagulant that is added to the system 100 can be determined in any of the ways mentioned above (e.g., based on the predetermined ratio of anticoagulant per unit of anticoagulated whole blood, by monitoring the volume of anticoagulant added to the system, etc.).

[0066] Once the technician/system 100 has calculated the percentage of anticoagulant within the plasma collection container 216, the technician/system 100 may then use this

information to calculate the volume of pure plasma within the plasma collection container 216 (Step 570). For example, as discussed above, the technician/system 100 may determine the volume of anticoagulant within the container (based on the percentage of anticoagulant within the container 216) and subtract this volume from the total volume of fluid within the container 216 as measured by the weight sensor 195. The system 100 may continue to monitor the volume of pure plasma collected within the container 216 and continue processing whole blood (e.g., continue performing Steps 530, 535, 540, 545, 560, 570 and, possibly, steps 550, 555 and 565) until the volume of pure plasma collected within the plasma collection container 216 reaches the target plasma volume (Step 575) (e.g., as calculated based on the individual plasma volume of the donor and the target percentage of plasma to collect).

[0067] Once the system 100 has collected the target plasma volume within the plasma collection container 216, the system 100 can return the remaining components (e.g., the components remaining within the bowl 214) to the subject (Step 580) by stopping the draw of whole blood from the subject and reversing the direction of the blood/first pump 232 to draw the RBCs (and other components) from the bowl 214 and back to the subject (e.g., directly via the blood/inlet line 218 or, if so equipped, via a dedicated return line.

[0068] It is important to note that, because the system 100/method 500 collect and do not return some of the blood components (e.g., the plasma), the volume of fluid that is returned to the donor/subject is less than the volume that was removed. This, in turn, creates an intravascular deficit that is equal to the amount of plasma collected (e.g., the volume of whole blood removed from the donor minus the volume of plasma collected/not returned). In instances in which the intravascular deficit is too large, the donor is at risk of fainting when the procedure is complete and they get up to leave the facility. To reduce the intravascular deficit (and the risk of donor injury), as noted above, some embodiments of the present invention return saline to the patient/subject (Step 585). The saline may be used as a compensation fluid to make up for the volume of the blood component (e.g., plasma) removed. To that end, during the return step (e.g., Step 580), the controller 226 (or the technician) may open the saline valve to allow saline from the saline container 217 to flow

through the saline line 223 and into the bowl 214 (via outlet 224), where it can be returned to the patient/donor with or after the remaining blood components.

[0069] As mentioned above, the volume of plasma that is collected from the donor varies from donor to donor (e.g., because it is based on the donor's height, weight, hematocrit, and blood volume). Therefore, the volume of saline that is returned to the donor to reduce the intravascular deficit may similarly be dependent on the donor. To that end, when returning the contents of the separation device and the saline (Steps 580 and 585) to the donor, the system 100/method 500 may calculate the intravascular deficit (Step 590) based on the total volume of whole blood removed from the donor and the volume of blood components and saline that has been returned (or based on the volume of plasma collected and the volume of blood components and saline that have been returned). The system 100/method 500 may continue returning saline until the donor's intravascular deficit reaches a target intravascular deficit (Step 595).

[0070] The target intravascular deficit may be any intravascular deficit that reduces the donor's risk for fainting and may be the same for each donor. For example, the target intravascular deficit may be set to 0 mL or 250 mL for each donor. Alternatively, like the target plasma volume to collect, the target intravascular deficit may be different for each donor. In other words, the target intravascular deficit may be set to 0 mL for some donors and 250 mL for others. It should be noted that 0 and 250 mL are provided as examples only and other embodiments may have target intravascular deficits between 0 and 250, or greater than 250 mL. Additionally, in some instances, it may be beneficial to return more fluid to the donor than was removed/collected. In such instances, the target intravascular deficit may be set less than zero (e.g., -1 to -250 mL) so that the donor has more fluid/volume after the procedure than they did before the procedure.

[0071] Like the method 400 shown in Figure 4, the method 500 may similarly perform some additional and optional steps to help determine the volume of pure plasma within the plasma collection container 216. For example, some embodiments may monitor the change in weight of the anticoagulant container 210 (e.g., as measured by a weight sensor/load cell on the anticoagulant container 210) (step 550). This measurement provides an indication of the volume of anticoagulant that has been added to the system 100, and may

be used help determine the percentage of anticoagulant within the plasma collection container 216. Additionally or alternatively, some embodiments may similarly, monitor the change in weight and/or volume of the plasma and anticoagulant collected within the plasma collection container 216 (e.g., via weight sensor 195) (step 555). This measurement may be used to calculate of the total volume of pure plasma collected within the plasma collection container 216 (e.g., to obtain the total weight from which to subtract the calculated volume of anticoagulant). Also, some embodiments may also monitor the volume of anticoagulant remaining in the bowl 214 (step 565) (e.g., anticoagulant that did not mix with the plasma and/or otherwise remained in the bowl) using the optical sensor on the bowl 214 to determine whether any anticoagulant remains within the bowl 214 and modify the calculation of the amount of pure plasma collected within the plasma collection container (e.g., either increase the calculated amount or decreased the calculated amount), based on the volume of anticoagulant remaining within the bowl 214.

[0072] As noted above, prior art systems that follow the current FDA nomogram for plasma collection collect a volume of plasma product (e.g., anticoagulant and plasma mixed together) based solely on the weight of the donor – the same volume is collected from every donor at the same weight. However, the total blood volume and plasma volume for two donors may vary greatly. For example, when comparing two donors in the same weight grouping according to the FDA nomogram – one obese and one not obese – the obese donor will effectively have a lower blood volume that the non-obese donor. Furthermore, with respect to the total plasma volume, donors with high hematocrit will have lower plasma volumes. In other words, because the total blood volume and total plasma volume vary from donor to donor (even among donors that weight the same), the percentage of the donor's plasma that is ultimately collected may vary widely from donor to donor. By tailoring the plasma collection to the donor (e.g., based on the donor's height, weight, BMI, hematocrit, total blood volume, and/or total plasma volume) and collecting a predetermined percent of plasma from each donor, embodiments of the preset invention are able to collect a greater volume of plasma (e.g., pure plasma) from some donors but less plasma from more vulnerable donors (e.g., smaller donors with high hematocrit, donors with lower plasma

volume, etc.), as compared to systems that do not base the collection volume on the individual donor.

[0073] Similarly, current systems do not tailor the saline return volume to the patient (e.g., each donor at a given level receives the same volume of saline, for example, if the target plasma product volume is 800 mL, the donor will receive 500 mL of saline). However, because prior art systems collect based on the volume of the plasma product (which includes both plasma and anticoagulant) and the volume of pure plasma that is actually collected (and therefore, the volume removed from the donor) varies based on the donor hematocrit, the intravascular deficit for each donor will vary. In other words, the volume of saline returned to the donor may be sufficient for some, but insufficient for others. By tailoring the saline return to the individual donor, embodiments of the present invention are able to ensure that each donor has the same intravascular deficit (if any) once the procedure is complete. This, in turn, allows embodiments of the present invention to achieve isovolemia for each donor and greatly reduce any adverse reactions that the donor may experience (e.g., falling, fainting, light-headedness, vasovagal reactions, etc.).

[0074] It is also important to note that, although the various embodiments discussed above are in relation to a blood processing system that collects plasma, the features discussed herein may be applied to any type of blood processing system. For example, the features described herein may be implemented on blood processing systems that collect and/or process red blood cells, platelets and/or white blood cells.

[0075] The embodiments of the invention described above are intended to be merely exemplary; numerous variations and modifications will be apparent to those skilled in the art. All such variations and modifications are intended to be within the scope of the present invention as defined in any appended claims.

What is claimed is:

1. A method for collecting plasma comprising:
 - (a) determining the weight and height of a donor;
 - (b) determining the hematocrit of the donor;
 - (c) calculating a donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor;
 - (d) calculating a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma;
 - (e) withdrawing whole blood from the donor through a venous-access device and a first line, the first line connected to a blood component separation device;
 - (f) introducing anticoagulant into the withdrawn whole blood through an anticoagulant line;
 - (g) separating the withdrawn whole blood into a plasma component and at least a second blood component;
 - (h) collecting the plasma component from the blood component separation device and into a plasma collection container;
 - (i) continuing steps (e) through (h) until the target plasma volume to collect is reached in the plasma collection container.
2. A method according to claim 1, further comprising:
 - calculating a volume of anticoagulant to be collected with the plasma component in the plasma collection container, the volume of anticoagulant to be collected with the plasma component based, at least in part, on the hematocrit of the donor.
3. A method according to claim 2, wherein the target plasma volume to collect is a target volume of pure plasma to collect plus the calculated volume of anticoagulant to be collected.
4. A method according to claim 2, wherein the target plasma volume to collect is a target volume of pure plasma to collect in the plasma collection container, the target volume of pure plasma to collect based, at least in part, upon the volume of anticoagulant to be collected with the plasma component in the plasma collection container.

5. A method according to claim 1, further comprising:

calculating the donor's body mass index based, at least in part on the weight and height of the donor, the donor plasma volume calculated based, at least in part, on the donor's body mass index.

6. A method according to claim 1, wherein the target plasma volume to collect is calculated before withdrawing whole blood.

7. A method according to claim 1, wherein the target percentage of plasma is between 26.5 and 29.5 percent of the donor's plasma volume.

8. A system for collecting plasma comprising:

a venous-access device for drawing whole blood from a subject and returning blood components to the donor;

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container;

a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump;

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to control the operation of the blood component separation device and the first pump, the controller configured to calculate (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, (2) a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, and (3) a volume of plasma component collected within the plasma collection container, the controller configured to stop the first pump when the calculated volume of plasma component collected within the plasma collection container equals the target plasma volume to collect.

9. A system according to claim 8, wherein the controller is further configured to calculate a volume of anticoagulant to be collected with the plasma component in the plasma collection container, the volume of anticoagulant to be collected with the plasma component based, at least in part, on the hematocrit of the donor.
10. A system according to claim 9, wherein the target plasma volume to collect is a target volume of pure plasma to collect plus the calculated volume of anticoagulant to be collected.
11. A system according to claim 9, wherein the target plasma volume to collect is a target volume of pure plasma to collect within the plasma collection container, the target volume of pure plasma to collect based, at least in part, upon the volume of anticoagulant to be collected with the plasma component in the plasma collection container, the controller configured to stop the first pump when the volume of pure plasma collected within the plasma collection container equals the target plasma collection volume.
12. A system according to claim 8, wherein the controller is further configured to calculate the donor's body mass index based, at least in part on the weight and height of the donor, the donor plasma volume calculated based, at least in part, on the donor's body mass index.
13. A system according to claim 8, wherein the target plasma volume to collect is calculated before withdrawing whole blood.
14. A system according to claim 8, wherein the target percentage of plasma is between 26.5 and 29.5 percent of the donor's plasma volume.
15. A method for programming a blood processing device comprising:
- (a) receiving, in a control system, a weight and height of a donor;
 - (b) receiving, in a control system, a hematocrit of the donor;
 - (c) calculating, using the control system, a donor plasma volume, the control system calculating the donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor;

(d) calculating, using the control system, a target plasma volume to collect, the control system calculating the target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma;

(e) determining a target collection volume based, at least in part, on the calculated target plasma volume to collect; and

(f) programming a controller of a blood processing device with a blood processing end point, the blood processing end point being based, at least in part, on the target collection volume.

16. A method according to claim 15, further comprising:

calculating, using the control system, a volume of anticoagulant to be collected with a plasma component in a plasma collection container, the control system calculating the volume of anticoagulant to be collected with the plasma component based, at least in part, on the hematocrit of the donor.

17. A method according to claim 16, wherein the target plasma volume to collect is a target volume of pure plasma to collect, the target volume of pure plasma to collect based, at least in part, upon the volume of anticoagulant to be collected with the plasma component.

18. A method according to claim 17, wherein the target collection volume is the target volume of pure plasma to collect.

19. A method according to claim 17, wherein the target collection volume is the target volume of pure plasma to collect plus the calculated volume of anticoagulant to be collected in the plasma collection container.

20. A method according to claim 15, further comprising:

calculating, using the control system, the donor's body mass index based, at least in part on the weight and height of the donor, the control system calculating the donor plasma volume based, at least in part, on the donor's body mass index.

21. A method according to claim 15, wherein the blood processing end point is when the target collection volume has been collected within a plasma collection container of the blood processing device.

22. A method according to claim 15, wherein the control system includes the controller.

23. A system for collecting plasma comprising:

a blood processing device including:

a venous-access device for drawing whole blood from a donor and returning blood components to the donor,

a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma collection container,

a blood draw line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device, the flow through the blood draw line being controlled by a blood draw pump, and

an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and

a controller configured to (1) calculate a donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor, (2) calculate a target plasma volume to collect based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, and (3) calculate a target collection volume based, at least in part, on the calculated target plasma volume to collect.

24. The system according to claim 23, wherein the blood processing device is configured to stop the blood draw pump when the target collection volume is collected within the plasma collection container.

25. The system according to claim 23, wherein the controller is part of the blood processing device.

26. The system according to 23, wherein the controller is further configured to program the blood processing device with a blood processing end point based, at least in part, on the target collection volume.

27. A system according to claim 26, wherein the blood processing end point is when the target collection volume has been collected within the plasma collection container.

28. A system according to claim 23, wherein the target plasma volume to collect is a target volume of pure plasma to collect in the plasma collection container, the target volume of pure plasma to collect based, at least in part, upon a volume of anticoagulant to be collected with the plasma component in the plasma collection container.

29. A system according to claim 28, wherein the target collection volume is the target volume of pure plasma to collect and/or the target volume of pure plasma to collect plus the volume of anticoagulant to be collected in the plasma container.

29. A system according to claim 23, wherein the blood processing end point is when the target collection volume has been collected within the plasma collection container.

30. A system according to claim 23, wherein the controller is further configured to calculate the donor's body mass index based, at least in part on the weight and height of the donor, the donor plasma volume based, at least in part, on the donor's body mass index.

Abstract

A method for collecting plasma includes determining the weight, height, and hematocrit of a donor, and calculating a donor plasma volume and a target plasma collection volume. The target plasma collection volume is based on the donor plasma volume and a target percentage of plasma. The method then withdraws blood from the donor through a line connected to a blood component separation device, and introduces anticoagulant into the withdrawn blood. The blood component separation device separates the blood into a plasma component and a second blood component, and the plasma component is collected from the blood component separation device and into a plasma collection container. The method may then calculate the volume of pure plasma collected within the plasma collection container, and continue processing/collecting until the calculated volume of pure plasma equals the target plasma collection volume.

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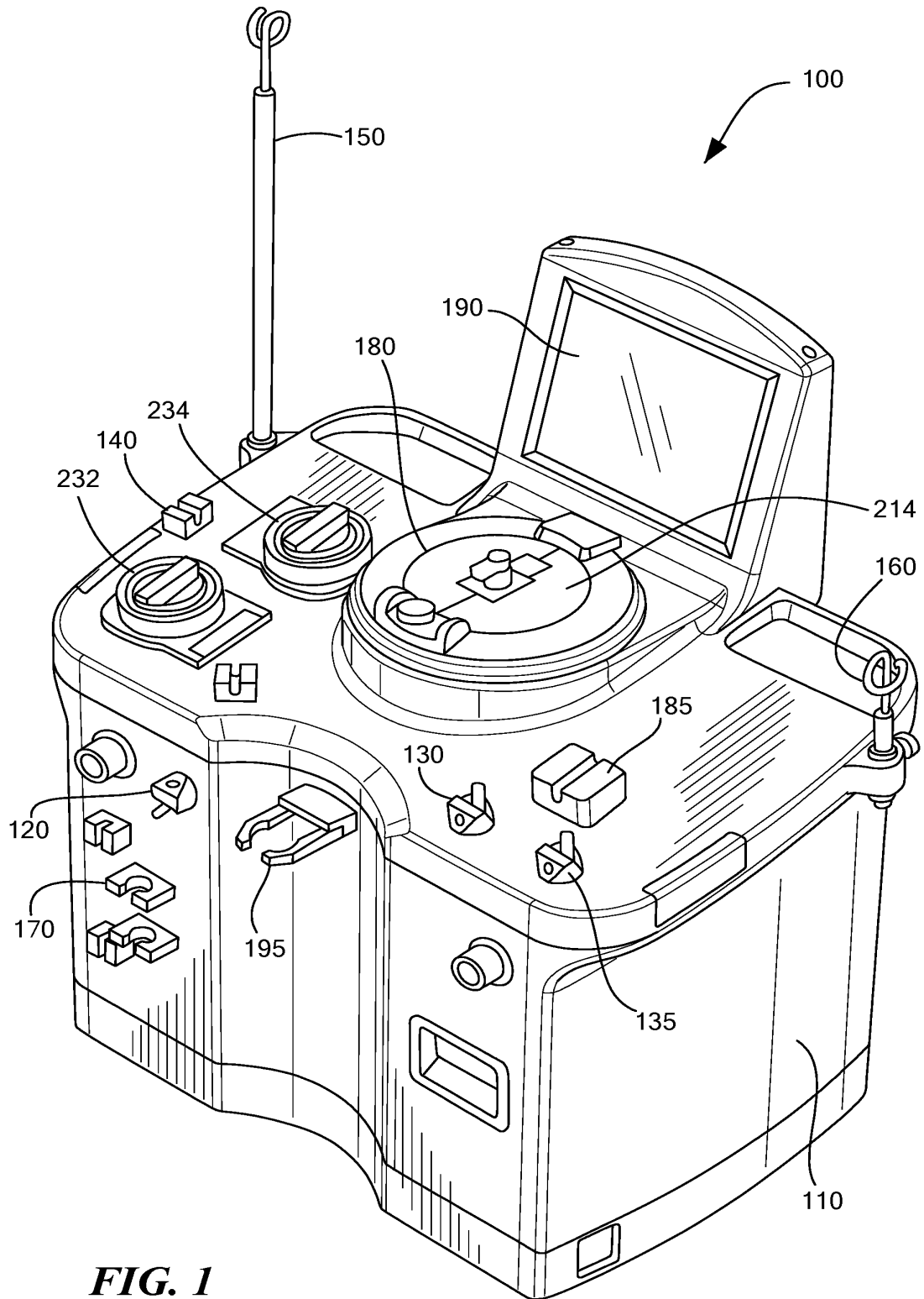
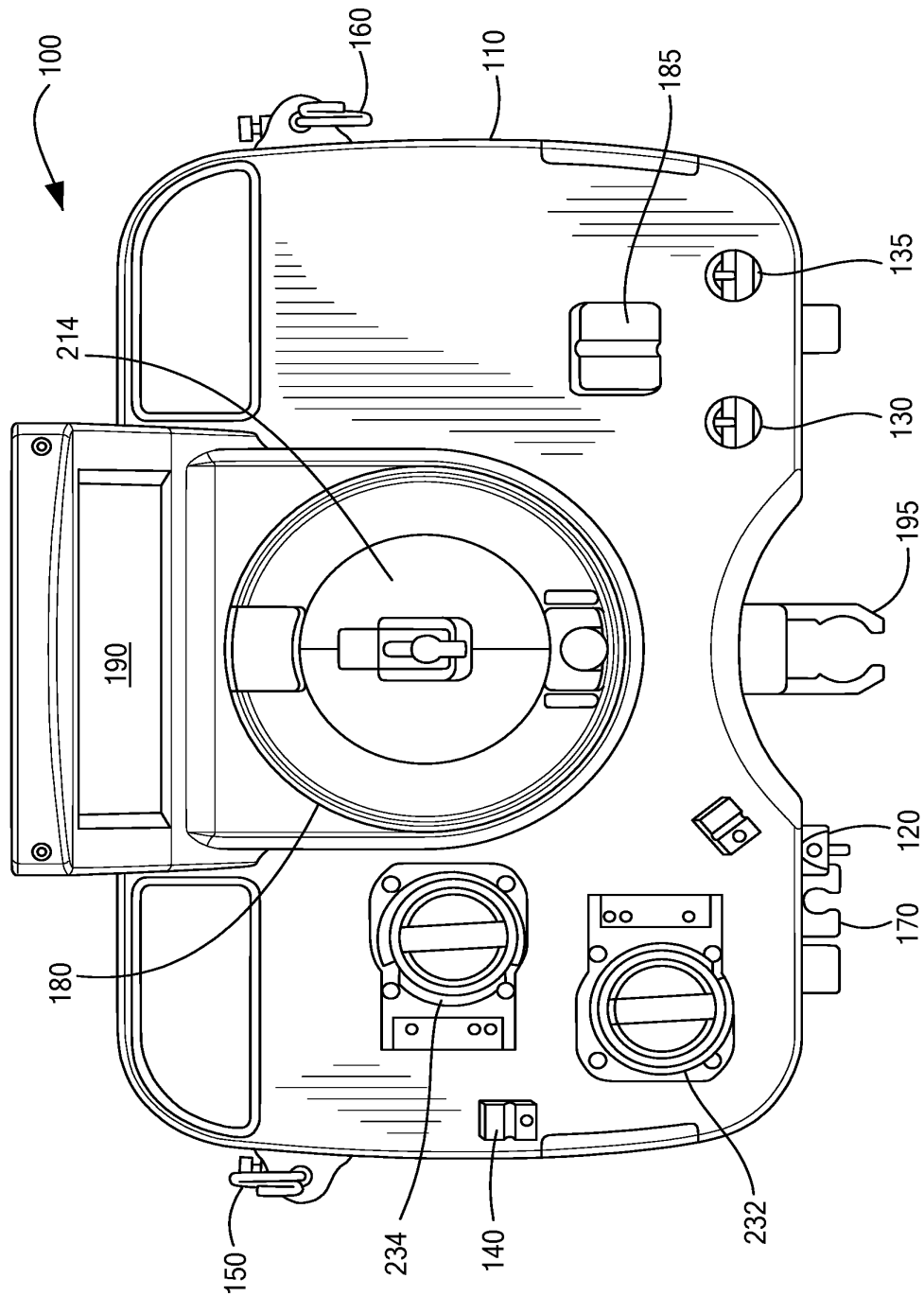
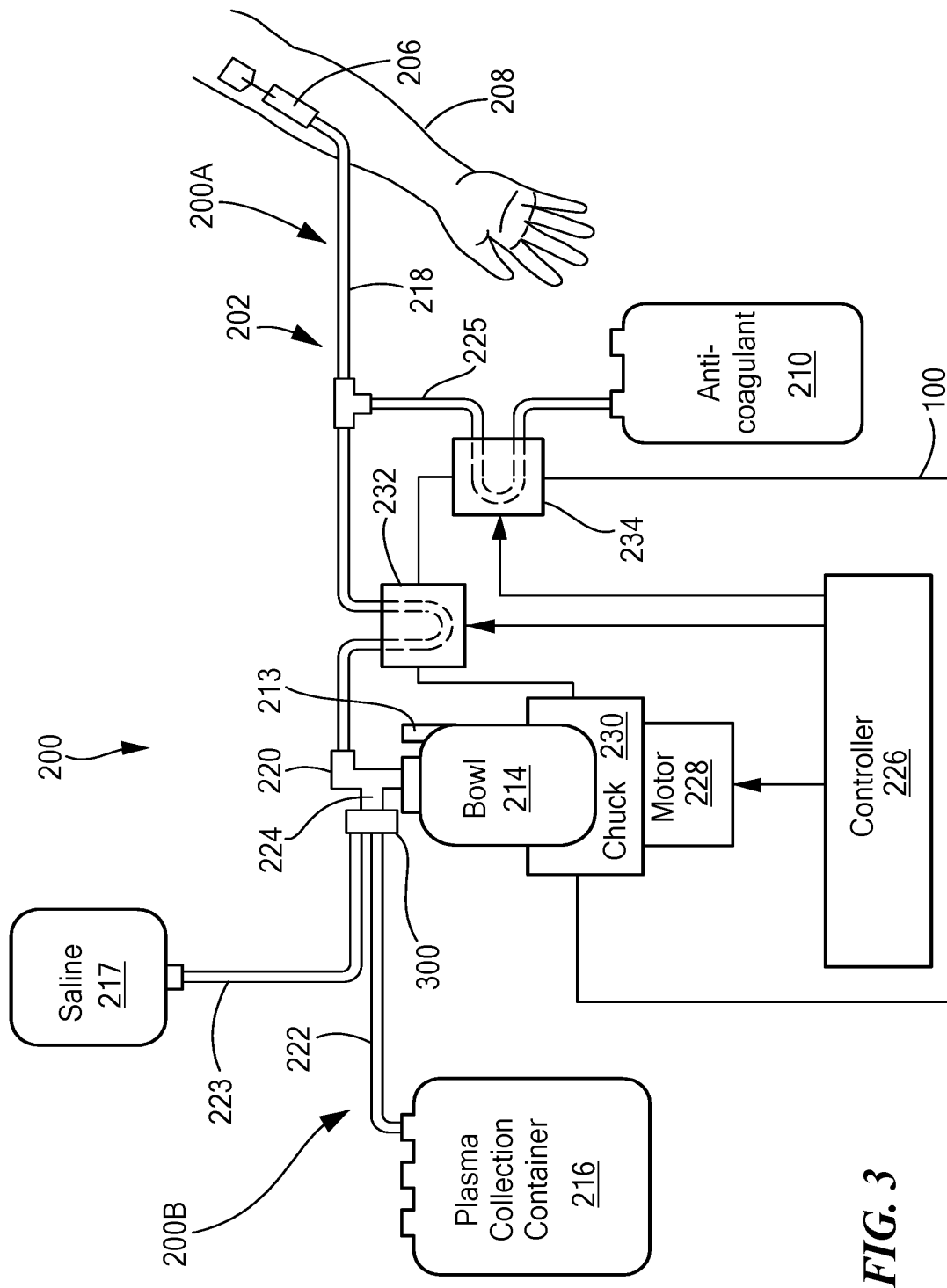


FIG. 1

**FIG. 2**

**FIG. 3**

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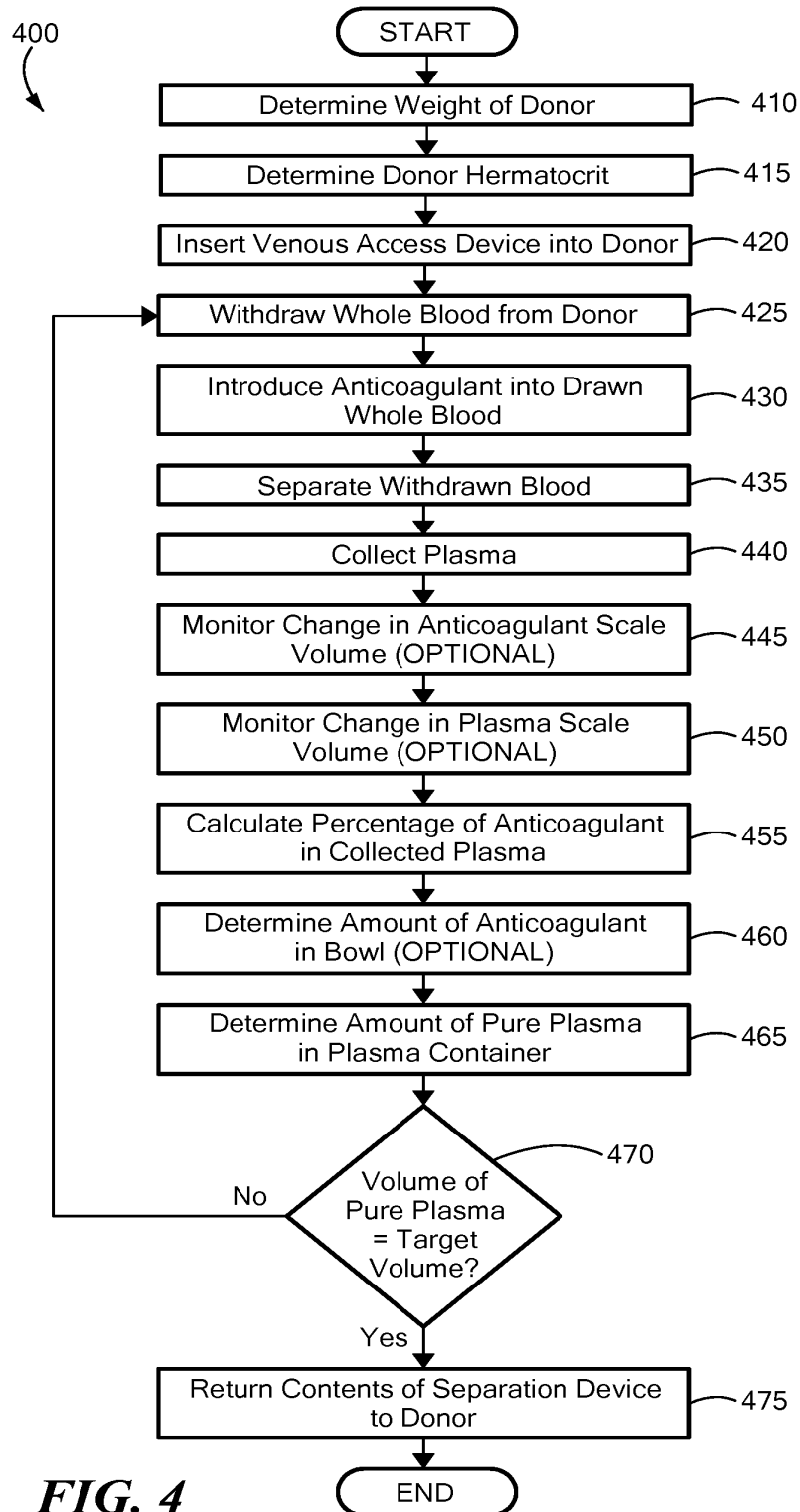
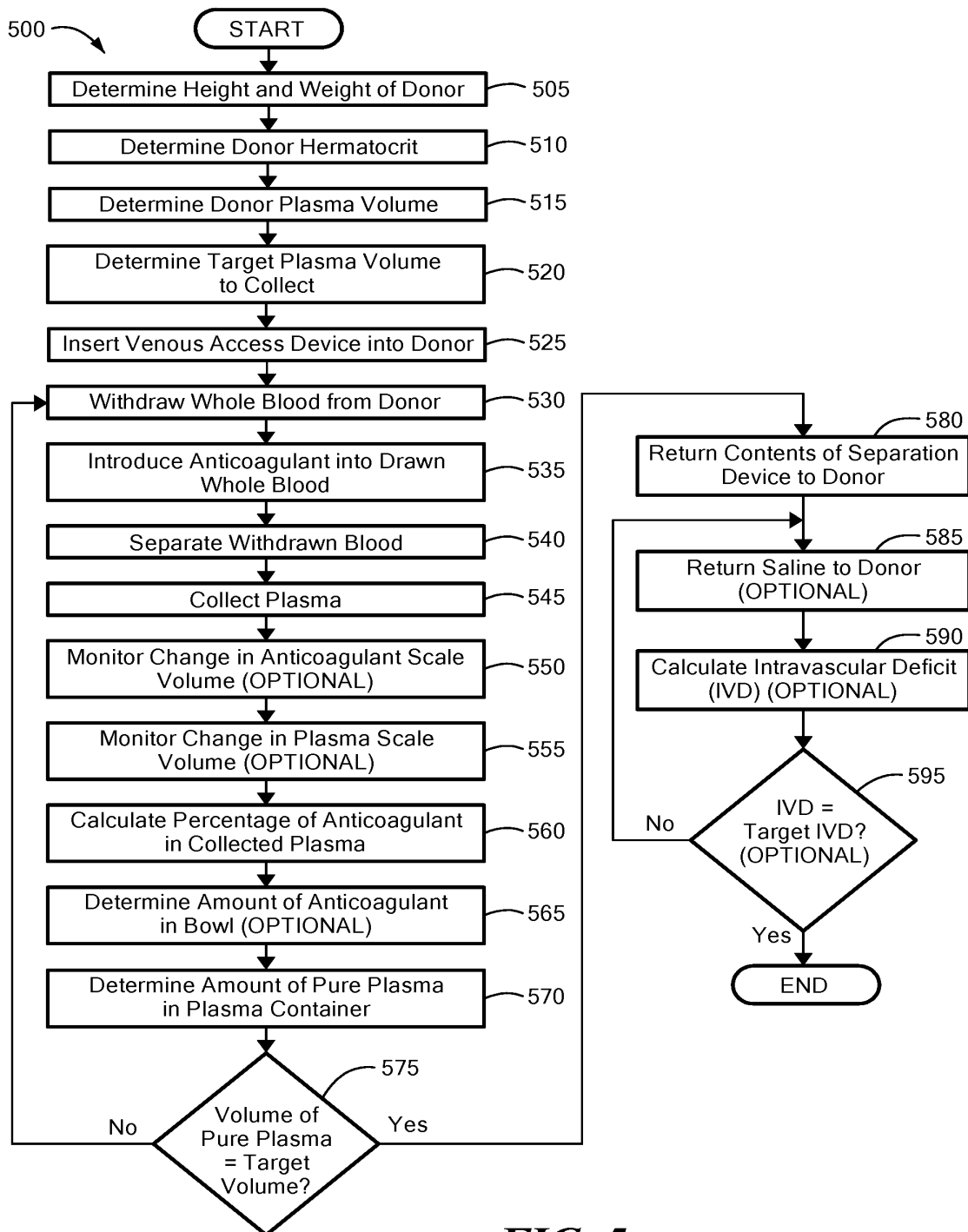


FIG. 4

**FIG. 5**

Docket No.: 130670-80103
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Utility Application of:
Michael Ragusa

Application No.: Not Yet Assigned

Confirmation No.: N/A

Filed: Concurrently Herewith

Art Unit: N/A

For: SYSTEM AND METHOD FOR COLLECTING
PLASMA

Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98, the attention of the United States Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of the above-identified application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed within three months of the U.S. filing date (37 C.F.R. § 1.97(b)(1)).

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications.

In accordance with 37 C.F.R. § 1.98(d)(1) the cited references are not supplied because they were previously cited by or submitted to the Office in prior application number 15/793,339 filed October 25, 2017 and relied on in the above-identified application for an earlier effective filing date

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under 35 U.S.C. § 120.

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in this Information Disclosure Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

It is submitted that the Information Disclosure Statement is in compliance with 37 C.F.R. § 1.98, and the Examiner is respectfully requested to consider the listed references.

Applicant believes no fee is due with this submission.

Dated: July 16, 2020

Respectfully submitted,
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