Docket Nos.: A0130.0107.01C8
10297USC16

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Manuel Luis Donnay et al.

Application No.: To be assigned

Confirmation No.: To be assigned

Filed: September 11, 2020

Art Unit: To be assigned

For: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

Examiner: To be assigned

PRELIMINARY AMENDMENT

EFS Web
Commissioner for Patents

INTRODUCTORY COMMENTS

Prior to examination, please amend the application as follows:

Amendments to the Claims beginning on page 2 of this paper; and

Remarks beginning on page 6 of this paper.

DEXCOM
EXHIBIT 1002

Docket No.: A0130.0107.01C8
(PATENT)

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INFORMATION DISCLOSURE STATEMENT (IDS)

EFS Web
Commissioner for Patents

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the 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 this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Timing of Filing of the Information Disclosure Statement:

☒ This IDS is being filed before the First Office Action.

☐ This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action.

☐ This IDS is being filed after the issuance of a Final Office Action, Ex Parte Quayle Action or Notice of Allowance but before the payment of the Issue Fee.

Certifications:

If checked, the undersigned makes the following statement(s):

☐ Statement under 37 CFR § 1.97(e):

☐ Each item of information contained in this information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

☐ Statement Under 37 C.F.R. § 1.704(d):

Each item of information contained in this information disclosure statement was cited a counterpart application less than thirty days prior to the filing of this information disclosure statement.

Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):

☐ If checked, the fee of $180.00 set forth in 37 C.F.R. §1.17(p).

Copies of Information:

In accordance with 37 C.F.R. §1.98(a), the following are enclosed:

☒ A legible copy of each document (or relevant portion thereof) cited in the attached PTO/SB/08, except for U.S. patent and U.S. published applications.

☒ With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most

knowledgeable about the content of the information, is attached. This concise explanation is provided by way of:

☒ A translation of the relevant portions of the non-English language information;

☐ A statement explaining the relevant portions of the non-English language information;

☐ A copy [and where not in the English language, a translation] of at least the relevant portion(s) of the communication from _____in which the information was cited; or

☐ This information is contained in the specification of the present application.

☒ In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not enclosed as they were provided in application Serial Nos. 13/071,461, filed March 24, 2011, and 13/436,768, filed March 30, 2012, which the present application relies upon for an earlier effective filing date under 35 U.S.C. 120.

Materiality:

Whether or not the information and references disclosed in this Information Disclosure Statement is "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Dated: September 11, 2020

Respectfully submitted,

Electronic signature: /Glen Liu/
Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Boulevard
East Tower, Suite 500
(949) 432-9993
Attorney for Applicants

PTO/SB/08 (09-08)
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

	Complete if Known
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned

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US PATENT DOCUMENTS

Examiner Initials*	Cite No.	Document Number Number-Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-3,123,790	03-03-1964	Tyler	
		US-3,581,062	05-21-1971	Aston	
		US-3,670,727	06-20-1972	Reiterman	
		US-3,949,388	04-06-1976	Fuller	
		US-4,036,749	07-19-1977	Anderson	
		US-4,120,292	10-17-1978	LeBlanc Jr., et al.	
		US-4,245,634	01-20-1981	Albisser, et al.	
		US-4,294,258	10-13-1981	Bernard	
		US-4,327,725	05-04-1982	Cortese, et al.	
		US-4,344,438	08-17-1982	Schultz	
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		US-4,373,527	02-15-1983	Fischell	
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		US-4,478,976	10-23-1994	Goertz, et al.	
		US-4,494,950	01-22-1985	Fischell	
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		US-4,527,240	07-02-1985	Kvitash	
		US-4,619,793	10-28-1986	Lee	
		US-4,627,842	12-09-1986	Katz	
		US-4,685,466	08-11-1987	Rau	
		US-4,698,057	10-06-1987	Joishy	
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		US-4,781,683	11-01-1988	Wozniak, et al.	
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		US-4,925,268	05-15-1990	Iyer, et al.	
		US-4,988,341	01-21-1991	Columbus, et al.	
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		US-5,106,365	04-21-1992	Hernandez	
		US-5,108,889	04-28-1992	Smith, et al.	
		US-5,122,925	06-16-1992	Inpyn	
		US-5,140,985	08-25-1992	Schroeder, et al.	
		US-5,234,835	08-10-1993	Nestor, et al.	
		US-5,238,729	08-24-1993	Debe	
		US-5,246,867	09-21-1993	Lakowicz, et al.	
		US-5,264,105	11-23-1993	Gregg, et al.	
		US-5,285,792	02-15-1994	Sjoquist, et al.	
		US-5,293,877	03-15-1994	O'Hara, et al.	
		US-5,299,571	04-05-1994	Mastrototaro	
		US-5,340,722	08-23-1994	Wolfbeis, et al.	
		US-5,342,789	08-30-1994	Chick, et al.	
		US-5,360,404	11-01-1994	Novacek, et al.	
		US-5,372,427	12-13-1994	Padovani, et al.	
		US-5,379,238	01-03-1995	Stark	
		US-5,408,999	04-25-1995	Singh, et al.	
		US-5,425,361	06-20-1995	Fenzlein, et al.	
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		US-5,653,239	08-05-1997	Pompei, et al.	
		US-5,665,071	09-09-1997	Wyrick	
		US-5,711,001	01-20-1998	Bussan, et al.	
		US-5,733,044	03-31-1998	Rose, et al.	
		US-5,735,285	04-07-1998	Albert, et al.	
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		US-5,766,131	06-16-1998	Kondo, et al.	
		US-5,772,586	06-30-1998	Heinonen, et al.	
		US-5,779,665	07-14-1998	Mastrototaro, et al.	
		US-5,851,197	12-22-1998	Marano, et al.	
		US-5,865,804	02-02-1999	Bachynsky	
		US-5,924,979	07-20-1999	Sedlow, et al.	
		US-5,925,021	07-20-1999	Castellano, et al.	
		US-5,931,814	08-03-1999	Alex, et al.	
		US-5,948,006	09-07-1999	Mann	
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		US-6,293,925	09-25-2001	Safabash, et al.	
		US-6,295,506	09-25-2001	Heinonen, et al.	
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		US-6,595,919	07-22-2003	Berner, et al.	
		US-6,605,200	08-12-2003	Mao, et al.	
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		US-6,610,012	08-26-2003	Mault	
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		US-6,648,821	11-18-2003	Lebel, et al.	
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		US-6,740,075	05-25-2004	Lebel, et al.	
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		US-6,758,810	07-06-2004	Lebel, et al.	
		US-6,790,178	09-14-2004	Mault, et al.	
		US-6,809,653	10-26-2004	Mann, et al.	
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		US-6,811,533	11-02-2004	Lebel, et al.	
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		US-6,849,052	02-01-2005	Ughigaki, et al.	
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		US-6,881,551	04-19-2005	Heller, et al.	
		US-6,892,085	05-10-2005	McIvor, et al.	
		US-6,895,265	05-17-2005	Silver	
		US-6,931,327	08-16-2005	Goode Jr., et al.	
		US-6,932,894	08-23-2005	Mao, et al.	
		US-6,942,518	09-13-2005	Liamos, et al.	
		US-6,950,708	09-27-2005	Bowman IV, et al.	

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Examiner Name	To be assigned

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				Application Number	To be assigned
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				First Named Inventor	Manuel Luis Donnay
				Art Unit	To be assigned
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First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
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				Examiner Name	To be assigned
Sheet	19	of	20	Attorney Docket No: A0130.0107.01C8	

NON PATENT LITERATURE DOCUMENTS			
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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
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				First Named Inventor	Manuel Luis Donnay
				Art Unit	To be assigned
(use as many sheets as necessary)				Examiner Name	To be assigned
Sheet	12	of	13	Attorney Docket Number	A0130.0107.01C8

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	345	U.S. Patent Reexamination Application No. 90/009,328, Order Granting Request for Reexamination mailed December 9, 2008.	

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	346	U.S. Patent Reexamination Application No. 90/009,328, Request for Reexamination of U.S. Patent No. 6,990,366 filed November 10, 2008.	
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	352	U.S. Patent Reexamination Application No. 90/011,730, Notice of Intent to Issue Reexam Certificate for U.S. Patent No. 6,990,366 mailed April 5, 2012.	
	353	U.S. Patent Reexamination Application No. 90/011,730, Office Action mailed January 11, 2012.	
	354	U.S. Patent Reexamination Application No. 90/011,730, Order Granting Request for Reexamination of U.S. Patent No. 6,990,366 mailed August 24, 2011.	
	355	U.S. Patent Reexamination Application No. 90/011,730, Request for Reexamination of U.S. Patent No. 6,990,366 filed June 3, 2011.	

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Sheet	1	of	2	Attorney Docket Number	A0130.0107.01C8

U.S. PATENT DOCUMENTS				
Examiner Initials	Cite No.[1]	U.S. Patent Document Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
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	2	6,102,896	08-15-2000	Roser
	3	7,407,493 B2	08-05-2008	Cane
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	32	EP 1704889 A1	09-27-2006	Kabushiki Kaisha Top	
	33	JP 2004-033438	02-05-2004	Arkray Inc.	Y
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OFFICE ACTIONS/SEARCH REPORTS

Examiner Initials'	Cite No.[1]	Country	Description	Date of Issuance MM-DD-YYY	T[2]
	36	EP	16176370.1 Extended Search Report	12-07-2016	
	37	JP	2016-44196 Office Action	04-11-2017	Y
	38				
	39				
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials'	Cite No.[1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 16/002,847 filed on June 7, 2018.

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.

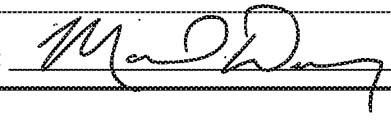
I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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: MANUEL LUIS DONNAY Date (Optional): 9/20/2018

Signature: 

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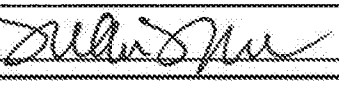
LEGAL NAME OF INVENTOR

Inventor: TUAN NGUYEN Date (Optional): 27 AUG 2018

Signature: 

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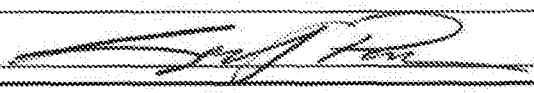
LEGAL NAME OF INVENTOR

Inventor: LOUIS G. PACE Date (Optional) :

Signature: 

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

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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.

PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

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

Title of Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

As the below named inventor, I hereby declare that:

This declaration is directed to:

☐ The attached application, or

☒ United States application or PCT international application number 16/002,847 filed on June 7, 2018

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 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: PETER G. ROBINSON Date (Optional): 27 Aug 2018

Signature: PGR

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

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1 minute 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.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Filer:	Glen Liu/Alana Fredericks
Attorney Docket Number:	A0130.0107.01C8

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:				
UTILITY APPL SIZE FEE PER 50 SHEETS >100	1081	1	400	400
Claims:				
CLAIMS IN EXCESS OF 20	1202	3	100	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous-Filing:				
PUBL. FEE- EARLY, VOLUNTARY, OR NORMAL	1504	1	0	0
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**6560**

Electronic Acknowledgement Receipt

EFS ID:	40539359
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	11-SEP-2020
Filing Date:	
Time Stamp:	20:31:32
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$6560
RAM confirmation Number	E20209AK34212370
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	10297USC16_A0130_0107_01C8_Track_One_Request.pdf	152445 17b2b9bbd969350f846a6fa50d8a8447b2f575b0	no	2
Warnings:					
Information:					
2	Application Data Sheet	10297USC16_A0130_0107_01C8_ADS.pdf	1504022 7861f32e5aae9160c88a36855c8963e293af3bc4	no	8
Warnings:					
Information:					
3		10297USC16_A0130_0107_01C8_Specification.pdf	308217 0163ed4e4f1b6b85d1137f99c024ffcfde2adbc1	yes	72

Multipart Description/PDF files in .zip description

Document Description	Start	End
Abstract	72	72
Claims	68	71
Specification	1	67

Warnings:					
Information:					
4	Drawings-only black and white line drawings	10297USC16_A0130_0107_01C8_Figures.pdf	3479603 5b28952ba1114542dd86eba92e21d10020ee44c7	no	99
Warnings:					
Information:					
5		10297USC16_A0130_0107_01C8_Preliminary_Amendment.pdf	104277 100c41813a8d0ced843d0948c8dc1b6dad7d8f5e	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	6	7
	Claims	2	5
	Preliminary Amendment	1	1

Warnings:					
Information:					
6	Transmittal Letter	10297USC16_A0130_0107_01C8_IDS_Transmittal.pdf	94018 2a6fc0306343ad59623ed6f6bc167d9055026087	no	4
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Information:					
7	Information Disclosure Statement (IDS) Form (SB08)	10297USC16_A0130_0107_01C8_IDS_1449_1.pdf	334747 991df91c051fa2b8a13d0ec0ba195af4a571172f	no	20
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Information:					
This is not an USPTO supplied IDS fillable form					
8	Information Disclosure Statement (IDS) Form (SB08)	10297USC16_A0130_0107_01C8_IDS_1449_2.pdf	237087 b242c150909ac909cd6595317e74eebf233a9a51	no	13
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Information:					
This is not an USPTO supplied IDS fillable form					
9	Information Disclosure Statement (IDS) Form (SB08)	10297USC16_A0130_0107_01C8_IDS_1449_3.pdf	136963 e5d85dcce300329815253f9abf038e207ab42e6b	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
10	Oath or Declaration filed	10297USC16_A0130_0107_01C8_Declarations.pdf	734283 8f7adb2480f36a1a4ebaca3d7acd478971a5a930	no	4
Warnings:					
Information:					

11	Fee Worksheet (SB06)	fee-info.pdf	43015 a7b67e9cbfffb84edda33822ade875bf33a483a2	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	7128677

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.

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (03-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Manuel Luis Donnay	Nonprovisional Application Number (if known):	
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES		

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), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. 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.

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, **or** 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 /Glen Liu/	Date 9/11/2020
Name (Print/Typed) Glen Liu	Practitioner Registration Number 75,058

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 1 forms are submitted.

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.

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0107.01C8
	Application Number	
Title of Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES	

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
	Manuel	Luis	Donnay	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
San Francisco	CA	US

Mailing Address of Inventor:

Address 1	944 Union Street
Address 2	
City	San Francisco
State/Province	CA
Postal Code	94133
Country	US

Inventor 2 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Tuan		Nguyen	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Dublin	CA	US

Mailing Address of Inventor:

Address 1	9855 Reimers Way
Address 2	
City	Dublin
State/Province	CA
Postal Code	94568
Country	US

Inventor 3 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Louis	G.	Pace	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0107.01C8
	Application Number	
Title of Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES	

City	San Carlos	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	219 Alberta Avenue		
Address 2			
City	San Carlos	State/Province	CA
Postal Code	94070	Country i	US

Inventor 4 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Peter	G.	Robinson	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Alamo	State/Province	CA	Country of Residence i	US

Mailing Address of Inventor:

Address 1	134 Canyon Vista Place		
Address 2			
City	Alamo	State/Province	CA
Postal Code	94507	Country i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

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	95508		
Email Address	ipdocketing@onellp.com	Add Email	Remove Email

Application Information:

Title of the Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES		
Attorney Docket Number	A0130.0107.01C8	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	99	Suggested Figure for Publication (if any)	

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0107.01C8
	Application Number	
Title of Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES	

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	95508		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this 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.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	16002847	2018-06-07
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
16002847	Continuation of	13436768	2012-03-30	10010280	2018-07-03

Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
13436768	Continuation of	13071461	2011-03-24	9215992	2015-12-22

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13071461	non provisional of	61411262	2010-11-08
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13071461	non provisional of	61361374	2010-07-02

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0107.01C8
	Application Number	
Title of Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13071461	non provisional of	61345562	2010-05-17
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
13071461	non provisional of	61317243	2010-03-24

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(d). 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(h)(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).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

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.

Authorization to Permit Access:

Authorization to Permit Access to the Instant Application by the Participating Offices

PTO/AIA/14 (03-13)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0107.01C8
	Application Number	
Title of Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES	

If 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 World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the instant patent application is filed access to the instant patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the instant patent application is filed to have access to the instant patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the instant patent application with respect to: 1) the instant patent application-as-filed; 2) any foreign application to which the instant patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the instant patent application; and 3) any U.S. application-as-filed from which benefit is sought in the instant patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date o f filing this Authorization.

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	ABBOTT DIABETES CARE INC.		
Mailing Address Information For Applicant:			
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City	Alameda	**State/Province**	CA
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Phone Number		Fax Number	

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0107.01C8
	Application Number	
Title of Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES	

Email Address	

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Signature	/Glen Liu/			Date (YYYY-MM-DD)	2020-09-11
First Name	Glen	Last Name	Liu	Registration Number	75058

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	A0130.0107.01C8
	Application Number	
Title of Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES	

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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

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

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

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

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

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

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

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

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

ABSTRACT

An apparatus for insertion of a medical device in the skin of a subject is provided, as well as methods of inserting medical devices. Embodiments include removing a substantially cylindrical cap from an inserter to expose a substantially cylindrical sleeve, removing a cover from a substantially cylindrical container holding sensor components, and fitting the sensor components into the inserter.

CLAIMS

1. An apparatus for inserting a medical device through the skin of a subject, which comprises:

a sheath defining a distal surface for placement on the skin of the subject;

a device support movable between a proximal and distal position, and adapted to support the medical device, the device support comprising a first engagement member for releasably coupling the device support to the sharp support and a second engagement member for engaging the medical device;

a sharp support movable between a proximal and a distal position and adapted to support a sharp for inserting the medical device into the skin of the subject and extending through a portion of said device support,

a handle movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from a proximal to a distal position to insert the sharp into the skin of the subject; and

a driver for advancing the sharp support towards the proximal position when the sharp support reaches the distal position.

2. The apparatus of claim 1, wherein the handle and sheath comprise an interlocking configuration which prevents relative movement of the handle with respect to the sheath which is overcome by a force applied to the handle.

3. The apparatus of claim 1, wherein the second engagement member comprises one or more movable arms for engaging the device.

4. The apparatus of claim 3, wherein the one or more movable arms are normally biased in a position spaced apart from the medical device.

5. The apparatus of claim 4, wherein the one or more movable arms are maintained in engagement with the medical device when the device support is in the proximal position.

6. The apparatus of claim 4, wherein the one or more movable arms are permitted to return to the configuration space apart from the medical device when the device support is in the distal position.

7. The apparatus of claim 1, wherein engagement member is released from the sharp support when the device support reaches a distal position.

8. The apparatus of claim 7, wherein the engagement member is maintained in engagement with the sharp support by a portion of the sheath.

9. The apparatus of claim 1, further comprising a stop to maintain the device support in the proximal position such that it protects the user from accessing the retracted sharp.

10. The apparatus of claim 1, wherein the handle comprises a button disposed within an outer housing.

11. The apparatus of claim 10, wherein the handle is flush with the top of the outer housing in an initial configuration when the medical device is supported in the device support, and the handle protrudes above the outer housing when the medical device is released from the device support.

12. The apparatus of claim 1, wherein the medical device is an analyte sensor.

13. A method for using a medical device comprising:

providing an apparatus comprising a sheath defining a distal surface, a device support adapted to support the medical device, a sharp support adapted to support a sharp extending through a portion of said device support, a handle movable relative to the sheath, and a driver for displacing the sharp support;

disposing the distal surface of the sheath on the skin of the subject; and

displacing the handle in a first longitudinal direction;

displacing the sharp support in the first longitudinal direction, the sharp support displacing the sharp and the medical device;

inserting the sharp into the skin of the subject;

delivering the medical device to the subject; releasing the driver; and

displacing the sharp in the second longitudinal direction by the driver.

14. The method of claim 13, wherein the first longitudinal direction is from a proximal to distal position, and the second longitudinal direction is from a distal to proximal position.

15. The method of claim 13, wherein the sharp is displaced towards the proximal direction when the sharp support reaches the distal position.

16. The method of claim 13, wherein the handle is maintained in a distal position when the sharp support is displaced to the proximal position.

17. The method of claim 13, wherein displacing the handle in the first longitudinal direction comprises overcoming an interlocking configuration between the handle and the sheath by applying a predetermined force.

18. The method of claim 13, wherein delivering the medical device to the subject comprises releasing the medical device from the device support.

19. The method of claim 18, wherein releasing the medical device from the device support comprises allowing on or more movable arms on the device support to displace radially outwardly.

20. A medical device insertion system comprising:

a sheath defining a distal surface for placement on the skin of the subject, the sheath having at least one biased retention feature;

a device support movable between a proximal and distal position, and adapted to support the medical device, the device support including at least one feature adapted to operatively engage the sharp support;

a sharp support movable between a proximal and a distal position and adapted to support a sharp extending through a portion of said device support;

a handle movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from a proximal to a distal position to insert the sharp into the skin of the subject,

wherein advancing the handle distally comprises applying a minimum force to overcome the at least one biased retention feature to allow distal movement of the handle relative to the detent; and

a driver for advancing the sharp support towards the proximal position when the sharp support reaches the distal position.

21. The system of claim 20, wherein one of the sharp support and the device support includes at least one retention feature.

22. The system of claim 21, wherein the retention feature is disposed on the device support.

23. The system of claim 21, wherein the sheath maintains the retention feature operatively engaged between the device support and the sharp support until advancement of the device support to the distal position.

24. The system of claim 23, wherein advancement of the device support to the distal position releases the retention feature to allow proximal movement of sharp support and sharp relative to the device support.

25. The system of claim 21, wherein the handle is maintained in a distal position when the sharp support is advanced to the proximal position.

MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation of U.S. Patent Application No. 16/002,847, filed June 7, 2018, which is a continuation of U.S. Patent Application No. 13/436,768, filed March 30, 2012, now U.S. Patent No. 10,010,280, which is a continuation of U.S. Patent Application No. 13/071,461, filed March 24, 2011, now U.S. Patent No. 9,215,992, which claims the benefit of U.S. Provisional Application Nos. 61/317,243, filed March 24, 2010; 61/345,562, filed May 17, 2010; 61/361,374, filed July 2, 2010; and 61/411,262, filed November 8, 2010, all of which are incorporated herein by reference in their entireties and for all purposes.

INCORPORATION BY REFERENCE

[0002] Patents, applications and/or publications described herein, including the following patents, applications and/or publications are incorporated herein by reference for all purposes: U.S. Patent Nos. 4,545,382; 4,711,245; 5,262,035; 5,262,305; 5,264,104; 5,320,715; 5,356,786; 5,509,410; 5,543,326; 5,593,852; 5,601,435; 5,628,890; 5,820,551; 5,822,715; 5,899,855; 5,918,603; 6,071,391; 6,103,033; 6,120,676; 6,121,009; 6,134,461; 6,143,164; 6,144,837; 6,161,095; 6,175,752; 6,270,455; 6,284,478; 6,299,757; 6,338,790; 6,377,894; 6,461,496; 6,503,381; 6,514,460; 6,514,718; 6,540,891; 6,560,471; 6,579,690; 6,591,125; 6,592,745; 6,600,997; 6,605,200; 6,605,201; 6,616,819; 6,618,934; 6,650,471; 6,654,625; 6,676,816; 6,730,200; 6,736,957; 6,746,582; 6,749,740; 6,764,581; 6,773,671; 6,881,551; 6,893,545; 6,932,892; 6,932,894; 6,942,518; 7,041,468; 7,167,818; and 7,299,082; 7,381,184; 7,740,581; 7,811,231; U.S. Published Application Nos. 2005/0182306, now U.S. Patent No. 8,771,183; 2006/0091006; 2007/0056858, now U.S. Patent No. 8,298,389; 2007/0068807, now U.S. Patent No. 7,846,311; 2007/0095661; 2007/0108048, now U.S. Patent No. 7,918,975; 2007/0149873, now U.S. Patent No. 9,014,773; 2007/0149875, now U.S. Patent No. 8,515,518; 2007/0199818, now U.S. Patent No. 7,811,430; 2007/0227911, now U.S. Patent No. 7,887,682; 2007/0233013; 2008/0058625, now U.S. Patent No. 7,920,907; 2008/0064937; 2008/0066305, now U.S. Patent No. 7,895,740; 2008/0071157; 2008/0071158; 2008/0081977, now U.S. Patent No. 7,618,369; 2008/0102441, now U.S. Patent No. 7,822,557; 2008/0148873, now U.S. Patent No. 7,802,467;

2008/0161666; 2008/0179187, now U.S. Patent No. 8,808,515; 2008/0267823; 2008/0319295, now U.S. Patent No. 8,597,188; 2008/0319296, now U.S. Patent No. 8,617,069; 2009/0018425, now U.S. Patent No. 8,160,670; 2009/0247857, now U.S. Patent No. 8,346,335; 2009/0257911, now U.S. Patent No. 8,252,229, 2009/0281406; 2009/0294277; 2009/0054748, now U.S. Patent No. 7,885,698; 2009/0054749; 2010/0030052; 2010/0065441, now U.S. Patent No. 8,636,884; 2010/0081905, now U.S. Patent No. 8,983,568; 2010/0081909, now U.S. Patent No. 8,219,173; 2010/0213057; 2010/0325868, now U.S. Patent No. 7,866,026; 2010/0326842; 2010/0326843, now U.S. Patent No. 8,437,827; 2010/0331643; 2011/0046466; U.S. Patent Application Serial Nos. 12/624,767, now U.S. Patent Publ. No. 2011/0124993; 12/625,185, now U.S. Patent No. 8,354,013; 12/625,208, now U.S. Patent No. 9,042,954; 12/625,524, now U.S. Patent No. 8,390,455; 12/625,525, now U.S. Patent No. 8,358,210; 12/625,528, now U.S. Patent No. 8,115,635; 12/628,177, now U.S. Patent Publ. No. 2010/0076289; 12/628,198, now U.S. Patent Publ. No. 2010/0076291; 12/628,201, now U.S. Patent Publ. No. 2010/0076280; 12/628,203, now U.S. Patent Publ. No. 2010/0076292; 12/628,210, now U.S. Patent Publ. No. 2010/0076293; 12/698,124, now U.S. Patent Publ. No. 2010/0198034; 12/698,129, now U.S. Patent Publ. No. 2010/03243925; 12/699,653, now U.S. Patent Publ. No. 2010/0198142; 12/699,844, now U.S. Patent No. 8,930,203; 12/714,439, now U.S. Patent Publ. No. 2010/0230285; 12/730,193; 12/794,721, now U.S. Patent No. 8,595,607; 12/807,278, now U.S. Patent Publ. No. 2011/0213225; 12/842,013, now U.S. Patent Publ. No. 2011/0021889; 12/870,818, now U.S. Patent Publ. No. 2011/0073475; 12/871,901, now U.S. Patent No. 8,514,086; 12/873,301, now U.S. Patent Publ. No. 2011/0054275; 12/873,302, now U.S. Patent Publ. No. 2011/0060196; 13/011,897, now U.S. Patent Publ. No. 2011/0184265; and U.S. Provisional Application Nos. 61/238,646; 61/246,825; 61/247,516; 61/249,535; 61/317,243; 61/325,155; 61/345,562; and 61/359,265.

BACKGROUND

[0003] The detection and/or monitoring of glucose levels or other analytes, such as lactate, oxygen, A1C, or the like, in certain individuals is vitally important to their health. For example, the monitoring of glucose is particularly important to individuals with diabetes. Diabetics generally monitor glucose levels to determine if their glucose levels are being maintained within a clinically safe range, and may also use this information to determine if and/or when insulin is

needed to reduce glucose levels in their bodies or when additional glucose is needed to raise the level of glucose in their bodies.

[0004] Growing clinical data demonstrates a strong correlation between the frequency of glucose monitoring and glycemic control. Despite such correlation, many individuals diagnosed with a diabetic condition do not monitor their glucose levels as frequently as they should due to a combination of factors including convenience, testing discretion, pain associated with glucose testing, and cost.

[0005] Devices have been developed for the automatic monitoring of analyte(s), such as glucose, in bodily fluid such as in the blood stream or in interstitial fluid ("ISF"), or other biological fluid. Some of these analyte measuring devices are configured so that at least a portion of the devices are positioned below a skin surface of a user, *e.g.*, in a blood vessel or in the subcutaneous tissue of a user, so that the monitoring is accomplished *in vivo*.

[0006] With the continued development of analyte monitoring devices and systems, there is a need for such analyte monitoring devices, systems, and methods, as well as for processes for manufacturing analyte monitoring devices and systems that are cost effective, convenient, and with reduced pain, provide discreet monitoring to encourage frequent analyte monitoring to improve glycemic control.

SUMMARY

[0007] In certain embodiments, an apparatus for inserting a medical device into the skin of a subject is provided, which includes a sheath defining a distal surface for placement on the skin of the subject; a device support movable between a proximal and distal position, and adapted to support the medical device; a sharp support movable between a proximal and a distal position and adapted to support a sharp for inserting the medical device into the skin of the subject and extending through a portion of said device support, the device support comprising a first engagement member for releasably coupling the sharp support to the device support and a second engagement member for engaging the medical device; a handle movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from a proximal to a distal position to insert the sharp into the skin of the subject; and a driver for advancing the sharp support towards the proximal position when the sharp support reaches the distal position.

[0008] In some embodiments, the handle and sheath define an interlocking configuration which

prevents relative movement of the handle with respect to the sheath which is overcome by a force applied to the handle. In some embodiment, the second engagement member includes one or more movable arms for engaging the device. The one or more movable arms are normally biased in a position spaced apart from the medical device in some embodiments. The one or more movable arms may be maintained in engagement with the medical device when the device support is in the proximal position. In some embodiments, the one or more movable arms return to the configuration space apart from the medical device when the device support is in the distal position.

[0009] In some embodiments, the engagement member is released from the sharp support when the device support reaches a distal position. In some embodiments, the engagement member is maintained in engagement with the device support by a portion of the sheath.

[0010] In some embodiments, a stop is provided to maintain the device support in the proximal position.

[0011] In some embodiments, the handle includes a button disposed within an outer housing. The handle may be flush with the top of the outer housing in an initial configuration when the medical device is supported in the device support, and the handle may protrude above the outer housing after the medical device is released from the device support.

[0012] In some embodiments, the medical device is an analyte sensor.

[0013] A method for using a medical device is provided which includes providing an apparatus comprising a sheath defining a distal surface, a device support adapted to support the medical device, a sharp support adapted to support a sharp extending through a portion of said device support, a handle movable relative to the sheath, and a driver for displacing the sharp support; disposing the distal surface of the sheath on the skin of the subject; and displacing the handle in a first longitudinal direction; displacing the sharp support in the first longitudinal direction, the sharp support displacing the sharp and the medical device. The method further includes inserting the sharp into the skin of the subject; delivering the medical device to the subject; releasing the driver; and displacing the sharp in the second longitudinal direction by the driver.

[0014] In some embodiments, the method further includes locking at least a portion of the sheath to the handle.

[0015] These and other features, objects, and advantages of the disclosed subject matter will

become apparent to those persons skilled in the art upon reading the detailed description as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] A detailed description of various aspects, features, and embodiments of the subject matter described herein is provided with reference to the accompanying drawings, which are briefly described below. The drawings are illustrative and are not necessarily drawn to scale, with some components and features being exaggerated for clarity. The drawings illustrate various aspects and features of the present subject matter and may illustrate one or more embodiment(s) or example(s) of the present subject matter in whole or in part.

[0017] FIG. 1 illustrates an analyte monitoring system for real time analyte (*e.g.*, glucose) measurement, data acquisition and/or processing in certain embodiments;

[0018] FIG. 2 is a view of an electrochemical sensor in accordance with an embodiment of the disclosed subject matter;

[0019] FIG. 3 is a view of the electrochemical sensor of FIG. 2 in a folded configuration in accordance with the disclosed subject matter;

[0020] FIG. 4 is a perspective view of an embodiment of an inserter in accordance with one embodiment of the disclosed subject matter;

[0021] FIGS. 5-6 are perspective views of the inserter of FIG. 4 in accordance with the disclosed subject matter;

[0022] FIGS. 7-8 are sectional, perspective views of the inserter of FIG. 4 in accordance with the disclosed subject matter;

[0023] FIGS. 9-10 are schematic views of a needle hub in accordance with one embodiment of the disclosed subject matter;

[0024] FIG. 11 is a distal end view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0025] FIG. 12 is a side view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0026] FIG. 13 is a side view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0027] FIG. 14 is a perspective view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0028] FIGS. 14A-B are top views of a sharp in accordance with one embodiment of the disclosed subject matter;

[0029] FIG. 14C is a side view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0030] FIG. 15 is a schematic view of an alternate embodiment for forming a sharp to be used in an inserter in accordance with one embodiment of the disclosed subject matter;

[0031] FIG. 16 is a perspective view of an inserter in accordance with one embodiment of the disclosed subject matter;

[0032] FIG. 17 is a perspective view with parts separated of an inserter in accordance with one embodiment of the disclosed subject matter;

[0033] FIG. 17A is an enlarged perspective view of a portion of an inserter in accordance with one embodiment of the disclosed subject matter.

[0034] FIG. 18 is an enlarged sectional view with parts separated of an inserter in accordance with one embodiment of the disclosed subject matter;

[0035] FIGS. 19-21 depict an alternative method for retaining a sharp and sensor within the on body housing;

[0036] FIG. 22 is a sectional, perspective views of the inserter of FIG. 4 in accordance with the disclosed subject matter;

[0037] FIGS. 23-24 are perspective views of the inserter of FIG. 4 in accordance with the disclosed subject matter;

[0038] FIGS. 25-26 are perspective views of another embodiment of an inserter in accordance with the disclosed subject matter;

[0039] FIGS. 27-32 are perspective views of components of the inserter of FIG. 25 in accordance with the disclosed subject matter;

[0040] FIG. 33 is a sectional view of the inserter of FIG. 25 in accordance with the disclosed subject matter;

[0041] FIG. 34 is a sectional, perspective view of the inserter of FIG. 25 in accordance with the disclosed subject matter;

[0042] FIG. 35 is a perspective view of the inserter of FIG. 25 in accordance with the disclosed subject matter;

[0043] FIGS. 36-37 are sectional, perspective views of the inserter of FIG. 25 in accordance with

the disclosed subject matter;

[0044] FIGS. 38-39 are perspective views of the inserter of FIG. 25 in accordance with the disclosed subject matter;

[0045] FIGS. 40-41 are perspective views of another embodiment of an inserter in accordance with the disclosed subject matter;

[0046] FIGS. 42-46 are perspective views of components of the inserter of FIG. 40 in accordance with the disclosed subject matter;

[0047] FIG. 47 is a sectional views of the inserter of FIG. 40 in accordance with the disclosed subject matter;

[0048] FIGS. 48-50 are sectional, perspective views of the inserter of FIG. 40 in accordance with the disclosed subject matter;

[0049] FIG. 51 is a cross-sectional view of another inserter in accordance with the disclosed subject matter;

[0050] FIG. 52 is an exploded perspective view of the inserter of FIG. 51 in accordance with the disclosed subject matter;

[0051] FIGS. 53 and 54 are side views of the inserter of FIG. 51 showing the assembly of various components in accordance with the disclosed subject matter;

[0052] FIGS. 55-60 are perspective views of the inserter of FIG. 51 showing the assembly of various components in accordance with the disclosed subject matter;

[0053] FIGS. 61-65 are cross-sectional views of the inserter of FIG. 51 in accordance with the disclosed subject matter;

[0054] FIGS. 66-68 illustrate a process for utilizing a sterilized versions of the inserter of FIG. 51 in accordance with the disclosed subject matter;

[0055] FIG. 69-72 illustrates an alternate process for utilizing a sterilized versions of the inserter of FIG. 51 in accordance with the disclosed subject matter;

[0056] FIG. 73 is a perspective view of another inserter in accordance with the disclosed subject matter;

[0057] FIG. 74 is a perspective view of a component of the inserter of FIG. 73 in accordance with the disclosed subject matter;

[0058] FIG. 75 is a cross-sectional view of a component of the inserter of FIG. 73 in accordance with the disclosed subject matter;

[0059] FIGS. 76-80 are perspective views of components of the inserter of FIG. 73 in accordance with the disclosed subject matter;

[0060] FIGS. 81-87 are cross-sectional views of the inserter of FIG. 73 in accordance with the disclosed subject matter;

[0061] FIGS. 88-90 illustrate a process for utilizing a sterilized version of the inserter of FIG. 73 in accordance with the disclosed subject matter;

[0062] FIG. 91 is a perspective view of another inserter in accordance with the disclosed subject matter;

[0063] FIGS. 92-99 are additional views of the components of the inserter of FIG. 91 in accordance with the disclosed subject matter;

[0064] FIGS. 100-106 are cross-sectional views of the inserter of FIG. 91 in accordance with the disclosed subject matter;

[0065] FIGS. 107-108 are views of an alternate embodiment of the inserter of FIG. 91 in accordance with the disclosed subject matter; and

[0066] FIGS. 109-134 are views of an alternate embodiment of the inserter of FIG. 73 in accordance with the disclosed subject matter.

[0067] FIGS. 135-136 illustrate bottom and top views, respectively, of the medical device carrier in accordance with the disclosed subject matter.

[0068] FIGS. 137-138 illustrate the sheath component of an inserter in accordance with the disclosed subject matter.

[0069] FIGS. 139-140 illustrate, in cross section, the progressive advancement of the on body housing in accordance with the disclosed subject matter.

[0070] FIGS. 141-144 illustrate the advancement of the on body housing within an inserter in accordance with the disclosed subject matter.

[0071] FIGS. 145a-147b illustrate the attachment of a two piece on body housing in accordance with the disclosed subject matter.

[0072] FIG. 148 illustrates a two-piece on body housing in accordance with the disclosed subject matter.

[0073] FIG. 149 illustrates another two-piece on body housing in accordance with the disclosed subject matter.

[0074] FIGS. 150-156 illustrate the advancement of a two piece on body housing in accordance

with the disclosed subject matter.

[0075] FIGS. 157-158 illustrate the assembly of the two piece on body housing in accordance with the disclosed subject matter.

[0076] FIGS. 159-164 illustrate two piece on body housings in accordance with the disclosed subject matter.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0077] A detailed description of the disclosure is provided herein. It should be understood, in connection with the following description, that the subject matter is not limited to particular embodiments described, as the particular embodiments of the subject matter may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the disclosed subject matter will be limited only by the appended claims.

[0078] Where a range of values is provided, it is understood that each intervening value between the upper and lower limit of that range, and any other stated or intervening value in that stated range, is encompassed within the disclosed subject matter. Every range stated is also intended to specifically disclose each and every "subrange" of the stated range. That is, each and every range smaller than the outside range specified by the outside upper and outside lower limits given for a range, whose upper and lower limits are within the range from said outside lower limit to said outside upper limit (unless the context clearly dictates otherwise), is also to be understood as encompassed within the disclosed subject matter, subject to any specifically excluded range or limit within the stated range. Where a range is stated by specifying one or both of an upper and lower limit, ranges excluding either or both of those stated limits, or including one or both of them, are also encompassed within the disclosed subject matter, regardless of whether or not words such as "from," "to," "through," or "including" are or are not used in describing the range.

[0079] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosed subject matter belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosed subject matter, this disclosure may specifically mention certain exemplary methods and materials.

[0080] All publications mentioned in this disclosure are, unless otherwise specified, incorporated by reference herein for all purposes, including without limitation to disclose and describe the

methods and/or materials in connection with which the publications are cited.

[0081] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present disclosed subject matter is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates, which may need to be independently confirmed.

[0082] As used herein and in the appended claims, the singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

[0083] Nothing contained in the Abstract or the Summary should be understood as limiting the scope of the disclosure. The Abstract and the Summary are provided for bibliographic and convenience purposes and due to their formats and purposes should not be considered comprehensive.

[0084] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present disclosed subject matter. Any recited method can be carried out in the order of events recited, or in any other order which is logically possible.

[0085] Reference to a singular item includes the possibility that there are plural of the same item present. When two or more items (for example, elements or processes) are referenced by an alternative "or," this indicates that either could be present separately or any combination of them could be present together except where the presence of one necessarily excludes the other or others.

[0086] Generally, embodiments of the present disclosure relate to an apparatus for inserting a medical device at least partially into the skin of the patient. Some embodiments relate to *in vivo* methods and devices for detecting at least one analyte such as glucose in body fluid. Accordingly, embodiments include *in vivo* analyte sensors configured so that at least a portion of the sensor is positioned in the body of a user (*e.g.*, within the ISF), to obtain information about at least one analyte of the body, *e.g.*, transcutaneously positioned in user's body. In certain embodiments, an *in vivo* analyte sensor is coupled to an electronics unit that is maintained on the body of the user to process information obtained from the sensor.

[0087] In certain embodiments, analyte information is communicated from a first device such as an on body electronics unit to a second device which may include user interface features, including a display, and/or the like. Information may be communicated from the first device to the second device automatically and/or continuously when the analyte information is available, or may not be communicated automatically and/or continuously, but rather stored or logged in a memory of the first device. Accordingly, in many embodiments of the system, analyte information derived by the sensor/on body electronics (for example, on body electronics) is made available in a user-usable or viewable form only when queried by the user such that the timing of data communication is selected by the user. In some embodiments, the display of information is selected by the user, while the timing of data communication is not.

[0088] In this manner, analyte information is only provided or evident to a user (provided at a user interface device) in some embodiments when desired by the user even though an *in vivo* analyte sensor automatically and/or continuously monitors the analyte level *in vivo*, *i.e.*, the sensor automatically monitors analyte such as glucose on a pre-defined time interval over its usage life. For example, an analyte sensor may be positioned *in vivo* and coupled to on body electronics for a given sensing period, *e.g.*, about 14 days. In certain embodiments, the sensor-derived analyte information is automatically communicated from the sensor electronics assembly to a remote monitor device or display device for output to a user throughout the 14 day period according to a schedule programmed at the on body electronics (*e.g.*, about every 1 minute or about every 5 minutes or about every 10 minutes, or the like). In certain embodiments, sensor-derived analyte information is only communicated from the sensor electronics assembly to a remote monitor device or display device at user-determined times, *e.g.*, whenever a user decides to check analyte information. At such times, a communications system is activated, and sensor-derived information is then sent from the on body electronics to the remote device or display device.

[0089] In still other embodiments, the information may be communicated from the first device to the second device automatically and/or continuously when the analyte information is available, and the second device stores or logs the received information without presenting or outputting the information to the user. In such embodiments, the information is received by the second device from the first device when the information becomes available (*e.g.*, when the sensor detects the analyte level according to a time schedule). However, the received information is

initially stored in the second device and only output to a user interface or an output component of the second device (*e.g.*, display) upon detection of a request for the information on the second device.

[0090] Accordingly, in certain embodiments an inserter as described herein is used to place a sensor electronics assembly on the body so that at least a portion of the *in vivo* sensor is in contact with bodily fluid such as ISF. Once the sensor is electrically coupled to the electronics unit, sensor derived analyte information may be communicated from the on body electronics to a display device on-demand by powering on the display device (or it may be continually powered), and executing a software algorithm stored in and accessed from a memory of the display device, to generate one or more request commands, control signal or data packet to send to the on body electronics. The software algorithm executed under, for example, the control of the microprocessor or application specific integrated circuit (ASIC) of the display device may include routines to detect the position of the on body electronics relative to the display device to initiate the transmission of the generated request command, control signal and/or data packet.

[0091] Display devices may also include programming stored in memory for execution by one or more microprocessors and/or ASICs to generate and transmit the one or more request command, control signal or data packet to send to the on body electronics in response to a user activation of an input mechanism on the display device such as depressing a button on the display device, triggering a soft button associated with the data communication function, and so on. The input mechanism may be alternatively or additionally provided on or in the on body electronics which may be configured for user activation. In certain embodiments, voice commands or audible signals may be used to prompt or instruct the microprocessor or ASIC to execute the software routine(s) stored in the memory to generate and transmit the one or more request command, control signal or data packet to the on body device. In the embodiments that are voice activated or responsive to voice commands or audible signals, on body electronics and/or display device includes a microphone, a speaker, and processing routines stored in the respective memories of the on body electronics and/or the display device to process the voice commands and/or audible signals. In certain embodiments, positioning the on body electronics and the display device within a predetermined distance (*e.g.*, close proximity) relative to each other initiates one or more software routines stored in the memory of the display device to generate and transmit a request command, control signal or data packet.

[0092] Different types and/or forms and/or amounts of information may be sent for each on demand reading, including but not limited to one or more of current analyte level information (*i.e.*, real time or the most recently obtained analyte level information temporally corresponding to the time the reading is initiated), rate of change of an analyte over a predetermined time period, rate of the rate of change of an analyte (acceleration in the rate of change), historical analyte information corresponding to analyte information obtained prior to a given reading and stored in memory of the assembly. Some or all of real time, historical, rate of change, rate of rate of change (such as acceleration or deceleration) information may be sent to a display device for a given reading. In certain embodiments, the type and/or form and/or amount of information sent to a display device may be preprogrammed and/or unchangeable (*e.g.*, preset at manufacturing), or may not be preprogrammed and/or unchangeable so that it may be selectable and/or changeable in the field one or more times (*e.g.*, by activating a switch of the system, etc.). Accordingly, in certain embodiments, for each on demand reading, a display device will output a current (real time) sensor-derived analyte value (*e.g.*, in numerical format), a current rate of analyte change (*e.g.*, in the form of an analyte rate indicator such as an arrow pointing in a direction to indicate the current rate), and analyte trend history data based on sensor readings acquired by and stored in memory of on body electronics (*e.g.*, in the form of a graphical trace). Additionally, the on skin or sensor temperature reading or measurement associated with each on demand reading may be communicated from the on body electronics to the display device. The temperature reading or measurement, however, may not be output or displayed on the display device, but rather, used in conjunction with a software routine executed by the display device to correct or compensate the analyte measurement output to the user on the display device.

[0093] As described, embodiments include inserters for *in vivo* analyte sensors and on body electronics that together provide body wearable sensor electronics assemblies. In certain embodiments, *in vivo* analyte sensors are fully integrated with on body electronics (fixedly connected during manufacture), while in other embodiments they are separate but connectable post manufacture (*e.g.*, before, during or after sensor insertion into a body). On body electronics may include an *in vivo* glucose sensor, electronics, battery, and antenna encased (except for the sensor portion that is for *in vivo* positioning) in a waterproof housing that includes or is attachable to an adhesive pad. In certain embodiments, the housing withstands immersion in about one meter of water for up to at least 30 minutes. In certain embodiments, the housing

withstands continuous underwater contact, *e.g.*, for longer than about 30 minutes, and continues to function properly according to its intended use, *e.g.*, without water damage to the housing electronics where the housing is suitable for water submersion.

[0094] Embodiments include sensor insertion devices, which also may be referred to herein as sensor delivery units, or the like. Insertion devices may retain on body electronics assemblies completely in an interior compartment, *i.e.*, an insertion device may be "pre-loaded" with on body electronics assemblies during the manufacturing process (*e.g.*, on body electronics may be packaged in a sterile interior compartment of an insertion device). In such embodiments, insertion devices may form sensor assembly packages (including sterile packages) for pre-use or new on body electronics assemblies, and insertion devices configured to apply on body electronics assemblies to recipient bodies.

[0095] Embodiments include portable handheld display devices, as separate devices and spaced apart from an on body electronics assembly, that collect information from the assemblies and provide sensor derived analyte readings to users. Such devices may also be referred to as meters, readers, monitors, receivers, human interface devices, companions, or the like. Certain embodiments may include an integrated *in vitro* analyte meter. In certain embodiments, display devices include one or more wired or wireless communications ports such as USB, serial, parallel, or the like, configured to establish communication between a display device and another unit (*e.g.*, on body electronics, power unit to recharge a battery, a PC, etc.). For example, a display device communication port may enable charging a display device battery with a respective charging cable and/or data exchange between a display device and its compatible informatics software.

[0096] Compatible informatics software in certain embodiments include, for example, but not limited to stand alone or network connection enabled data management software program, resident or running on a display device, personal computer, a server terminal, for example, to perform data analysis, charting, data storage, data archiving and data communication as well as data synchronization. Informatics software in certain embodiments may also include software for executing field upgradable functions to upgrade firmware of a display device and/or on body electronics unit to upgrade the resident software on the display device and/or the on body electronics unit, *e.g.*, with versions of firmware that include additional features and/or include software bugs or errors fixed, etc. Embodiments may include a haptic feedback feature such as a

vibration motor or the like, configured so that corresponding notifications (*e.g.*, a successful on-demand reading received at a display device), may be delivered in the form of haptic feedback.

[0097] Embodiments include programming embedded on a computer readable medium, *i.e.*, computer-based application software (may also be referred to herein as informatics software or programming or the like) that processes analyte information obtained from the system and/or user self-reported data. Application software may be installed on a host computer such as a mobile telephone, PC, an Internet-enabled human interface device such as an Internet-enabled phone, personal digital assistant, or the like, by a display device or an on body electronics unit. Informatics programming may transform data acquired and stored on a display device or on body unit for use by a user.

[0098] Embodiments of the subject disclosure are described primarily with respect to glucose monitoring devices and systems, and methods of glucose monitoring, for convenience only and such description is in no way intended to limit the scope of the disclosure. It is to be understood that the analyte monitoring system may be configured to monitor a variety of analytes at the same time or at different times.

[0099] As described in detail below, embodiments include devices, systems, kits and/or methods to monitor one or more physiological parameters such as, for example, but not limited to, analyte levels, temperature levels, heart rate, user activity level, over a predetermined monitoring time period. Also provided are methods of manufacturing. Predetermined monitoring time periods may be less than about 1 hour, or may include about 1 hour or more, *e.g.*, about a few hours or more, *e.g.*, about a few days of more, *e.g.*, about 3 or more days, *e.g.*, about 5 days or more, *e.g.*, about 7 days or more, *e.g.*, about 10 days or more, *e.g.*, about 14 days or more, *e.g.*, about several weeks, *e.g.*, about 1 month or more. In certain embodiments, after the expiration of the predetermined monitoring time period, one or more features of the system may be automatically deactivated or disabled at the on body electronics assembly and/or display device.

[0100] For example, a predetermined monitoring time period may begin with positioning the sensor *in vivo* and in contact with a body fluid such as ISF, and/or with the initiation (or powering on to full operational mode) of the on body electronics. Initialization of on body electronics may be implemented with a command generated and transmitted by a display device in response to the activation of a switch and/or by placing the display device within a predetermined distance (*e.g.*, close proximity) to the on body electronics, or by user manual

activation of a switch on the on body electronics unit, *e.g.*, depressing a button, or such activation may be caused by the insertion device, *e.g.*, as described in U.S. Patent Application No. 12/698,129, filed on February 1, 2010, and U.S. Provisional Application Nos. 61/238,646, 61/246,825, 61/247,516, 61/249,535, 61/317,243, 61/345,562, and 61/361,374, the disclosures of each of which are incorporated herein by reference for all purposes.

[0101] When initialized in response to a received command from a display device, the on body electronics retrieves and executes from its memory software routine to fully power on the components of the on body electronics, effectively placing the on body electronics in full operational mode in response to receiving the activation command from the display device. For example, prior to the receipt of the command from the display device, a portion of the components in the on body electronics may be powered by its internal power supply such as a battery while another portion of the components in the on body electronics may be in powered down or maintained in a low power state including no power state, inactive mode, or all components may be in an inactive, powered down mode. Upon receipt of the command, the remaining portion (or all) of the components of the on body electronics is switched to active, fully operational mode.

[0102] Embodiments of on body electronics may include one or more printed circuit boards with electronics including control logic implemented in ASIC, microprocessors, memory, and the like, and transcutaneously positionable analyte sensors forming a single assembly. On body electronics may be configured to provide one or more signals or data packets associated with a monitored analyte level upon detection of a display device of the analyte monitoring system within a predetermined proximity for a period of time (for example, about 2 minutes, *e.g.*, 1 minute or less, *e.g.*, about 30 seconds or less, *e.g.*, about 10 seconds or less, *e.g.*, about 5 seconds or less, *e.g.*, about 2 seconds or less) and/or until a confirmation, such as an audible and/or visual and/or tactile (*e.g.*, vibratory) notification, is output on the display device indicating successful acquisition of the analyte related signal from the on body electronics. A distinguishing notification may also be output for unsuccessful acquisition in certain embodiments.

[0103] In certain embodiments, the monitored analyte level may be correlated and/or converted to glucose levels in blood or other fluids such as ISF. Such conversion may be accomplished with the on body electronics, but in many embodiments will be accomplished with display device electronics. In certain embodiments, glucose level is derived from the monitored analyte

level in the ISF.

[0104] Analyte sensors may be insertable into a vein, artery, or other portion of the body containing analyte. In certain embodiments, analyte sensors may be positioned in contact with ISF to detect the level of analyte, where the detected analyte level may be used to infer the user's glucose level in blood or interstitial tissue.

[0105] Embodiments include transcutaneous sensors and also wholly implantable sensors and wholly implantable assemblies in which a single assembly including the analyte sensor and electronics are provided in a sealed housing (*e.g.*, hermetically sealed biocompatible housing) for implantation in a user's body for monitoring one or more physiological parameters.

[0106] Embodiments include analyte monitors that are provided in small, lightweight, battery-powered and electronically-controlled systems. Such systems may be configured to detect physical parameters of subjects, such as signals indicative of *in vivo* analyte levels using an electrochemical sensor, and collect such signals, with or without processing. Any suitable measurement technique may be used to obtain signals from the sensors, *e.g.*, may detect current, may employ potentiometry, etc. Techniques may include, but are not limited to amperometry, coulometry, and voltammetry. In some embodiments, sensing systems may be optical, colorimetric, and the like. In some embodiments, the portion of the system that performs this initial processing may be configured to provide the raw or at least initially processed data to another unit for further collection and/or processing. Such provision of data may be affected, for example, by a wired connection, such as an electrical, or by a wireless connection, such as an IR or RF connection.

[0107] In certain systems, the analyte sensor is in communication with on body electronics. The on-body unit may include a housing in which the on body electronics and at least a portion of the sensor are received.

[0108] Certain embodiments are modular. The on-body unit may be separately provided as a physically distinct assembly from a monitor unit, *e.g.*, which displays or otherwise indicates analyte levels to a user. The on-body unit may be configured to provide the analyte levels detected by the sensor and/or other information (such as temperature, sensor life, etc.) over a communication link to the monitor unit. The monitor unit, in some embodiments, may include, *e.g.*, a mobile telephone device, an *in vitro* glucose meter, a personal digital assistant, or other consumer electronics such as MP3 device, camera, radio, personal computer, etc., or other

communication-enabled data-processing device.

[0109] The display unit may perform a variety of functions such as but not limited to data storage and/or processing and/or analysis and/or communication, etc., on the received analyte data to generate information pertaining to the monitored analyte levels and/or process the other information. The monitor unit may incorporate a display screen, which can be used, for example, to display measured analyte levels, and/or an audio component such as a speaker to audibly provide information to a user, and/or a vibration device to provide tactile feedback to a user. It is also useful for a user of an analyte-monitoring system to be able to see trend indications (including the magnitude and direction of any ongoing trend, *e.g.*, the rate of change of an analyte or other parameter, and the amount of time a subject is above and/or below a threshold, such as a hypoglycemic and/or hyperglycemic threshold, etc.); such data may be displayed either numerically, or by a visual indicator such as an arrow that may vary in visual attributes, like size, shape, color, animation, or direction. The monitor unit may further be adapted to receive information from or about an *in vitro* analyte test strip, which may be manually or automatically entered into the monitor unit. In some embodiments a monitor unit may incorporate an *in vitro* analyte test strip port and related electronics in order to be able to make discrete (*e.g.*, blood glucose) measurements using an *in vitro* test strip (see, *e.g.*, U.S. Patent No. 6,175,752, the disclosure of which is incorporated by reference herein for all purposes).

[0110] The modularity of these systems may vary where one or more components may be constructed to be single use and one or more may be constructed to be re-useable. In some embodiments the sensor is designed to be attachable and detachable from the on body electronics (and the on-body unit may be reusable), *e.g.*, so that one or more of the components may be reused one or more times, while in other embodiments, the sensor and on body electronics may be provided as an integrated, undetachable package, which may be designed to be disposable after use, *i.e.*, not re-used.

Embodiments of *In Vivo* Monitoring Systems

[0111] For purpose of illustration, and not limitation, the inserters described herein may be used in connection with an exemplary analyte monitoring system as depicted in FIG. 1. It is understood that the inserters described herein may be used with any medical device on its own or in connection with a system. FIG. 1 shows an exemplary *in vivo*-based analyte monitoring

system 100 in accordance with embodiments of the present disclosure. As shown, in certain embodiments, analyte monitoring system 100 includes on body electronics 1100 electrically coupled to *in vivo* analyte sensor 14 (a proximal portion of which is shown in FIG. 1, and attached to adhesive layer 218 for attachment on a skin surface on the body of a user. On body electronics 1100 includes on body housing 122 that defines an interior compartment.

[0112] Also shown in FIG. 1 is insertion device 200 (or insertion devices 300, 400, 2400, 2500, 2700, 3700 described herein) that, when operated, transcutaneously positions a portion of analyte sensor 14 through a skin surface and in fluid contact with ISF, and positions on body electronics 1100 and adhesive layer 218 on a skin surface, as will be described in greater detail herein. In certain embodiments, on body electronics 1100, analyte sensor 14 and adhesive layer 218 are sealed within the housing of insertion device 200 before use, and in certain embodiments, adhesive layer 218 is also sealed within the housing or the adhesive layer can provide a seal for preserving the sterility of the apparatus. Additional details regarding insertion devices are discussed, *e.g.*, in U.S. Patent Application No. 12/698,129 and U.S. Provisional Application Nos. 61/238,646, 61/246,825, 61/247,516, 61/249,535, and 61/345,562, the disclosures of each of which are incorporated herein by reference for all purposes.

[0113] Referring back to the FIG. 1, analyte monitoring system 100 includes display device 1200 which includes a display 1220 to output information to the user, an input component 1210 such as a button, actuator, a touch sensitive switch, a capacitive switch, pressure sensitive switch, jog wheel or the like, to input data or command to display device 1200 or otherwise control the operation of display device 1200. It is noted that some embodiments may include display-less devices or devices without any user interface components. These devices may be functionalized to store data as a data logger and/or provide a conduit to transfer data from on body electronics and/or a display-less device to another device and/or location. Embodiments will be described herein as display devices for exemplary purposes which are in no way intended to limit the embodiments of the present disclosure. It will be apparent that display-less devices may also be used in certain embodiments.

[0114] In certain embodiments, on body electronics 1100 may be configured to store some or all of the monitored analyte related data received from analyte sensor 14 in a memory during the monitoring time period, and maintain it in memory until the usage period ends. In such embodiments, stored data is retrieved from on body electronics 1100 at the conclusion of the

monitoring time period, for example, after removing analyte sensor 14 from the user by detaching on body electronics 1100 from the skin surface where it was positioned during the monitoring time period. In such data logging configurations, real time monitored analyte level is not communicated to display device 1200 during the monitoring period or otherwise transmitted from on body electronics 1100, but rather, retrieved from on body electronics 1100 after the monitoring time period.

[0115] In certain embodiments, input component 1210 of display device 1200 may include a microphone and display device 1200 may include software configured to analyze audio input received from the microphone, such that functions and operation of the display device 1200 may be controlled by voice commands. In certain embodiments, an output component of display device 1200 includes a speaker for outputting information as audible signals. Similar voice responsive components such as a speaker, microphone and software routines to generate, process and store voice driven signals may be provided to on body electronics 1100.

[0116] In certain embodiments, display 1220 and input component 1210 may be integrated into a single component, for example a display that can detect the presence and location of a physical contact touch upon the display such as a touch screen user interface. In such embodiments, the user may control the operation of display device 1200 by utilizing a set of pre-programmed motion commands, including, but not limited to, single or double tapping the display, dragging a finger or instrument across the display, motioning multiple fingers or instruments toward one another, motioning multiple fingers or instruments away from one another, etc. In certain embodiments, a display includes a touch screen having areas of pixels with single or dual function capacitive elements that serve as LCD elements and touch sensors.

[0117] Display device 1200 also includes data communication port 1230 for wired data communication with external devices such as remote terminal (personal computer) 1700, for example. Example embodiments of the data communication port 1230 include USB port, mini USB port, RS-232 port, Ethernet port, Firewire port, or other similar data communication ports configured to connect to the compatible data cables. Display device 1200 may also include an integrated *in vitro* glucose meter, including *in vitro* test strip port 1240 to receive an *in vitro* glucose test strip for performing *in vitro* blood glucose measurements.

[0118] Referring still to FIG. 1, display 1220 in certain embodiments is configured to display a variety of information--some or all of which may be displayed at the same or different time on

display 1220. In certain embodiments the displayed information is user-selectable so that a user can customize the information shown on a given display screen. Display 1220 may include but is not limited to graphical display 1380, for example, providing a graphical output of glucose values over a monitored time period (which may show important markers such as meals, exercise, sleep, heart rate, blood pressure, etc., numerical display 1320, for example, providing monitored glucose values (acquired or received in response to the request for the information), and trend or directional arrow display 1310 that indicates a rate of analyte change and/or a rate of the rate of analyte change, *e.g.*, by moving locations on display 1220.

[0119] As further shown in FIG. 1, display 1220 may also include date display 1350 providing for example, date information for the user, time of day information display 1390 providing time of day information to the user, battery level indicator display 1330 which graphically shows the condition of the battery (rechargeable or disposable) of the display device 1200, sensor calibration status icon display 1340 for example, in monitoring systems that require periodic, routine or a predetermined number of user calibration events, notifying the user that the analyte sensor calibration is necessary, audio/vibratory settings icon display 1360 for displaying the status of the audio/vibratory output or alarm state, and wireless connectivity status icon display 1370 that provides indication of wireless communication connection with other devices such as on body electronics, data processing module 1600, and/or remote terminal 1700. As additionally shown in FIG. 1, display 1220 may further include simulated touch screen button 1250, 1260 for accessing menus, changing display graph output configurations or otherwise for controlling the operation of display device 1200.

[0120] Referring back to FIG. 1, in certain embodiments, display 1220 of display device 1200 may be additionally, or instead of visual display, configured to output alarms notifications such as alarm and/or alert notifications, glucose values etc., which may be audible, tactile, or any combination thereof. In one aspect, the display device 1200 may include other output components such as a speaker, vibratory output component and the like to provide audible and/or vibratory output indication to the user in addition to the visual output indication provided on display 1220. Further details and other display embodiments can be found in, *e.g.*, U.S. Patent Application No. 12/871,901, U.S. Provisional Application Nos. 61/238,672, 61/247,541, 61/297,625, the disclosures of each of which are incorporated herein by reference for all purposes.

[0121] After the positioning of on body electronics 1100 on the skin surface and analyte sensor 14 *in vivo* to establish fluid contact with ISF (or other appropriate body fluid), on body electronics 1100 in certain embodiments is configured to wirelessly communicate analyte related data (such as, for example, data corresponding to monitored analyte level and/or monitored temperature data, and/or stored historical analyte related data) when on body electronics 1100 receives a command or request signal from display device 1200. In certain embodiments, on body electronics 1100 may be configured to at least periodically broadcast real time data associated with monitored analyte level which is received by display device 1200 when display device 1200 is within communication range of the data broadcast from on body electronics 1100, *i.e.*, it does not need a command or request from a display device to send information.

[0122] For example, display device 1200 may be configured to transmit one or more commands to on body electronics 1100 to initiate data transfer, and in response, on body electronics 1100 may be configured to wirelessly transmit stored analyte related data collected during the monitoring time period to display device 1200. Display device 1200 may in turn be connected to a remote terminal 1700 such as a personal computer and functions as a data conduit to transfer the stored analyte level information from the on body electronics 1100 to remote terminal 1700. In certain embodiments, the received data from the on body electronics 1100 may be stored (permanently or temporarily) in one or more memory of the display device 1200. In certain other embodiments, display device 1200 is configured as a data conduit to pass the data received from on body electronics 1100 to remote terminal 1700 that is connected to display device 1200.

[0123] Referring still to FIG. 1, also shown in analyte monitoring system 1000 are data processing module 1600 and remote terminal 1700. Remote terminal 1700 may include a personal computer, a server terminal a laptop computer or other suitable data processing devices including software for data management and analysis and communication with the components in the analyte monitoring system 1000. For example, remote terminal 1700 may be connected to a local area network (LAN), a wide area network (WAN), or other data network for uni-directional or bi-directional data communication between remote terminal 1700 and display device 1200 and/or data processing module 1600.

[0124] Remote terminal 1700 in certain embodiments may include one or more computer terminals located at a physician's office or a hospital. For example, remote terminal 1700 may be located at a location other than the location of display device 1200. Remote terminal 1700 and

display device 1200 could be in different rooms or different buildings. Remote terminal 1700 and display device 1200 could be at least about one mile apart, *e.g.*, at least about 100 miles apart, *e.g.*, at least about 1000 miles apart. For example, remote terminal 1700 could be in the same city as display device 1200, remote terminal 1700 could be in a different city than display device 1200, remote terminal 1700 could be in the same state as display device 1200, remote terminal 1700 could be in a different state than display device 1200, remote terminal 1700 could be in the same country as display device 1200, or remote terminal 1700 could be in a different country than display device 1200, for example.

[0125] In certain embodiments, a separate, optional data communication/processing device such as data processing module 1600 may be provided in analyte monitoring system 1000. Data processing module 1600 may include components to communicate using one or more wireless communication protocols such as, for example, but not limited to, infrared (IR) protocol, Bluetooth® protocol, Zigbee protocol, and 802.11 wireless LAN protocol. Additional description of communication protocols including those based on Bluetooth® protocol and/or Zigbee protocol can be found in U.S. Patent Publication No. 2006/0193375, incorporated herein by reference for all purposes. Data processing module 1600 may further include communication ports, drivers or connectors to establish wired communication with one or more of display device 1200, on body electronics 1100, or remote terminal 1700 including, for example, but not limited to USB connector and/or USB port, Ethernet connector and/or port, FireWire connector and/or port, or RS-232 port and/or connector.

[0126] In certain embodiments, data processing module 1600 is programmed to transmit a polling or query signal to on body electronics 1100 at a predetermined time interval (*e.g.*, once every minute, once every five minutes, or the like), and in response, receive the monitored analyte level information from on body electronics 1100. Data processing module 1600 stores in its memory the received analyte level information, and/or relays or retransmits the received information to another device such as display device 1200. More specifically in certain embodiments, data processing module 1600 may be configured as a data relay device to retransmit or pass through the received analyte level data from on body electronics 1100 to display device 1200 or a remote terminal (for example, over a data network such as a cellular or WiFi data network) or both.

[0127] In certain embodiments, on body electronics 1100 and data processing module 1600 may

be positioned on the skin surface of the user within a predetermined distance of each other (for example, about 1-12 inches, or about 1-10 inches, or about 1-7 inches, or about 1-5 inches) such that periodic communication between on body electronics 1100 and data processing module 1600 is maintained. Alternatively, data processing module 1600 may be worn on a belt or clothing item of the user, such that the desired distance for communication between the on body electronics 1100 and data processing module 1600 for data communication is maintained. In a further aspect, the housing of data processing module 1600 may be configured to couple to or engage with on body electronics 1100 such that the two devices are combined or integrated as a single assembly and positioned on the skin surface. In further embodiments, data processing module 1600 is detachably engaged or connected to on body electronics 1100 providing additional modularity such that data processing module 1600 may be optionally removed or reattached as desired.

[0128] Referring again to FIG. 1, in certain embodiments, data processing module 1600 is programmed to transmit a command or signal to on body electronics 1100 at a predetermined time interval such as once every minute, or once every 5 minutes or once every 30 minutes or any other suitable or desired programmable time interval to request analyte related data from on body electronics 1100. When data processing module 1600 receives the requested analyte related data, it stores the received data. In this manner, analyte monitoring system 1000 may be configured to receive the continuously monitored analyte related information at the programmed or programmable time interval, which is stored and/or displayed to the user. The stored data in data processing module 1600 may be subsequently provided or transmitted to display device 1200, remote terminal 1700 or the like for subsequent data analysis such as identifying frequency of periods of glycemic level excursions over the monitored time period, or the frequency of the alarm event occurrence during the monitored time period, for example, to improve therapy related decisions. Using this information, the doctor, healthcare provider or the user may adjust or recommend modification to the diet, daily habits and routines such as exercise, and the like.

[0129] In another embodiment, data processing module 1600 transmits a command or signal to on body electronics 1100 to receive the analyte related data in response to a user activation of a switch provided on data processing module 1600 or a user initiated command received from display device 1200. In further embodiments, data processing module 1600 is configured to transmit a command or signal to on body electronics 1100 in response to receiving a user

initiated command only after a predetermined time interval has elapsed. For example, in certain embodiments, if the user does not initiate communication within a programmed time period, such as, for example about 5 hours from last communication (or 10 hours from the last communication, or 24 hours from the last communication), the data processing module 1600 may be programmed to automatically transmit a request command or signal to on body electronics 1100. Alternatively, data processing module 1600 may be programmed to activate an alarm to notify the user that a predetermined time period of time has elapsed since the last communication between the data processing module 1600 and on body electronics 1100. In this manner, users or healthcare providers may program or configure data processing module 1600 to provide certain compliance with analyte monitoring regimen, so that frequent determination of analyte levels is maintained or performed by the user.

[0130] In certain embodiments, when a programmed or programmable alarm condition is detected (for example, a detected glucose level monitored by analyte sensor 14 that is outside a predetermined acceptable range indicating a physiological condition) which requires attention or intervention for medical treatment or analysis (for example, a hypoglycemic condition, a hyperglycemic condition, an impending hyperglycemic condition or an impending hypoglycemic condition), the one or more output indications may be generated by the control logic or processor of the on body electronics 1100 and output to the user on a user interface of on body electronics 1100 so that corrective action may be timely taken. In addition to or alternatively, if display device 1200 is within communication range, the output indications or alarm data may be communicated to display device 1200 whose processor, upon detection of the alarm data reception, controls the display 1220 to output one or more notification.

[0131] In certain embodiments, control logic or microprocessors of on body electronics 1100 include software programs to determine future or anticipated analyte levels based on information obtained from analyte sensor 14, *e.g.*, the current analyte level, the rate of change of the analyte level, the acceleration of the analyte level change, and/or analyte trend information determined based on stored monitored analyte data providing a historical trend or direction of analyte level fluctuation as function time during monitored time period. Predictive alarm parameters may be programmed or programmable in display device 1200, or the on body electronics 1100, or both, and output to the user in advance of anticipating the user's analyte level reaching the future level. This provides the user an opportunity to take timely corrective action.

[0132] Information, such as variation or fluctuation of the monitored analyte level as a function of time over the monitored time period providing analyte trend information, for example, may be determined by one or more control logic or microprocessors of display device 1200, data processing module 1600, and/or remote terminal 1700, and/or on body electronics 1100. Such information may be displayed as, for example, a graph (such as a line graph) to indicate to the user the current and/or historical and/or and predicted future analyte levels as measured and predicted by the analyte monitoring system 1000. Such information may also be displayed as directional arrows (for example, see trend or directional arrow display 1310) or other icon(s), *e.g.*, the position of which on the screen relative to a reference point indicated whether the analyte level is increasing or decreasing as well as the acceleration or deceleration of the increase or decrease in analyte level. This information may be utilized by the user to determine any necessary corrective actions to ensure the analyte level remains within an acceptable and/or clinically safe range. Other visual indicators, including colors, flashing, fading, etc., as well as audio indicators including a change in pitch, volume, or tone of an audio output and/or vibratory or other tactile indicators may also be incorporated into the display of trend data as means of notifying the user of the current level and/or direction and/or rate of change of the monitored analyte level. For example, based on a determined rate of glucose change, programmed clinically significant glucose threshold levels (*e.g.*, hyperglycemic and/or hypoglycemic levels), and current analyte level derived by an *in vivo* analyte sensor, the system 1000 may include an algorithm stored on computer readable medium to determine the time it will take to reach a clinically significant level and will output notification in advance of reaching the clinically significant level, *e.g.*, 30 minutes before a clinically significant level is anticipated, and/or 20 minutes, and/or 10 minutes, and/or 5 minutes, and/or 3 minutes, and/or 1 minute, and so on, with outputs increasing in intensity or the like.

[0133] Referring again back to FIG. 1, in certain embodiments, software algorithm(s) for execution by data processing module 1600 may be stored in an external memory device such as an SD card, microSD card, compact flash card, XD card, Memory Stick card, Memory Stick Duo card, or USB memory stick/device including executable programs stored in such devices for execution upon connection to the respective one or more of the on body electronics 1100, remote terminal 1700 or display device 1200. In a further aspect, software algorithms for execution by data processing module 1600 may be provided to a communication device such as a mobile

telephone including, for example, WiFi or Internet enabled smart phones or personal digital assistants (PDAs) as a downloadable application for execution by the downloading communication device.

[0134] Examples of smart phones include Windows®, Android™, iPhone® operating system, Palm® WebOS™, Blackberry® operating system, or Symbian® operating system based mobile telephones with data network connectivity functionality for data communication over an internet connection and/or a local area network (LAN). PDAs as described above include, for example, portable electronic devices including one or more microprocessors and data communication capability with a user interface (*e.g.*, display/output unit and/or input unit, and configured for performing data processing, data upload/download over the internet, for example. In such embodiments, remote terminal 1700 may be configured to provide the executable application software to the one or more of the communication devices described above when communication between the remote terminal 1700 and the devices are established.

[0135] In still further embodiments, executable software applications may be provided over-the-air (OTA) as an OTA download such that wired connection to remote terminal 1700 is not necessary. For example, executable applications may be automatically downloaded as software download to the communication device, and depending upon the configuration of the communication device, installed on the device for use automatically, or based on user confirmation or acknowledgement on the communication device to execute the installation of the application. The OTA download and installation of software may include software applications and/or routines that are updates or upgrades to the existing functions or features of data processing module 1600 and/or display device 1200.

[0136] Referring back to remote terminal 1700 of FIG. 1, in certain embodiments, new software and/or software updates such as software patches or fixes, firmware updates or software driver upgrades, among others, for display device 1200 and/or on body electronics 1100 and/or data processing module 1600 may be provided by remote terminal 1700 when communication between the remote terminal 1700 and display device 1200 and/or data processing module 1600 is established. For example, software upgrades, executable programming changes or modification for on body electronics 1100 may be received from remote terminal 1700 by one or more of display device 1200 or data processing module 1600, and thereafter, provided to on body electronics 1100 to update its software or programmable functions. For example, in certain

embodiments, software received and installed in on body electronics 1100 may include software bug fixes, modification to the previously stalled software parameters (modification to analyte related data storage time interval, resetting or adjusting time base or information of on body electronics 1100, modification to the transmitted data type, data transmission sequence, or data storage time period, among others). Additional details describing field upgradability of software of portable electronic devices, and data processing are provided in U.S. Application Nos. 12/698,124, 12/794,721, 12/699,653, and 12/699,844, and U.S. Provisional Application Nos. 61/359,265, and 61/325,155 the disclosures of which are incorporated by reference herein for all purposes.

The Sensor

[0137] The analyte sensor 14 of the analyte measurement system 100 may be used to monitor levels of a wide variety of analytes. Analytes that may be monitored include, for example, acetylcholine, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (*e.g.*, CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid-stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (*e.g.*, gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be monitored. One or more analyte may be monitored by a given sensor. In those embodiments that monitor more than one analyte, the analytes may be monitored at the same or different times, which may use the same on body electronics (*e.g.*, simultaneously) or with different on body electronics.

[0138] In one embodiment of the present disclosure, sensor 14 is physically positioned in or on the body of a user whose analyte level is being monitored. Sensor 14 may be configured to continuously sample the analyte level of the user and convert the sampled analyte level, *e.g.*, glucose concentration into a corresponding data signal, *e.g.*, a current or voltage, for input into on body electronics. Alternatively, sensor 14 may be configured to sample analyte levels on demand. The on body electronics may amplify, filter, average, and/or otherwise process signal provided by the sensor.

[0139] An embodiment of the sensor 14 is illustrated in FIG. 2. It is understood that the inserters described herein can be used with other medical devices. The shape(s) described herein are

exemplary only. Other sensor shapes are contemplated. In some embodiments, sensor 14 includes a substrate which is a dielectric, *e.g.*, a polymer or plastic material, such as polyester or polyamide. In this embodiment, the sensor is constructed so that a portion is positionable beneath skin and a portion is above skin. Accordingly, sensor 14 includes an insertion or internal portion 30 and an external or electrical contact portion 32. In some embodiments, the contact portion 32 includes several conductive contacts 36, 38, and 40 (herein shown as three contacts) for connection to other electronics, *e.g.*, at the on body electronics 1100. (See FIG. 1.) The contacts provided in this embodiment are for a working electrode, a reference electrode, and a counter electrode. In some embodiments, two or more working electrodes are provided. The operative portions of these electrodes, that is, working electrode, reference electrode, and counter electrode (not individually shown), are provided at the insertion portion, *e.g.*, at the distal end of insertion portion 30, *e.g.*, portion 34. In some embodiments, one or more electrodes may be external to the body, *e.g.*, an external counter electrode. The contact and operative portions of the electrodes are connected by circuit traces 42, 44, and 46 running on the surface of the substrate. In some embodiments, the traces are provided in channels, or may be embedded within the substrate, or may traverse different sides of the substrate. The conductive contacts, conductive traces, and electrodes are fabricated from conductive material, such as platinum, palladium, gold, carbon, or the like. More than one material may be used for a given sensor. Further details of sensors are described, *e.g.*, in U.S. Patent Nos. 6,175,572 and 6,103,033, which are incorporated by reference herein for all purposes.

[0140] Sensor 14 may include a proximal retention portion 48. The insertion portion 30 and the proximal retention portion 48 are sized and configured to be positioned with a sharp for installation into the skin of a subject, as described herein. In use, the sensor 14 may be configured to bend (*e.g.*, along the line B) and therefore be positioned in two substantially perpendicular, intersecting planes. Such bending may occur prior to or during coupling to the on body electronics as described below. (See FIG. 17).

[0141] Portions 48 and 52 provide a path for electrical connections, *e.g.*, the conductive traces, between the proximal and distal portions of the sensor. Sensor 14 is further provided with a notch or cut-out 54. Such configuration facilitates the sensor 14 to bend (*e.g.*, along the line indicated by line B) such that retention portion 48 remains upright and therefore be positioned in two substantially perpendicular, intersecting planes, as illustrated in FIG. 3. As will be described

below, the sensor tab 50 can be encased in the on body housing 122 to aid in securing and positioning the sensor 14. Proximal retention portion 48 maintains its longitudinal alignment with insertion portion 30 for positioning within an insertion sharp.

[0142] Embodiments of analyte sensors have been described herein to operate electrochemically, through an arrangement of electrodes having chemical sensing layers applied thereto, by generating an electrical current proportional to the volume of a redox reaction of the analyte (and indicative of analyte concentration), catalyzed by an analyte-specific oxidizing enzyme. Embodiments exist in which the number of electrodes provided to bring about and detect the level of these reactions is two, three, or a greater number. However, other types of sensors may be employed as described herein.

[0143] A portion of sensor 14 may be situated above the surface of the skin, with a distal portion 30 penetrating through the skin and into the subcutaneous space in contact with the user's biofluid, such as ISF. Further details regarding the electrochemistry of sensor 14 is provided in U.S. Patent Nos. 5,264,104; 5,356,786; 5,262,035; 5,320,725; and 6,990,366, each of which is incorporated by reference herein for all purposes.

[0144] In some embodiments, the sensor is implantable into a subject's body for a usage period (*e.g.*, a minute or more, at least one day or more, about one to about 30 days or even longer, about three to about fourteen days, about three to about seven days, or in some embodiments, longer periods of up to several weeks) to contact and monitor an analyte present in a biological fluid. In this regard, the sensor can be disposed in a subject at a variety of sites (*e.g.*, abdomen, upper arm, thigh, etc.), including intramuscularly, transcutaneously, intravascularly, or in a body cavity.

[0145] In some embodiments, sensor 14 is employed by insertion and/or implantation into a user's body for some usage period. In such embodiments, the substrate may be formed from a relatively flexible material.

[0146] While the embodiments illustrated in FIGS. 2-3 have three electrodes, other embodiments can include a fewer or greater number of electrodes. For example, a two-electrode sensor can be utilized. The sensor 14 may be externally-powered and allow a current to pass which is proportional to the amount of analyte present. Alternatively, the sensor 14 itself may act as a current source in some embodiments. In some two-electrode embodiments, the sensor may be self-biasing and there may be no need for a reference electrode. An exemplary self-powered,

two-electrode sensor is described in U.S. Patent Application No. 12/393,921, filed February 26, 2009, and entitled "Self-Powered Analyte Sensor," which is hereby incorporated by reference herein for all purposes. The level of current provided by a self-powered sensor may be low, for example, on the order of nanoamperes, in certain embodiments.

Insertion Assembly

[0147] Insertion assemblies are provided, which are used to install a medical device to the subject. In some embodiments, an insertion assembly includes an inserter and the medical device itself. The inserter can be configured to insert various medical devices into the subject, such as for example, an analyte sensor, an infusion set, or a cannula. In some embodiments, the inserter can be configured to install a combination of such devices, *e.g.*, a combined sensor/infusion set, etc., at the same or different times or locations. For example, in certain embodiments a given inserter can be configured to install a first device and a second device at different times. In this regard, the inserter can be reusable. For example, an inserter may be modifiable to be used with more than one medical device, to include more than one type of medical device, *e.g.*, by attaching an adapter and/or removing detaching a portion of an inserter. The inserter can install the medical device in, under, or through the skin of the subject, or place the medical device on the surface of the skin. The medical device can include features or structures, *e.g.*, barbs, tabs, adhesive, etc., to maintain the device in position with respect to the skin after insertion. The inserter device may also be used as a lancet, *e.g.*, to pierce the skin without inserting or installing a medical device.

[0148] In some embodiments, an insertion assembly includes an inserter, an analyte sensor, and a power supply. The power supply may be applied to the patient, *e.g.*, to the surface of the skin, simultaneously with the analyte sensor by the inserter. In other embodiments, the battery is installed after or before installation of the analyte sensor. In such case the power supply may be applied by the inserter or separately. The power supply may be used to provide a current or a potential to the sensor and/or to provide power for communication of one or more signals to the monitor unit.

[0149] In some embodiments, an insertion assembly includes an inserter, a medical device such as an analyte sensor, and on body electronics. The on body electronics may be deployed and/or installed simultaneously with the analyte sensor by the inserter. In other embodiments, the on

body electronics are installed after or before installation of the analyte sensor. For example, the analyte sensor may be installed by the inserter, and the on body electronics may be subsequently installed.

[0150] In some embodiments, the on body electronics provide a voltage or current to the analyte sensor. In some embodiments, the on body electronics process signals provided by the analyte sensor. In further embodiments, the on body electronics may include communications functionality for providing signal relating to signal provided by the analyte sensor to a further component, such as, *e.g.*, a monitor unit, a computer, or other component. In some embodiments, communications circuitry, such as an RFID antenna, is provided. The power supply may be used to power some or all of these functions. In some embodiments, power is provided from the monitor unit, *e.g.*, via inductive coupling.

[0151] An inserter can include a plurality of different components. For example, an inserter may include one or more components for advancing a sharp towards the skin of the subject. The sensor and on body electronics may be supported by a support structure, such as a carriage. A driver may be provided for advancing the sharp and/or the analyte sensor/support structure towards the skin of the patient. In some embodiments, the actuator is directly or indirectly coupled to the sharp and/or support structure, such that manual force applied by the user to the actuator is transferred to the sharp and/or support structure. In some embodiments, the applied force drives the sharp and/or support structure between a retracted position (disposed within the insertion device) and an advanced position (disposed towards the skin of the patient). In some embodiments, the sensor and on body electronics is maintained in a retracted position prior to installation by contacting projections extending inwardly from a recess in the inserter. In accordance with this embodiment, the sensor and on body electronics are temporarily maintained operatively between the support structure and the projections disposed on the interior wall of the sheath.

[0152] An inserter can also include one or more components for retracting the sharp, while allowing the analyte sensor and optional on body electronics to remain on the subject. The components for retracting the sharp can include a retractor. It is understood that the retractor and the actuator may be the same structure or include some common components. In some embodiments, the retractor is directly or indirectly coupled to the sharp such that the manual force applied by the user is transferred from the retractor to the sharp to retract the sharp from the

skin. In other embodiments, a drive assembly may be provided to retract the sharp. For example, the drive assembly may include a spring, motor, hydraulic piston, etc., to retract the sharp away from the skin of the subject. The drive assembly may also include a linear drive component.

[0153] In some embodiments, the retractor withdraws the sharp upon actuation by the user. In such cases, the user actuates the retractor when it is desired to withdraw the sharp. For example, the retractor may include a release switch. Upon activation of the release switch, the drive assembly, *e.g.*, the spring or other driver, retracts the sharp from the skin. In other embodiments, the retractor and the actuator include common components. After activating the actuator to advance the sharp and the analyte sensor, the user releases the actuator, which allows the drive assembly to withdraw the sharp from the skin.

[0154] In some embodiments, the retractor withdraws the sharp without further user interaction after actuation of insertion. For example, the inserter may include features or components which automatically retract the sharp upon advancement of the sharp and support structure by a predetermined amount. Inserter devices, in which no further action by the user is required to initiate withdrawal of the sharp after insertion, are referred to herein as having "automatic" withdrawal of the sharp.

Inserter Devices

[0155] An inserter 200 in accordance with an exemplary embodiment is illustrated in FIG. 4. Inserter 200 includes a housing 202 and a removable distal cap 204 for maintaining a sterile environment for the medical device and sharp housed therein. In some embodiments, inserter 200 has a maximum diameter, of about 30 mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 200 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 200 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc. In the case of inserter 200, the dimensions are defined with respect to the housing 202.

[0156] Housing 202 and distal cap 204 may be fabricated from any suitable materials such as metal, plastic, etc. In some embodiments cap 204 may be fabricated from a polymer or plastic

material. Also provided is a removable proximal cover 206, which, among other things, prevents accidental deployment of the inserter 200 and maintains a sterile environment. In some embodiments, proximal cover 206 is a sheet of material such as a foil sheet or the like secured to the upper surface of housing 202 using an adhesive, and may include a tab 208 to assist removal of the cover 206. Proximal cover 206 may also be a plastic sheet or member that forms a seal with housing 202. In some embodiments, proximal cover 206 may include a pull tab or a perforated section for easy removal.

[0157] As illustrated in FIG. 5, proximal cover 206 and distal cap 204 are shown removed from inserter 200. Distal cap 204 is secured to housing 202, *e.g.*, by use of threads 210. In some embodiments, distal cap 204 is secured by a friction fit, snap fit, a bayonet mount, an adhesive, etc. The distal portion of cap 204 may include a recess for retaining a desiccant therein. In some embodiments, a silica gel or molecular sieves may be used. Such material can be in granular form (pellets) or pressed into tablets, or otherwise. In some embodiments, silica gel tablets are used. Embodiments may include desiccant and/or packaging as described in U.S. Patent Application No. 12/714,439, which is incorporated by reference herein for all purposes. Cap 204 may be provided with one or more apertures, which allows for passage of air to the desiccant to remove moisture from the interior of the inserter 200.

[0158] Housing 202 includes a distal portion 212 for placement on the skin of a subject. Inserter 200 includes an actuator 214 to advance a medical device into the skin of the subject. In some embodiments, actuator 214 is disposed within an opening 216 in housing 202 and can be longitudinally moveable within housing 202.

[0159] The distal portion of inserter 200 is illustrated in FIG. 6. In some embodiments, an adhesive pad 218, having adhesive material 218 on both faces, is provided across the distal portion 212 of the housing 202. A central aperture 220 may be provided in adhesive pad 218. As will be described in greater detail herein, inserter 200 supports a medical device, such as on body housing 122 (not shown) and a sharp 224. In some embodiments, on body housing 122, includes an analyte sensor 14. During insertion, sharp 224 passes through aperture 220 and into the skin of the subject carrying at least the sensor 14 with it.

[0160] FIG. 7 illustrates inserter 200 in cross-section, in an initial configuration prior to use, after removal of the distal cap 204. Actuator 214 may be cylindrical in shape (or other shape as appropriate) and, including an upper contact surface 226, capable of being depressed by a user

and/or a mechanism, as described herein. Actuator 214 may further include side walls 228 extending downwardly from upper surface 226, and which engage or otherwise contact the upper surface of carriage 230. Carriage 230 provides a support for holding the medical device, such as on body housing 122, prior to and during installation. In some embodiments, carriage 230 includes a distal portion 232, which may be configured to form a substantially concave recess 232a as shown in this embodiment, for supporting the medical device therein. In some embodiments, the on body housing 122 is supported within the recess 232a of carriage 230 in a snap-fit or other relationship. In some embodiments, carriage 230 does not include a recess. In such embodiments, carriage may include one or more projections which contact and/or advance the on body housing 122. (See, *e.g.*, FIGS. 122, 135-136 herein.)

[0161] In FIG. 8 the longitudinal axis L of the inserter 200 is illustrated. Extending distally from the upper surface 226 of actuator 214 and substantially parallel to the longitudinal axis is a support member 234, which may have an elongated configuration. Support member 234 supports needle hub 236, from which sharp 224 extends longitudinally within the inserter 200. In some embodiments, the sharp 224 is supported at an oblique angle, e.g., between about 0° and 90° with respect to the skin surface. Needle hub 236 can be secured to support member 234 via an interlocking O-ring configuration, adhesive, or other techniques known in the art. Support member 234 can be omitted and needle hub 236 can be secured to the actuator 214 directly in some embodiments, *e.g.*, by manufacturing needle hub 236 as a single component with actuator 214 or by otherwise adhering needle hub 236 to actuator 214.

[0162] In some embodiments, sharp 224 is a solid needle, for example, if inserter 200 is used to insert a cannula. In some embodiments, sharp 224 is provided with a substantially cylindrical configuration defining an interior bore, *e.g.*, a rigid cylindrical member or a hypodermic-style needle. Sharp 224 may also be provided with an elongated longitudinal opening or gap in the wall of the sharp 224 (see, sharp 224 in FIGS. 11-18). In some embodiments, sharp 224 is fabricated from a sheet of metal, and folded into a substantially "V" or "U" or "C" configuration in cross-section to define the longitudinal recess.

[0163] Needle hub 236 is further illustrated in FIGS. 9-10. Needle hub 236 supports sharp 224, having a sharpened distal portion 260. In some embodiments, as discussed herein, a longitudinal wall opening or gap 262 is provided in at least a portion of the wall of the sharp 224. The length N of the gap 262 is selected to be commensurate with the length of the insertion portion 30

through to the proximal retention portion 48 of the sensor 14 where the bend at line B occurs (See FIGS. 2-3), and in certain embodiments may be about 3 mm to about 50 mm, *e.g.*, about 5 mm, or about 10 mm, or about 15 mm, or about 20 mm. The length L of the sharp 224 may be about 3 mm to about 50 mm, *e.g.*, 5 mm or more, or about 10 mm, or about 20 mm, or about 30 mm, or about 50 mm, and is selected based upon the length of the insertion portion 30 of a sensor and the desired depth of the insertion portion 30 of the sensor 14. In some embodiments, the distance or spacing between the two edges of the gap is about 0.2 mm to about 0.5 mm, *e.g.*, about 0.22 mm, about 0.25 mm, etc. (See, spacing 257 in FIG. 11).

[0164] The distal portion 260 of sharp 224 is illustrated in greater detail in FIGS. 11-13. As illustrated in FIG. 11, sharp 224 has a substantially "C"- or "U"-shaped profile in this embodiment, but may have other configurations, *e.g.*, substantially "V"-shaped. A longitudinal gap 262 is provided in the wall of the sharp 224. FIG. 12 illustrates distal portion 260 is provided with an angled tip. In some embodiments, the angled tip may be provided with a first angled tip portion 264 and a second steep-angled tip portion 266. The exemplary configuration, which includes multiple edges and faces, provides a sharp point to reduce penetration force, trauma, and bleeding for the subject. The distal section of the sensor body has a width sized to fit within the gap 262 of the insertion sharp 224 having a diameter less than about 20 to about 26 gauge, *e.g.*, 21 gauge to about 25 gauge, where in certain embodiments the sharp is 21 gauge or 23 gauge or 25 gauge. Such sharp may be used with a sensor having a width or diameter--at least the portion that is carried by the sharp--of about 0.20 mm to about 0.80 mm, *e.g.*, about 0.25 mm to about 0.60 mm, where in some embodiments the width or diameter of at least a portion of a sensor is 0.27 mm or 0.33 mm or 0.58 mm. In some embodiments, sharp 224 is fabricated from a sheet of metal and folded into a substantially "V" or "U" or "C" configuration in cross-section.

[0165] Various technologies can be used to manufacture a folded sheet of metal to form sharp 224. For example, etched-sheet metal technology can be used to form the sharp 224. In this manner, the sharp can be formed having a very sharp edge so that penetration through the skin during insertion is less painful. In other embodiments, a progressive die technology may be utilized to form a complex sheet-metal shape that has a sharp edge as depicted in FIG. 14. In some embodiments, the sharp 224 can be molded with a plastic cap so that the sharp can be handled during the inserter assembly process. Further, the die cut sharp may be molded with plastic to reinforce the "V," "U," or "C" shaped sheet metal configuration. In some

embodiments, a "U" shaped cross-section can be provided with having flat, rather than curved walls. The "U" shaped configuration provides the advantage that they can more securely and closely hold the sensor. Also, the "U" shaped configuration provides the advantage that it has a reduced cross-section when compared with a comparable circular cross section. Further details of the tip of sharp 224 are illustrated in FIGS. 14A-C. As illustrated in FIGS. 14A-B, a top view of the sharp 224 is shown. This represents a flat portion of the sharp, *e.g.*, the bottom of the "U" configuration. A tip is formed by first distal edges 263 closest to the distal tip and second distal edges 265 between the first distal edges 263 and the substantially parallel side walls 269. In some embodiments, the first distal edges 263 form an "included tip" angle of about 15 degrees, about 30 degrees, or about 60 degrees. Such angle is symmetrical, that is, equal angles from the longitudinal axis of the sharp 224. The second distal edges 265 provide a somewhat less acute angle than the first distal edges 263. In some embodiments, the "lead in" angle may be about 20 degrees, about 45 degrees, or about 65 degrees. By having a tip defined by two angles, a first, smaller "included angle" and a second, larger "lead in angle," allows the tip to meet several objectives. First, the small included angle allows the tip to pierce the skin with less trauma. Second, by broadening out to a larger angle, the overall length of the tip is reduced, and strength of the tip is increased. FIG. 14C illustrates a side view of the sharp 224 and illustrates the side walls 269. An additional angle, *i.e.*, the "lead-out" angle is provided by the rising edge 267 of the sharp. The edge 267 provides the ability to separate the tissue to allow placement of the sensor 14. In other embodiments, a laser-cut sharp can be formed. In this manner, the laser can be used to form the wall opening or gap 262 and first-angled tip portion 264 and a second, steep-angled tip portion 266.

[0166] In another embodiment, sharp 224 may be formed from a standard hypodermic needle utilizing the method depicted in FIG. 15. First, the hypodermic needle (having a circular cross-section) is cut to the desired length for sharp 224. Next, the hypodermic needle is compressed so that its cross-section is permanently deformed from a circular shape to an oval shape. The tip of the hypodermic needle is then ground to a bevel to produce a sharp point to reduce the required penetration force, as previously discussed. Finally, the top section of the needle is removed by appropriate techniques (*e.g.*, grinding, electropolish, etc.). The resulting sharp 224 has a "U"-shaped configuration and provides ample space for the insertion of sensor 14. In some embodiments, the tip-grinding step and the compression step may be carried out in reversed

order.

[0167] Due to the compression step, a user may initially start with a larger diameter hypodermic needle so that the finished sharp 224 will have similar dimensions to the previously described sharps.

[0168] FIGS. 16-18 illustrate the position of on body housing 122 with respect to the needle hub 236 and sharp 224. The on body housing 122 can be configured to hold at least a portion of sensor 14 and on body electronics 1100 (also referred to herein as electronics 80). As illustrated in FIG. 16, the sharp 224 extends through an aperture 168 in the on body housing 122. Thus, in some embodiments, the sharp 224 is uncoupled to on body housing 122. The distal portion of sensor 14 is positioned within the sharp 224. As further illustrated in FIG. 17, on body electronics 1100 and sensor hub 123 are positioned within on body housing 122. Sensor 14 may include an optional positioning structure, or slit 127, which receives a positioning member, such as tab 129 of sensor hub 123. A power supply 82, such as a battery, *e.g.*, a single use disposable battery, or rechargeable battery, is optionally provided.

[0169] FIG. 17A illustrates a detail of sensor hub 123, which includes an aperture 190 through which sharp 224 and sensor 14 are configured to pass through. In some embodiments, aperture 190 is provided with an additional side channel 192 continuous with the aperture 190. Side channel 192 is positioned in the location in which the pointed tip 260 of the sharp 224 would first pass through the aperture. Ideally, the tip 260 passes through the aperture without contacting the sensor hub 123. However, if there is any misalignment, the tip 260 makes contact with the sensor hub 123 and may be damaged and/or it may become jammed or otherwise unable to pass through the aperture. The side channel 192 provides additional clearance for the tip 260 to pass through the aperture undamaged.

[0170] FIG. 18 illustrates in cross-section the orientation of the on body housing 122 with respect to the sharp 224 of inserter 200. As discussed herein, sensor 14 is disposed in a substantially bent configuration in some embodiments, such that a portion of the sensor, *e.g.*, the insertion portion 30 and the proximal retention portion 48, are substantially vertical (*e.g.*, substantially aligned with the longitudinal axis of the inserter 200 and substantially perpendicular to the skin surface) and the contact portion 32 (shown in profile) is oriented in a substantially horizontal configuration, and in electrical contact with on body electronics 1100. The sensor tab 50 can be encapsulated in the plastic of the on body housing 122 and secured in place. The notch

56 provides further stability to the sensor 14, *e.g.*, by allowing the sensor tab 50 to be encased by the material of the on body housing 122, and further provides a means for vertically orienting the sensor 14 during mounting, *e.g.*, by allowing vertical positioning of the notch 56 with respect the on body housing 122.

[0171] The sensor 14, mounted with the on body housing 122, can be disposed within a recess of the carriage 230 such as a concave recess in the carriage 230. Alternatively, the sensor 14, mounted with the on body housing 122 can be disposed between the support structure and one or more projections extending from the wall of the sheath 242 (not shown). In yet another alternative, the sensor 14 mounted with the on body housing 122 can be held in position by a releasable friction fit coupling to the sharp 224. In this manner, the carriage need not have a recess within which the sensor mounted with the on body housing is disposed. In the initial configuration of the inserter 200 (see, *e.g.*, FIG. 7) the sharp 224 extends through a longitudinal aperture 168 formed in a carriage 230. In some embodiments, the aperture 168 is appropriately sized, such that neither the sharp 224 nor needle hub 236 is in contact with the carriage 230. Accordingly, the needle hub 236 (and sharp 224) on the one hand, and the carriage 230 and the on body housing 122, on the other hand, move simultaneously but independently from one another. In other embodiments, a friction fit may be provided between the aperture and the sharp.

[0172] The insertion portion 30 and proximal retention portion 48 of the sensor 14 are disposed within a longitudinal bore 162 within the sharp 224 (See, *e.g.*, FIG. 7). The proximal retention portion 48 is disposed within the longitudinal bore of the sharp 224 and provides additional stability to the mounting of the sensor 14 within the sharp 224. The longitudinal wall gap or opening 262 of sharp 224 is aligned with the sensor 14, such that the tab 50 and the contact portion 32 extend laterally outward from the sharp 224.

[0173] In some embodiments, a resilient member 70 may be included to provide frictional contact with the sharp 224 and/or the sensor 14. Such frictional contact provides additional stability between the on body housing 122 and sharp 224, as depicted in FIGS. 19-21. In some embodiments, resilient member 70 may be formed as a spherical, ovoid, cylindrical, cube-shaped member, etc. Resilient member 70 may be formed from any elastomeric material, *e.g.*, molded plastic components, rubber, nitrile, viton, urethane, etc..

[0174] In some embodiments, resilient member 70 is press-fit into a recess, such as an eccentric bore 72 located in on body housing 122 (FIG. 21). When sharp 224 is inserted within an aperture

in the on body housing 122, the resilient member 70 exerts a pressure on sharp 224 and sensor 14 to hold them firmly in groove 74. In some embodiments, groove 74 is a V-shape. Alternatively, groove 74 may be U-shaped depending on the configuration of sensor 14 and sharp 224. In some embodiments, resilient member 70 is provided with a flattened or recessed surface which abuts sharp 224.

[0175] The sensor 14, mounted with the on body housing 122, is carried by the carriage, *e.g.*, disposed within the concave recess 232a in the carriage 230, as described hereinabove (see, *e.g.*, FIGS. 16-21). In the initial configuration of the inserter 200 (see, *e.g.*, FIG. 7), the sharp 224 extends through a longitudinal aperture formed in the carriage 230. In some embodiments, the aperture is appropriately sized, such that neither the sharp 224 nor needle hub 236 is in contact with the carriage 230. In other words, in some embodiments a clearance may be provided between the surfaces of the carriage and the sharp and needle hub. In some cases, sharp 224 is capable of substantial lateral movement or "play" with respect to aperture. Accordingly, the needle hub 236 (and sharp 224) on the one hand, and the carriage 230 and the on body housing 122, on the other hand, can move simultaneously but independently from one another.

[0176] Referring back to FIG. 17, the insertion portion 30 and proximal retention portion 48 of the sensor 14 are disposed within a longitudinal bore of the sharp 224. The proximal retention portion 48 is disposed within the longitudinal bore 225 of the sharp 224 and provides additional stability to the disposition of the sensor 14 within longitudinal bore 225 of the sharp 224. The longitudinal wall gap of sharp 224 is aligned with the sensor 14, such that the tab 50 and the contact portion 32 extend laterally outward from the sharp 224.

[0177] With continued reference to FIG. 7, an optional sheath 242 is positioned within housing 202, having an annular configuration and including a circumferential recess 244 in which a retraction spring 246 is positioned. The distal portion of spring 246 contacts a spring retention portion 248 in sheath 242. The proximal portion of spring 246 contacts one or more tabs 250 extending laterally outwardly from actuator 214. In the initial configuration, the spring 246 may be in a semi-compressed state, *i.e.*, not fully compressed, nor fully extended. It is understood that sheath 242 may be omitted from inserter 200, and a recess, such as recess 244, provided within housing 202. Similarly, recess 244 may be omitted entirely, and spring 246 or other actuator may be disposed between stops in housing 202.

[0178] Depression of the actuator 214 causes distal longitudinal movement of the carriage 230

and sharp 224, from a proximal position (spaced apart from the skin of the subject) to a distal position (closer to the skin of the subject). During such downward, distal movement, spring 246 is further compressed between spring retention portion 248 and flanges 270.

[0179] As illustrated in FIG. 8, depression of the contact surface 226 moves the actuator side walls 228 and the tabs 250 downwardly distally against the bias of spring 246. Contact of the side wall 228 of the actuator 214 with the upper surface of the carriage 230 during depression of the actuator 214 imposes a downward force and consequential distal movement of the carriage 230. As the sharp 224 is urged distally, it carries the sensor insertion portion 30 into the subcutaneous portion of the subject's skin S.

[0180] As illustrated in FIG. 7, flanges 270 are disposed in the inner wall of sheath 242. When carriage 230 reaches a distal position, as shown in FIG. 8, the flanges 270 engage the proximal (upper) surface of the carriage 230, and thereby inhibit proximal movement of the carriage 230 (see also FIG. 24). The distal (lower) surface of the on body housing 122 engages the upper surface of adhesive pad 218, thereby becoming adhered to the skin surface S of the subject. As the flanges 270 engage the carriage 230, the flanges 270 also engage fingers 274 disposed on the proximal face of the carriage 230. Fingers 274 are pivoted inwards by flanges 270. Such pivoting of fingers 274 causes fingers 274 to become disengaged from retention tab 250 on actuator 214. Spring 246 is thereby permitted to decompress and expand, and thereby provide an upward force on actuator 214. If the user or some apparatus provides no downward force, or minimal downward force to overcome the bias of spring 246, the actuator 214, along with needle hub 236 and sharp 224 move proximally, withdrawing the sharp 224 from the skin S of the subject.

[0181] As shown in FIGS. 22 and 23, the actuator 214 and coupled sharp 224 advances to a more proximal position than at the initial configuration illustrated in FIGS. 5 and 7 due to the decoupling of actuator 214 from carrier 30. Thus, the sharp 224 retracts from a distal position to a proximal position after installation of the on body housing 122 and insertion of at least a portion of the sensor.

[0182] A further embodiment of an inserter is illustrated in FIGS. 25-39 and designated inserter 300. In some embodiments, inserter 300 has a maximum diameter of about 30 mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 300 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. Such

height is defined by the total length of the housing 302 and the sheath 342. In some embodiments, inserter 300 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc. Such dimensions are defined by the total length of the housing 302 and the sheath 342.

[0183] As illustrated in FIGS. 25-26, inserter 300 in certain embodiments includes, *e.g.*, a handle 302, a sheath 342, and a removable distal cap 304 for maintaining a sterile environment for the medical device and sharp housed therein. FIG. 26 illustrates that distal cap 304 is removed from handle 302. Distal cap 304 is secured to handle 302 by one of a number of securement means, *e.g.*, by use of threads 310. Sheath 342 defines a distal surface 312 for placement on the skin of a subject. Inserter 300 may be utilized to advance a medical device into the skin of the subject. In some embodiments, handle 302 is advanced relative to sheath 342 in order to advance the medical device into the skin of the patient.

[0184] The components of inserter 300 in certain embodiments are illustrated in FIGS. 27-32. As illustrated in FIG. 27, handle 302 may include threads 310 for attachment of cap 304 via threads 311 (as illustrated in FIG. 29). It is understood that other securement techniques, such as a snap-fit or friction-fit may be used to secure cap 304. Cap 304 may include a receptacle 325 for positioning of the sharp 324. Sheath 342, as illustrated in FIG. 28, includes longitudinal notches 382.

[0185] Projections 386 on carriage 330, as illustrated in FIG. 30, are configured to engage sheath to secure carriage 330 within the inserter 300, thereby preventing release of the carriage 330 from the inserter 300. When the projections 386 of carrier reach the bottom of the notches 382, such bottom surface acts as the retention portion that prevents the carriage 330 from falling out of the inserter 300. Projections 375 engage with the triangular latch features 370 of the sheath 342 as illustrated in FIGS. 34 and 36.

[0186] Carriage 330 also is provided with fingers 375 which engage a shoulder wall 376 of sharp 324 (as illustrated in FIG. 34), as will be described in greater detail herein.

[0187] In certain embodiments, inserter 300 also includes a spring retention component 348, as illustrated in FIG. 31. Spring retention component 348 defines an upper surface 349, which engages spring 346 (as illustrated in FIG. 34). Spring retention component 348 also includes locking towers 351 including projections, which engage apertures 328 of needle carrier 334 to

prevent accidental deployment of the sharp 324 after use of the inserter 300 is completed.

[0188] Inserter 300 is illustrated in cross-section in FIG. 33 prior to use. Cap 304 is attached to the distal portion of inserter 300, via securement means, such as inter-engagement of threads 310 and 311. Cap 304 includes a desiccant tablet 390; a seal, such as a foil seal 392; and a Tyvek® layer 394, which allows breathability between the desiccant tablet 390 and the interior of the inserter 300.

[0189] As illustrated in FIG. 34, the inserter 300 includes an initial configuration in which the handle 302 is disposed in a proximal position with respect to the sheath 342. In such configuration, the sharp 324 is disposed in a configuration spaced apart from the aperture 320 of the adhesive layer 318. The distal portion of inserter 300 is illustrated in FIG. 35.

[0190] With continued reference to FIG. 34, the longitudinal axis L of the inserter 300 is illustrated. Extending distally from the upper surface of handle 302 is an inner wall portion 326 and intermediate wall portion 374. Support member 334 extends from wall portion 326 and supports needle hub 336, from which sharp 324 extends longitudinally within the inserter 300. In some embodiments, the sharp is supported at an oblique angle, *e.g.*, between 0° and 90° with respect to the skin surface.

[0191] Sheath 342 is positioned within handle 302, having an annular configuration in which a retraction spring 346 is positioned. The distal portion of spring 346 contacts a surface 349 of spring retention component 348. The proximal portion of spring 346 contacts the inner surface 350 of handle 302. In the initial configuration, the spring 346 is in an extended or semi-extended configuration.

[0192] FIG. 36 illustrates inserter 300 in cross-section, during insertion. Depression of handle 302 with respect to sheath 342 against the bias of spring 346 causes distal longitudinal movement of the carriage 330 and sharp 324, from a proximal position towards a distal position. During such downward, distal movement, spring 346 is compressed between surface 349 of spring retention component 348 and surface 350 of handle 302. As the sharp 324 is urged distally by housing 302, it carries the sensor insertion portion 30 of sensor 14 into the subject's skin S.

[0193] As carriage 330 reaches a distal position, the distal surface of the on body housing 122 engages the upper surface of adhesive pad 318, thereby becoming adhered to the skin surface S of the subject. Also, flange 370 engages fingers 375 disposed on the carriage 330. Fingers 375 are pivoted outwards by flanges 370 in direction T. Such pivoting of fingers 375 causes fingers

375 to become disengaged from slots 376 in intermediate housing walls 374. Carriage 330 is thereby disengaged from handle 302 and needle carrier 334.

[0194] As illustrated in FIG. 37, handle 302, along with needle hub 336 and sharp 324 are permitted to move proximally, while the sheath 342 and on body housing 122 remain adjacent to the skin of the subject. If the user or some apparatus provides no downward force, or minimal downward force to the handle 302 to overcome the bias of spring 346, spring 346 is permitted to expand, thereby withdrawing the sharp 324 from the skin S of the subject.

[0195] Upon reaching the proximal position, flanges 328 on needle carrier 334 engage locking towers 351 of needle floor component 348. The inter-engagement of flanges 328 and locking towers 351 prevents inadvertent deployment of sharp 324 after installation of the medical device.

[0196] A further embodiment of an inserter is illustrated in FIGS. 40-50, and designated inserter 400. In some embodiments, inserter 400 has a maximum diameter of about 30 mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 400 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 400 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc. The maximum height is measured from the top of the housing 402 to the distal surface 412. The volume is measured as the combined volume of the housing 402 and the sheath 442 in an expanded position.

[0197] Inserter 400 generally includes, *e.g.*, a handle 402, sheath 442, and a removable distal cap 404 for maintaining a sterile environment for the medical device and sharp housed therein. As illustrated in FIG. 41, distal cap 404 is shown removed from handle 402. Distal cap 404 is detachably secured to handle 402, *e.g.*, by use of threads 410. Sheath 442 includes a distal surface 412 for placement on the skin of a subject. Inserter 400 may be utilized to advance a medical device into the skin of the subject. In some embodiments, handle 402 is advanced relative to sheath 442 in order to advance the medical device distally and into the skin of the patient.

[0198] The components of inserter 400 are illustrated in FIGS. 42-46. As illustrated in FIG. 42, handle 402 includes threads 410 for attachment of cap 404 via threads 411 (as illustrated in FIG. 44). Cap 404 may include a receptacle 425 for positioning of the sharp 424. Sheath 442, as

illustrated in FIG. 43, includes longitudinal notches 482. Projections 486 on carriage 430, as illustrated in FIG. 45, are configured to engage sheath 442 to secure carriage 430 within inserter 400, thereby preventing release of the carriage from the inserter. Sheath 442 also includes notches 484 which receive projection 475 of carriage 430. The bottom of the notches acts as the retention portion that prevents the carriage 430 from falling out of the inserter 400. Projections 475 engage with the latch features 470 of the sheath 442 as illustrated in FIGS. 49 and 50. Carriage 430 also is provided with fingers 474 which engage a shoulder wall 476 of needle carrier 436, as illustrated in FIGS. 48-49, and as will be described in greater detail herein.

[0199] Sheath 442 also includes a spring retention portion 448, provided at the distal end of circumferential notch 496, as illustrated in FIG. 48. Needle carrier 434, as illustrated in FIG. 46, includes wings 450, which provide an upper engagement surface for spring 446. Wings 450 also include a shoulder 476 for engagement with fingers 474 of carriage 430.

[0200] Inserter 400 is illustrated in cross-section in FIG. 47 in a state prior to use and prior to removal of cap 404, which is shown attached to the distal portion of handle 402, via inter-engagement of threads 410 and 411. Cap 404 includes a desiccant tablet 490, a seal such as a foil seal 492, and a Tyvek® layer 494, which allows breathability between the desiccant tablet 490 and the interior of the inserter 400.

[0201] As illustrated in FIG. 48, the inserter 400 is shown in an initial configuration in which handle 402 is disposed in a proximal position with respect to the sheath 442. In such configuration, the sharp 424 is disposed in a configuration spaced apart from the aperture 420 of the adhesive layer 418. The longitudinal axis L of the inserter 400 is illustrated. Extending distally from the upper surface of handle 402 is inner wall 475. The distal end portions of wall 475 provide a downward force on the carriage 430 upon depression of the handle 402 by a user. Alternatively, instead of handle having a distally extending inner wall, the carriage can include one or more upwardly extending walls or projections (not shown). The one or more upwardly extending inner walls or projections can have a length sufficient to either contact the upper surface of 402 or, alternatively, contact corresponding downwardly extending inner walls of the handle 402. In this manner, depression of handle 402 by a user provides a downward force on the one or more upwardly extending walls or projections of the carriage to advance the carriage (and on-body unit) distally to an installation and insertion position. (See FIGS. 49-50.) In one embodiment a downwardly extending wall of the handle 402 and a corresponding upwardly

extending wall of the carriage are aligned such that depression of the handle 402 by a user allows the upwardly extending wall and the downwardly extending wall to make direct contact, thereby permitting the carriage 430 and on-body unit to advance distally. In such embodiment, the downwardly extending inner wall of the handle has a distal end that is disposed proximally of the proximal most end of sheath 442.

[0202] Needle carrier 434 can be axially moveable within handle 402. Needle carrier 434 supports needle hub 436, from which sharp 424 extends longitudinally within inserter 400. In some embodiments, sharp 424 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface. Initially, needle carrier 434 is coupled to carriage 430 via inter-engagement of fingers 474 of carriage 430 with shoulder 476 of needle carrier 434. Spring 446 is disposed between spring retention portion 448 of sheath 442 and wings 450 (FIG. 46) of needle carrier 434. Initially, spring 446 is in an expanded or semi-expanded state while handle 402 is disposed proximally from sheath 442. In another exemplary embodiment, needle carrier 434 can be secured to handle 402, for example, secured to downwardly extending inner wall 475. In this manner, needle carrier and carriage 430 are longitudinally moveable along the line defined by L shown in FIG. 48 with respect to sheath 442. In this regard, needle carrier 434 includes one or more apertures to receive one or more downwardly extending inner walls 475 of handle 402. In some embodiments, neither the needle carrier 434 nor the carriage 430 are in slidable contact with sheath 442, *e.g.*, spaced apart from sheath 442, during longitudinal movement of the needle carrier 434 and/or carriage 430.

[0203] FIG. 49 illustrates inserter 400 in cross-section, during insertion. Depression of handle 402 with respect to sheath 442, against the bias of spring 446, causes distal longitudinal movement of the carriage 430 and needle carrier 434, from a proximal position towards a distal position. During such downward proximal movement, spring 446 is compressed between spring retention portion 448 and wings 450 (FIG. 46) of needle carrier 434. As the sharp 424 is urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIG. 17) into the subcutaneous portion of the subject's skin S.

[0204] As carriage 430 reaches a distal position (close to the skin of the subject), the distal surface of the on body housing 122 engages the upper surface of adhesive pad 418, thereby becoming adhered to the skin surface S of the subject. Flange 470 engages fingers 474 disposed on the carriage 430. Fingers 474 are pivoted outwards by flanges 470 in direction T. Such

pivoting of fingers 474 causes fingers 474 to become disengaged from shoulder 476 of needle carrier 434. Needle carrier 434 is thereby disengaged from carriage 430. Such pivoting of fingers 474 also engages opening in 474 with flange 470, thus locking carriage 430 in the distal position.

[0205] As illustrated in FIG. 50, disengagement of the needle carrier 434 from the carriage 430 permits the spring 446 to expand, thereby advancing the needle carrier 434 to a proximal position (away from the skin of the subject) and withdrawing the sharp 424 from under the skin surface S of the subject while leaving the sensor 14 in the skin. Once the sharp 424 has been withdrawn from the subject, it is no longer accessible from the distal portion of the inserter 400 and unable to make contact by accident with the subject's skin because it is positioned at a proximal position within the carrier handle 402.

[0206] An inserter 2400 in accordance with another exemplary embodiment is illustrated in FIG. 51. In some embodiments, inserter 2400 has a maximum diameter, of about 30 mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 2400 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 2400 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc. The height is measured from the distal surface of the housing 2402 (adjacent to adhesive 218) to the top surface. The volume is measure by the volume of the housing 2402.

[0207] With reference to FIG. 51, inserter 2400 includes a housing 2402 and a removable distal cap 2412 for protecting the medical device and sharp housed therein. Housing 2402 and distal cap 2412 may be fabricated from any suitable materials such as metal, plastic, etc. In some embodiments, cap 2412 may be fabricated from a polymer or plastic material.

[0208] An exploded view of the components of inserter 2400 is illustrated in FIG. 52. As shown, inserter 2400 generally comprises plunger 2405, spring 2406, housing 2402, sharp 2404 (not shown in FIG. 52), on body housing 122, sharp holder 2408, adhesive patch 218, and cap 2412 when fully assembled.

[0209] A more detailed view of sharp holder 2408 is shown in FIG. 53. Needle holder 2408 retains sharp 2404 in a fixed position with respect to itself within inserter 2400, thereby allowing it to safely penetrate a subject's skin during later use.

[0210] To assemble inserter 2400, sharp 2404 and hub 2408 are inserted through an opening in on body housing 122 as shown in FIG. 54. Needle holder 2408 prevents sharp 2404 from being fully inserted through on body housing 122. In some embodiments, on body housing 122 includes an analyte sensor 14 and on body electronics 1100.

[0211] Next, plunger 2405, spring 2406, and housing 2402 are assembled as shown in FIGS. 55-57. Plunger 2405 contains a spring retention member which is inserted through the center of spring 2406. Lip 2414 of plunger 2405 engages inner wall 2416 of housing 2402 when assembled (FIG. 51). This causes spring 2406 to be contained between lip 2418 of housing member 2402 and the bottom surface 2424 of plunger 2405. The resulting sub-assembly of inserter 2400 shown in allows plunger 2405 to move between a proximal position, with spring 2406 in a preloaded condition, and a distal position, wherein bottom surface 2424 engages wall 2426 of housing 2402.

[0212] The on body housing assembly shown in FIG. 54 is then inserted into the inserter sub-assembly shown in FIGS. 55-57. As shown in FIG. 57, on body housing 122 is inserted into housing 2402 with the tip of sharp 2404 pointing away from plunger 2405. The resulting assembly is depicted in FIG. 58. As shown in FIG. 51, grooves on sharp holder 2408 engage tabs 2422 on plunger 2405. The on body housing 122 is axially retained in the housing 2402 by the housing arms detent features 2440.

[0213] Finally, adhesive patch 218 is placed over the opening of housing 2402 and cap 2412 is friction fit over housing 2402 as shown in FIG. 59. The fully assembled inserter 2400 is depicted in FIG. 60. In some embodiments, adhesive pad 218 has an adhesive material on both faces. A central aperture 220 may be provided in adhesive pad 218 to allow sharp 2404 to be deployed into the skin of a subject. During insertion, sharp 2404 passes through aperture 220 and into the skin of the subject carrying at least the sensor with it.

[0214] FIG. 61 illustrates inserter 2400 in cross-section, in an initial configuration prior to use, after removal of the distal cap 2412. As shown, sharp 2404 extends longitudinally within the inserter 2400. In some embodiments, sharp 2404 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface.

[0215] In some embodiments, sharp 2404 is provided with a substantially cylindrical configuration defining an interior bore, *e.g.*, a rigid cylindrical member or a hypodermic-style needle. Sharp 2404 may also be provided with an elongated longitudinal opening or gap in the

wall of the sharp 2404. In some embodiments, sharp 2404 is fabricated from a sheet of metal, and folded into a substantially "V" or "U" or "C" configuration in cross-section to define the longitudinal recess.

[0216] Depression of plunger 2405 causes distal longitudinal movement of on body housing 122 and sharp 2404, from a proximal position to a distal position. During such downward, distal movement, spring 246 is further compressed between lip 2418 and bottom surface 2424. Detent 2440 provides a minimum force threshold to overcome before on body housing 122 can continue on its downward distal movement. Beyond a minimum force threshold, detent 2440 is pushed outward by on body housing 122, and on body housing 122 then translates onto ramp 2442. The friction between on body housing 122 and ramp 2442 of the housing hold the on body housing 122 up against plunger 2405.

[0217] As illustrated in FIG. 62, depression of plunger 2405 advances the inserter 2400 from an initial configuration to a deployed configuration. Contact of plunger 2405 and hub 2408 during depression of plunger 2405 imposes a downward force and consequential distal movement of sharp 2404. As the sharp 2404 is urged distally, it carries the sensor insertion portion 30 into the subcutaneous portion of the subject's skin S. Contact of plunger 2405 and sensor housing 122 during depression of plunger 2405 imposes a downward force and consequential distal movement of sensor housing 122. Lip features 2414 of plunger 2405 maintain parallelism of sensor housing 122 to subject skin S during distal movement.

[0218] When plunger 2405 reaches a distal position, as shown in FIG. 63, bottom surface 2424 engages wall 2426 and prevents further downward movement. The distal (lower) surface of on body housing 122 engages the upper surface of adhesive pad 218, thereby becoming adhered to the skin surface S of the subject.

[0219] As the subject or some apparatus removes force from plunger 2405, spring 2406 urges plunger 2405 toward its proximal position (away from the skin surface) as shown in FIG. 64, leaving on body housing 122 adhered to the skin surface S of the subject. Tabs 2427 provide additional downward force to the on body housing 122 to assist holding it to adhesive patch 218 while the sharp 2404 is withdrawn through on body housing 122. Eventually, the upward force exerted by spring 2406 returns inserter 2400 to its initial configuration as illustrated in FIG. 65.

[0220] In some embodiments, inserter 2400 may be distributed in a sterilized package 2480 as depicted in FIG. 66. To use inserter 2400 in this configuration, a user would first clean the

insertion site on the skin with alcohol. The user would then remove inserter 2400 from sterilized package 2480 as shown in FIG. 66. Next a user would place the inserter on the insertion site and push down on plunger 2405 until on body housing 122 is adhered to the subject's skin as shown in FIGS. 67-68. The user would then release the plunger 2405. Finally, the user would remove inserter 2400 from the insertion site and dispose of the inserter.

[0221] A further embodiment of an inserter is illustrated in FIGS. 73-87, and designated inserter 2500. In some embodiments, inserter 2500 has a maximum diameter of about 30 mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.25 mm, about 52 mm, etc. In some embodiments, inserter 2500 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50.25 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 2500 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc. The height of the inserter is measured from the top of housing 2502 to the distal surface of the sheath 2512 that is intended to contact the skin of the subject. The volume of the inserter may be measured as the volume of the housing and the portion of the sheath 2512 that may extend from the housing 2502.

[0222] Inserter 2500 generally includes, *e.g.*, a handle 2502, sheath 2512, and a removable distal cap 2504 for maintaining a sterile environment for the medical device and sharp housed therein (FIG. 73). As illustrated in FIGS. 74-75, handle 2502 is shown removed from distal cap 2504. Distal cap 2504 is detachably secured to handle 2502, *e.g.*, by use of threads 2506. It is understood that cap may be secured using snap-fit or press-fit configuration. Inserter 2500 may be utilized to advance a medical device into the skin of the subject. In some embodiments, handle 2502 is advanced relative to sheath 2512 in order to advance the medical device distally and into the skin of the patient.

[0223] Handle 2502 further includes needle carrier guides 2508 which allow the needle carrier 2514 to slidingly move relative to distal cap 2504. In an alternate embodiment, a detent prevents sheath 2512 from moving towards a "firing position" until a minimum force is applied. Location feature 2510 allows for the proper positioning of carriage 2516 when engaged.

[0224] Further components of inserter 2500 are illustrated in FIGS. 76-80. Sheath 2512, as illustrated in FIG. 76, may include longitudinal notches 2518 which snap into detents 2507. Retention members, such as ribs 2520, pinch spring arms 2522 located on carriage 2516 to

prevent on body housing 122 from falling out of inserter 2500. Ribs 2520 do not extend to the bottom of sheath 2512, thus allowing carriage 2516 to release on body housing 122 when it has traveled to the bottom of sheath 2512 during insertion. Interfering structure, such as locking beam 2524, prevents inserter 2500 from being used again once needle carrier 2514 passes the locking beam (FIG. 87). Specifically, locking feature 2526 of needle carrier 2514 engages with locking beam 2524 to prevent further use of inserter 2500.

[0225] Needle carrier 2514 is illustrated in greater detail in FIGS. 77-78. In some embodiments, needle carrier 2514 includes guides, such as rail guides 2528, which interface with rail guides 2508, thereby allowing needle carrier 2514 to slidingly move relative to handle 2502. Notches 2527 are provided in sheath 2512 which has a larger dimension than the wings of needle carrier 2514, such that the needle carrier 2514 does not contact sheath 2512 during longitudinal movement of needle carrier 2514. Needle carrier 2514 also comprises detents/notches 2530 which interface with the upper edge of the spring when inserter 2500 is fully assembled (see FIGS. 81-87). In some embodiments, needle carrier 2514 comprises an attachment feature 2532 capable of accommodating a custom needle hub or attachment.

[0226] Carriage 2516 is illustrated in greater detail in FIGS. 79-80. As shown, carriage 2516 may comprise latches 2538 which connect it to needle carrier 2514 by locking with latches 2540. Spring hook 2542 allows for support for retaining on body housing 122 when the inserter has not been fired and allows for release of on body housing 122 when it has been attached to the skin of the user. (See, FIGS. 122, 125, 135-140.)

[0227] Inserter 2500 is illustrated in cross-section in FIG. 81 in a state prior to use in which handle 2502 is disposed in a proximal position with respect to the sheath 2512. In such configuration, the sharp 2550 is disposed in a configuration spaced apart from the aperture 420 of the adhesive layer (not shown). The longitudinal axis L of the inserter 2500 is illustrated. The upper surface of spring 2544 is retained in inserter 2500 by detents/notches 2530 located on needle carrier 2514. The bottom surface of spring 2544 is retained by spring floor 2545 located on sheath 2512. Initially, spring 2544 is in an expanded or semi-expanded state while handle 2502 is disposed proximally from sheath 2512.

[0228] Extending distally from the upper surface of handle 2502 is inner wall 2508. In some embodiments, the distal end portions of wall 2508 provide a downward force on carriage 2516 upon depression of handle 2502 by a user. Alternatively, instead of handle 2502 having a distally

extending inner wall 2508, carriage 2516 can include one or more upwardly extending walls or projections (not shown). The one or more upwardly extending inner walls or projections of the carriage 2516 can have a length sufficient to either contact the inside of the upper surface of handle 2502 or, alternatively, contact corresponding downwardly extending inner walls of handle 2502. In this manner, depression of handle 2502 by a user provides a downward force on the one or more upwardly extending walls or projections of carriage 2516 to advance carriage 2516 (and on body housing 122) distally to an installation and insertion position (FIG. 84). In such embodiment, the downwardly extending inner wall of the handle has a distal end that is disposed proximally of the proximal most end of sheath 2512.

[0229] Sharp 2550 extends longitudinally from needle carrier 2514 within inserter 2500. In some embodiments, sharp 2550 is supported at an oblique angle, *e.g.*, between about 0°and 90° with respect to the skin surface.

[0230] FIG. 82 illustrates inserter 2500 in cross-section after a user applies an initial downward force to button 2502. Further depression of handle 2502 with respect to sheath 2512, against the bias of spring 2544, causes distal longitudinal movement of the carriage 2516 and needle carrier 2514, from a proximal position towards a distal position as shown in FIG. 83. During such downward proximal movement, spring 2544 is compressed between detents/notches 2530 and retention tab 2546. As sharp 2550 is further urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIG. 17) into the subject's skin S.

[0231] As carriage 2516 reaches a distal position (near the subject's skin) as shown in FIG. 83, the distal surface of the on body housing 122 engages the upper surface of adhesive pad (not shown), thereby becoming adhered to the skin surface S of the subject. Latch 2538 engages the upper surface of retention tab 2546 as shown in FIG. 84. As a result, the top portion of latch 2538 is pivoted outward in direction T. Such pivoting of latch 2538 causes needle carrier to become disengaged from carriage 2516.

[0232] As illustrated in FIG. 85, disengagement of the needle carrier 2514 from the carriage 2516 permits spring 2544 to expand, thereby advancing the needle carrier 2514 to a proximal position and withdrawing the sharp 2550 from the skin S of the subject while leaving the on body housing 122 attached to the skin. As the sharp is withdrawn (FIG. 86), locking feature 2526 advances past locking beam 2524 because of the upward force exerted on needle carrier 2514 by spring 2544.

[0233] Referring now to FIG. 87, once the sharp 2550 has been withdrawn from the subject, button 2502 cannot be pressed again because any downward movement will be blocked by the interaction of locking beam 2524 and locking feature 2526.

[0234] In some embodiments, inserter 2500 may come in a sterilized package which is capable of a one-time use as shown in FIGS. 88-90. To use inserter 2500 in this manner, a user would first sterilize the insertion site on the skin with alcohol. The subject would then twist off cap 2504 as shown in FIG. 88. Next a subject would place the inserter on the sterilized insertion site and push down on inserter 2500 until on body housing 122 is adhered to the subject's skin as shown in FIGS. 89-90. Finally, the subject would remove inserter 2500 from the insertion site and dispose of the inserter. In this manner, the inserter 2500 itself serves as its own sterilized packaging. This procedure applies also to the other inserters described herein.

[0235] A further embodiment of an inserter is illustrated in FIGS. 91-108, and designated inserter 2700. In some embodiments, inserter 2700 has a maximum diameter of about 30 mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 46 mm, about 50 mm, etc. In some embodiments, inserter 2700 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 49.5 mm, about 55 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 2700 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc.. The maximum height refers to the height defined from the top of the housing 2702 to the portion of the sheath 2708 that contacts the subject's skin. The volume is measured as the volume of the housing 2702 and the portion of the sheath 2708 extending from the housing.

[0236] Inserter 2700 generally includes, *e.g.*, a housing 2702 (FIGS. 92-93), sheath 2708 (FIGS. 94-95), and a removable distal cap 2704 for maintaining a sterile environment for the medical device and sharp housed therein (FIG. 91). As illustrated in FIGS. 92-93, housing 2702 is shown removed from distal cap 2704. Distal cap 2704 is detachably secured to housing 2702, *e.g.*, by use of threads 2706. It is understood that cap may be secured using snap-fit or press-fit configuration. Inserter 2700 may be utilized to advance a medical device into the skin of the subject. Sheath 2708 generally defines a cavity or open space, within which sharp carrier 2716 and medical device carrier 2730 are moveable. In some embodiments, housing 2702 is advanced relative to sheath 2708 in order to advance the medical device distally and into the skin of the

patient.

[0237] Housing 2702 includes sheath guide rail 2710 which interfaces with rail guides 2712 located on sheath 2708 (FIG. 94), thereby allowing housing 2702 to slidingly move longitudinally relative to sheath 2708. Housing 2702 may further include sharp carrier guide rail 2714 which interfaces with rail guides 2718 located on sharp carrier 2716 (FIG. 97). Sheath 2708, sharp carrier 2716, and housing 2702 may alternatively move relative to one another without the use of guide rails.

[0238] Ledge 2720 and/or ledge 2722 are provided on an interior portion of housing 2702. Ledge 2720 engages sheath 2708 to hold sheath 2708 in a pre-use position prior to insertion of the medical device. Ledge 2722 engages sheath 2708 to secure sheath 2708 in a post-use position after insertion of the medical device. Housing 2702 further includes detent 2724 which prevents housing 2702 from moving relative to sheath 2708 until a minimum force has been applied, *e.g.*, distally by user to housing 2702. The sheath 2708 is secured to the housing 2702 via snap 2726. Snap 2726 snaps into the housing detent 2724. (In some embodiments, it is pinched between ledge 2720 and detent 2724, thus controlling its longitudinal position relative to the housing 2702). The needle carrier 2716 is located and secured to the medical device carrier 2730 (located via interaction of locating features 2748 and 2750 and secured via interaction of carrier arms 2732 and angled top surface of 2716). The ledge 2720 is a controlled surface onto which the top of sheath surface 2728 will engage at the end of the insertion stroke to prevent further relative movement in some embodiments.

[0239] Further components of inserter 2700 are illustrated in FIGS. 94-99. Sheath 2708 is a generally cylindrical component. As illustrated in FIGS. 94-95, sheath 2708 may include attachment snaps 2726 which are biased into detent 2724 of housing 2702 to create a minimum force that must be overcome in order to advance sharp 224 into the subject's skin and install the on body housing 122. The interaction of the snap 2726 with the detent 2724 and ledge 2720 holds the assembly in a slop/rattle free position. In some embodiments, the force to be overcome can be about 0.5 lbf to about 5 lbf., *e.g.*, about 1 lbf, about 2 lbf, about 3 lbf, about 4 lbf, etc. Support wall 2728 prevents carrier arms 2732 on carrier 2730 from bending outwardly, clear of sharp carrier 2716. Ribs 2734 pinch carrier arms 2732 on carrier 2730, thus preventing on body housing 122 from falling out of inserter 2700 when sheath 2708 is in the extended position. Ribs 2734 are not present at the bottom of sheath 2708, thus allowing room for spring arms 2736 on

carrier 2730 to release on body housing 122 when carrier 2730 has traveled to the bottom of sheath 2708. Slot 2738, located on sheath 2708, interfaces with locating feature 2740 on carrier 2730, thus orienting carrier 2730 to sheath 2708 during assembly. Once force is overcome to allow carrier 2730 to move distally towards the subject's skin, no further force is required to retract the sharp 324 from the subject's skin.

[0240] Referring next to FIGS. 96-97, depicted is sharp carrier 2716 in a perspective and cross-sectional view, respectively. Sharp carrier 2716 contains notches 2724 which allow clearance for the passage of carrier arms 2732 located on medical device carrier 2730. Guidance walls 2744 securely hold spring 2746 in place (FIG. 100). Locating features 2748, *e.g.*, bosses or tabs, align with locating features 2750, *e.g.*, recesses or apertures, on carrier 2730. Snap features 2752 secure sharp 224 securely within inserter 2700. It is contemplated that sharp 224 may be secured to sharp carrier 2716 by other techniques, *e.g.*, friction fit, adhesive, welding, etc.

[0241] Medical device carrier 2730 is depicted in more detail in FIGS. 98-99. As shown, carrier 2730 contains spring locating ring 2754 which receives one end of spring 2746. In some embodiments, spring 2746 surrounds spring locating ring 2754. In some embodiments, the inner area remains clear to leave room for the deflection of sharp carrier feature snaps 2752 that move outwardly when the sharp is inserted. Carrier 2730 further comprises locating features 2756 which interface with locating features on housing 2702. (See FIGS. 135-136).

[0242] Inserter 2700 is illustrated in cross-section in FIG. 100 in a state prior to use in which housing 2702 is disposed in a proximal position with respect to the sheath 2708. In such orientation, sharp 224 is disposed in a configuration spaced apart from the aperture 420 of the adhesive layer 118. The upper surface of spring 2746 is retained in inserter 2700 by sharp carrier 2716. The bottom surface of spring 2746 is retained by spring location ring 2754. Initially, spring 2746 is in a compressed or semi-compressed state while housing 2702 is disposed proximally from sheath 2708.

[0243] Sharp 224 extends longitudinally from sharp carrier 2716 within inserter 2700. In some embodiments, sharp 224 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface.

[0244] FIG. 101 illustrates inserter 2700 in cross-section after a user applies an initial downward force to housing 2702. In some embodiments, a predetermined minimum force must be used so that attachment snaps 2726 advance past detent 2724.

[0245] After detent 2724 has been overcome, *e.g.*, snap 2726 is radially displaced, further depression of housing 2702 with respect to sheath 2708 causes distal longitudinal movement of the carrier 2730 and sharp carrier 2716, from a proximal position towards a distal position as shown in FIG. 103. As sharp 224 is further urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIG. 17) into the subcutaneous portion of the subject's skin S.

[0246] As carrier 2716 reaches a distal position (FIG. 103), the distal surface of the on body housing 122 engages the upper surface of adhesive pad 2718, thereby becoming adhered to the skin surface S of the subject. Concurrently, carrier arms 2732 are advanced distally and clear the support wall 2728. This allows carrier arms 2732 to deflect radially outwardly. (See, FIG. 104). When carrier arms 2732 deflect radially outwardly, shoulder portions of carrier arms 2732 are no longer in an interference relationship with the sharp carrier 2716. Thus spring 2746 is permitted to expand as shown in FIG. 105, thereby advancing the sharp carrier 2716 to a proximal position and withdrawing the sharp 224 from the skin S of the subject while leaving the on body housing 122 attached to the skin. Handle 2702 is maintained in the distal position. Sheath snap 2726 of the sheath 2708 have now moved up to lock over feature 2722 of the housing 2702. Now the housing 2702 and the sheath 2708 can no longer move longitudinally with respect to each other, and provides an indication to a user that the inserter has been used. In FIG. 106, the medical device carrier 2730 acts as a needle guard to prevent a user for touching the needle.

[0247] In some embodiments, the changing interaction of sheath snap 2726 with the housing detent/ledges 2720, 2724, and 2722 determine whether the sheath 2708 is locked. When snap 2726 is in the pre-fire position, ledge 2720 prevents sheath 2708 from being pulled out of the housing 2702. In this position, detent 2724 may also impede the movement of pushing the sheath 2708 into the housing 2702. When the detent is overcome by at least a minimum force, the sheath 2704 moves longitudinally with respect to the housing 2702 until the snap 2726 snaps over housing ledge 2722. At this point, ledge 2722 prevents the sheath 2708 from being pulled out of the housing again, but from a new position (this position may be referred to as the used/post-fire position). Sharp carrier snap 2752 function is to hold onto the sharp 224. In some embodiments, the sharp carrier 2716 is held in the post-fire position relative to the housing 2702 by, *e.g.*, an interference between the rails of the housing 2714 and the guide rails of the sharp carrier 2718 (this interference is only present once the sharp carrier is fully retracted) and/or by medical device carrier projections interfering with the bottom/floor of the sharp carrier (See, *e.g.*,

FIG. 106). In another embodiment of inserter 2700, adhesive pad 118 may be attached directly to on body housing 122. This necessitates a different shape of inserter 2700 as depicted in FIG. 107. Additionally, carrier 2730 is slightly wider to accommodate adhesive pad 118 attached to on body housing 122 (FIG. 108).

[0248] A further embodiment of an inserter is illustrated in FIGS. 109-134. In some embodiments, inserter 3700 has a maximum diameter of about 30 mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 46 mm, about 50 mm, etc. In some embodiments, inserter 3700 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 49.5 mm, about 55 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 3700 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc. The maximum height refers to the height defined from the top of the housing 3702 to the portion of the sheath 3708 that contacts the subject's skin. The volume is measured as the volume of the housing 3702 and the portion of the sheath 3708 extending from the housing.

[0249] FIGS. 109-112 depict the various stages of insertion from an initial stage in which the cap is attached (FIG. 109), to removal of the cap (FIG. 110), deployment of the sharp and on body housing unit (FIG. 111) and removal of the inserter from the subject's skin (FIG. 112).

[0250] Inserter 3700 generally includes, *e.g.*, a housing 3702 (FIGS. 109, 113-114), sheath 3708 (FIGS. 115-116), and a removable distal cap 3704 (FIGS. 117-119) for maintaining a sterile environment for the medical device and sharp housed therein. As illustrated in FIGS. 109 and 117-119, housing 3702 is shown removed from distal cap 3704. Distal cap 3704 is detachably secured to housing 3702, *e.g.*, by use of threads 3706. It is understood that in some embodiments, the cap may be secured using snap-fit or press-fit configuration.

[0251] Inserter 3700 may be utilized to advance a medical device into the skin of the subject. Sheath 3708 generally encloses or defines a cavity, within which sharp carrier 3716 (FIGS. 120-121) and medical device carrier 3730 (FIG. 122) are moveable. In some embodiments, housing 3702 is advanced relative to sheath 3708 in order to advance the medical device distally and into the skin of the patient.

[0252] Housing 3702 includes sheath guide rail 3710 which interfaces with rail guides 3712 located on sheath 3708, thereby allowing housing 3702 to slidingly move relative to sheath 3708.

Sheath 3708, sharp carrier 3716, and housing 3702 may alternatively move relative to one another without the use of guide rails. The housing can include a distally extending sidewall having a non-linear or arcuate shape. In the embodiment illustrated in FIGS. 109-134 the housing is configured with an undulating sidewall which transitions from a concave portion (upper portion of housing 3702) to a convex portion (lower portion of housing 3702). (FIG. 114). This contour enhances the user's tactile recognition and provides a more ergonomic gripping surface which reduces accidental slippage by the user's hand. Further, the housing is configured with a cavity sized to receive the sheath 3708, as described in further detail below.

[0253] Housing ledge 3720 and/or ledge 3722 are provided on an interior portion of housing 3702. Ledge 3720 engages sheath 3708 to hold sheath 3708 in a pre-use position prior to insertion of the medical device. Ledge 3722 engages sheath 3708 to secure sheath 3708 in a post-use position after insertion of the medical device. Housing 3702 further includes detent 3724 which prevents housing 3702 from moving relative to sheath 3708 until a minimum force has been applied, *e.g.*, distally by user to housing 3702. The sheath 3708 is secured to the housing 3702 via retention features 3726, which can be configured, *e.g.*, as a snap. Retention feature 3726 snaps into the housing detent 3724 (In some embodiments, it is pinched between ledge 3720 and detent 3724, thus controlling its height relative to the housing 3702). In some embodiments, the surfaces of the housing ledges 3720, 3722, 3724 and retention features 3726 are configured to engage in a single point of contact or a plurality of discrete points of contact, *e.g.*, line. Such discrete points of contact are advantageous over conformal surface-to-surface contact in that a more thorough sterilization process can be performed. A variety of sterilization mediums can be employed, *e.g.*, Ethylene Oxide (EtO), wherein the gaseous medium is delivered over the various inserter components. Accordingly, the discrete points of contact allow for a greater surface area of each inserter component to be exposed to the gaseous medium, thereby providing for a more thorough and rapid sterilization process. The housing includes distally extending protrusions 3727 which are received in apertures 3756 of the medical device carrier 3730 to couple the housing and medical device carrier, by such techniques as, *e.g.*, heat staking, ultrasonic bonding, adhesive bonding, snap fit, etc. Coupling the housing and the medical device is performed, in some embodiments, by *e.g.*, heat staking, ultrasonic bonding, adhesive bonding, snap fit, etc.. Consequently, there is no relative movement between the housing 3702 and the medical device carrier 3730.

[0254] Sheath 3708 is generally formed as a unitary tubular member having proximal 3708a and distal 3708c cylindrical portions. In some embodiments, the portions 3708a and 3708c have an elliptical, square, hexagonal, or other cross-section. As illustrated in FIGS. 115-116, the distal cylindrical portion 3708c (*i.e.*, the lower portion) can be formed with a greater diameter than the proximal portion 3708a, with the proximal and distal portions integrally connected via a shelf 3708b. Accordingly, the sheath 3708 can be formed as a single-piece and generally cylindrical member with the proximal portion having sufficient rigidity to prevent displacement of the carrier arms 3732, as described in further detail below. Sheath 3708 can include retention members 3726, e.g., detent snaps, which are biased into detent 3724 of housing 3702 to create a minimum force that must be overcome in order to advance sharp 324 into the subject's skin and install the on body housing 322. The retention members 3726 can extend proximally from the shelf 3708b of the sheath and be formed as a separate member such that the retention members are spaced or offset from the cylindrical wall of the sheath. The actuation force of the inserter is determined by the stiffness of retention members 3726 (which is a function of length, thickness, and cross section) as well as the steepness of the angle of detent 3724 of the housing. In some embodiments, the force to be overcome can be about 0.5 lbf to about 5 lbf., *e.g.*, about 1 lbf, about 2 lbf, about 3 lbf, about 4 lbf, etc.

[0255] As described above, the proximal portion 3708a of the sheath is sized such that an interior support wall surface 3728 prevents carrier arms 3732 on medical device carrier 3730 from displacement or bending outwardly, clear of sharp carrier 3716. Maintaining the carrier arms 3732 in a fixed or constrained position within the sheath allows a user to accurately know the relative positioning of the needle within the inserter. Conversely, the distal portion 3708c of the sheath is sized such that the diameter of the interior wall surface is greater than the carrier arms 3732, thus allowing room for spring arms 3732 on carrier 3730 to expand or displace radially outward thereby releasing the sharp carrier 3716 to retract to the proximal position. Guide rails 3712 are included on the exterior surface of the proximal portion of the sheath 3708a. The guide rails 3712 remain engaged with the housing guide rail 3710 of the housing throughout the insertion operation, *i.e.*, from advancement of the housing from the proximal position to the distal position. Thus even prior to insertion, rotational position of the housing and sheath is controlled, and "rocking" is minimized. In general, rocking is minimized by increasing the length of engagement with respect to the diameter of engagement. In the embodiment disclosed herein,

the length of engagement between the sheath and housing, *i.e.* along the longitudinal axis, is relatively large while the diameter at which the engagement occurs is relatively small, *i.e.* at proximal portion of sheath 3708a. Additionally, sheath 3708 includes a slot 3738 extending distally from the shelf 3708b and configured to receive the guide rail 3710 of the housing upon delivery of the medical device and insertion of the sharp into the subject.

[0256] Referring next to FIGS. 120-121, depicted is sharp carrier 3716 in a perspective and cross-sectional view, respectively. Sharp carrier 3716 contains notches 3724 which allow clearance for the passage of carrier arms 3732 located on medical device carrier 3730. Guidance walls 3744 securely hold spring 3746 in place (FIGS. 127-128). The top or proximal edge of the sharp carrier includes a chamfered or sloped edge 3725. Locating features 3748, *e.g.*, standoffs or distally extending protrusions, aligned with locating features 3750, *e.g.*, recesses or apertures, on carrier 3730. Accordingly, the sharp carrier 3716 is located and secured to the medical device carrier 3730 (located via interaction of locating features 3748 and 3750 and secured via interaction of carrier arms 3732 and angled edge surface of 3725. These locating features can extend through the medical device carrier 3730 and directly engage the on body housing 322. Accordingly, when a user actuates the inserter, the sharp carrier drives the on body housing 322 and sharp 324 towards the subject via the protrusions 3748. The direct coupling of the sharp carrier enhances the control of the positioning of on body housing 322, and prevents skewing of the on body housing 322 or sharp 324. Additionally, snap features 3752 secure sharp 324 securely within inserter 3700. It is contemplated that sharp 324 may be secured to sharp carrier 3716 by other techniques, *e.g.*, friction fit, adhesive, welding, etc.

[0257] Medical device carrier 3730 is depicted in more detail in FIG. 122. As shown, carrier 3730 contains spring locating ring 3754 that receives one end of spring 3746. In some embodiments, spring 3746 surrounds spring locating ring 3754. In some embodiments, the inner area remains clear to leave room for the deflection of sharp carrier feature snaps 3752 that deflect out when the sharp is inserted. As described above, carrier 3730 further comprises locating features 3756 which interface with locating features on housing 3702. Furthermore, detents can be formed at the end of carrier arms 3732 of the medical device carrier to abut or otherwise the sloped edge 3725 of the sharp carrier. As described above, the detents on carrier arms 3732 are configured to engage the edge 3725 of the sharp carrier in a discrete point of contact fashion in order to realize the aforementioned sterilization advantages. Additionally, these surfaces can be

configured with rounded surfaces that ensure that there is no surface to "snag" during the release of the sharp carrier. The medical device carrier 3700 further includes one or more housing gripping arms 3762 (*e.g.*, three are depicted in FIG. 122) which hold the on body housing 322 in place. In some embodiments, gripping arms 3762 are provided with engagement boss 3764 which are configured to engage with corresponding recesses 3766 provided on the side walls of the on body housing 322. Such engagement of the recesses 3766 with the gripping arms 3762 maintains the proper height location of the on body housing 322. Ribs 3768 or other projections on the interior surface of the distal portion 3708c of the sheath 3708 hold these gripping arms 3762 securely in place against the on body housing 322 while the sheath is fully extended. When the medical device carrier 3730 advances along the sheath 3708 to reach the proximal position during use, the gripping arms 3762 are no longer supported by the sheath 3708 and the force of the adhesive skin patch 318 overcomes the retention force of the gripping arms 3762.

[0258] Inserter 3700 is illustrated in cross-section in FIGS. 123-125 in a state prior to use in which housing 3702 is disposed in a proximal position with respect to the sheath 3708 and the cap 3704 secured to the housing. FIG. 126 illustrates a cross-sectional view of the inserter in a state prior to use after the cap 3704 has been removed. The upper surface of spring 3746 is retained in inserter 3700 by sharp carrier 3716. The bottom surface of spring 3746 is retained by spring location ring 3754 of the medical device carrier 3730. Initially, spring 3746 is in a compressed or semi-compressed state while housing 3702 is disposed proximally from sheath 3708.

[0259] Sharp 324 extends longitudinally from sharp carrier 3716 within inserter 3700. In some embodiments, sharp 324 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface.

[0260] FIGS. 127-128 depict the relationship between the medical device carrier 3730 and the sharp carrier 3716 (with the housing 3702 and sheath 3708 omitted for sake of clarity). FIG. 127 depicts the initial position of the medical device carrier 3730 and the sharp carrier 3716 with the carrier arms 3732 engaged with the sloped edge 3725 of the sharp carrier. In this position there is no relative movement between the medical device carrier 3730 and the sharp carrier 3716. However, the carrier arms 3732 are not of sufficient rigidity or bias to counteract the bias of the spring 3746 in order to maintain the sharp carrier in the position shown in FIG. 127 without support from the sheath, as shown in FIG. 129. Accordingly, the spring 3746 urges the sharp

carrier 3716 in the proximal direction thereby displacing the carrier arms 3732 radially outward as shown in FIG. 128.

[0261] FIG. 130 illustrates inserter 3700 in cross-section after a user applies an initial downward force to housing 3702. In some embodiments, a predetermined minimum force must be used so that attachment snaps 3726 advance past detent 3724.

[0262] After detent 3724 has been overcome, *e.g.*, snap 3726 of the sheath is displaced radially inward, further depression of housing 3702 with respect to sheath 3708 causes distal longitudinal movement of the medical device carrier 3730 and sharp carrier 3716, from a proximal position towards a distal position as shown in FIGS. 131-132. During this phase of insertion, the interior surface of proximal portion 3708a of the sheath remains engaged with the carrier arms 3732 to prevent radial displacement of the arms 3732, and thus maintains the coupling of the medical device carrier 3730, on body housing 322, sharp 324 and sharp carrier 3716. As sharp 324 is further urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIG. 17) into the subcutaneous portion of the subject's skin S.

[0263] As carrier 3716 reaches a distal position, the on body housing 322 along with the adhesive pad 318 engage the skin surface S of the subject, thereby becoming adhered. Concurrently, carrier arms 3732 are advanced distally beyond shelf 3708b of the sheath and clear the support wall 3708a (as highlighted by focus point "A" in FIG. 132). This allows carrier arms 3732 to deflect radially outwardly into the larger diameter distal portion 3708c of the sheath as shown in FIG. 133. When carrier arms 3732 deflect outwardly, shoulder portions of carrier arms 3732 are no longer in an interference relationship with the sharp carrier 3716. Thus spring 3746 is permitted to expand as shown in FIG. 133, thereby retracting the sharp carrier 3716 to a proximal position and withdrawing the sharp 324 from the skin S of the subject while leaving the on body housing 322 attached to the skin. Housing (or handle) 3702 is maintained in the distal position and extends over the sheath in a telescoping manner. Sheath detent or snap 3726 of the sheath 3708 can then lock over feature 3722 of the housing 3702. Accordingly, the housing 3702 and the sheath 3708 can no longer move longitudinally with respect to each other.

[0264] In some embodiments, the changing interaction of sheath detent or snap 3726 with the housing detent/ledges 3720, 3724, and 3722 determine whether the sheath 3708 is locked. When snap 3726 is in the pre-fire position, ledge 3720 prevents sheath 3708 from being pulled out of the housing 3702. In this position, detent 3724 may also impede the movement of pushing the

sheath 3708 into the housing 3702. When the detent is overcome by at least a minimum force, the sheath 3708 moves longitudinally with respect to the housing 3702 until the snap 3726 snaps over housing ledge 3722. At this point, ledge 3722 prevents the sheath 3708 from being pulled out of the housing again, but from a new position (this position may be referred to as the used/post-fire position). Sharp carrier snap 3752 function is to hold onto the sharp/needle. In some embodiments, the sharp/needle carrier 3716 is held in the post-fire position relative to the housing 3702 by, *e.g.*, an interference between the rails of the housing 3710 and the guide rails of the sharp carrier 3718 (this interference is only present once the sharp carrier is fully retracted) and/or by medical device carrier projections 3732 interfering with the bottom/floor of the sharp carrier (See, *e.g.*, FIG. 134). In another embodiment of inserter 3700, adhesive pad 318 may be attached to sheath 3708 prior to use. Upon reaching the distal position, the distal surface of on body housing 322 engages the upper surface of adhesive pad 318, thereby becoming adhered to the skin surface S of the subject.

[0265] Another embodiment of the inserter 3700' is substantially identical to the inserter 3700 discussed hereinabove with the differences noted herein. As illustrated in FIGS. 135-136, the medical device carrier 3730' is substantially identical to carrier 3730. However, carrier 3730' includes one or more gripping arms 3762' including an engagement boss 3764' which is configured to engage with corresponding recesses 3766 provided on the side walls of the on body housing 322. In some embodiments, the gripping arms 3762' are configured to be spaced radially apart from the on body housing 322 in the relaxed, unstressed configuration. When an inwardly directed force is applied to the gripping arms 3762', they may be directed into contact with the on body housing 322.

[0266] Perspective and sectional views of sheath 3708' are illustrated, respectively, in FIGS. 137-138. The inside of distal portion 3708c' includes one or more ramp members 3768', which are positioned to engage the gripping arms 3762' and provide a radially inwardly directed force. As illustrated in FIG. 139, in the initial configuration, the medical device carrier 3730' is positioned in a proximal position with respect to the sheath 3708'. In this configuration, the gripping arms 3762' are deflected radially inwardly by the ramp member 3768' such that the engagement boss 3764' is in contact with the recesses 3766 of the on body housing 322. This configuration provides support for the on body housing 322. As illustrated in FIG. 140, as the carrier 3730' is advanced distally, the gripping arms 3762' clear the ramp member 3768', the

gripping arms 3762' begin to deflect radially outwardly according to their normal bias, thereby releasing the engagement boss 3764' from the recesses 3768' of on body housing 322. Release of the gripping arms 3762' facilitates the separation of the on body housing 322 form the inserter 3700'.

[0267] In some embodiments, the on body housing is assembled on the body of the user. For example, the on body housing may be comprised of a mounting unit 3780 and an electronics housing 3782. The mounting unit 3780 may include a mount and a sensor. In some embodiments, the sensor is at least partially positioned within the mount and the distal insertion portion extends out of the mount. An inserter, such as inserter 3700 described herein, is used to advance the distal portion of the sensor into the skin of the subject and to adhere the mount to the skin of the user. Subsequently, the electronics housing 3782 is mounted onto the mounting unit 3780. Electrical contact is made between the electronics housing 3782 and the sensor in order to transfer the analyte readings from the sensor to the electronics housing 3782.

[0268] As illustrated in FIG. 141, the inserter 3700 is initially arranged with the cap 3704 attached to the housing 3702. The mounting unit 3780 is positioned in the medical device carrier 3730, with the sharp 324 extending distally in a surrounding position about the sensor. FIGS. 142-144 illustrate the sequence of inserting the sensor into the skin of the user and the attachment of the mounting unit 3780 to the skin of the user. In FIG. 142, the sheath 3708 is placed on the skin. In FIG. 143, the housing 3702 is advanced distally towards the skin of the user, thereby advancing the medical device carrier, the mounting unit 3780 and the sharp 324 towards the skin of the patient. In FIG. 144, upon reaching the distal position of the housing 3702, the sharp carrier 3716 is released, thereby moving to the proximal position.

[0269] As illustrated in FIGS. 145a and 145b, the mounting unit 3780 is positioned on the skin with the distal portion of the sensor inserted into the skin. As illustrated in FIGS. 146a and 146b, the electronics housing 3782 is inserted into the mounting unit 3780, and shown in the final configuration in FIGS. 147a and 147b.

[0270] In an exemplary embodiment of on body housing 3800 illustrated in FIG. 148, electronics housing 3882 is mounted on mounting unit 3880. Mounting unit 3880 includes a detent 3884 for coupling with a recess 3886 on the electronics housing 3882 in, *e.g.*, a toe-in snap configuration. It is understood that the detent and recess configuration may be reversed such that the recess is on the mounting unit and the detent is on the electronics housing. The electronics housing 3882

electrically couples with the mounting unit 3880 by the electrical contacts 3888 on the mounting unit 3880 which are coupled to electrical contacts (not shown) on the electronics housing 3882. The sensor hub 3890 stores at least a portion of the sensor which is electrically coupled to the contacts 3888.

[0271] In another exemplary embodiment illustrated in FIG. 149, the on body housing 3900 is attached by first attaching the mounting unit 3980 to the skin of the user. Subsequently, sensor 14 is positioned at least partially beneath the skin of the user. Electronics housing 3982 is coupled to the mounting unit 3980 by inserting the flanges 3986 under a corresponding flange of the mounting unit 3980. Contacts 3988 of the electronics housing 3982 are then coupled to contacts on the sensor 14 in order to provide the sensor readings from the sensor to the electronics housing 3982.

[0272] In some embodiments, the on body housing is assembled on a surface (such as a tabletop) prior to insertion into the user. For example, as illustrated in FIGS. 150-156, the on body housing may be comprised of a housing unit 4020 and a sensor hub 4022. The housing unit 4020 may include a mount and on body electronics. In some embodiments, the sensor is at least partially positioned within the sensor hub 4022 and the distal insertion portion extends out of the sensor hub 4022. The sensor hub 4022 is contained in the inserter, and the housing unit 4020 is positioned in the inserter 3700. Electrical contact is made between the housing unit 4020 and the sensor in order to transfer the analyte readings from the sensor to the housing unit 4020. The inserter, similar to inserter 3700 described herein, is used to advance the distal portion of the sensor into the skin of the subject and to adhere the housing unit 4020 to the skin of the user.

[0273] As illustrated in FIG. 150, the inserter 3700 is initially arranged with the cap 3704 attached to the housing 3702. The sensor hub 4022 is supported by the sharp carrier 3716, with the sharp 324 extending distally in a surrounding position about the sensor. FIGS. 151-155 illustrate the sequence of inserting the sensor into the skin of the user and the attachment of the housing unit 4020 to the skin of the user. In FIG. 151, the cap 3704 is removed. In FIGS. 152-153, the housing unit 4020 is positioned in the housing support 3731, for example, by use of adhesive patch 4028. In FIG. 154, the sharp carrier 3716 is advanced distally, thereby advancing the sensor hub 4022 distally and into engagement with the housing unit 4020. In FIG. 155, the sharp carrier 3716 is released, thereby allowing the sharp carrier 3716 to move proximally. The inserter 3700 is removed, leaving the sensor hub 4022 coupled to the housing unit 4020, as

illustrated in FIG. 156.

[0274] In some embodiments, the housing unit 4020 and the adhesive patch 4028 are stored in a sealed compartment 4100 as shown in FIG. 157. The compartment 4100 includes a lower cap portion 4104 and a cover portion 4102, manufactured from a flexible material such as metal foil or plastic. As shown in FIG. 158, the lower cap portion 4104 stores the sterilized housing unit 4020 and adhesive patch 4028 therein until ready for use. In some embodiments, the adhesive patch 4028 includes adhesive on both sides.

[0275] In some embodiments, on body housing 4200 includes housing unit 4220 and sensor hub 4222 as illustrated in FIG. 159. The sensor may be insert molded with mechanical contacts. The PCB in the housing unit 4220 may include leaf spring contacts 4230. The sensor hub 4222 may be mechanically attached to the housing unit 4220, *e.g.*, the electrical contacts may function as mechanical snaps. Sealing may be provided by an elastomeric gasket. The housing unit 4220 may be macromelt or injection molded.

[0276] In some embodiments, on body housing 4300 includes housing unit 4320 and sensor hub 4322 as illustrated in FIG. 160. The sensor may have insert molded contacts. The PCB in housing unit 4320 may include exposed pads. Mechanical attachment of the housing unit and sensor hub may be accomplished by molded snaps. The needle guide may be injection molded or overmolded macromelt of TPE (thermoplastic elastomer). The housing unit 4320 may be macromelt or injection molded.

[0277] In some embodiments, on body housing 4400 includes housing unit 4420 and sensor hub 4422 as illustrated in FIG. 161. The sensor may have exposed pads on the flag or contact portion of the sensor. The PCB in housing unit 4420 may include a SMT ZIF connector, or similar 4430. Mechanical attachment of the housing unit and sensor hub may be accomplished by molded snaps. The needle guide may be injection molded plastic with elastomer overmold. The housing unit 4320 may be macromelt overmold.

[0278] In some embodiments, a clamshell type arrangement 4500 is provided which includes a needle guide 4550 having a living hinge arrangement 4552. The sensor may include bent metal contacts that are inserted after molding. The PCB may include PCB pads. The mechanical attachment is performed by adhesive of mechanical snap to PCB. The transponder housing, not shown, may be injection molded, UV or ultrasonic bonded.

[0279] In some embodiments, on body housing 4600 includes housing unit 4620 and sensor hub

4622 as illustrated in FIG. 163. The sensor 14 may have exposed pads on the flag or contact portion of the sensor. The PCB in housing unit 4620 may include concentric exposed pads 4690. Mechanical attachment of the housing unit and sensor hub may be accomplished by molded snaps or PSA. The needle guide may be injection molded plastic with elastomer overmold. The housing unit 4620 may be macromelt overmold.

[0280] In some embodiments, on body housing 4700 includes housing unit 4720 and sensor hub 4722 as illustrated in FIG. 164. The sensor may have exposed pads on the flag and may also include a compressed anisotropic zebra, conductive elastomeric or similar. The PCB in housing unit 4720 may include exposed pads. Mechanical attachment of the housing unit and sensor hub may be accomplished by snaps. The needle guide may overmold macromelt or TPE. The housing unit 4720 may be macromelt overmold.

[0281] It is understood that the subject matter described herein is not limited to particular embodiments described, as such may, of course, vary. It is also understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present subject matter is limited only by the appended claims.

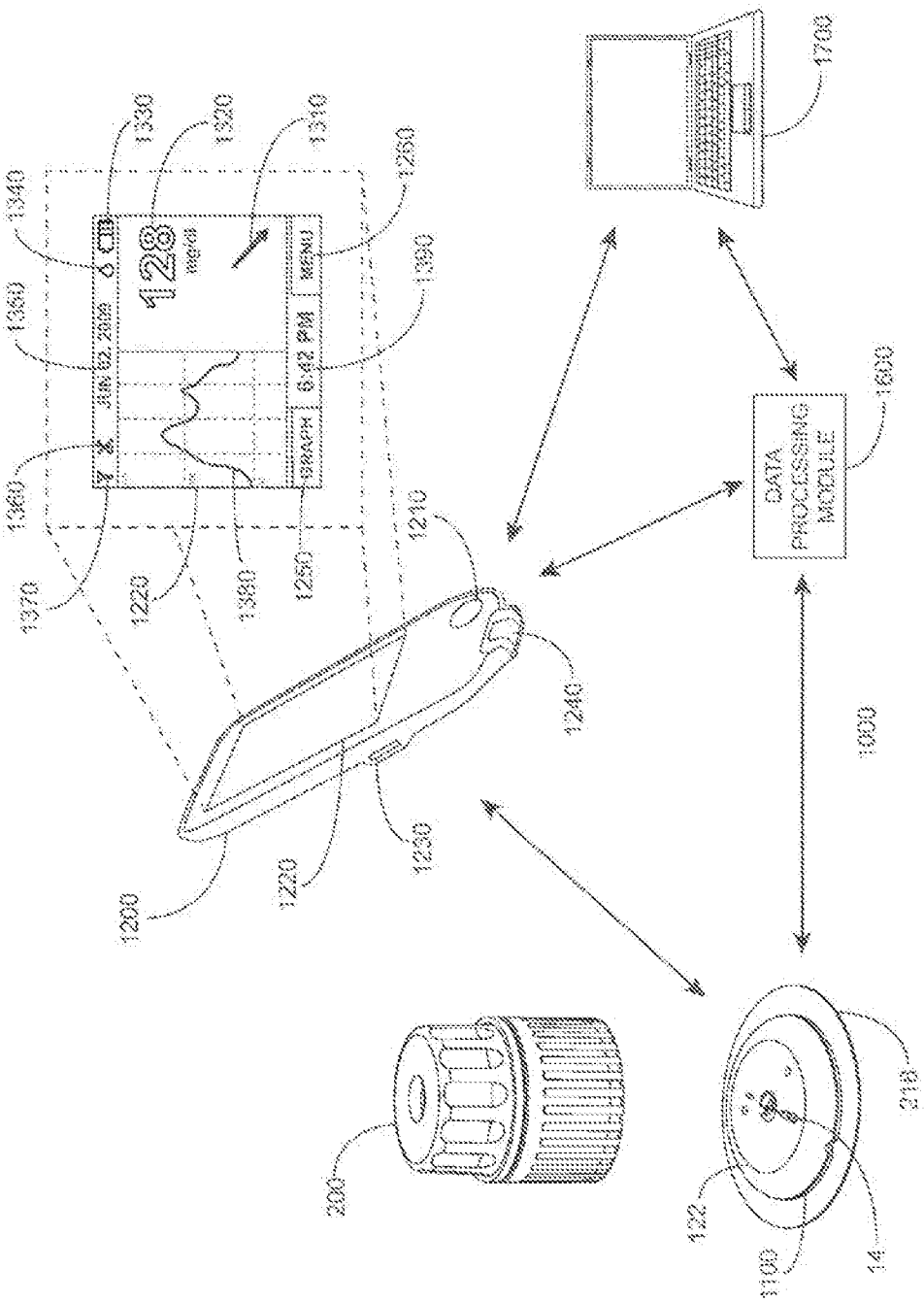
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FIG. 1

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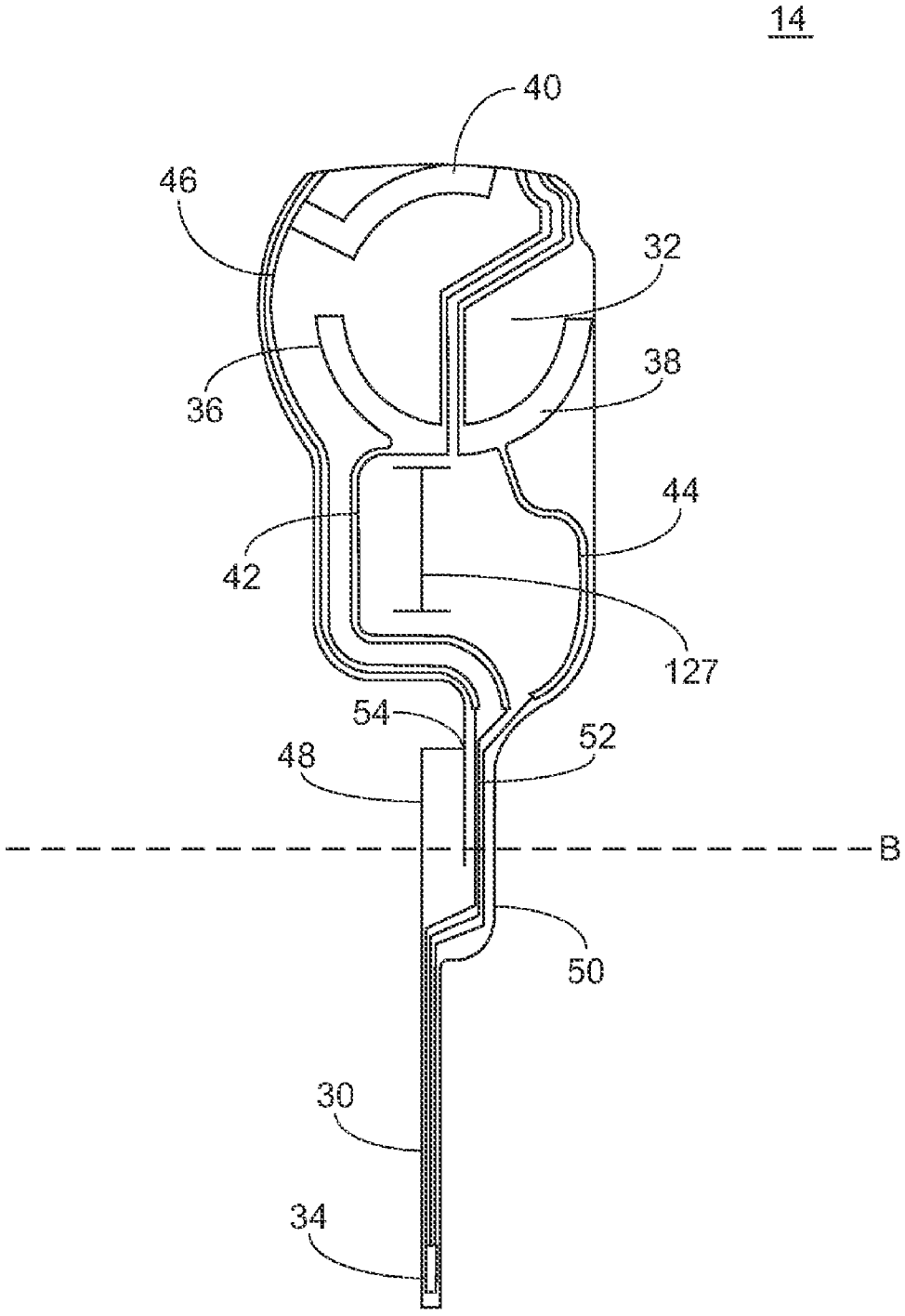

FIG. 2

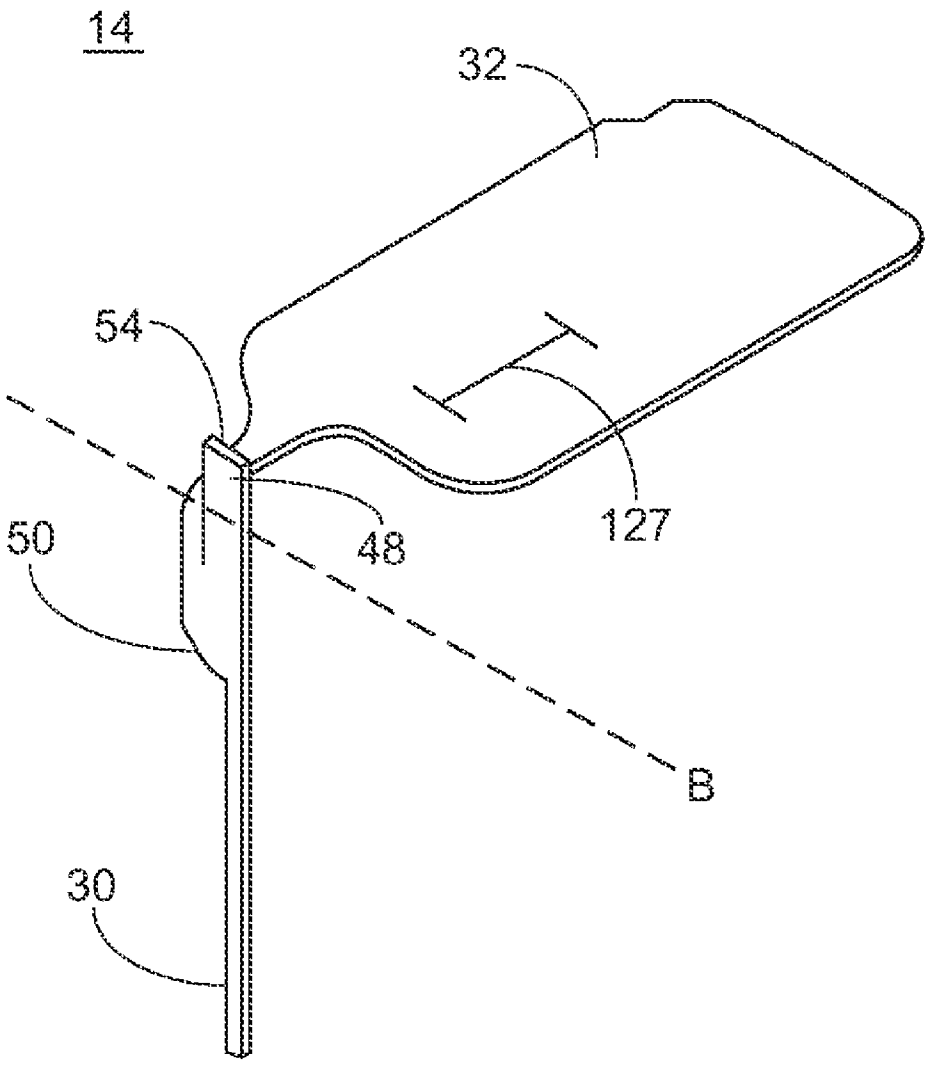

FIG. 3

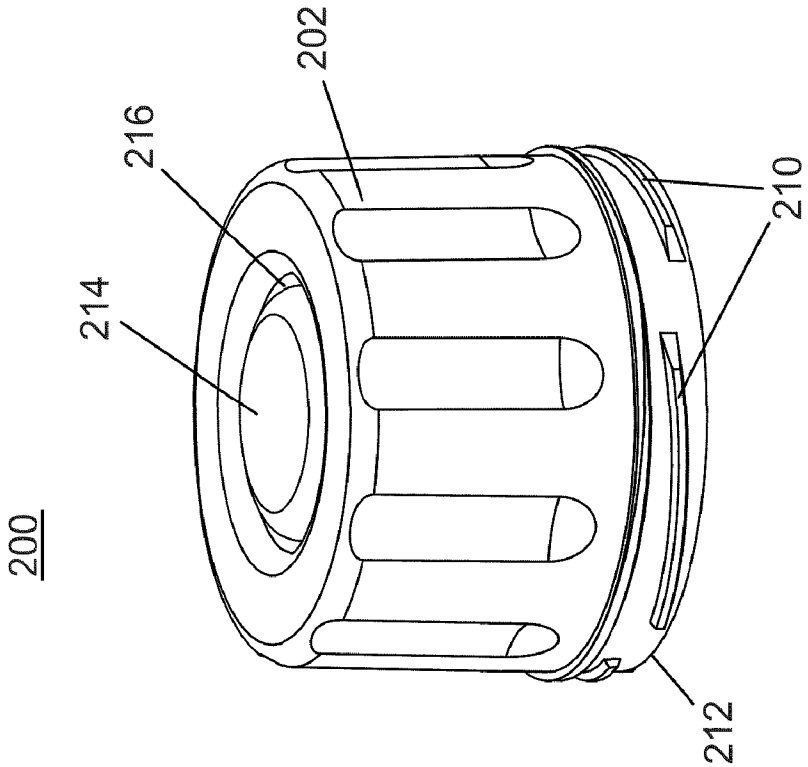

FIG. 5

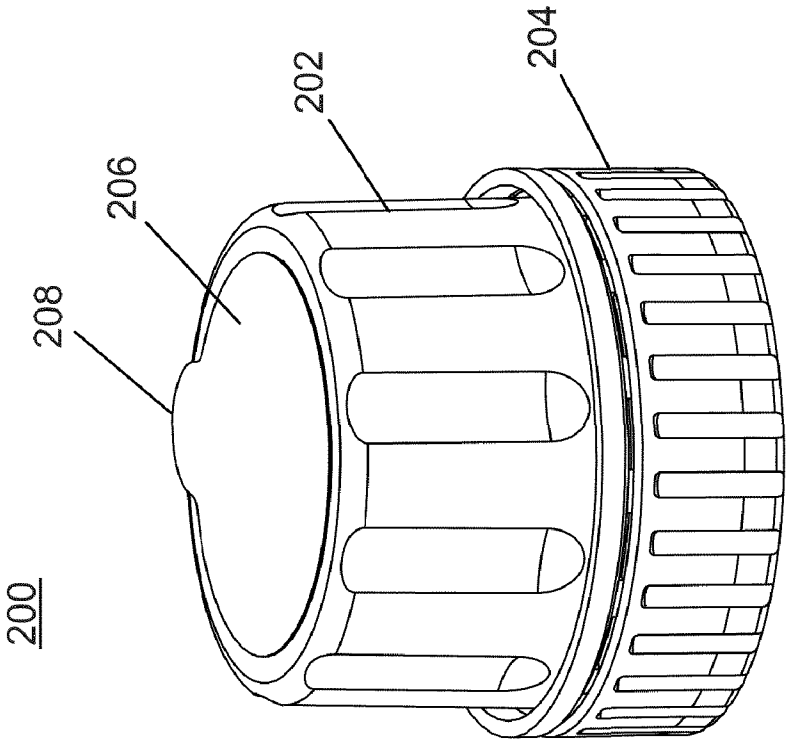

FIG. 4

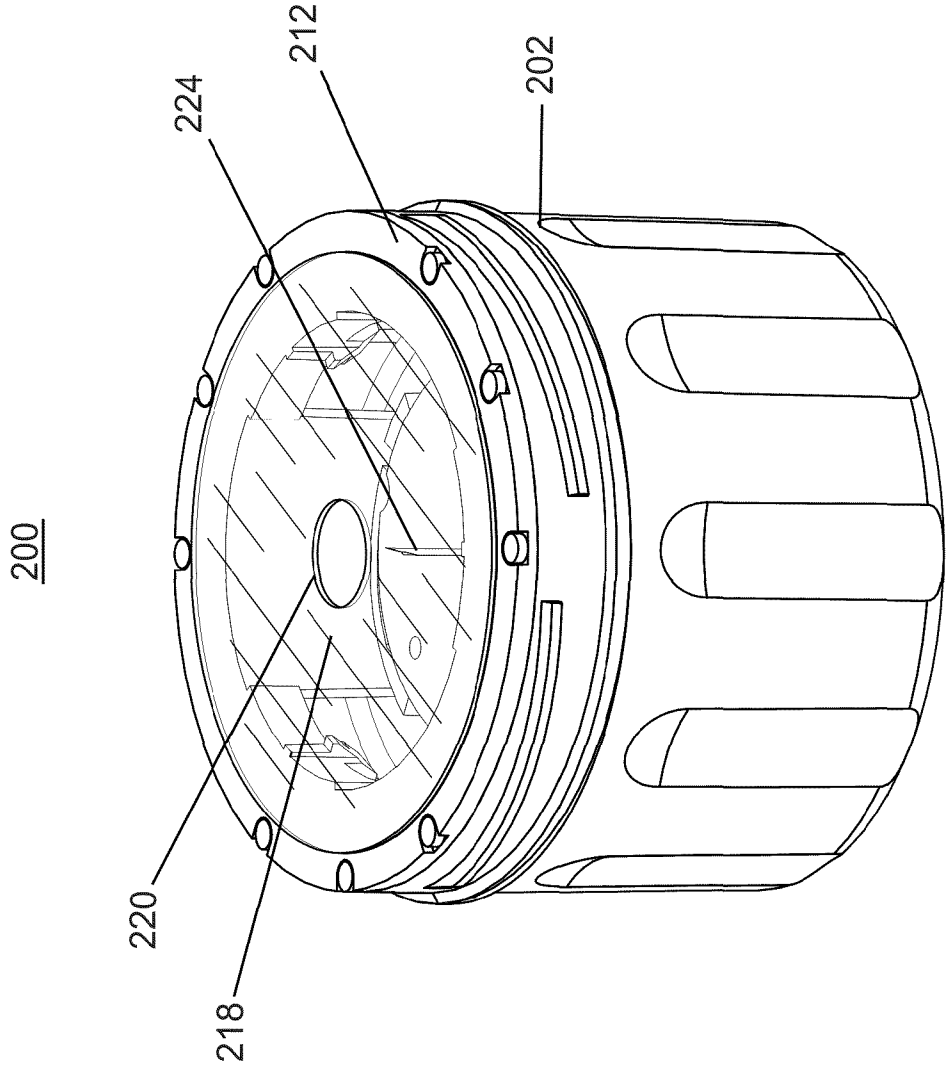

FIG. 6

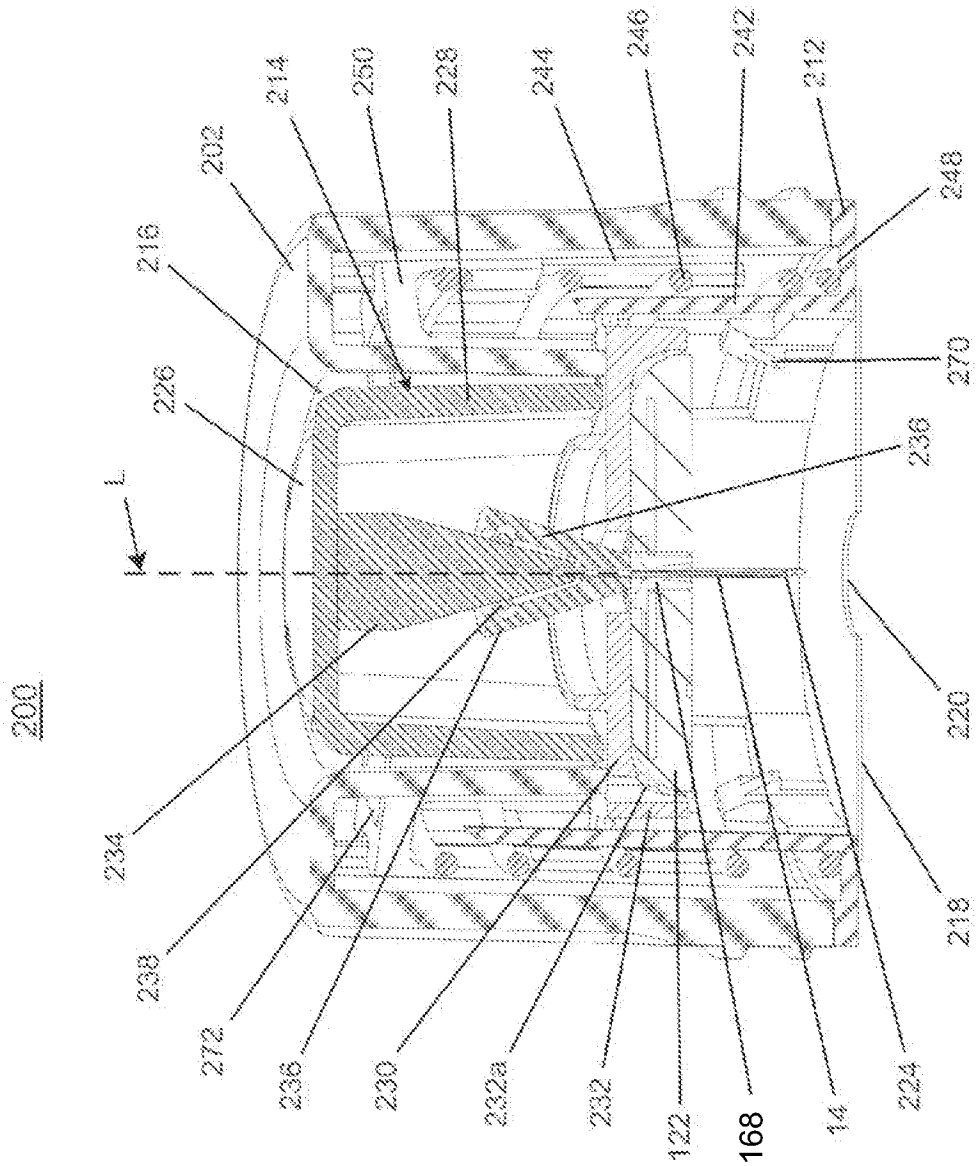
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FIG. 7

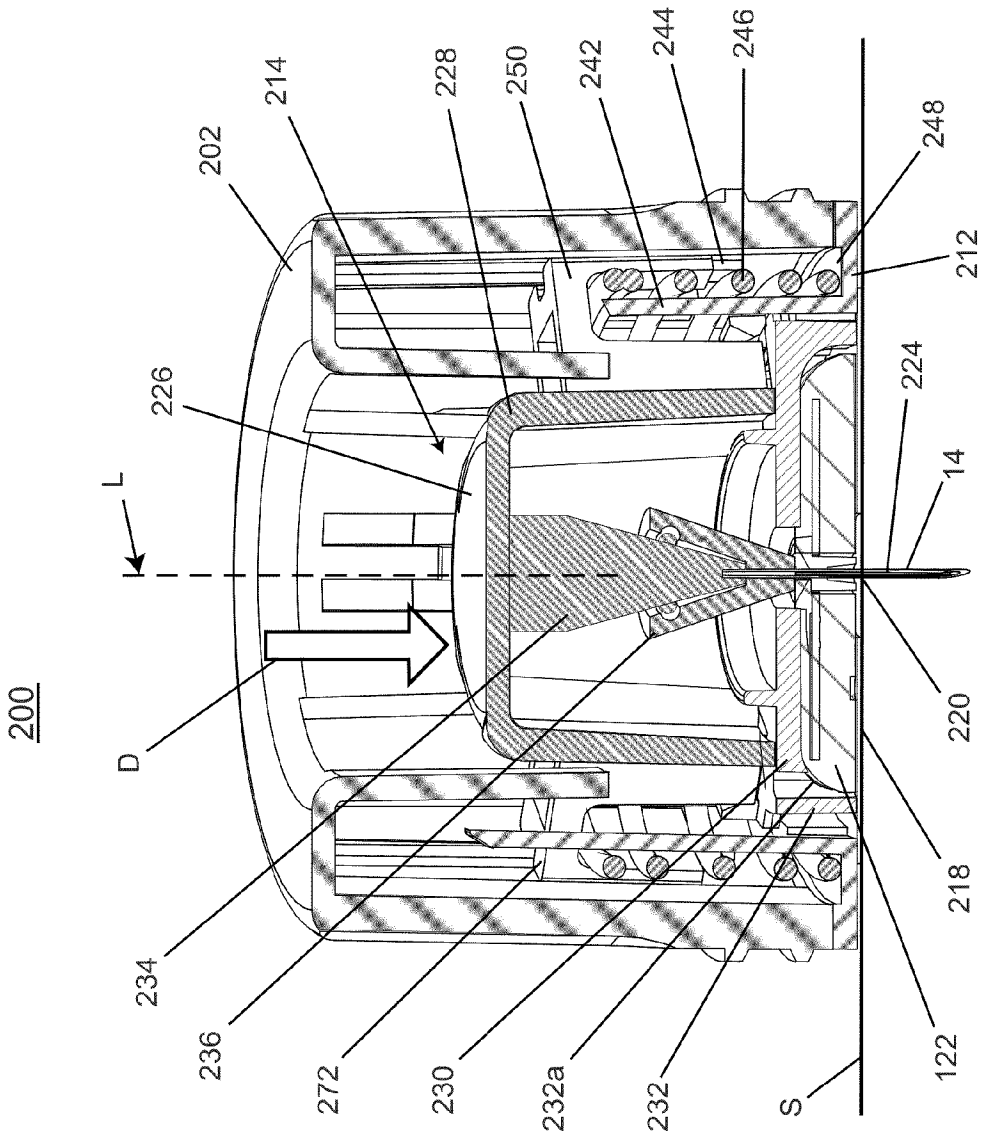
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FIG. 8

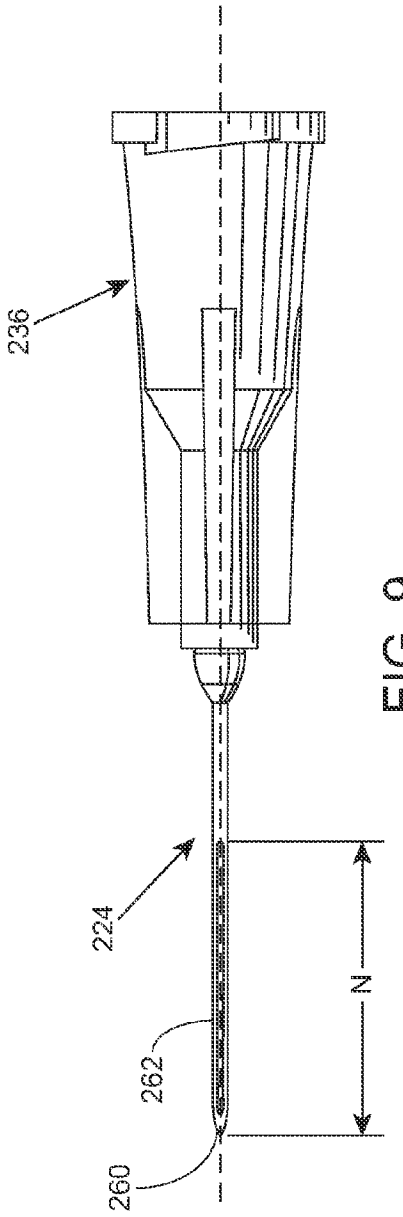

FIG. 9

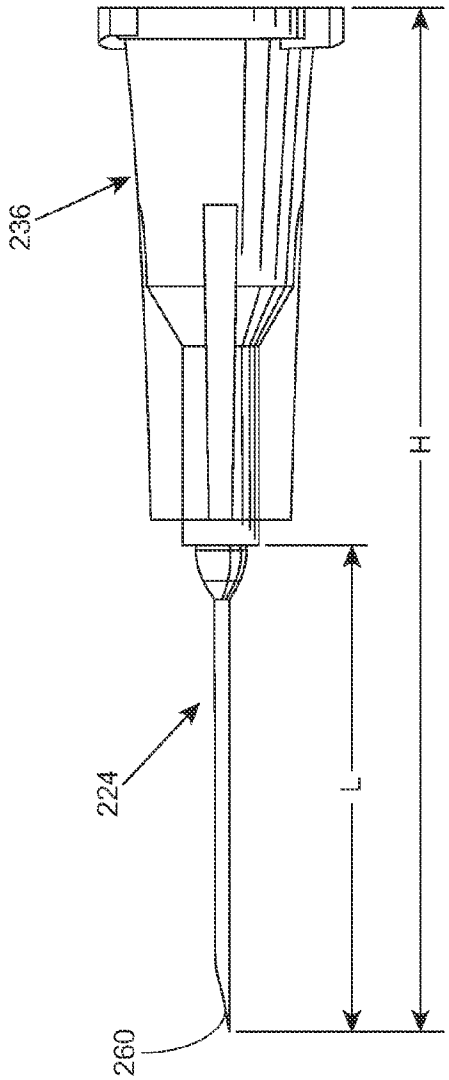

FIG. 10

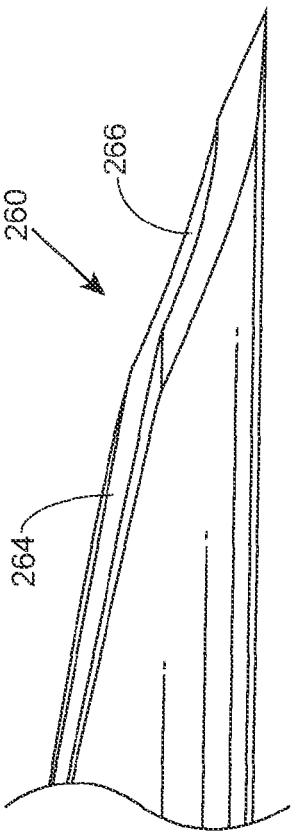

FIG. 12

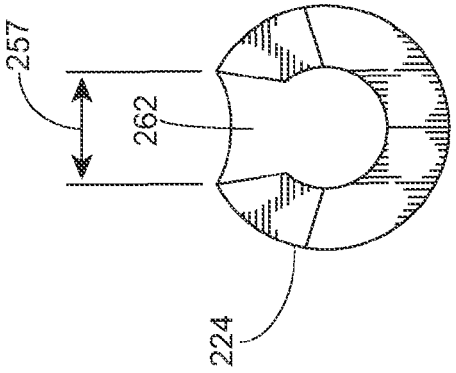

FIG. 11

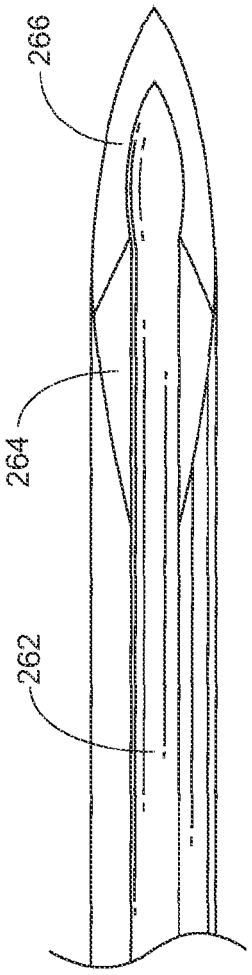

FIG. 13

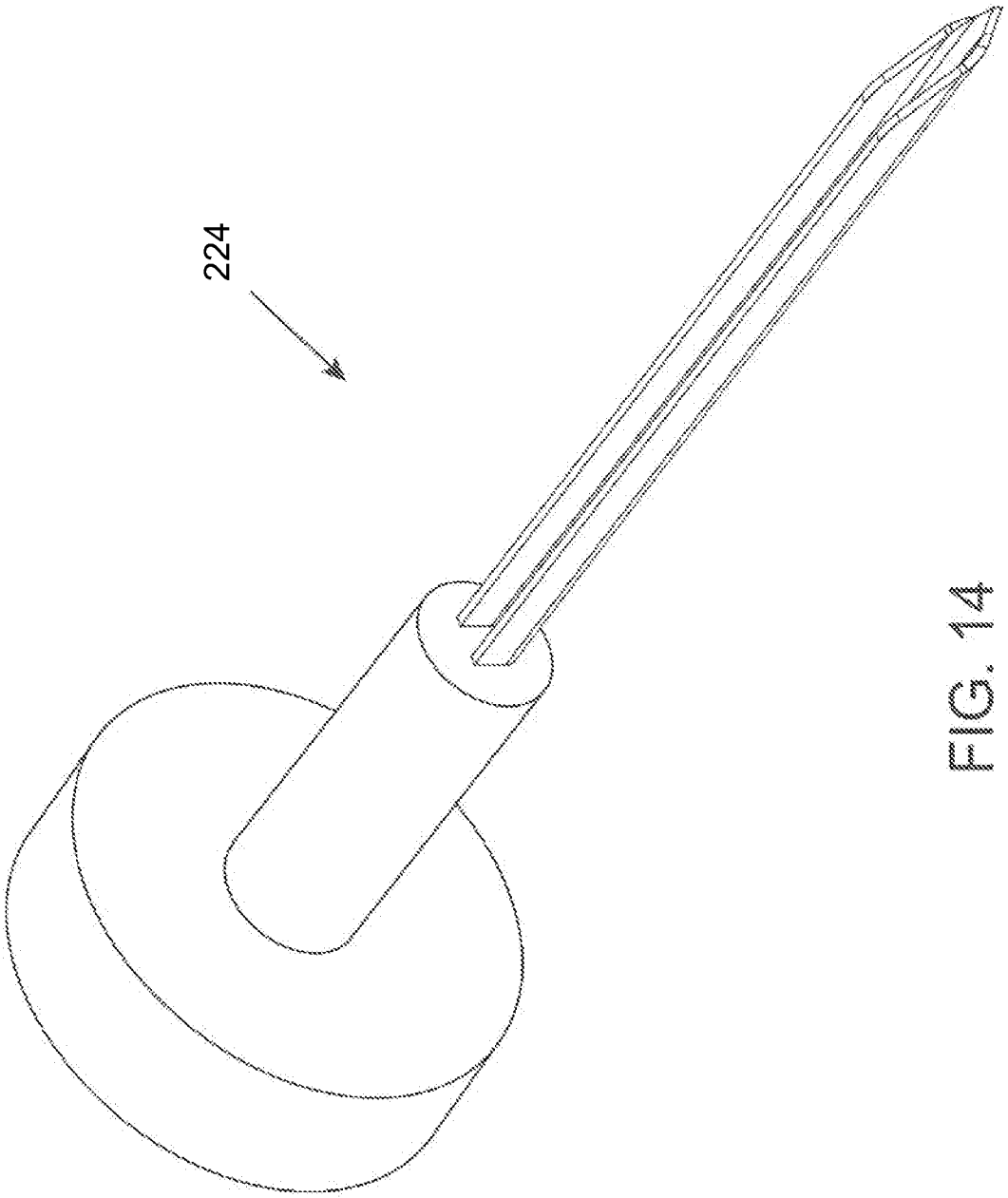

FIG. 14

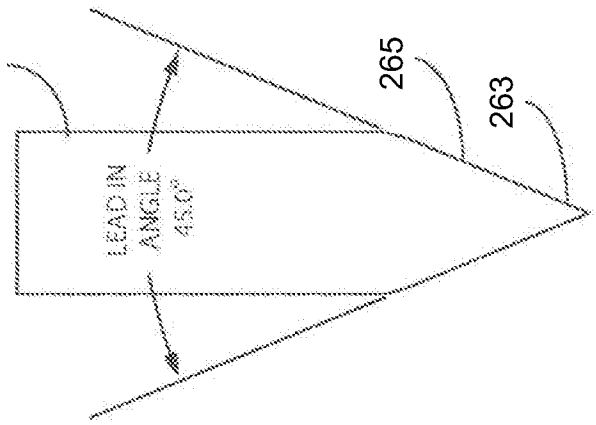

FIG. 14B

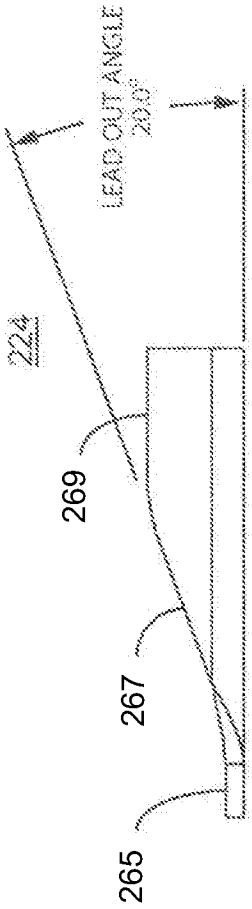

FIG. 14C

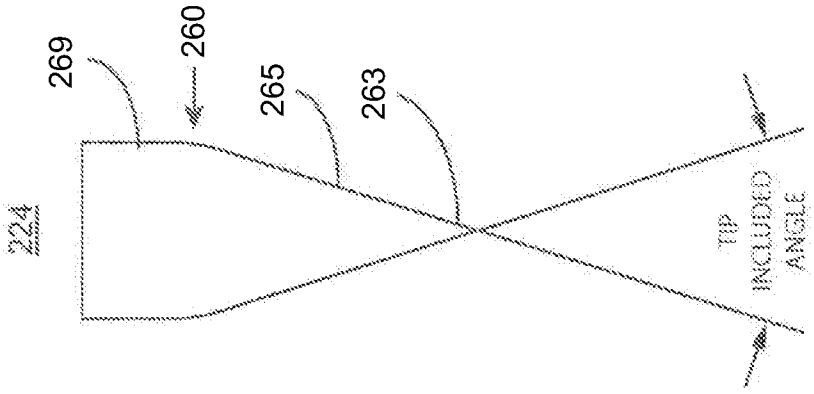

FIG. 14A

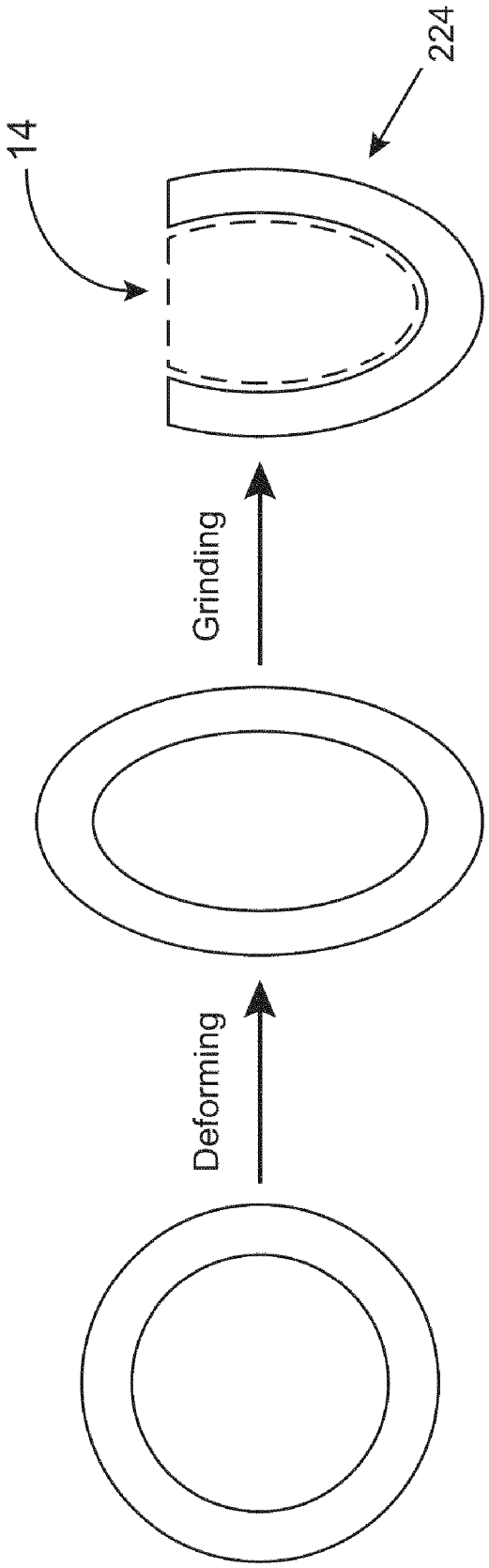

FIG. 15

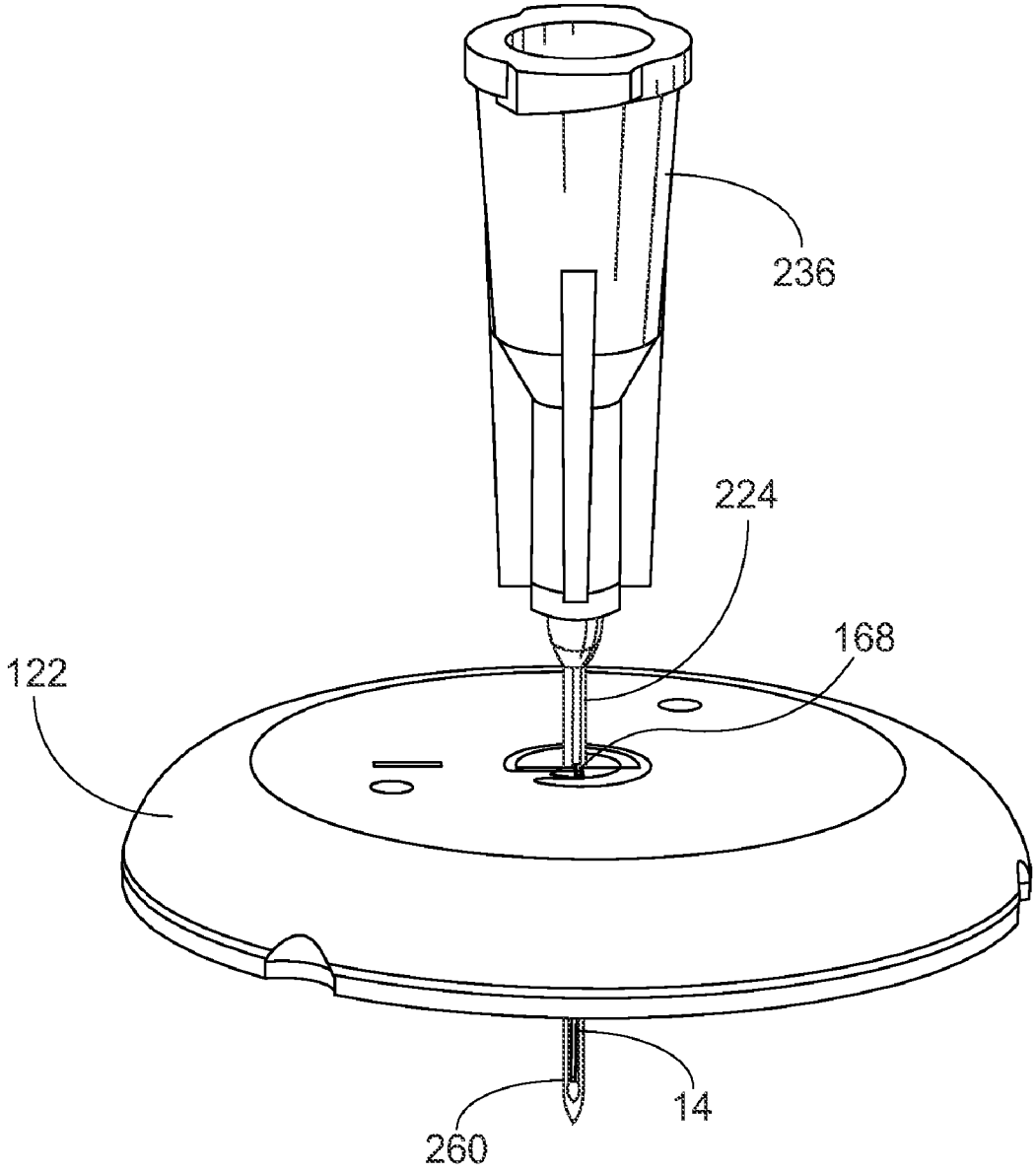

FIG. 16

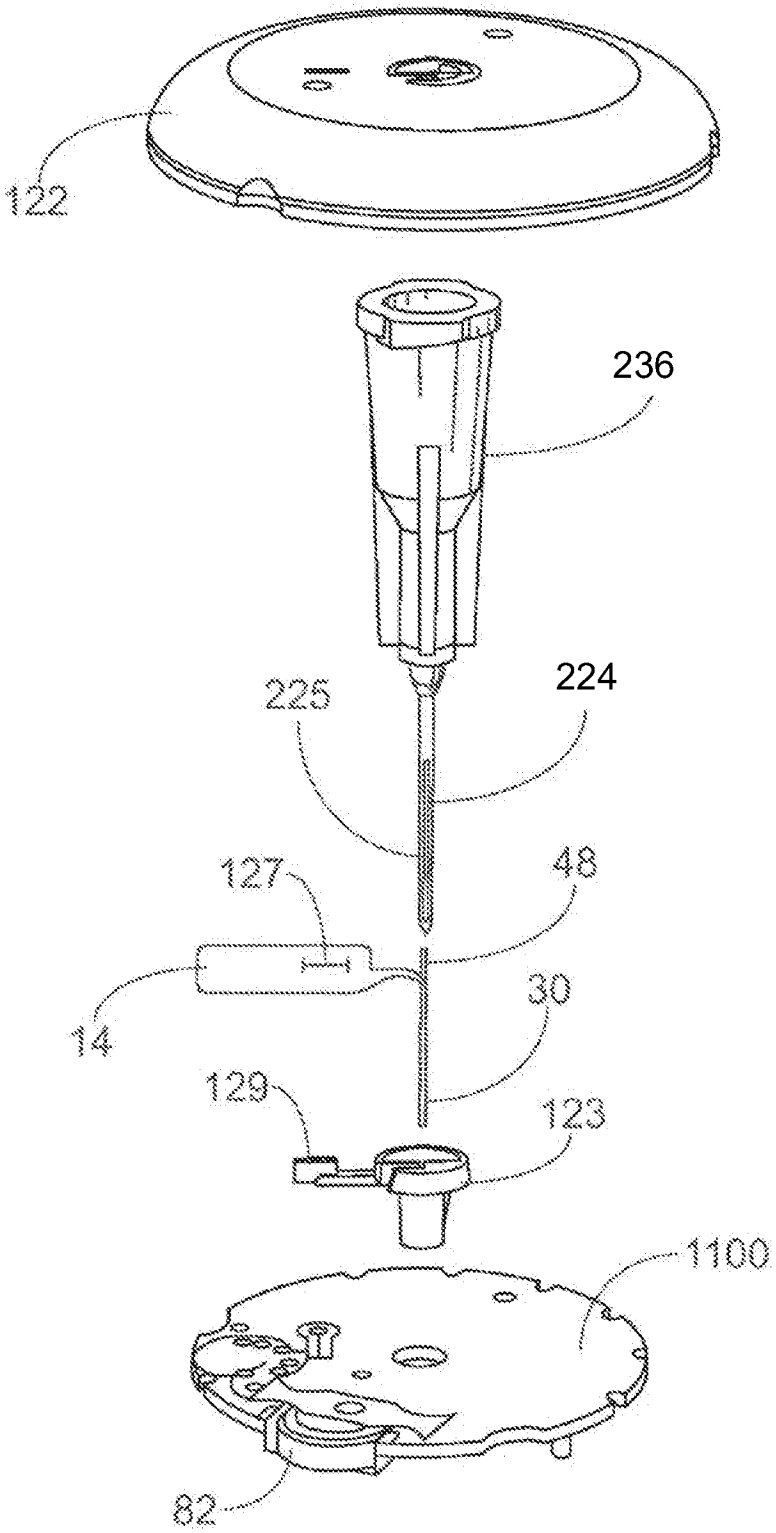

FIG. 17

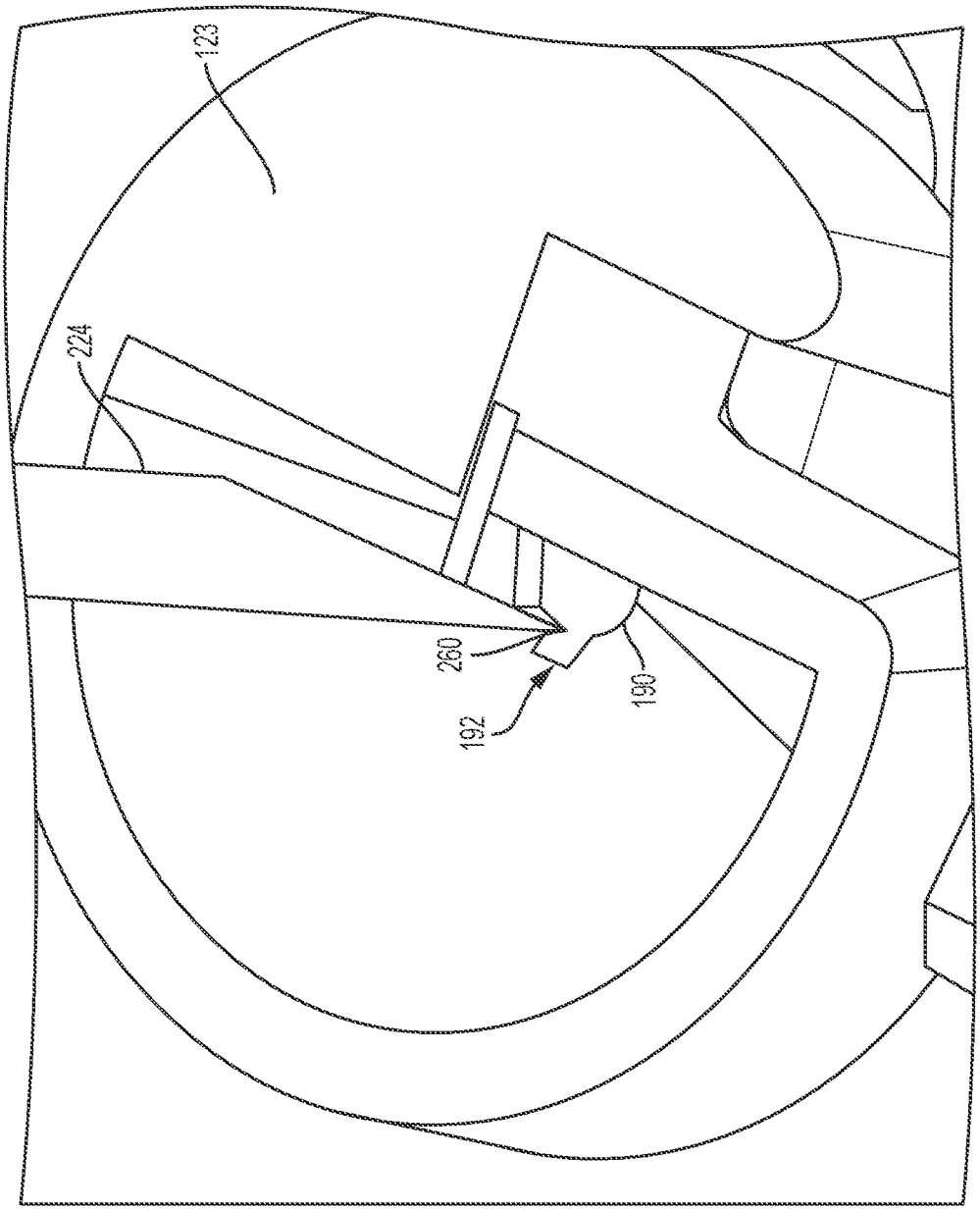

FIG. 17A

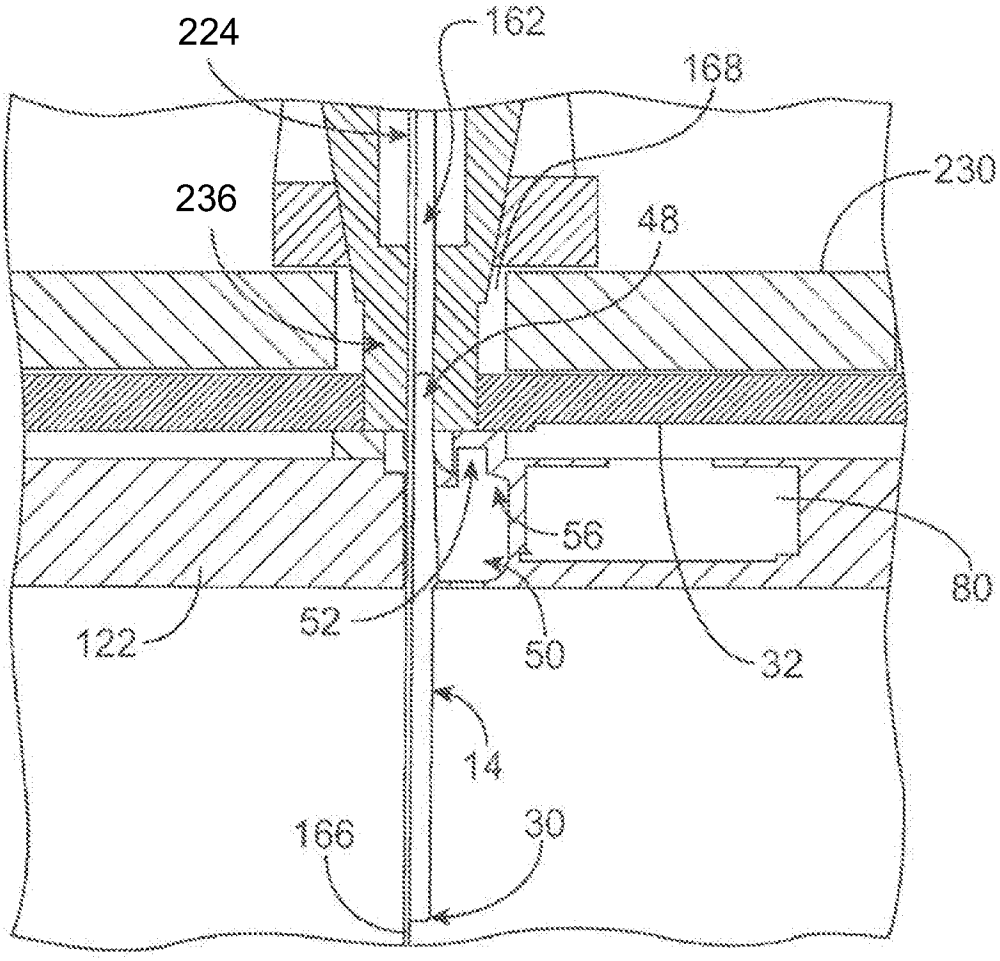

FIG. 18

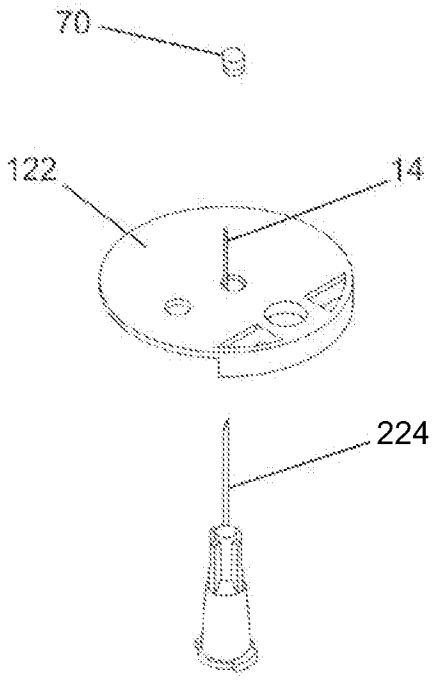

FIG. 19

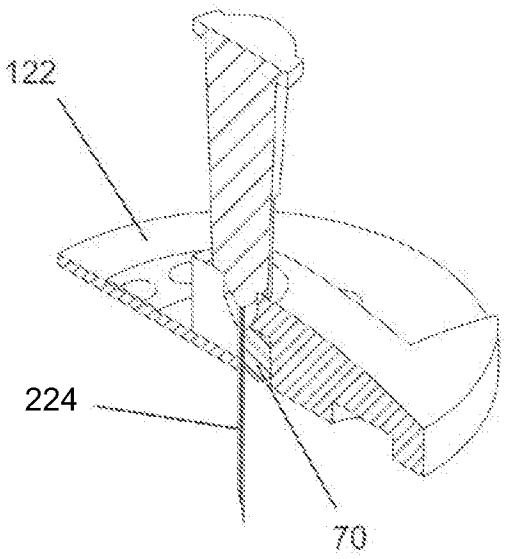

FIG. 20

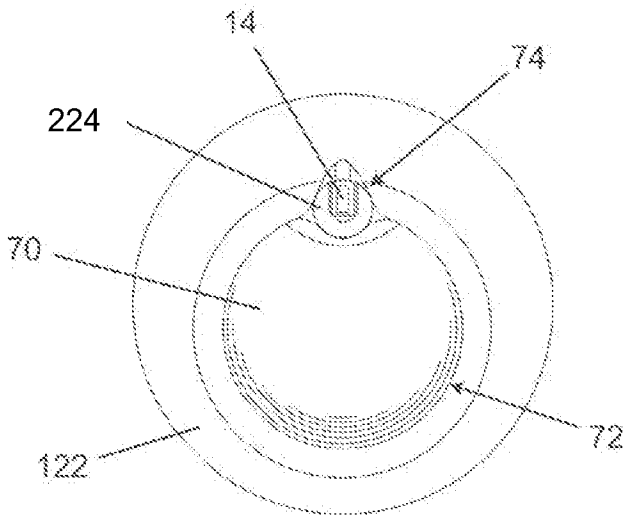

FIG. 21

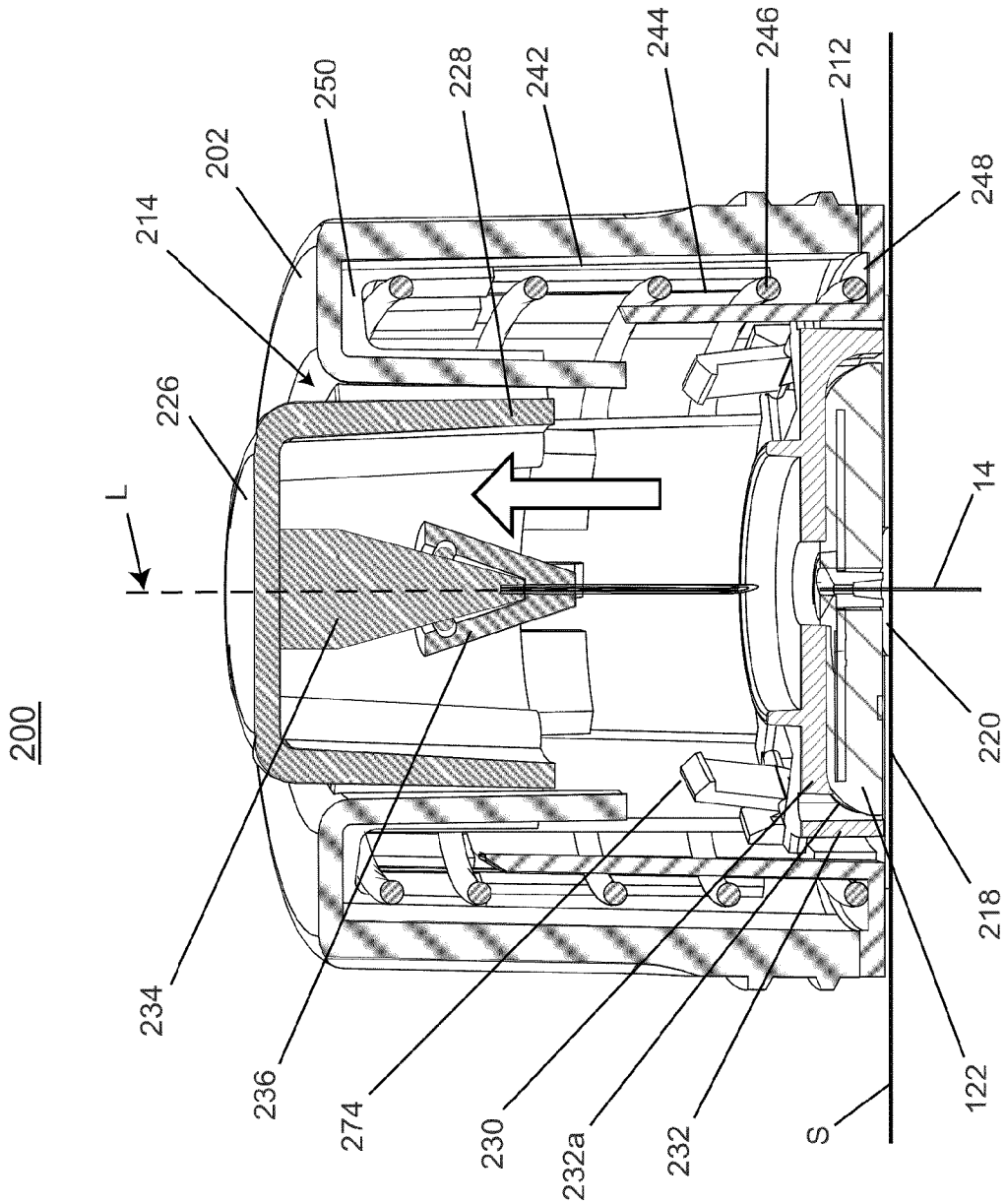
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FIG. 22

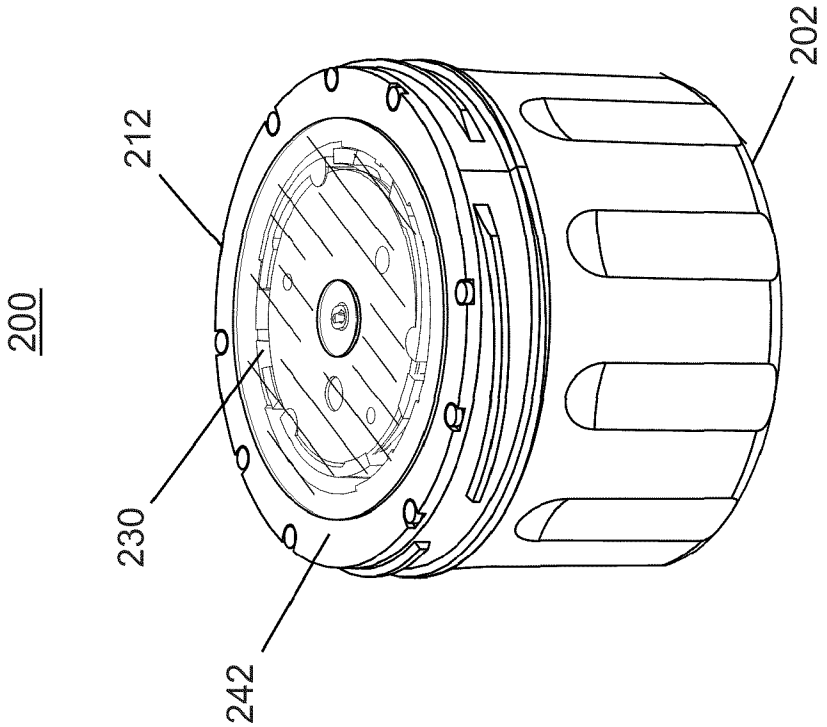

FIG. 24

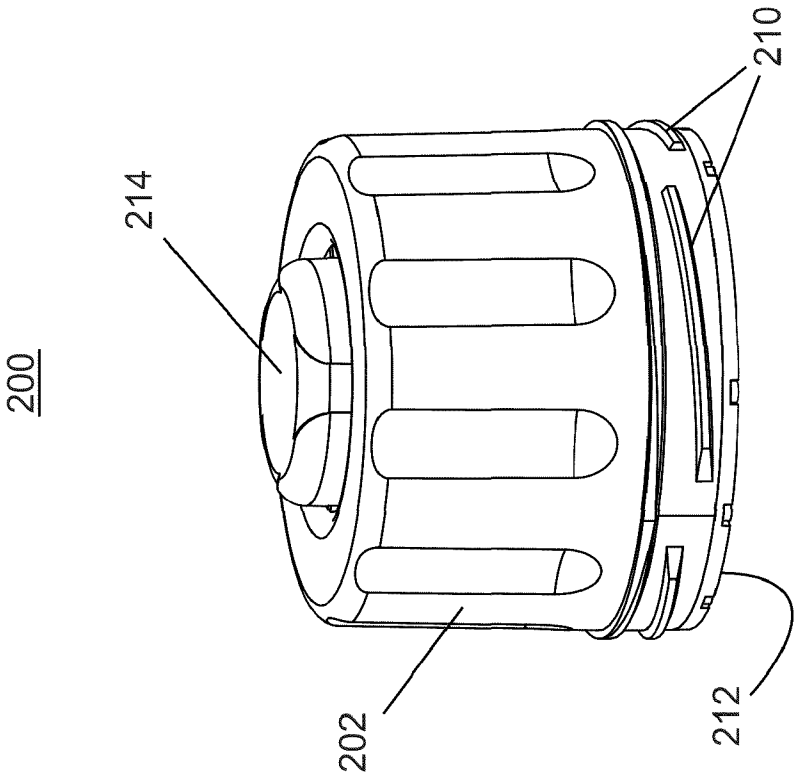

FIG. 23

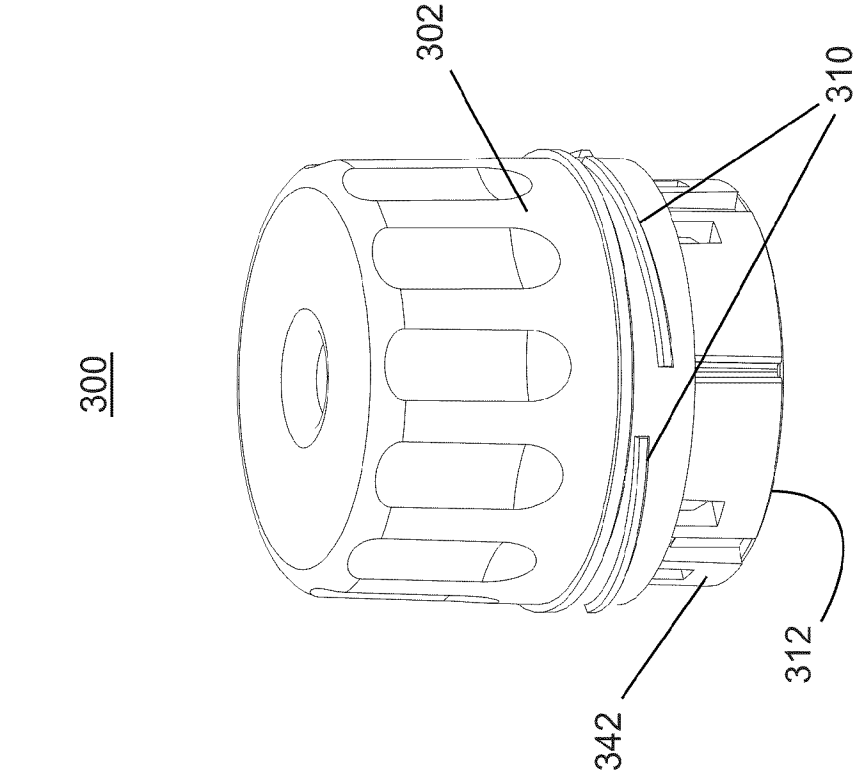

FIG. 26

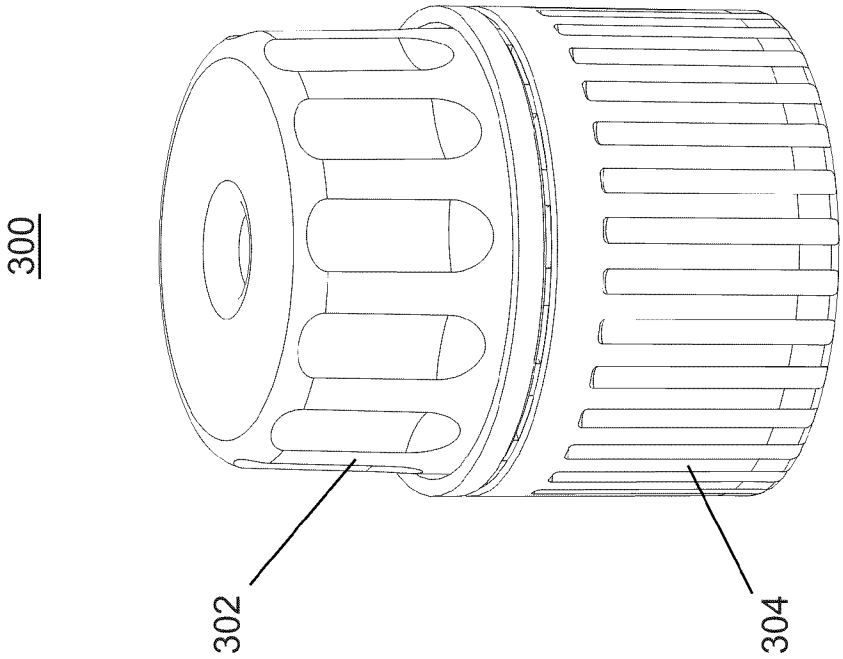

FIG. 25

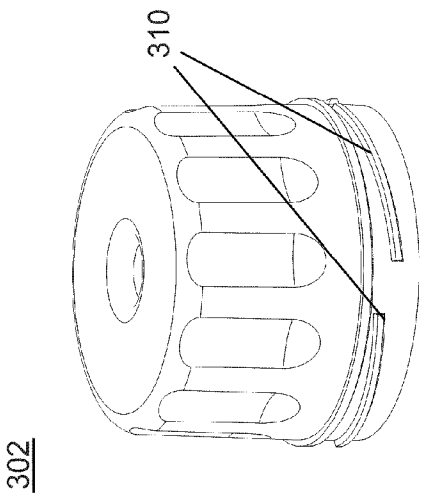

FIG. 27

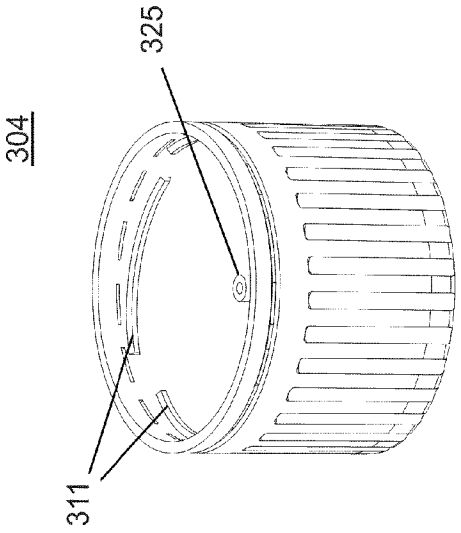

FIG. 29

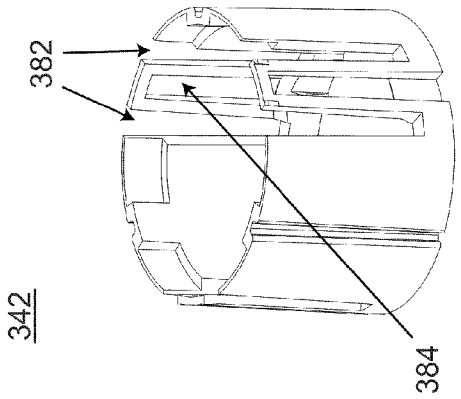

FIG. 28

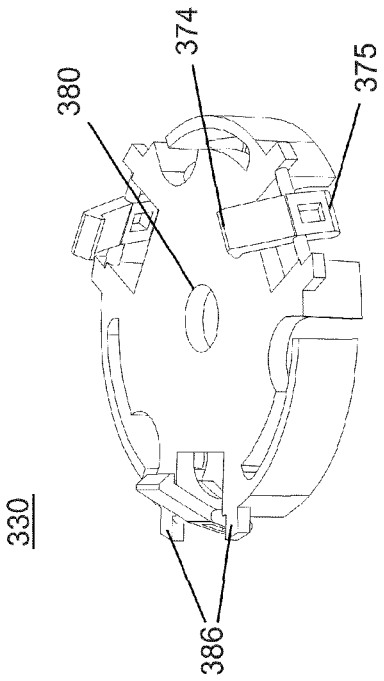

FIG. 30

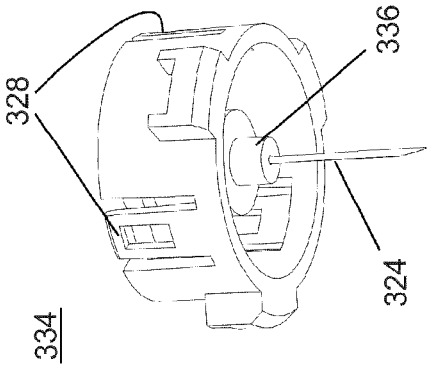

FIG. 32

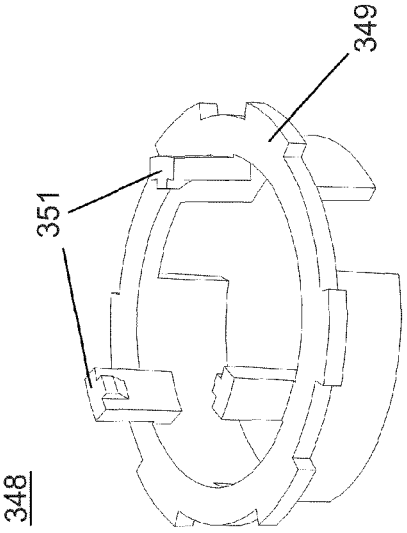

FIG. 31

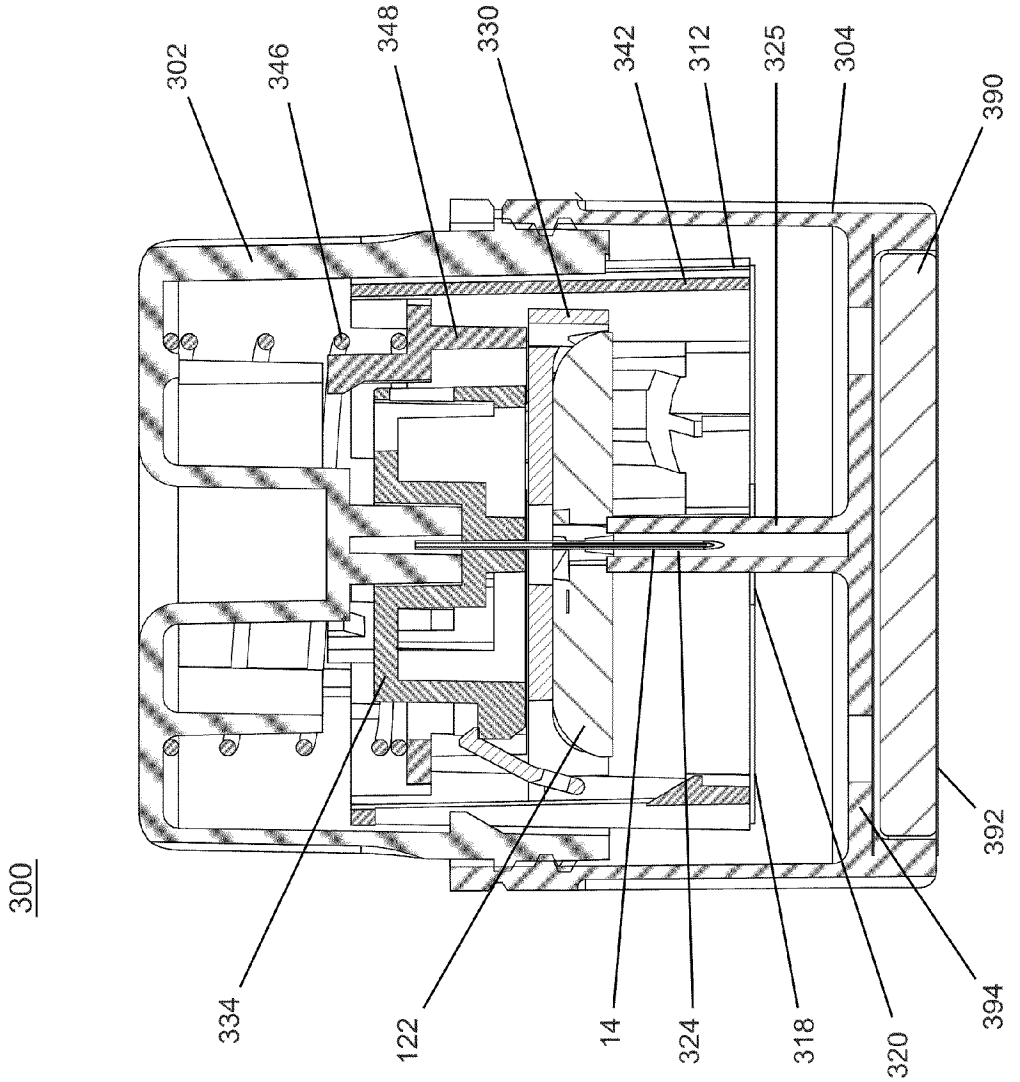
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FIG. 33

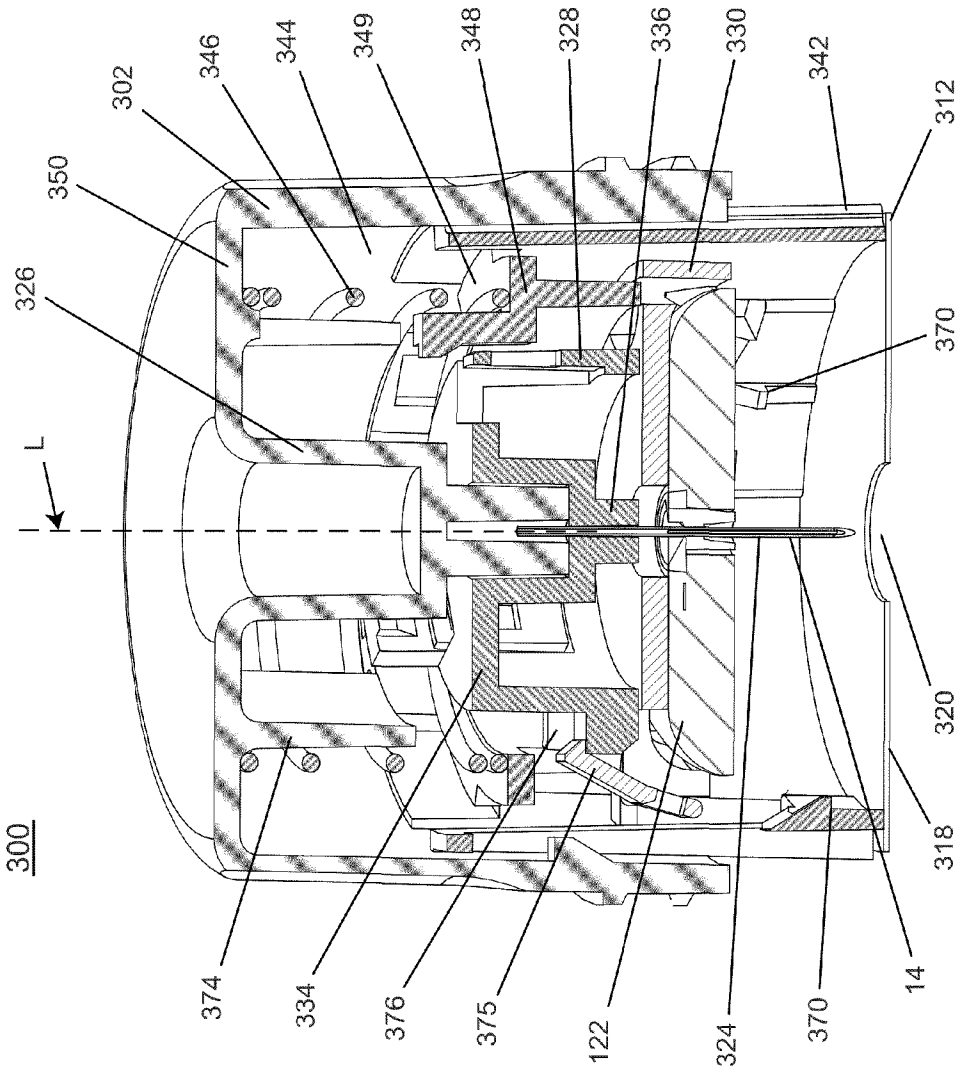
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FIG. 34

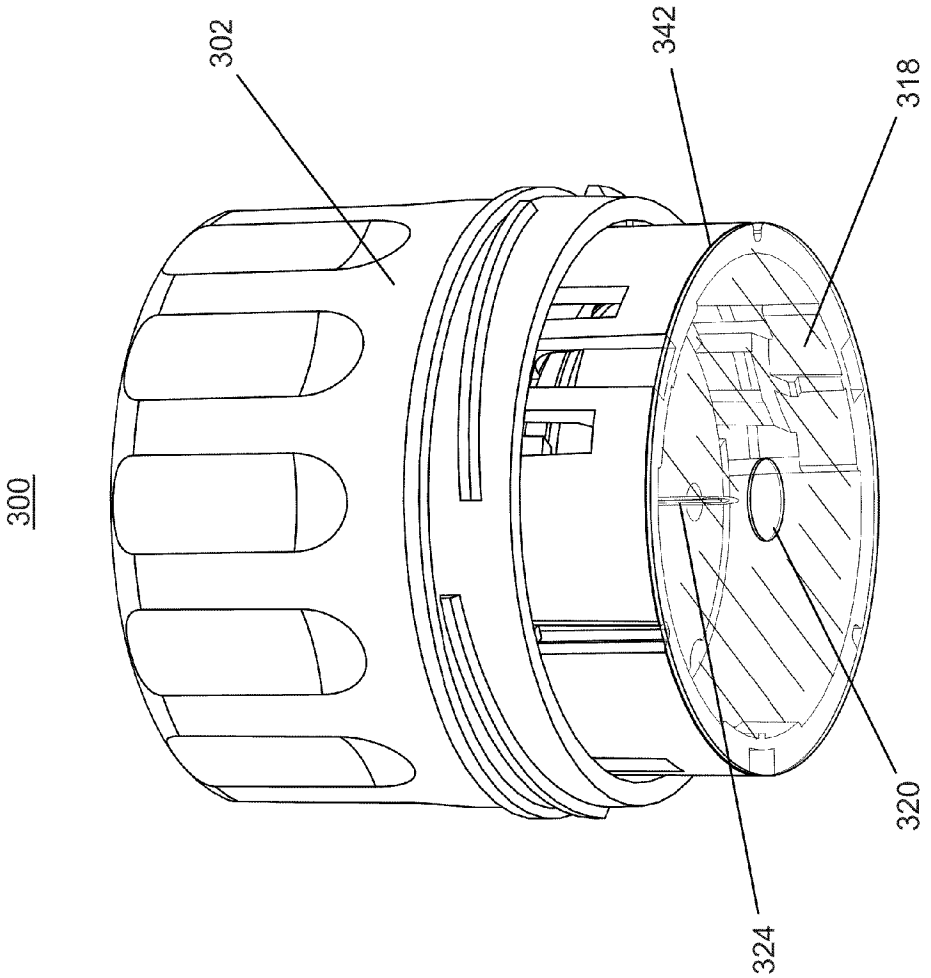

FIG. 35

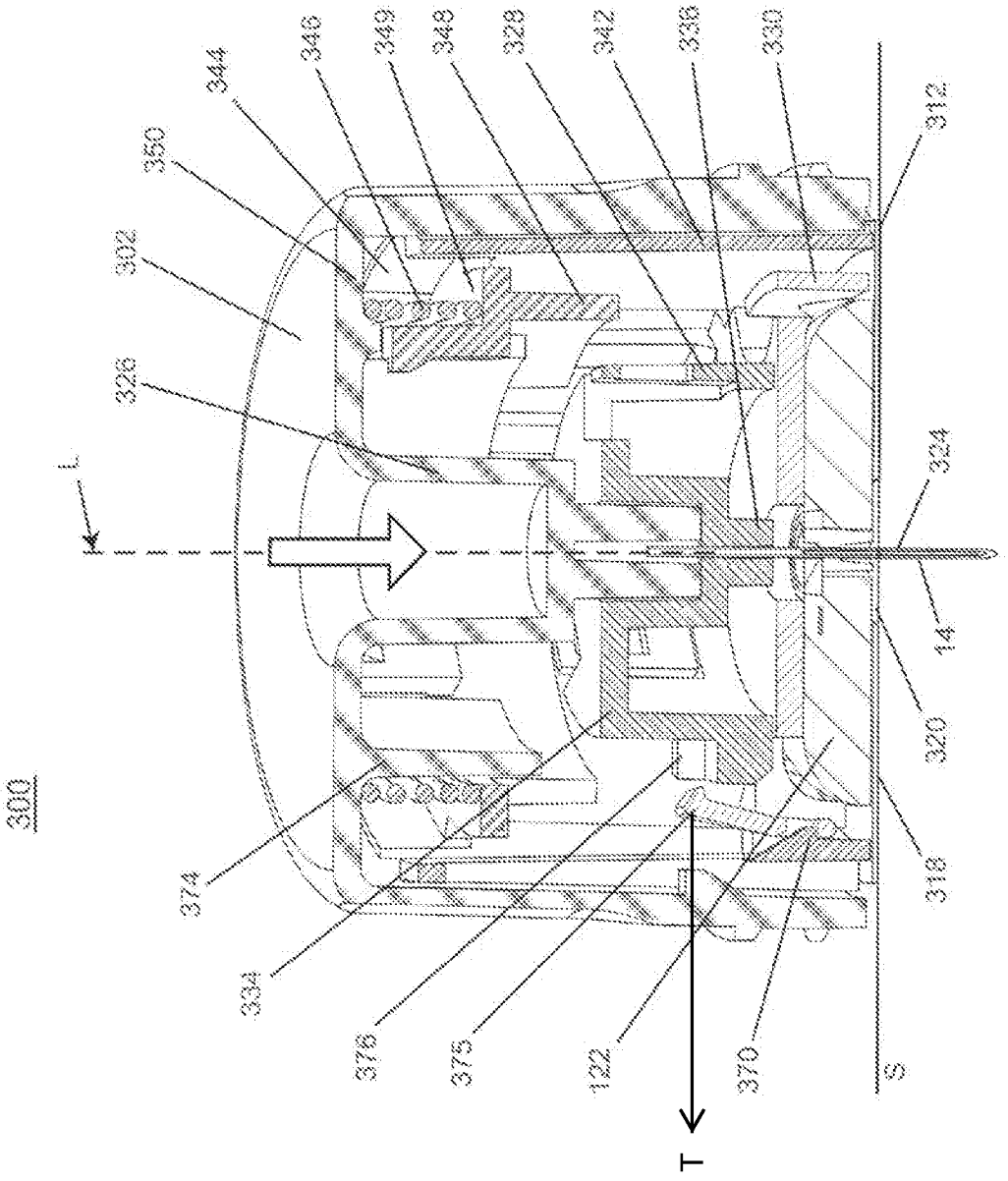
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FIG. 36

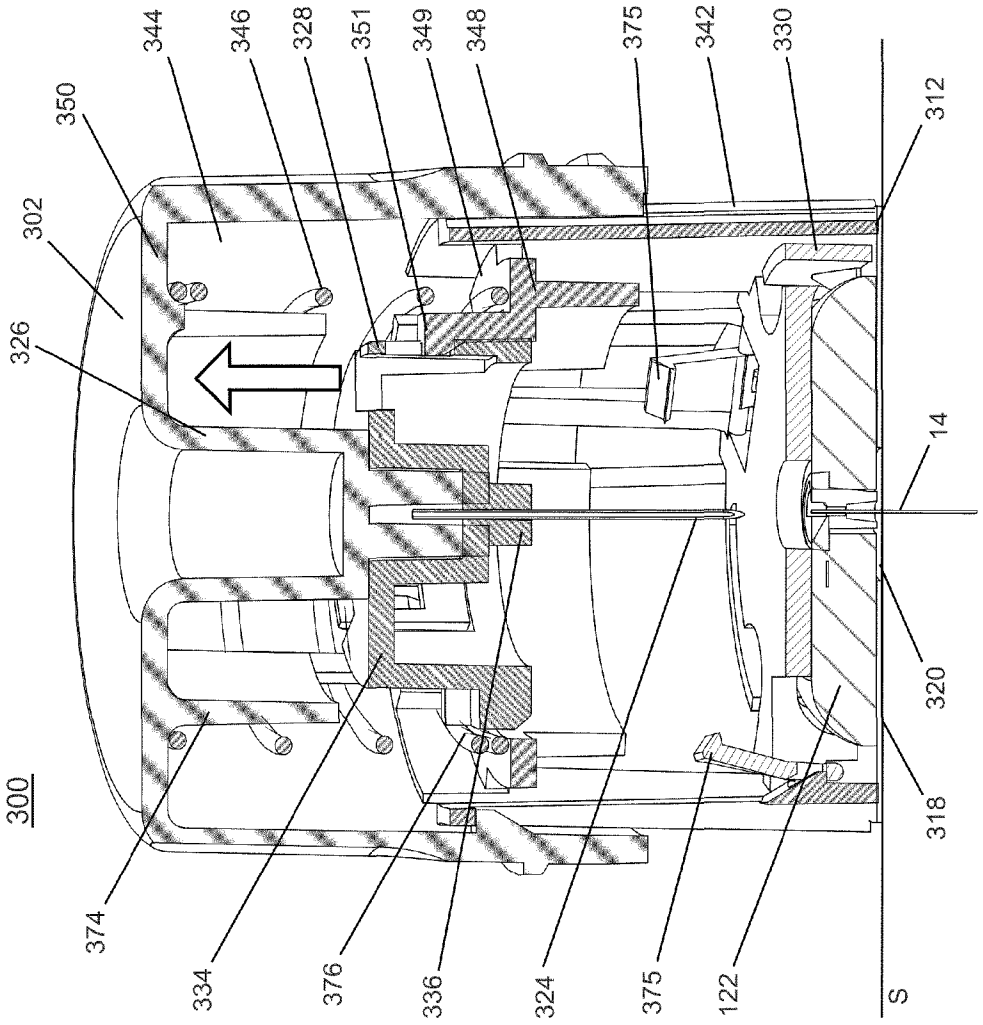
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FIG. 37

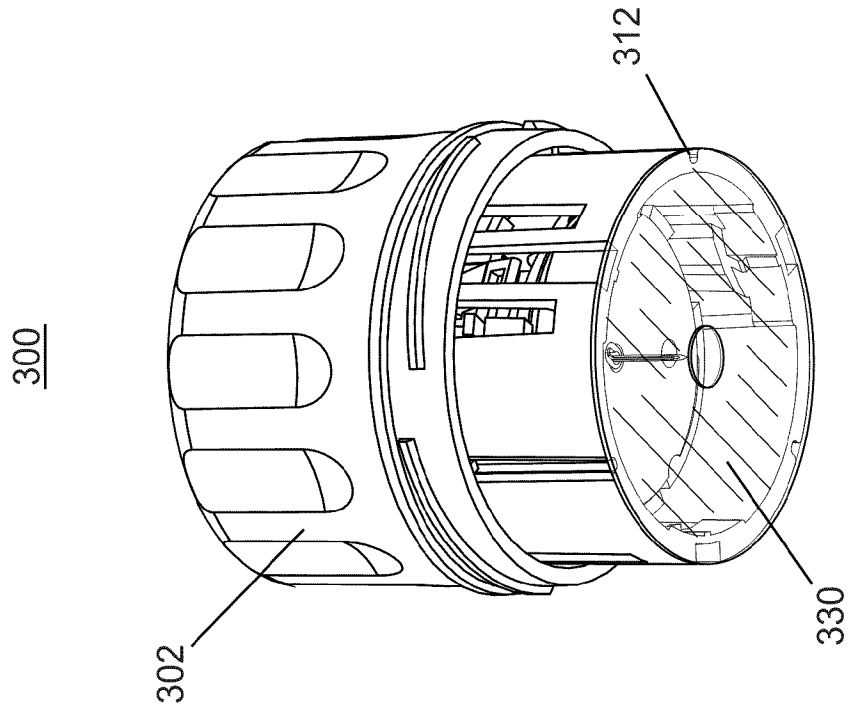

FIG. 39

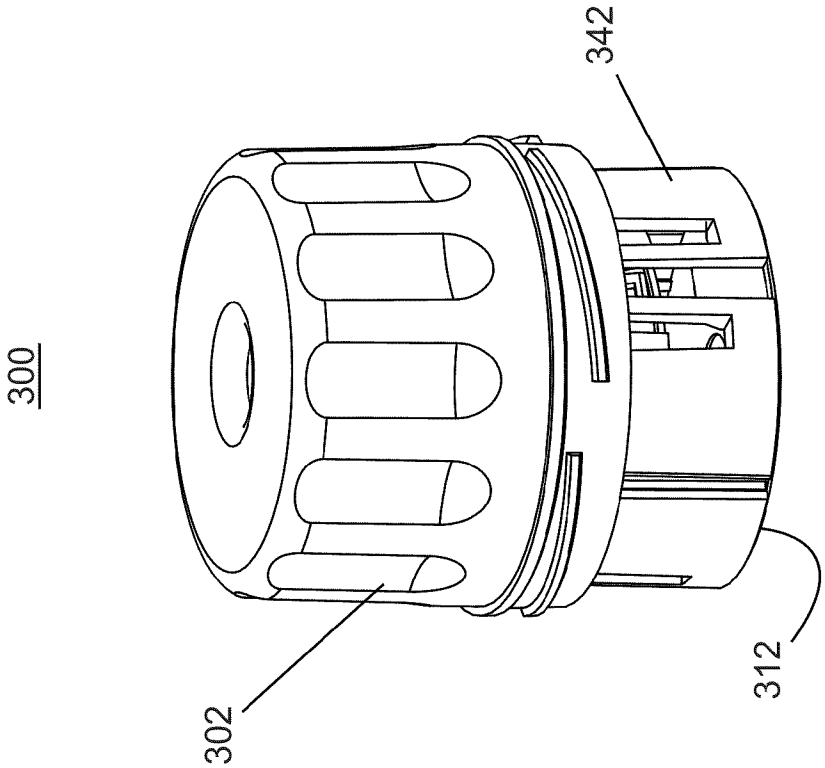

FIG. 38

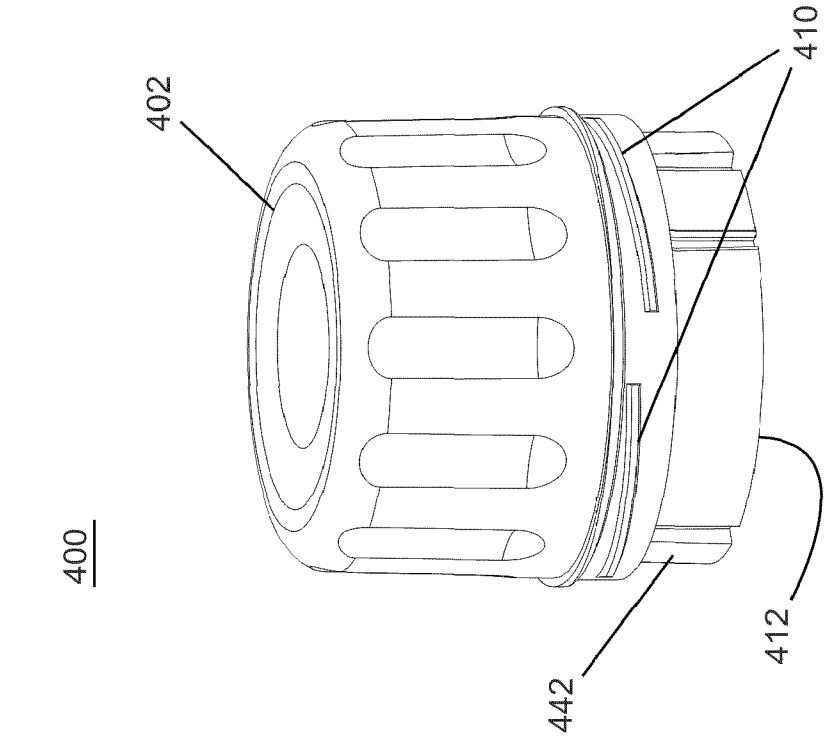

FIG. 41

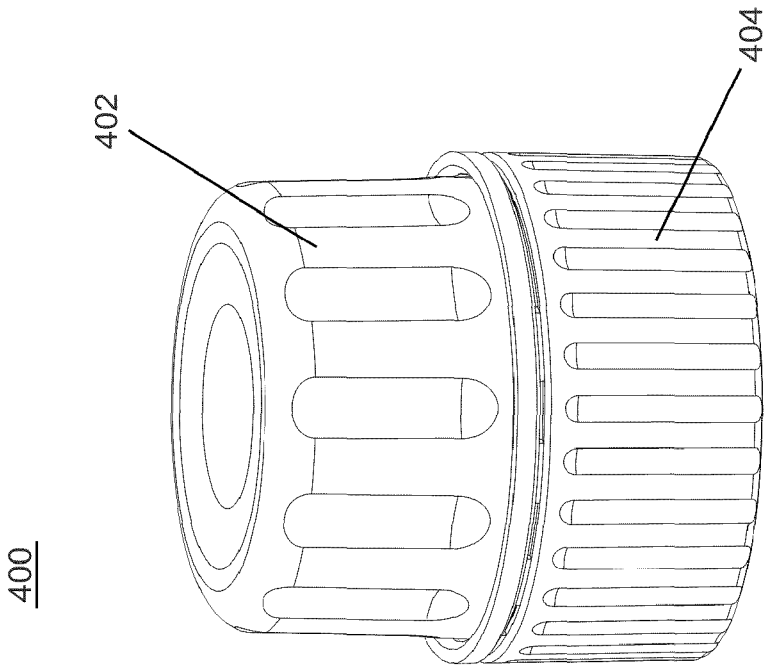

FIG. 40

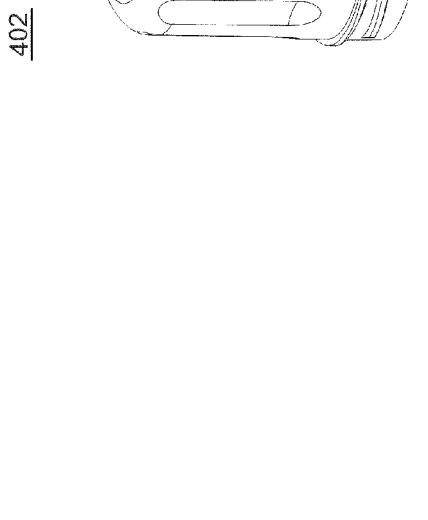

FIG. 42

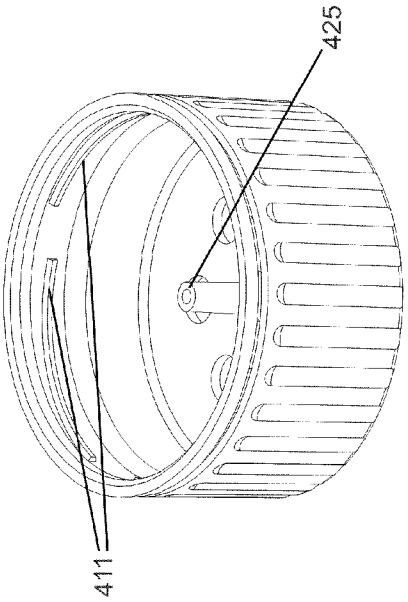

FIG. 44

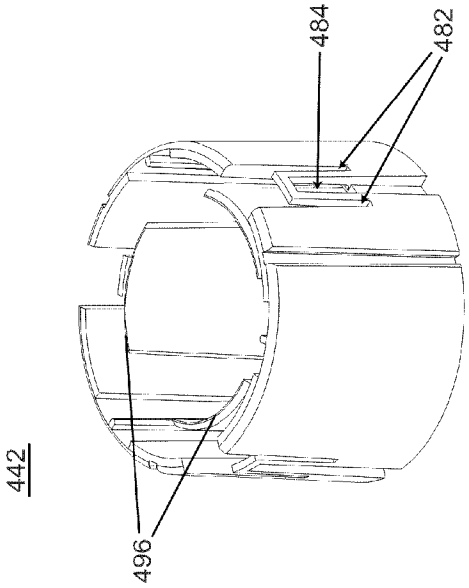

FIG. 43

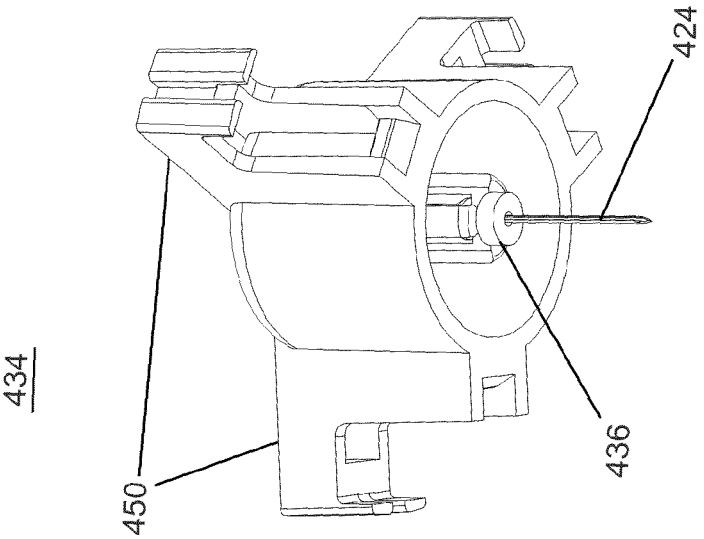

FIG. 46

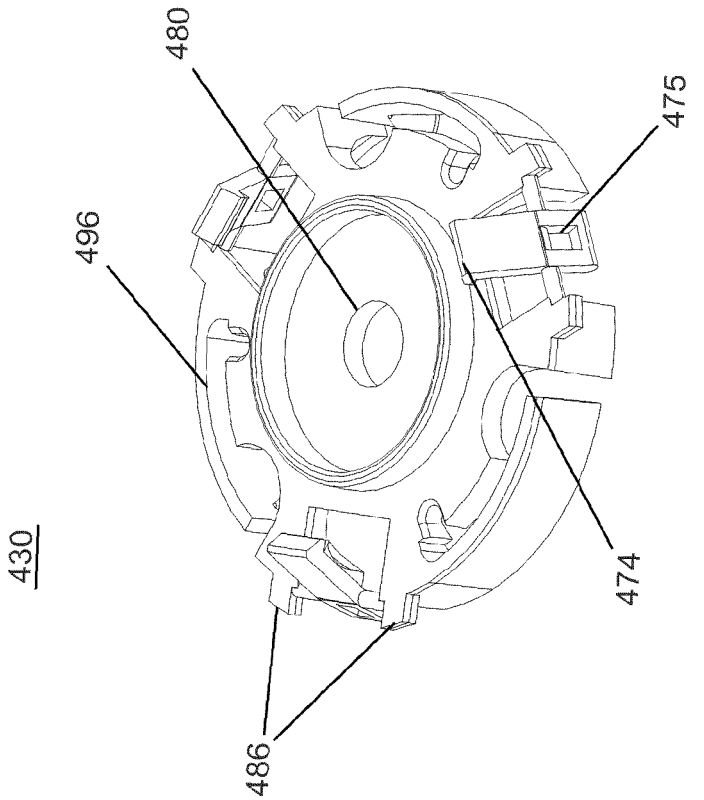

FIG. 45

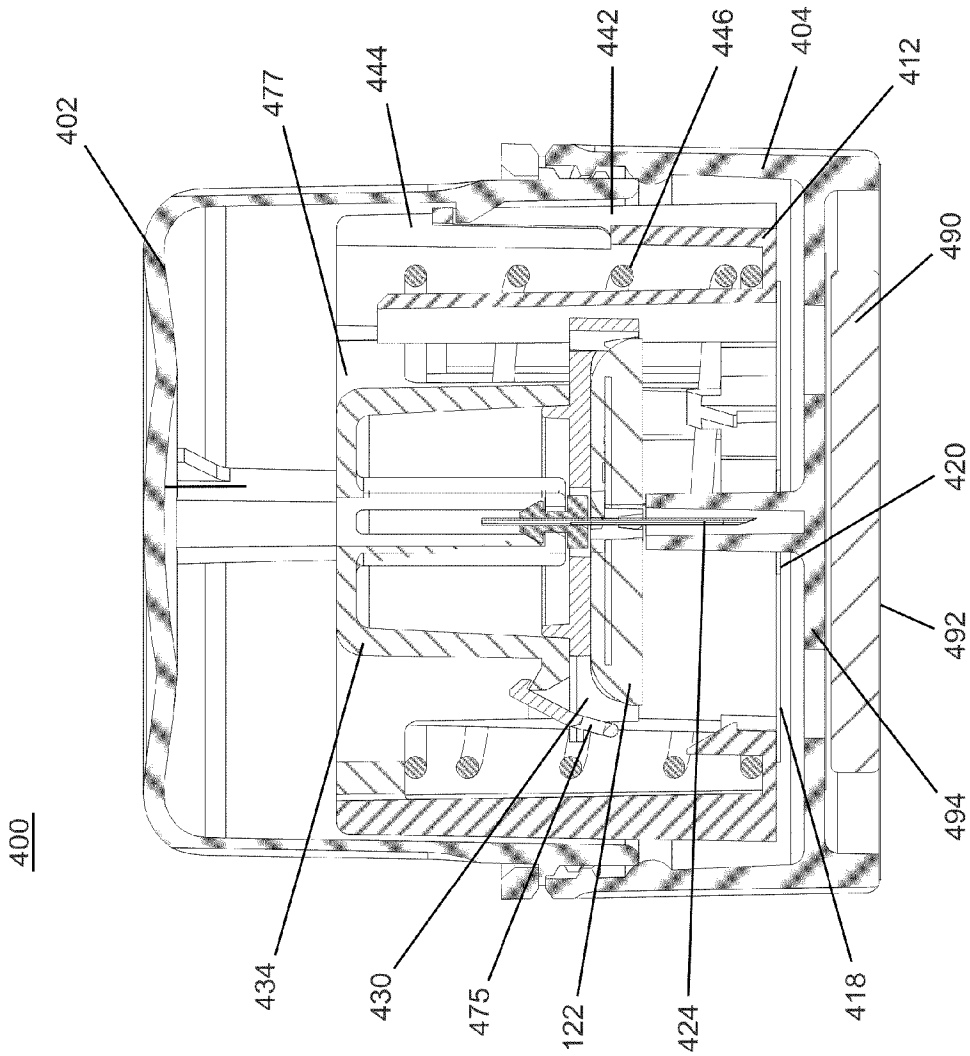
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FIG. 47

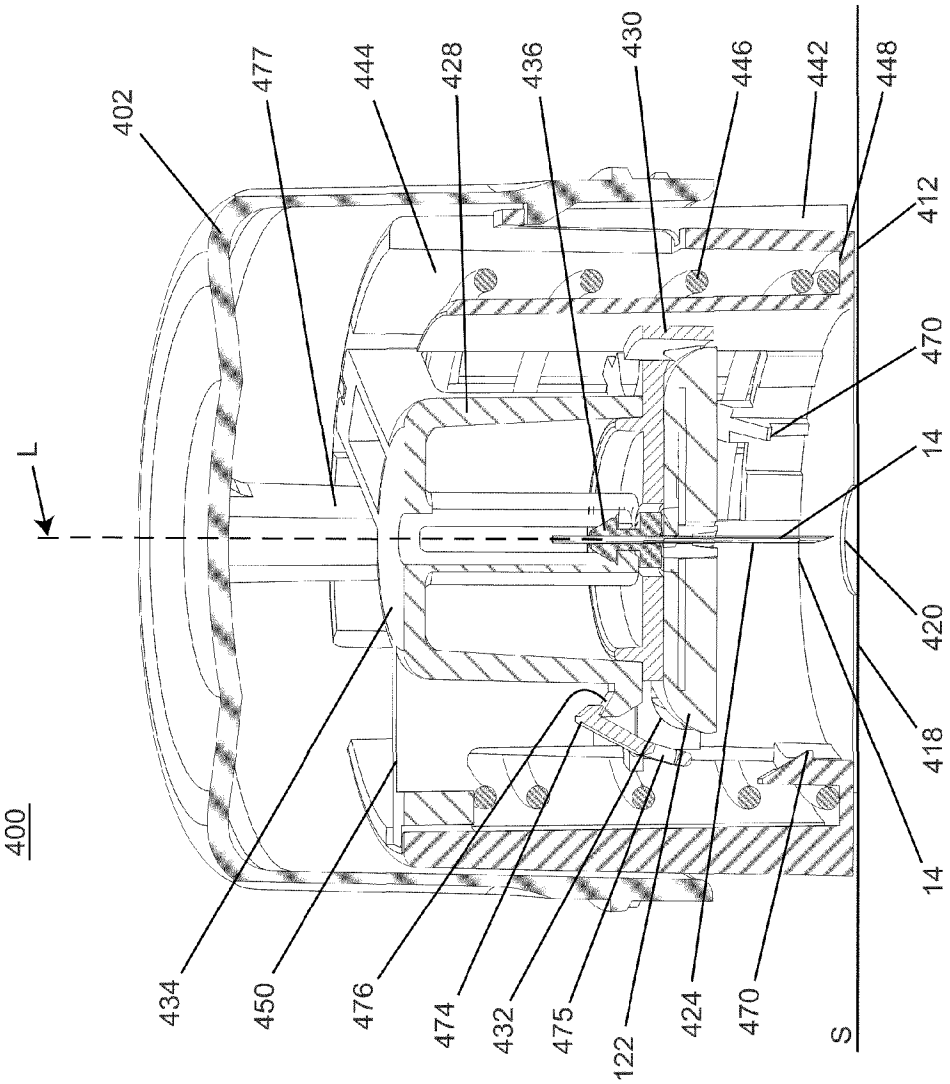
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FIG. 48

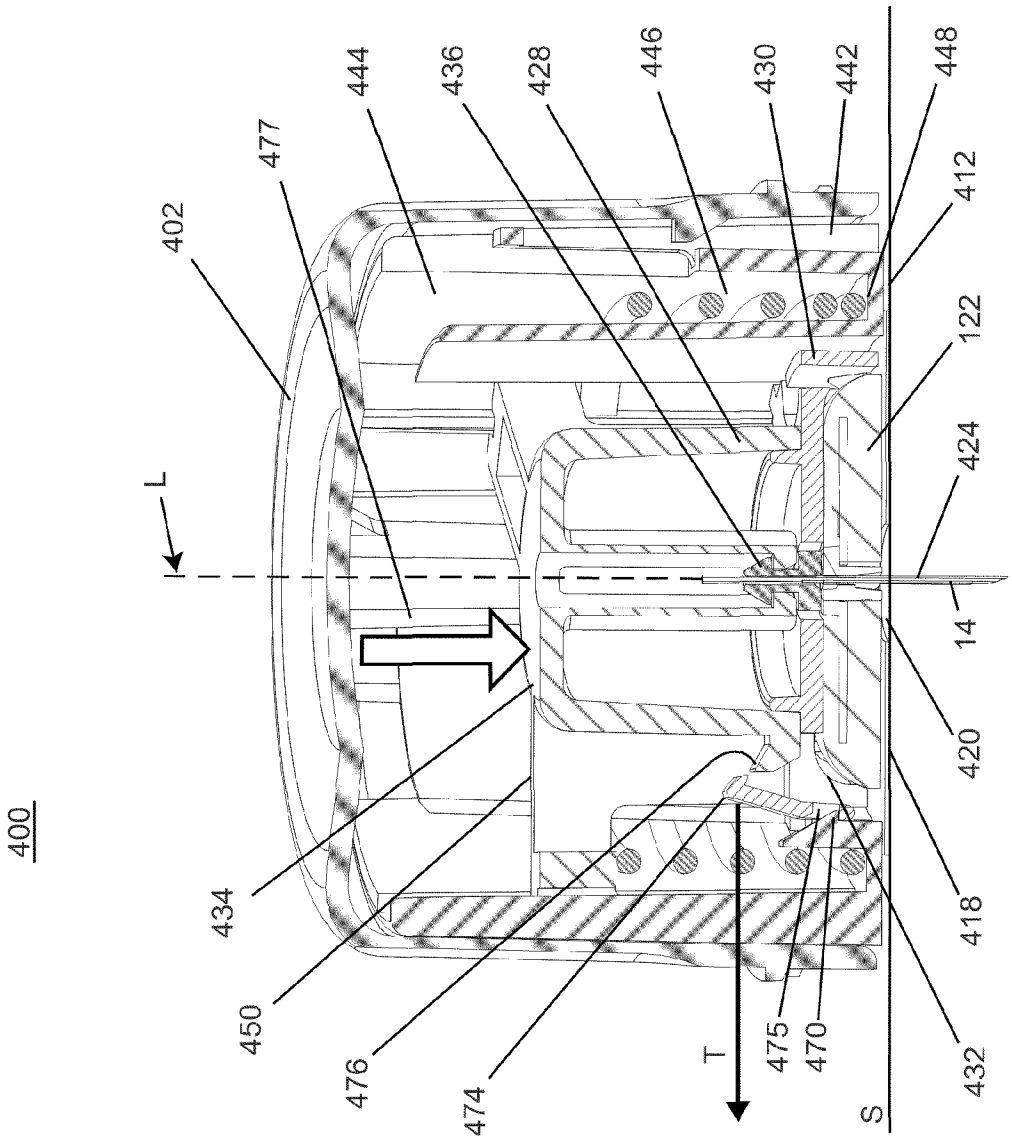
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FIG. 49

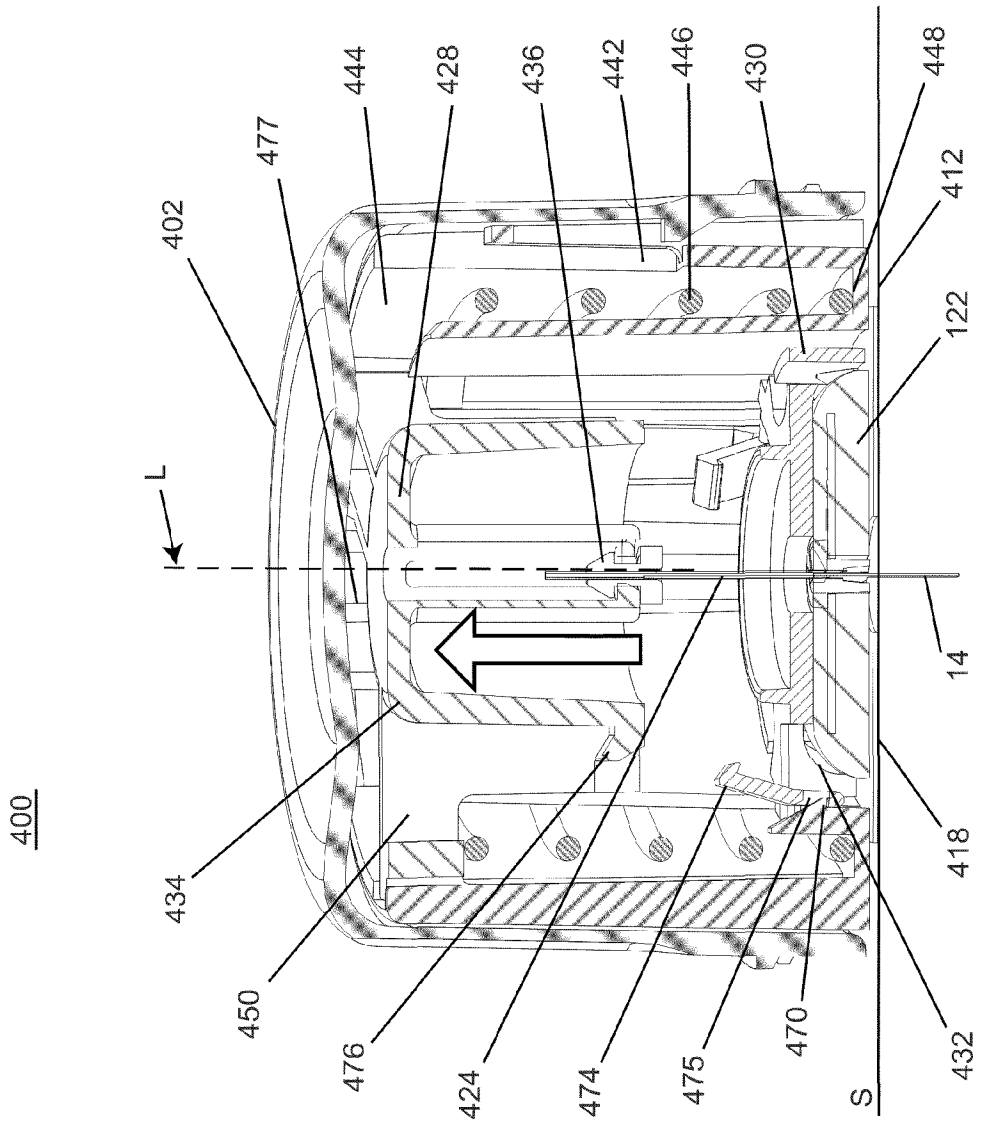
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FIG. 50

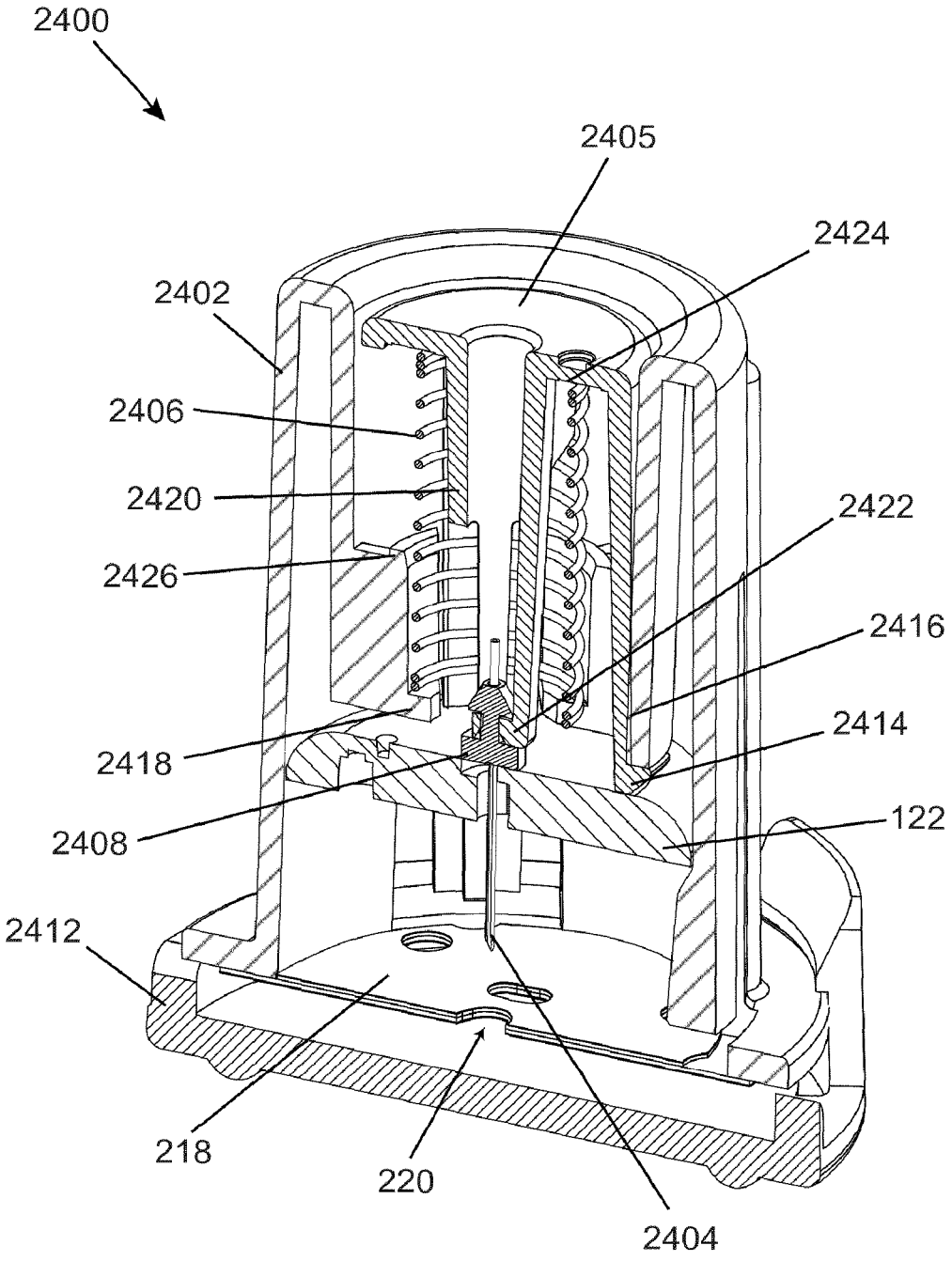
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FIG. 51

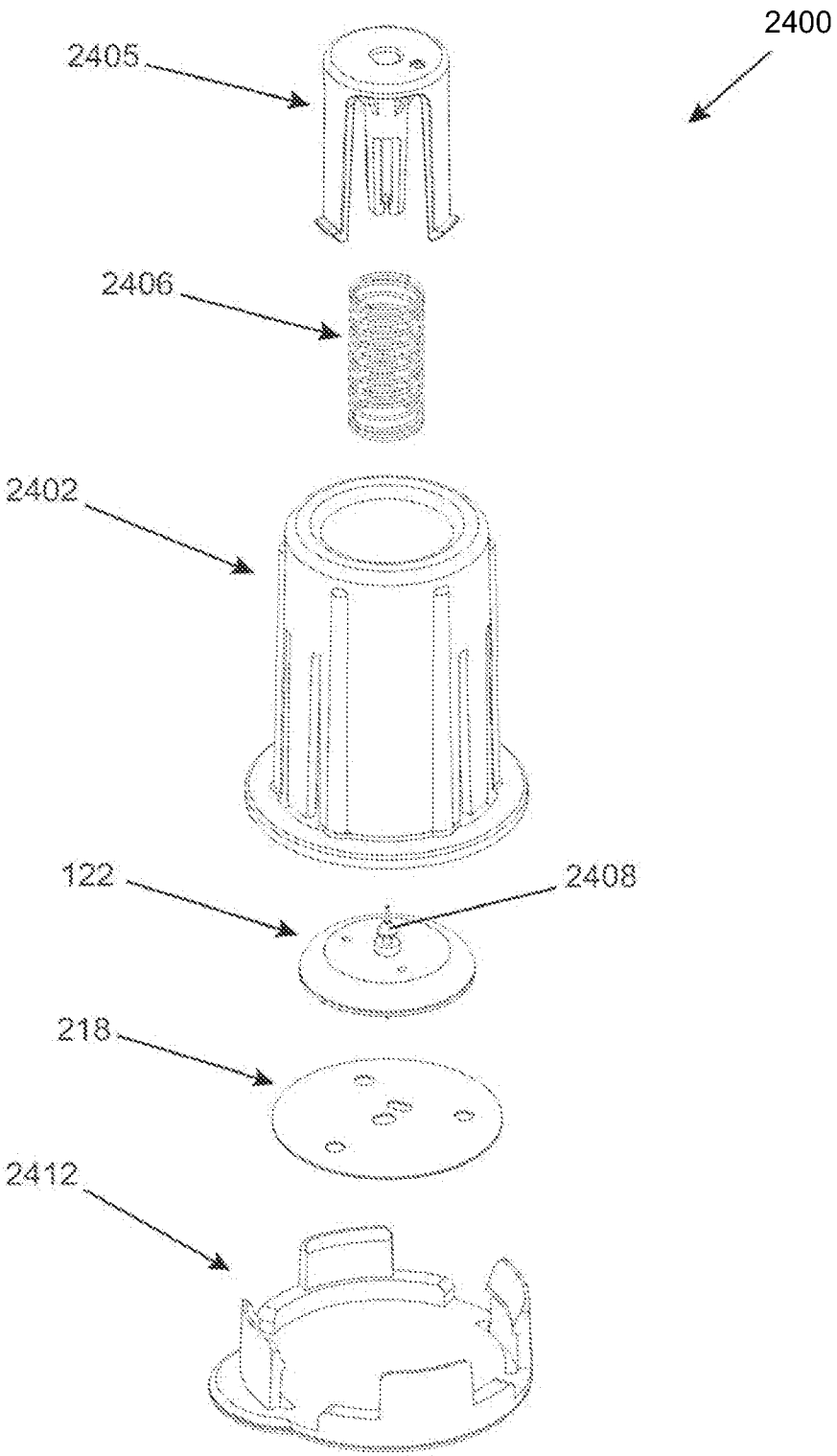

FIG. 52

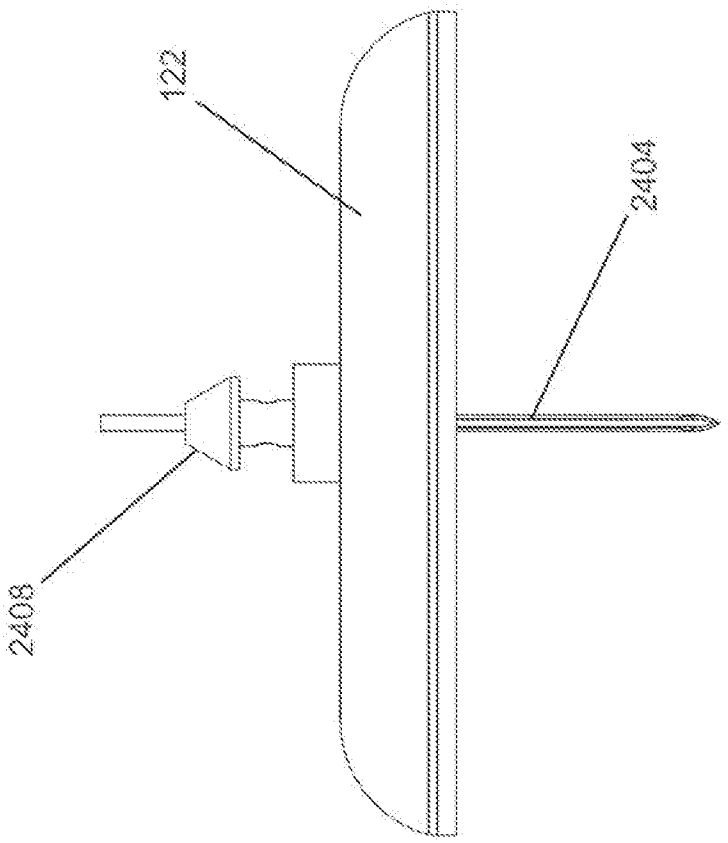

FIG. 54

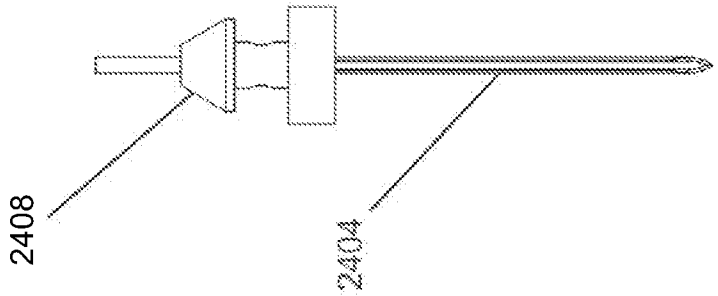

FIG. 53

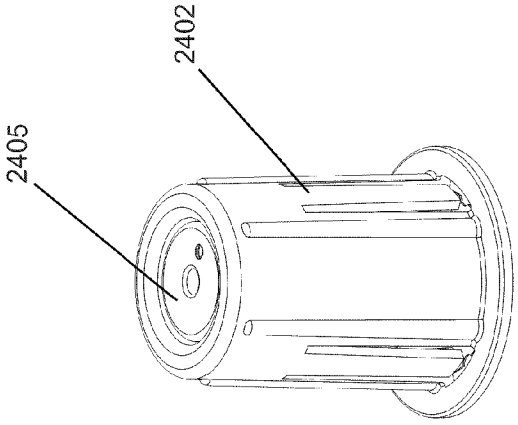

FIG. 56

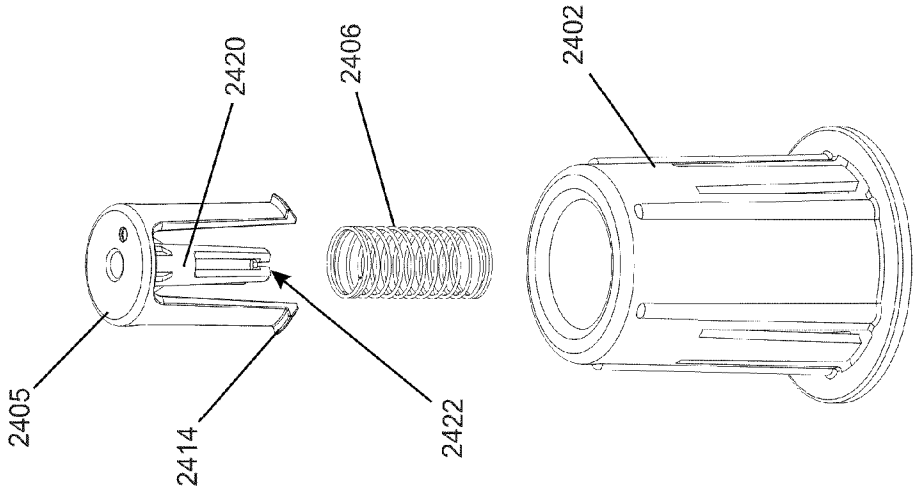

FIG. 55

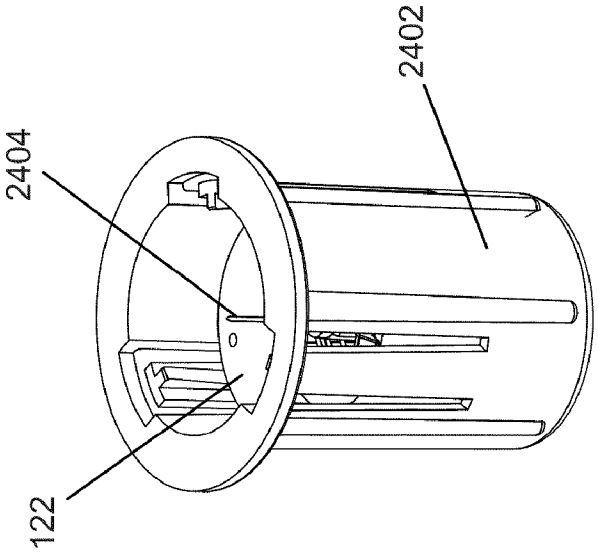

FIG. 58

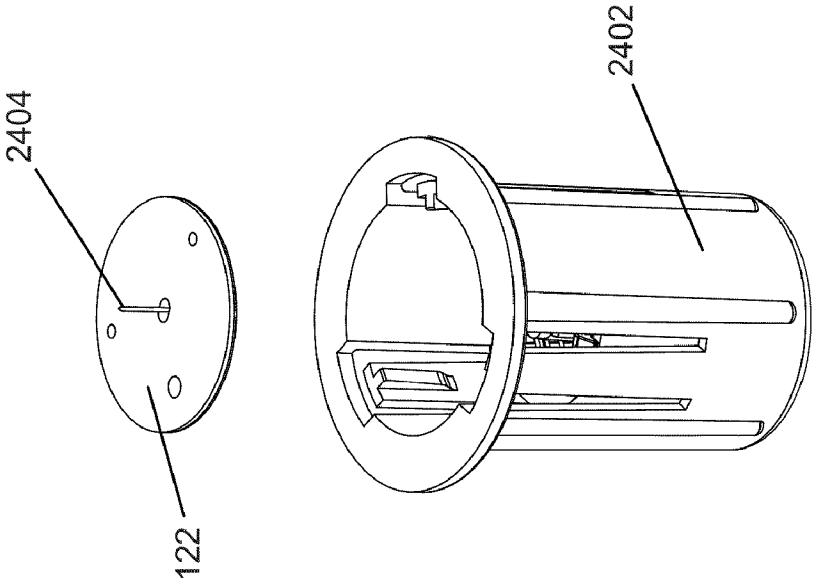

FIG. 57

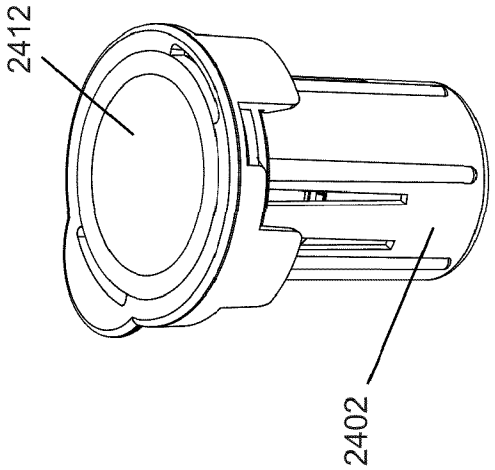

FIG. 60

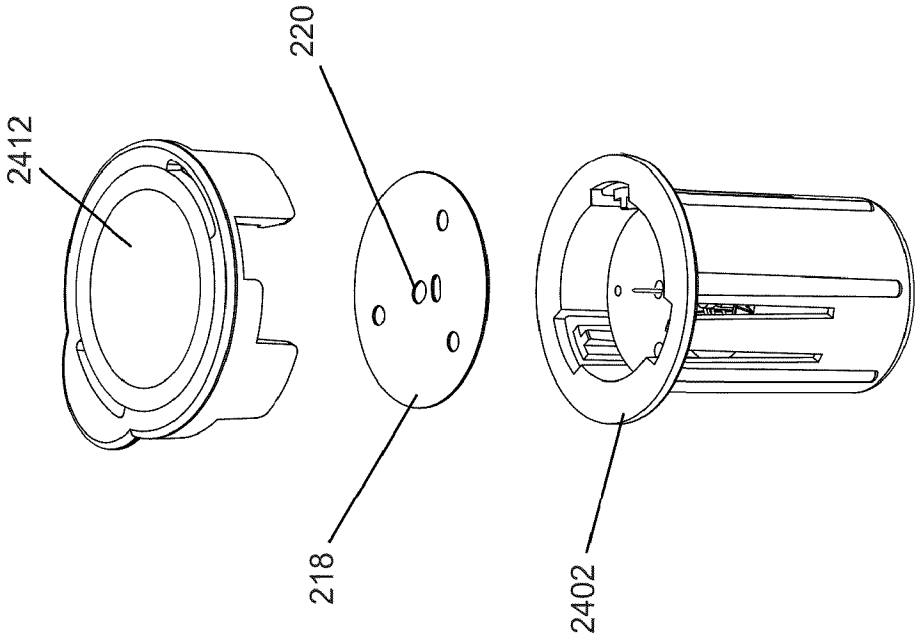

FIG. 59

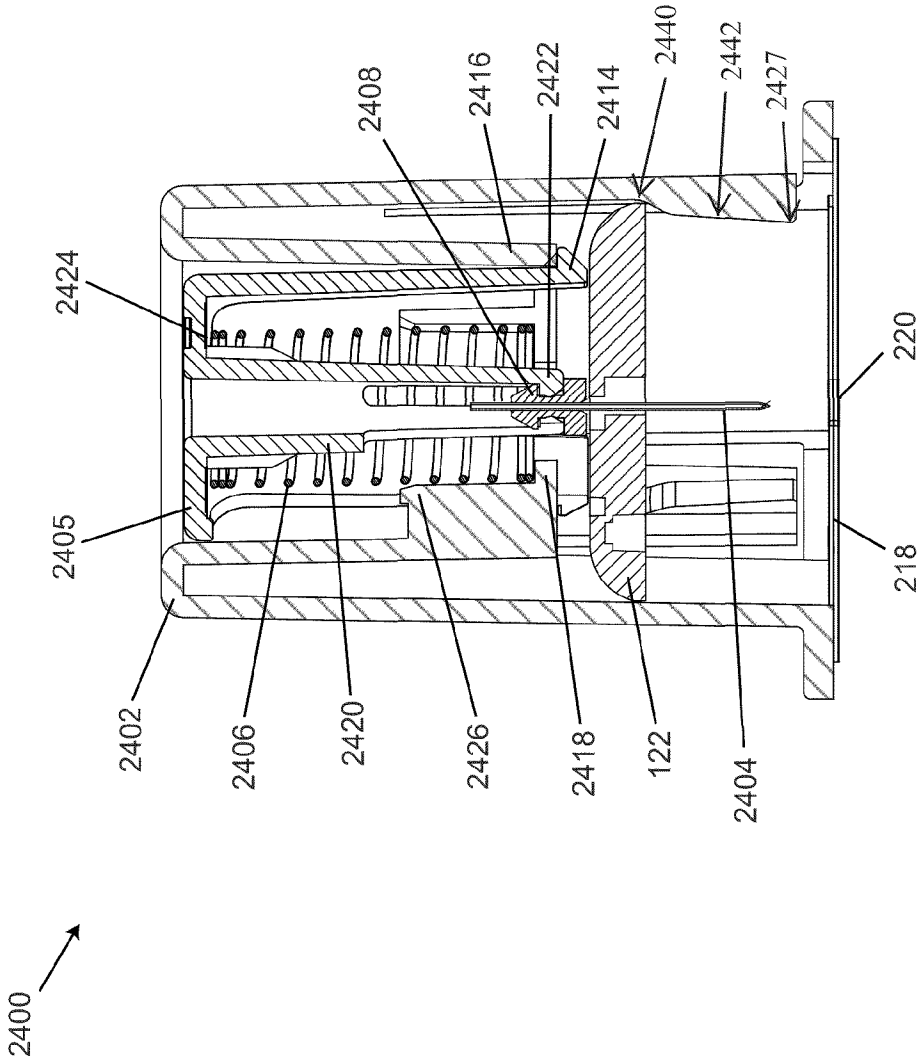
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FIG. 61

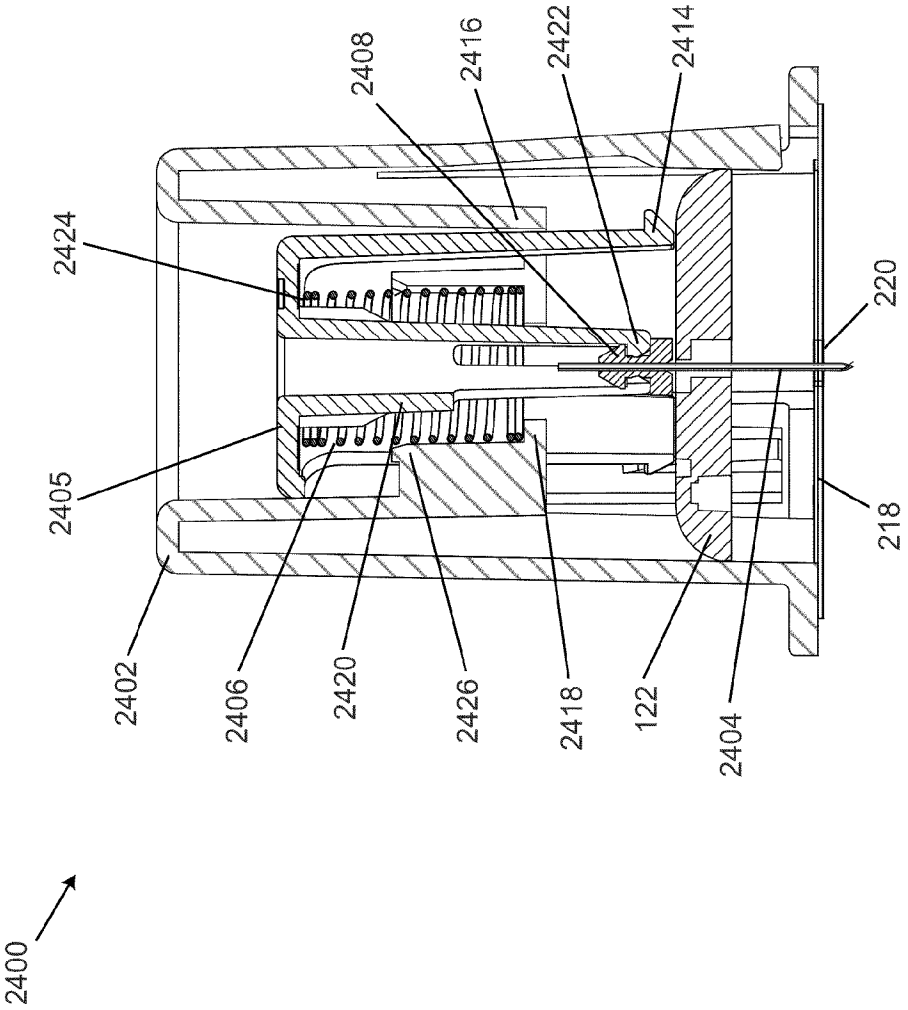
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FIG. 62

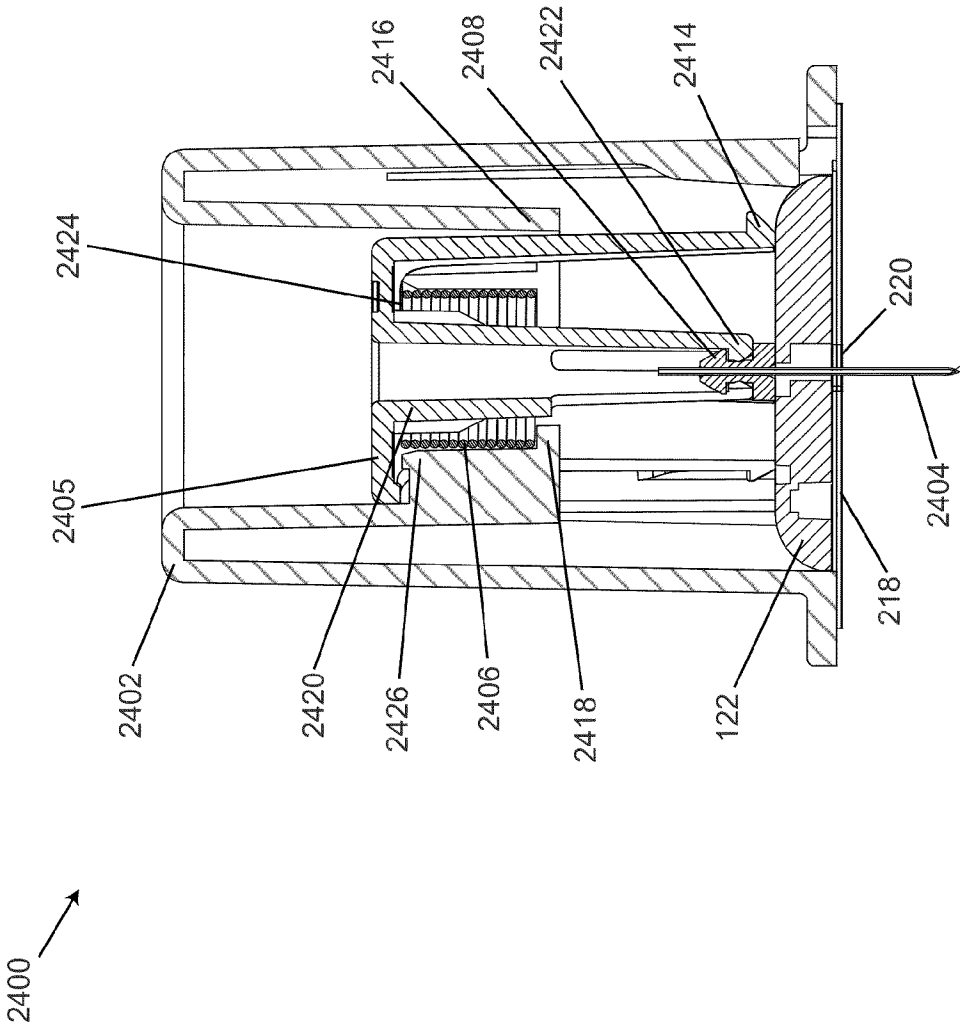
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FIG. 63

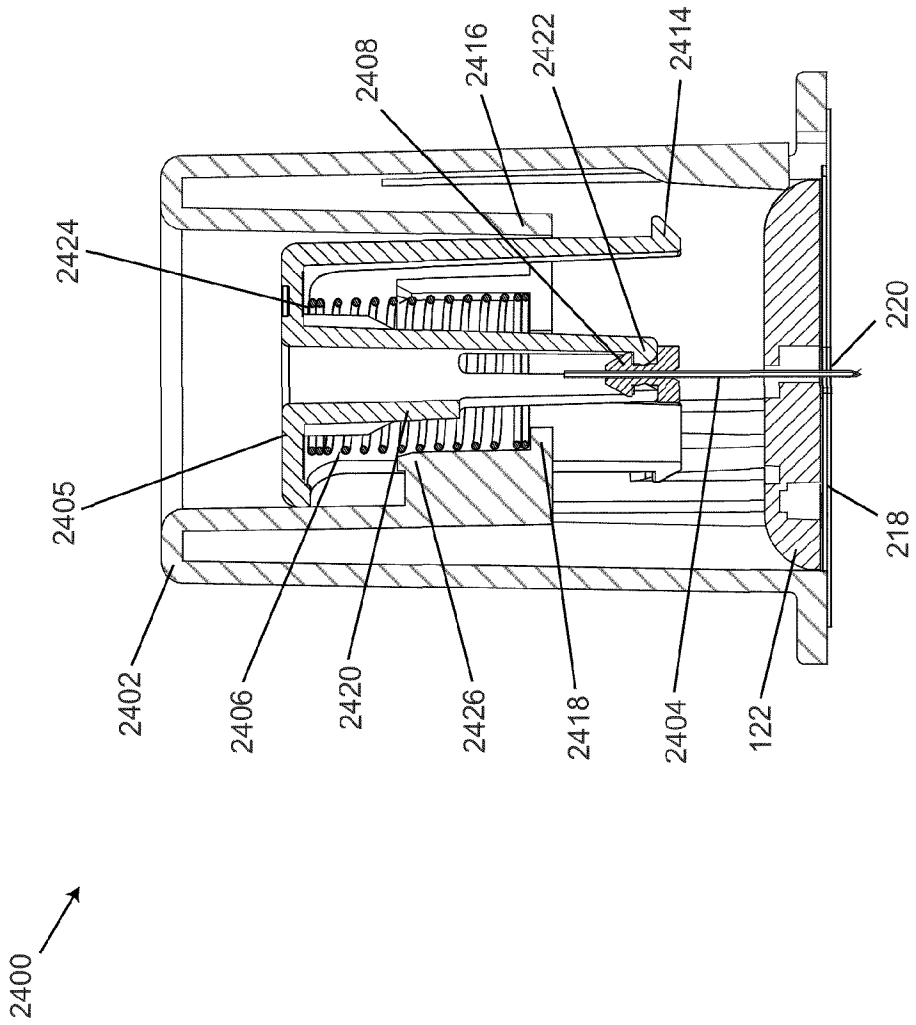
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FIG. 64

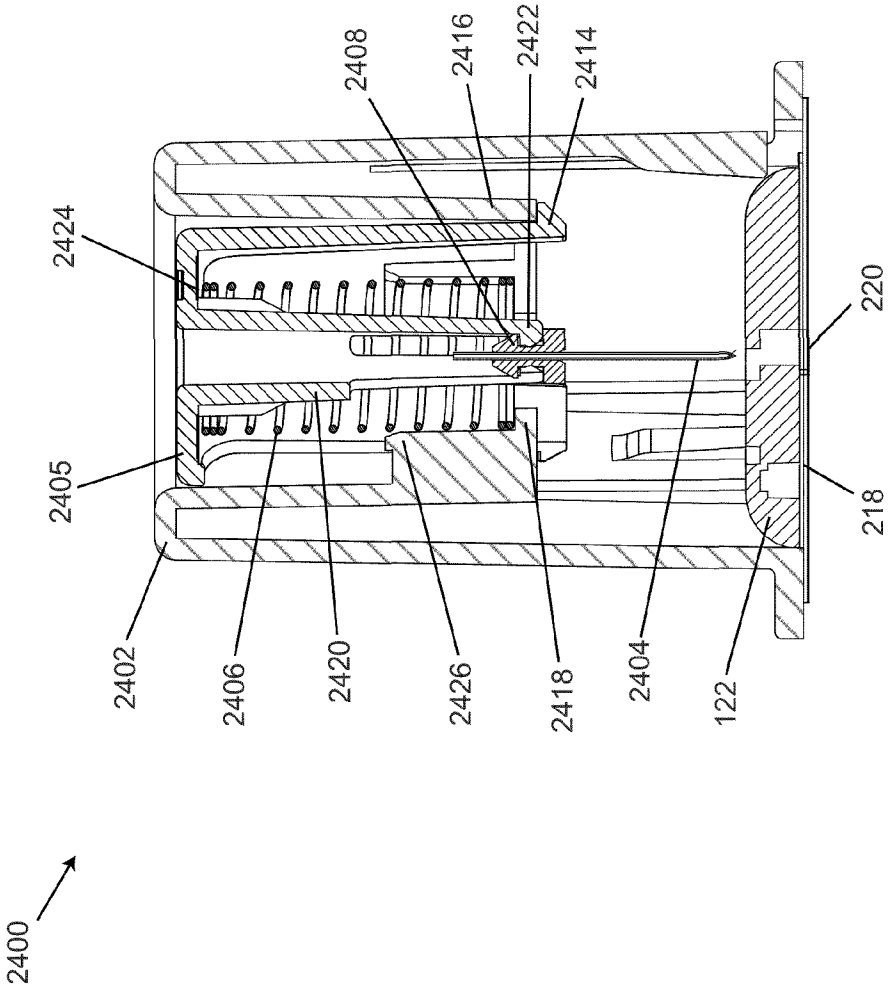
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FIG. 65

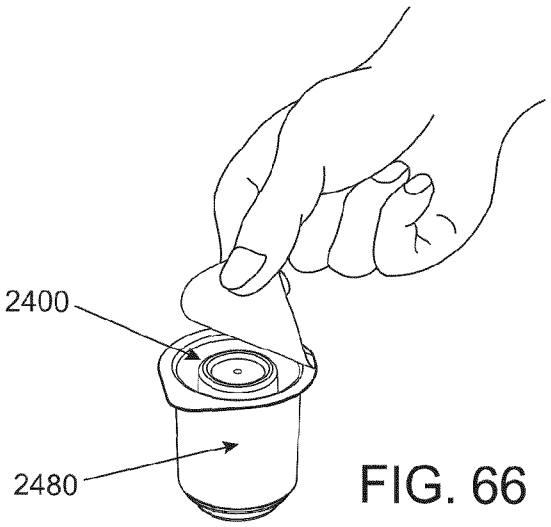

FIG. 66

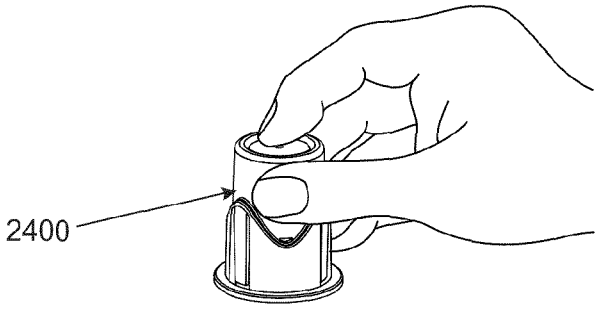

FIG. 67

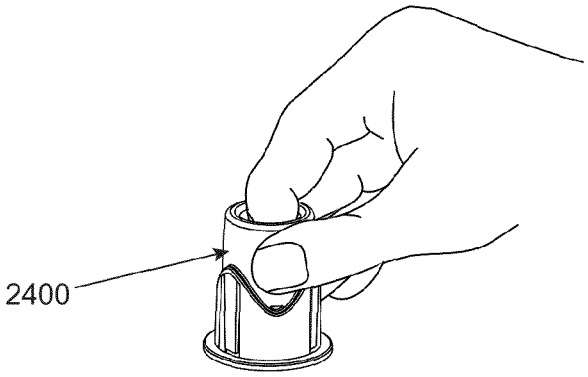

FIG. 68

FIG. 69

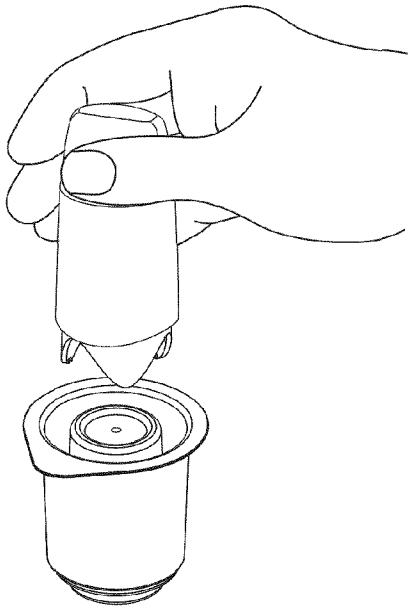

FIG. 70

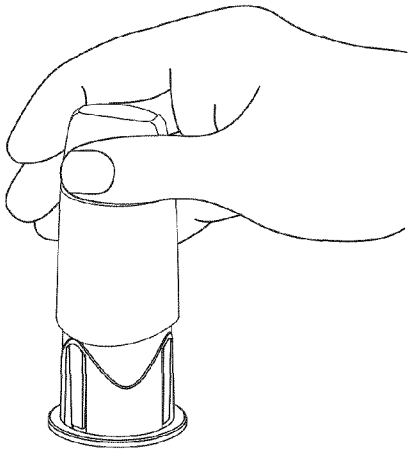

FIG. 71

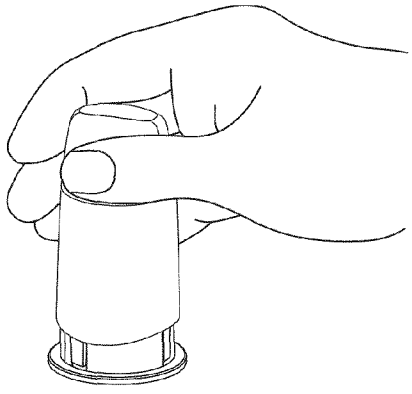

FIG. 72

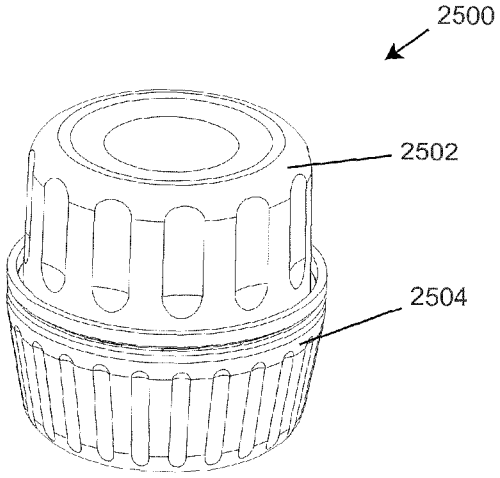

FIG. 73

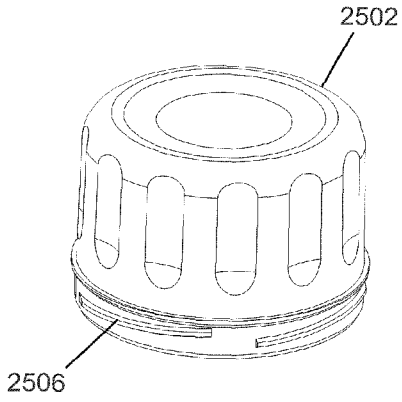

FIG. 74

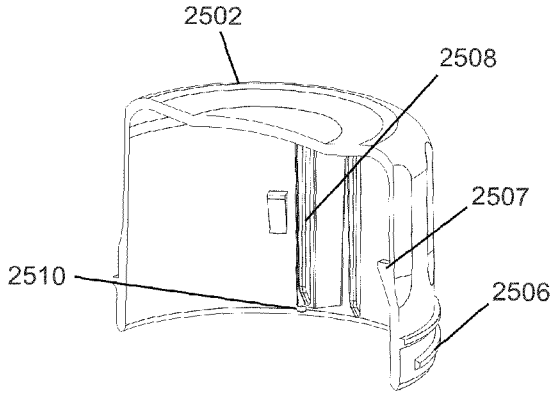

FIG. 75

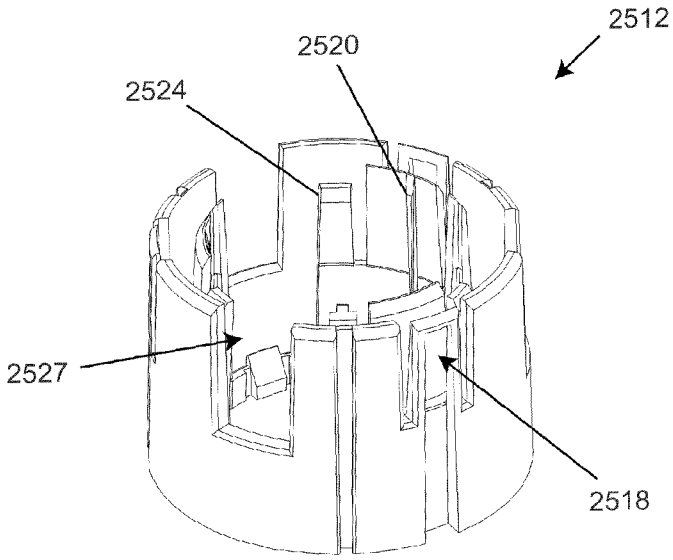

FIG. 76

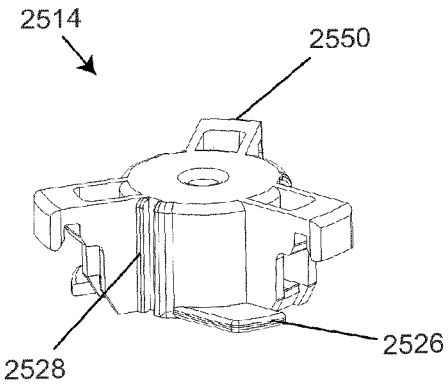

FIG. 77

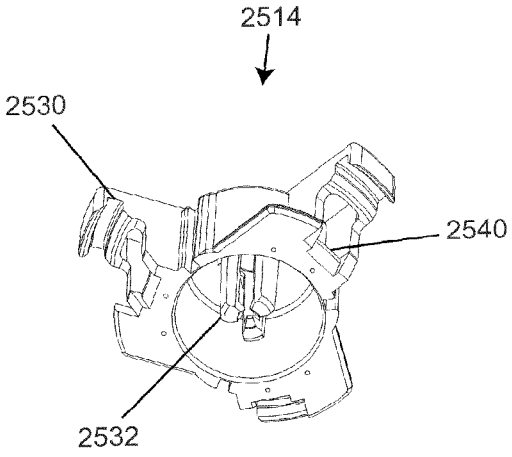

FIG. 78

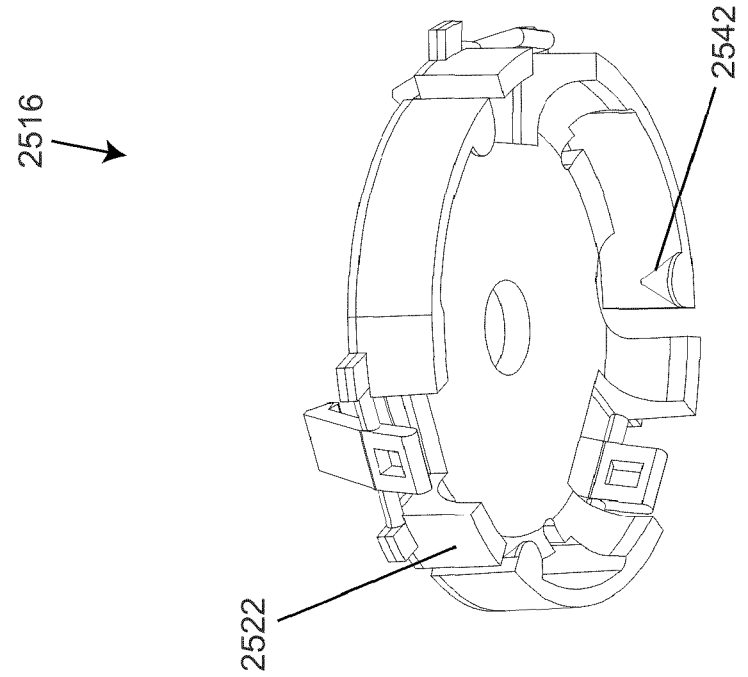

FIG. 80

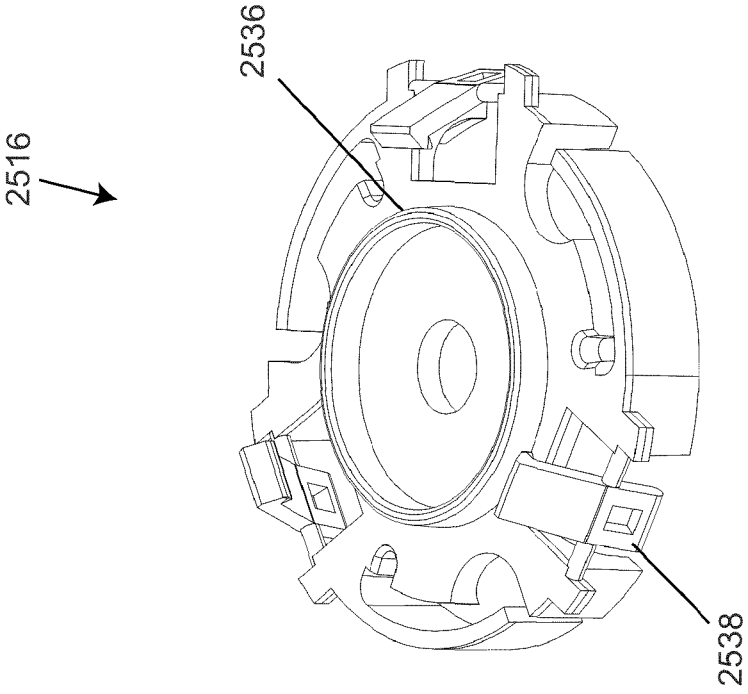

FIG. 79

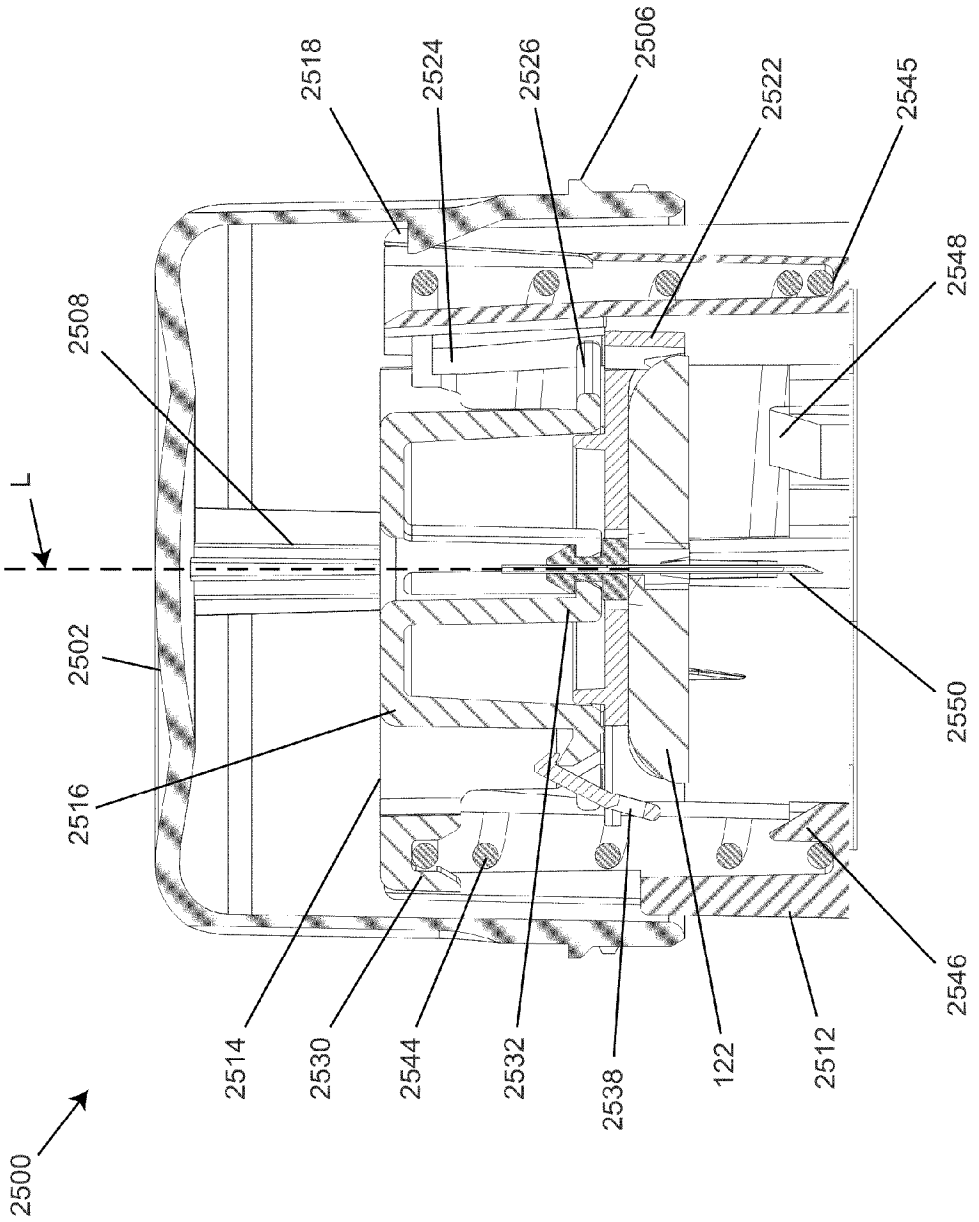
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FIG. 81

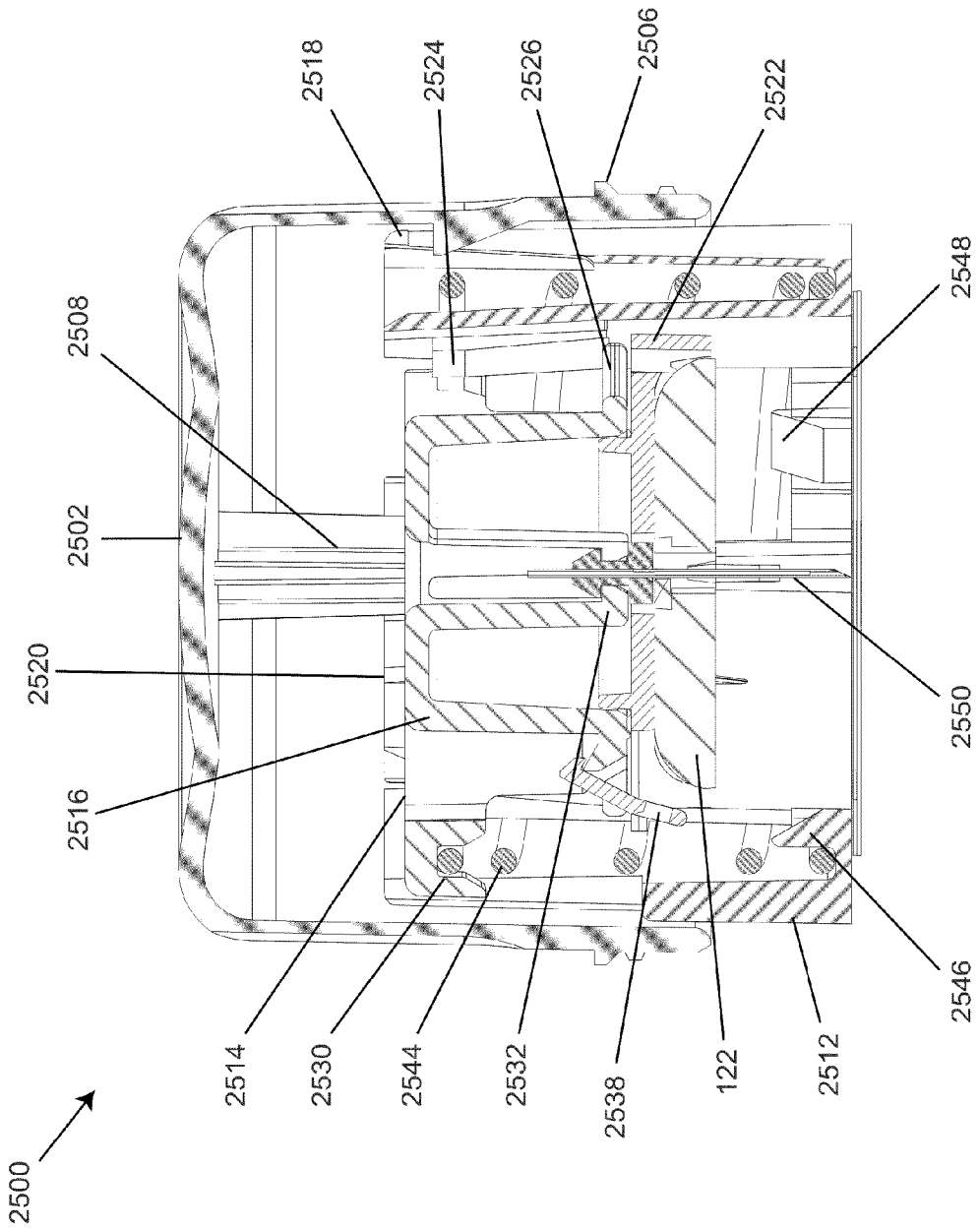
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FIG. 82

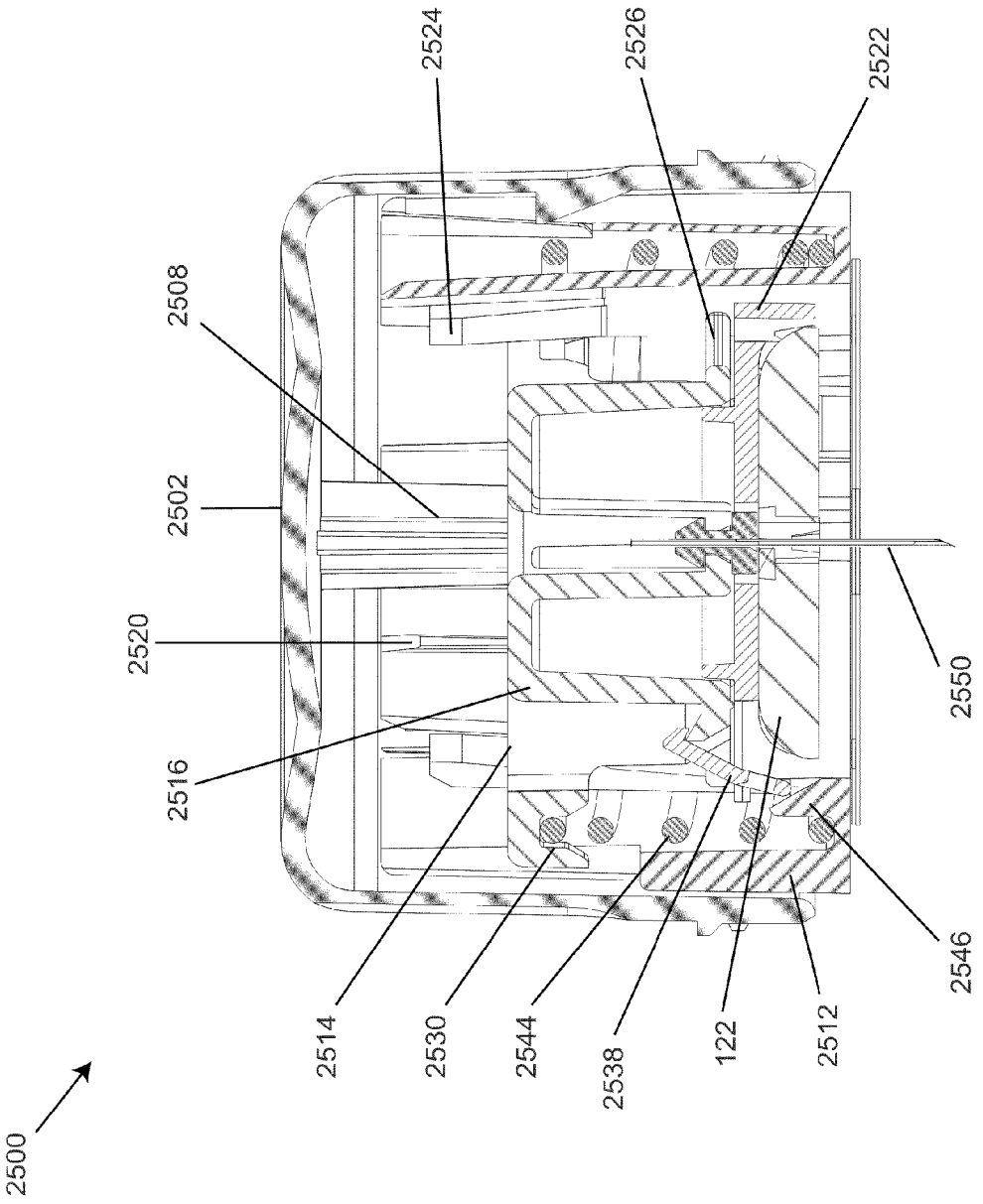
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FIG. 83

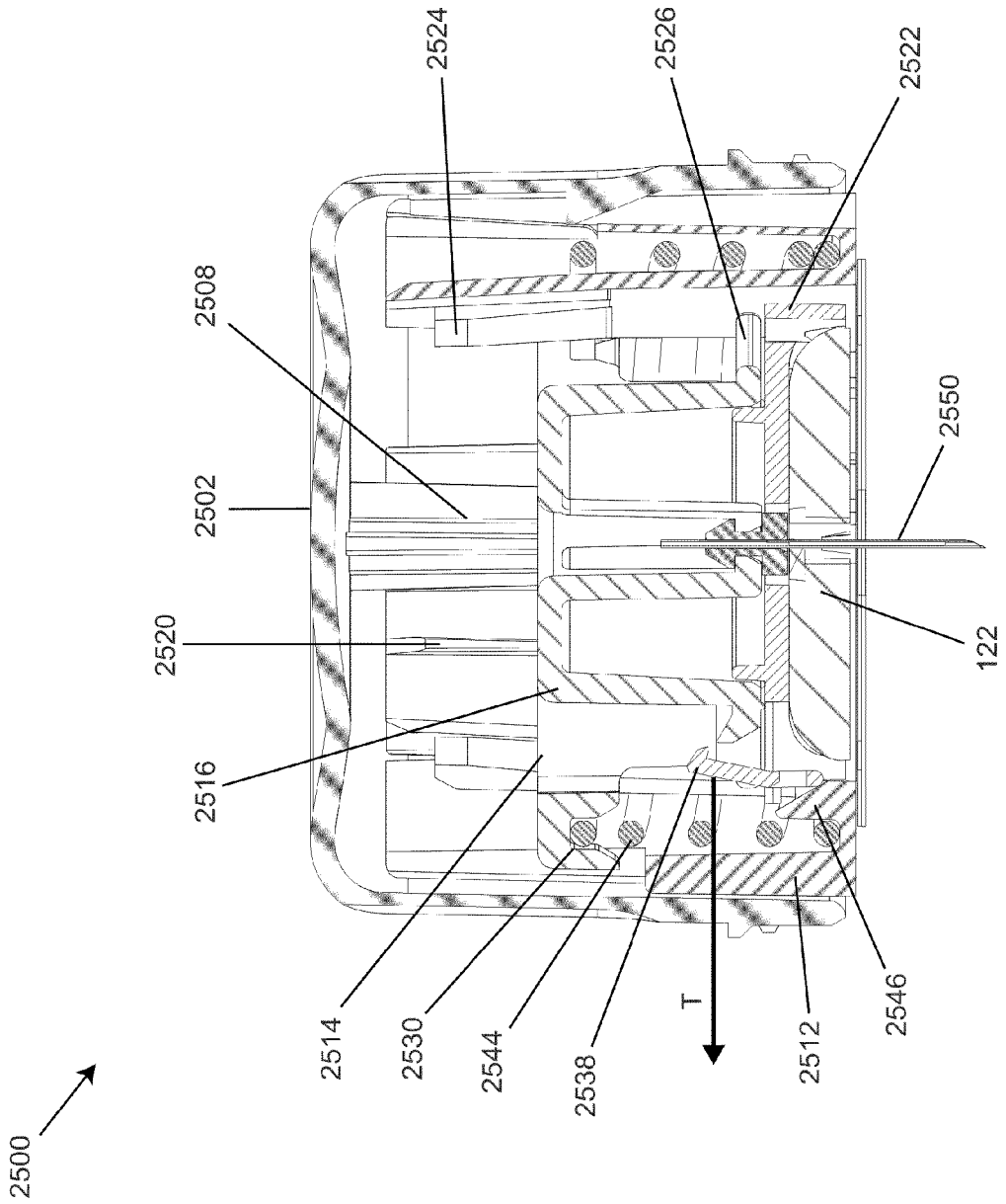
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FIG. 84

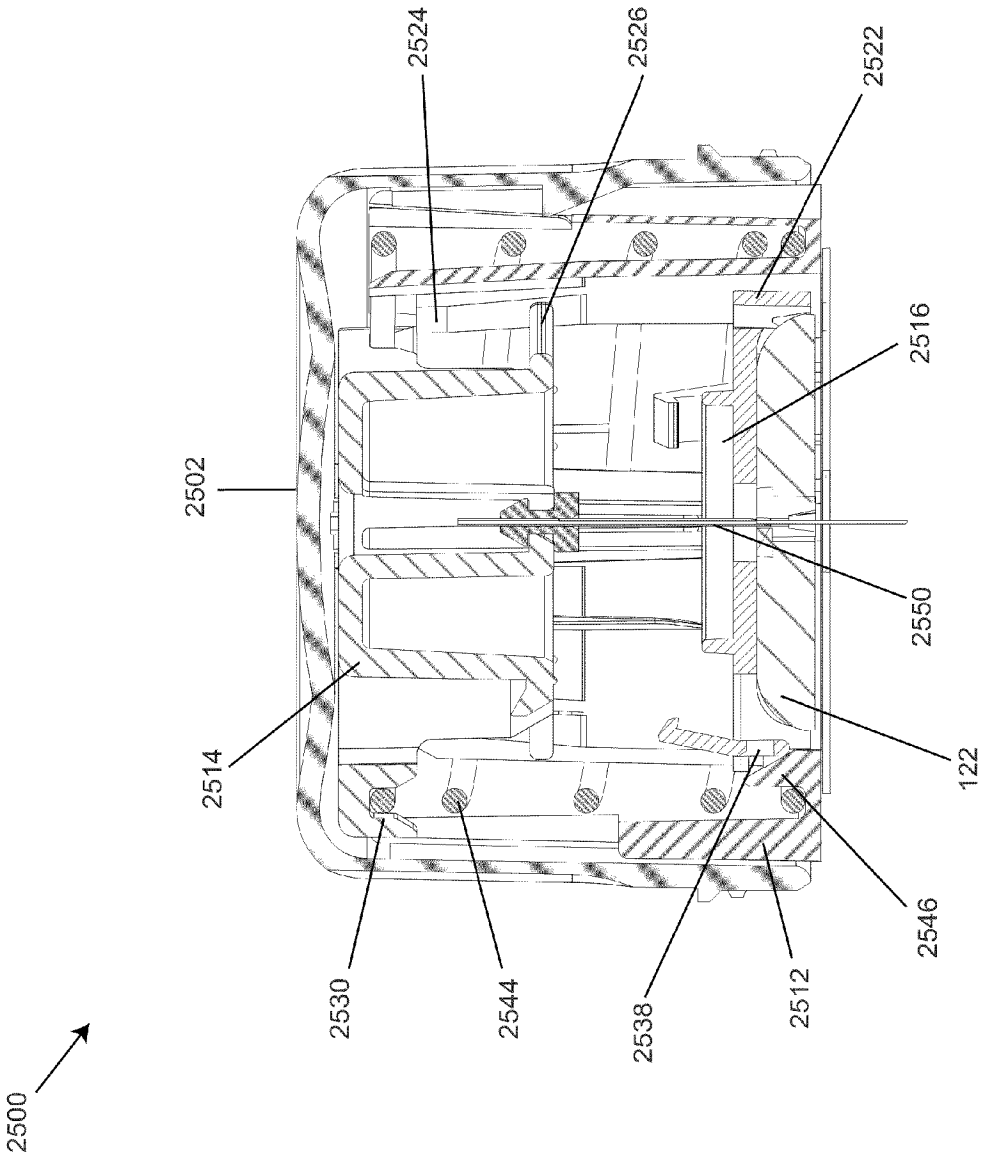
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FIG. 85

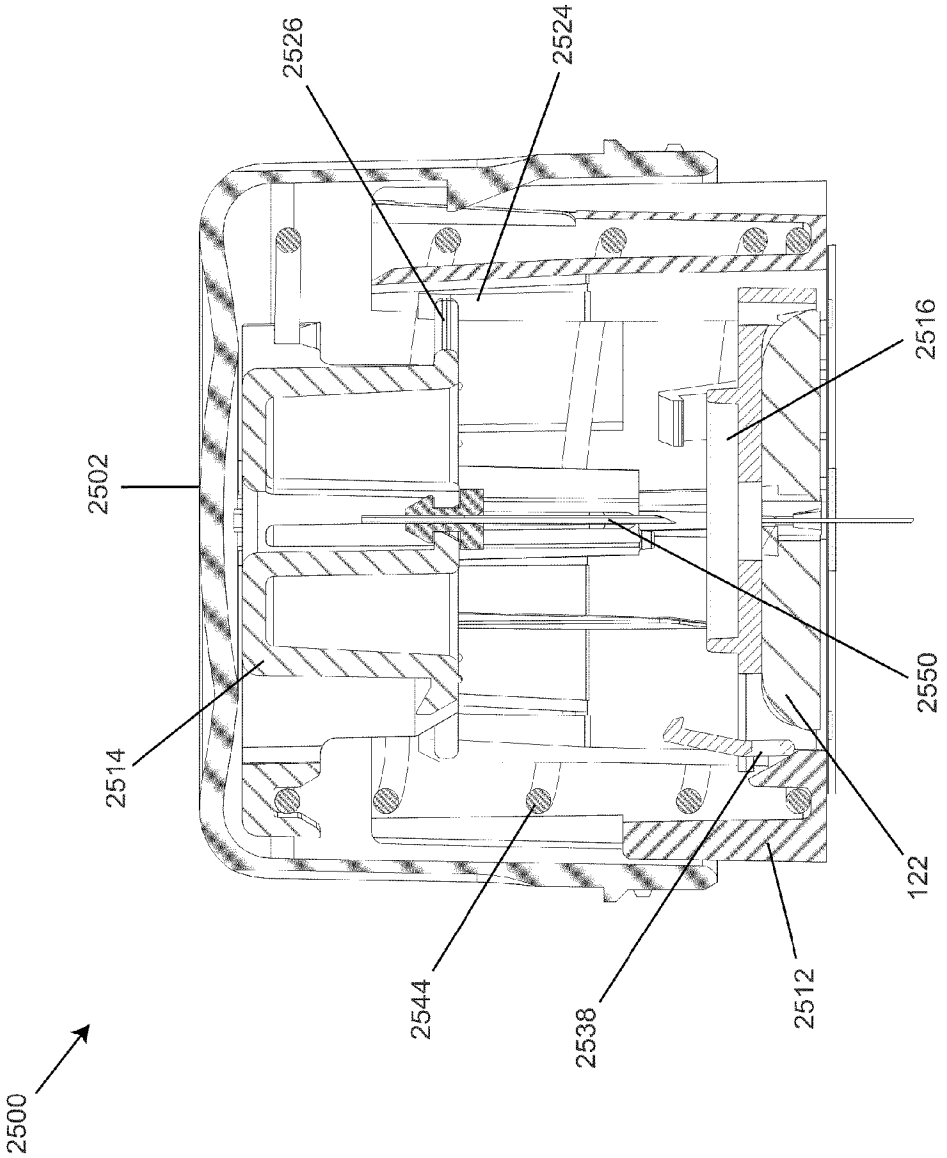

FIG. 86

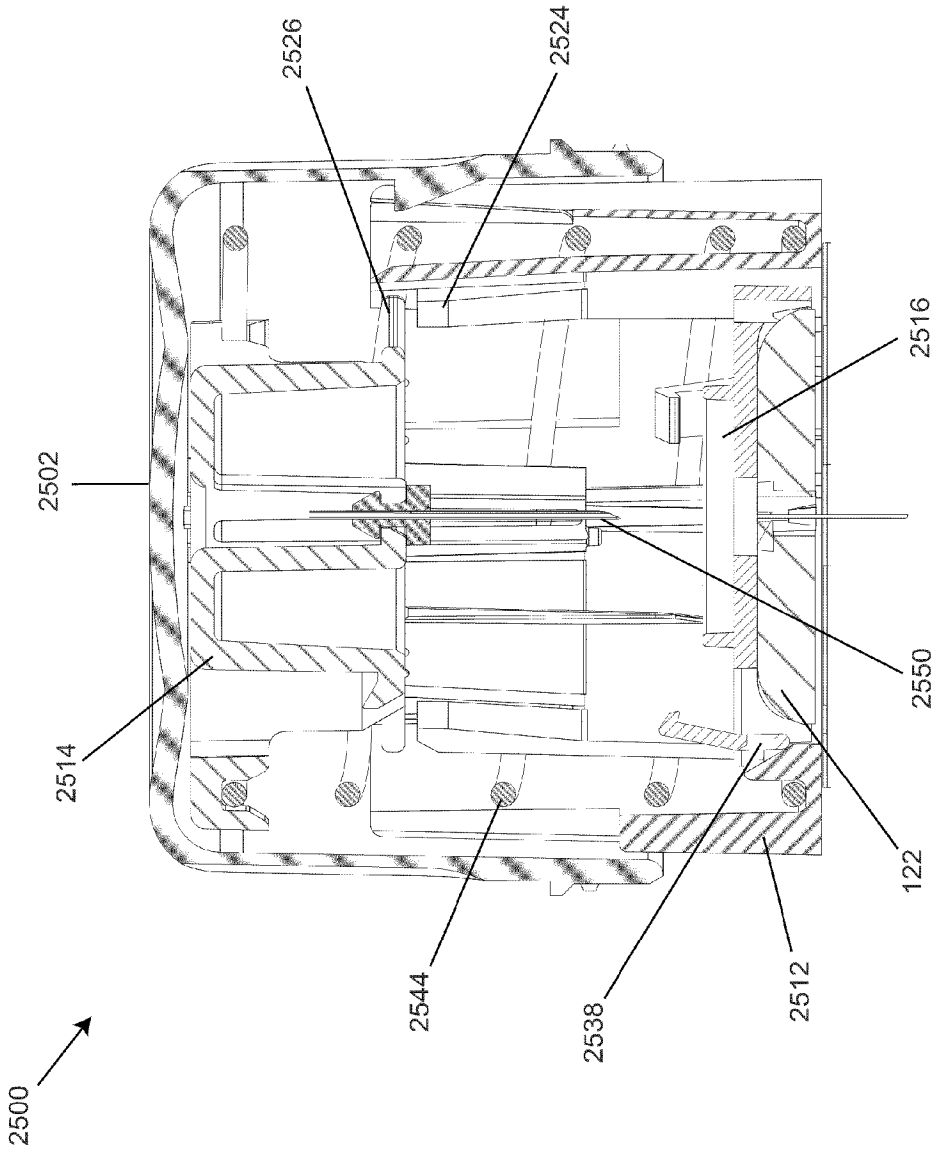

FIG. 87

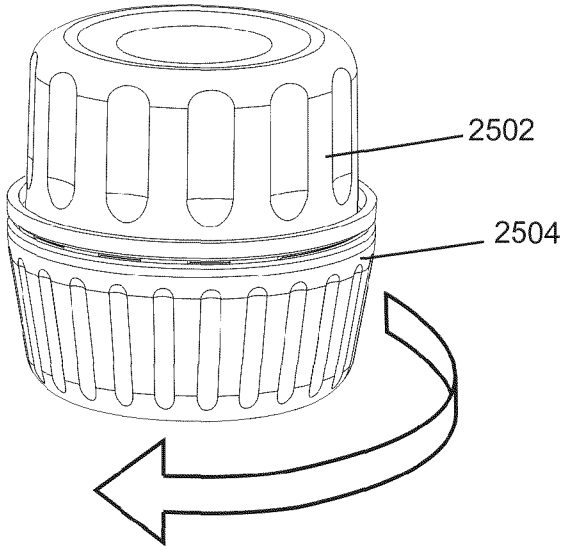

FIG. 88

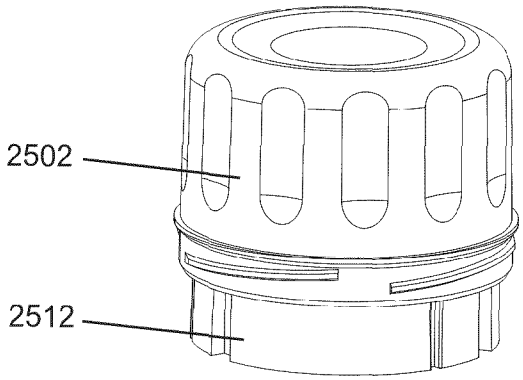

FIG. 89

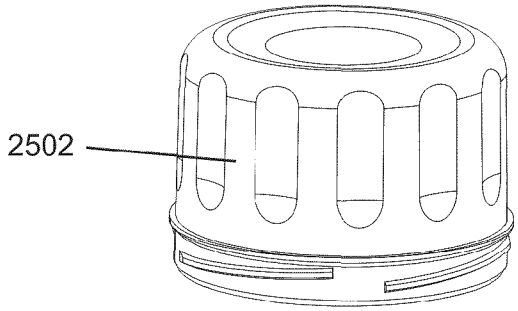

FIG. 90

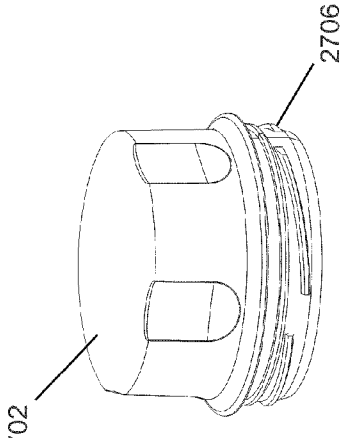

FIG. 92

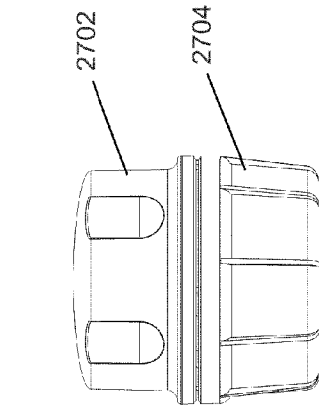

FIG. 91

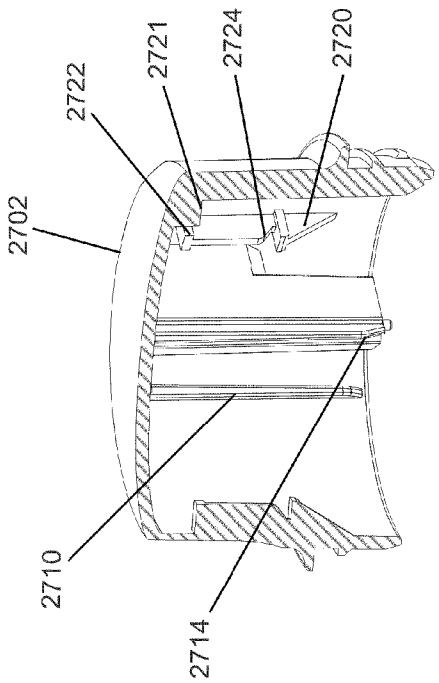

FIG. 93

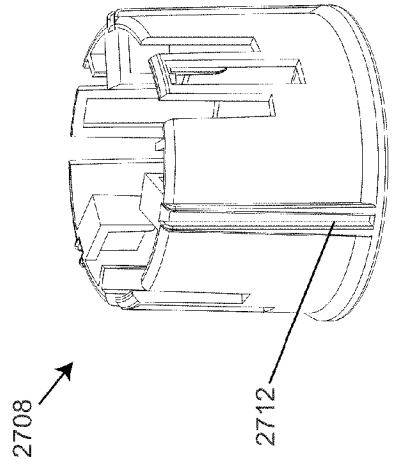

FIG. 94

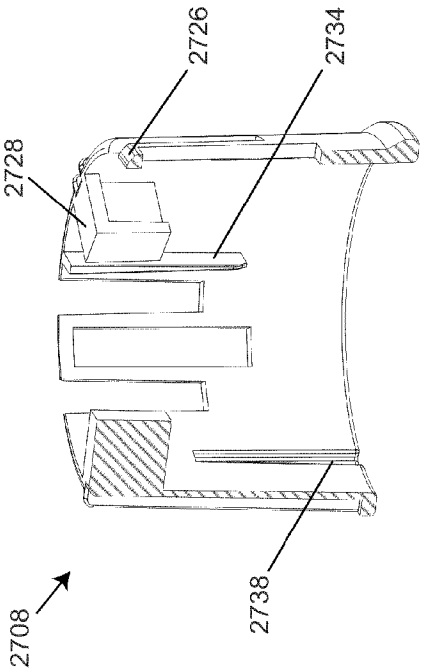

FIG. 95

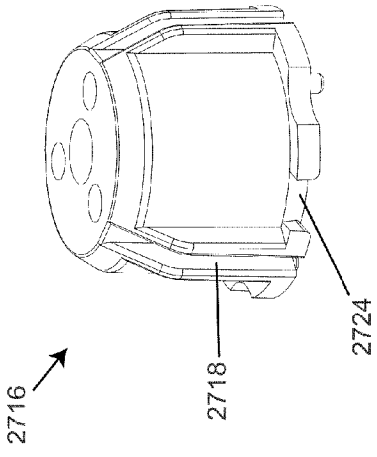

FIG. 96

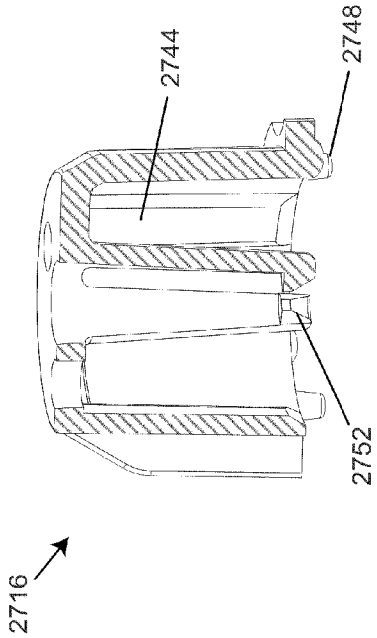

FIG. 97

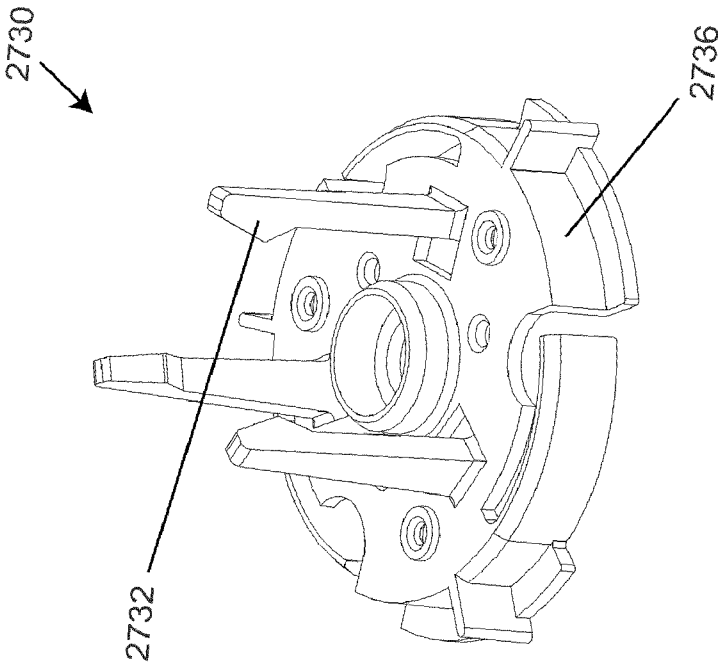

FIG. 98

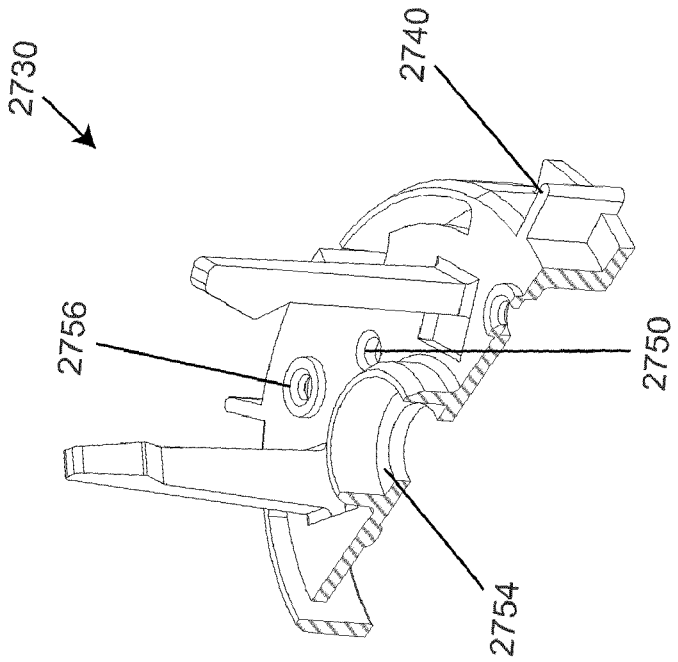

FIG. 99

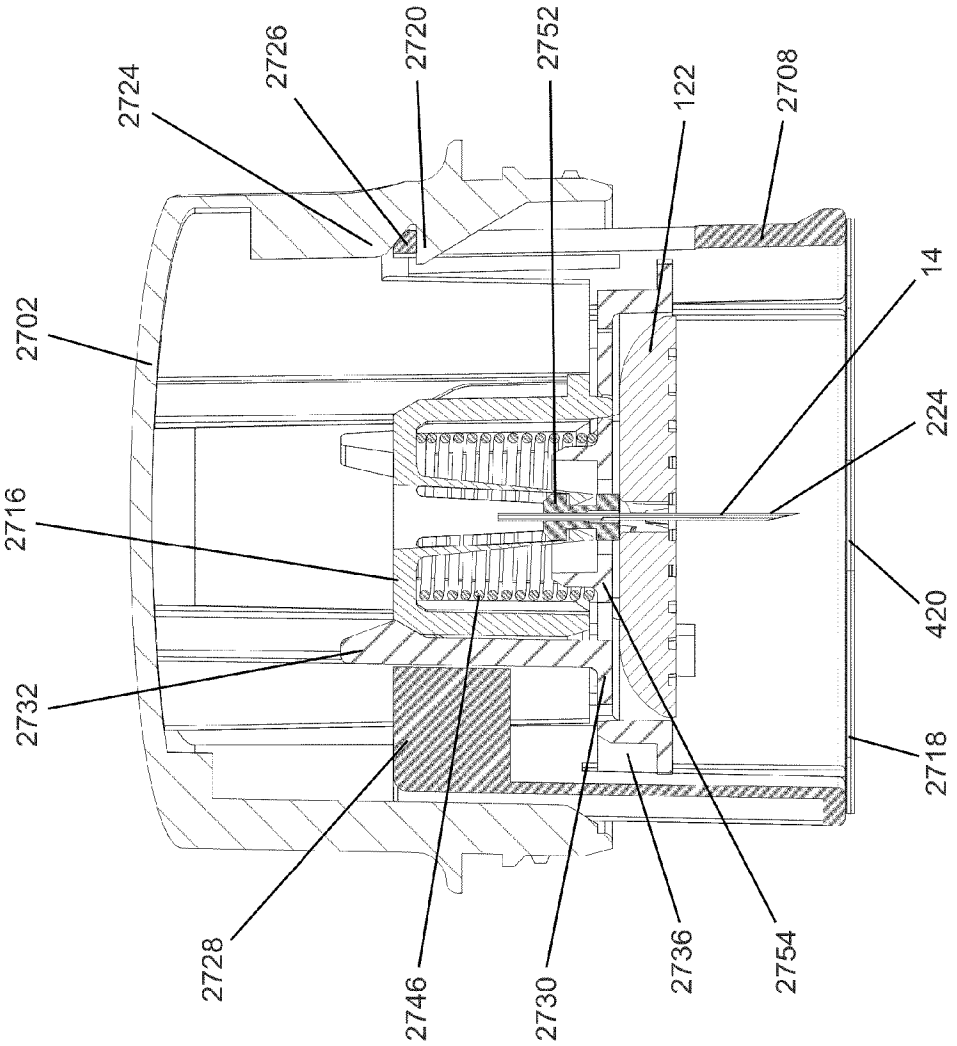
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FIG. 100

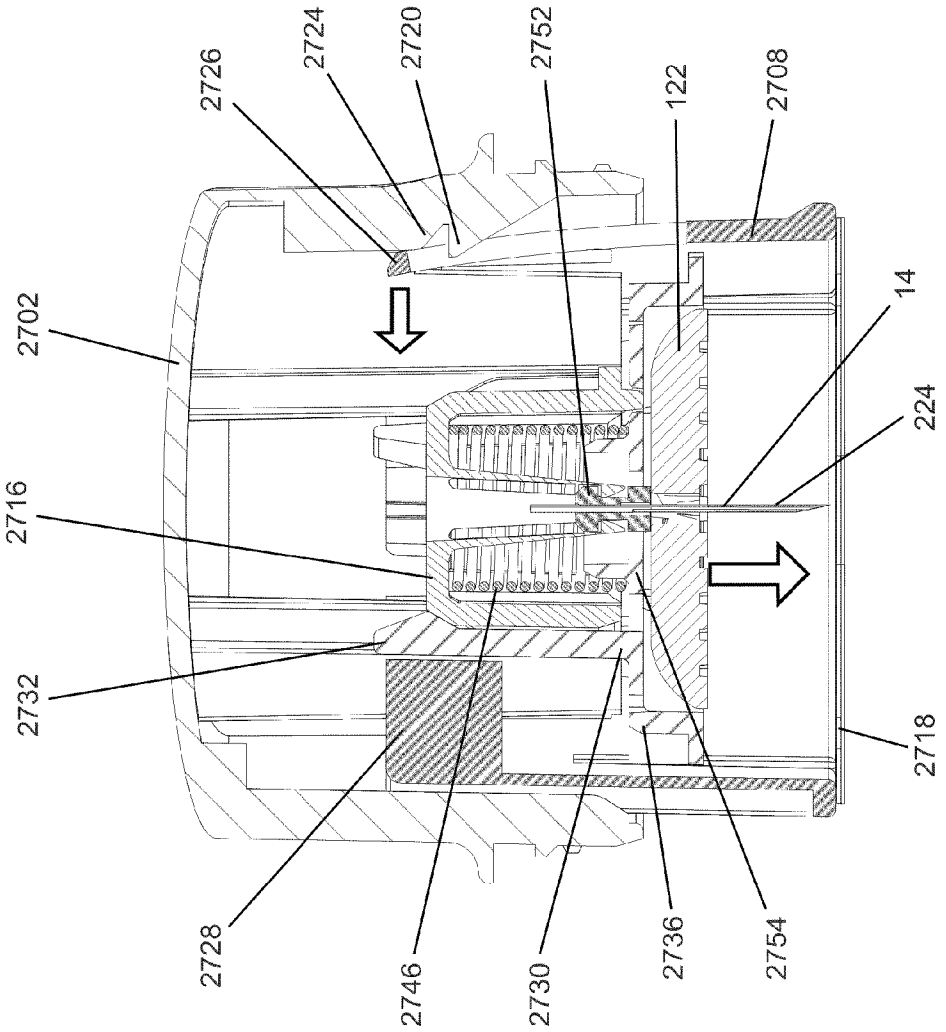
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FIG. 101

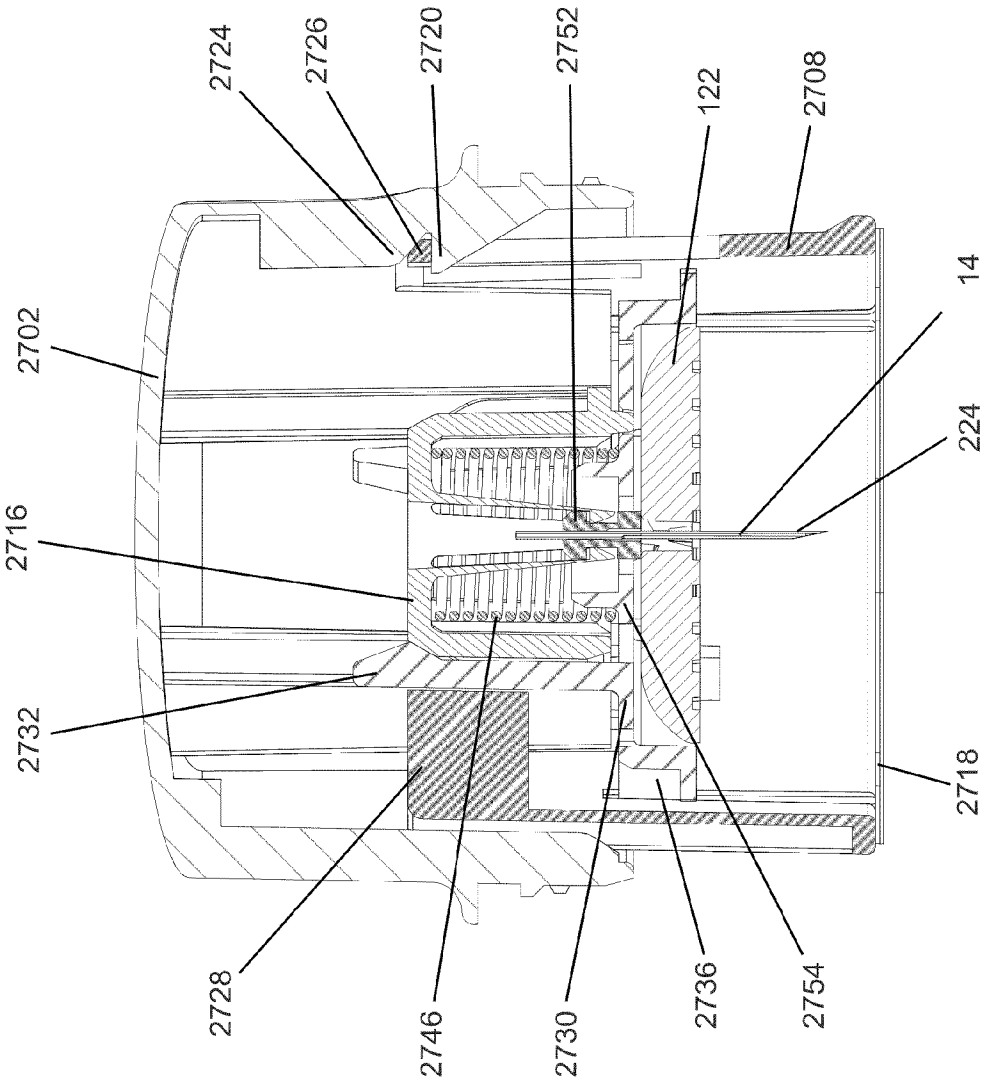
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FIG. 102

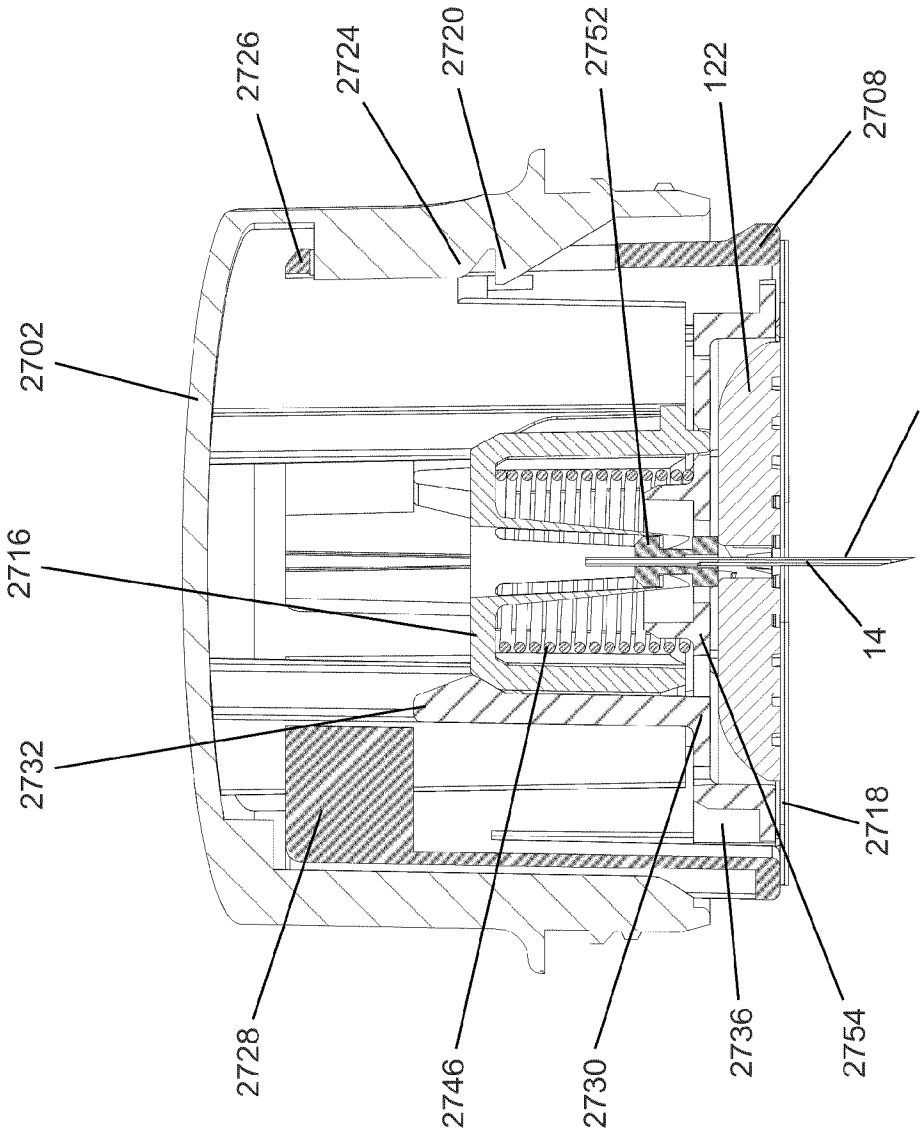
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FIG. 103

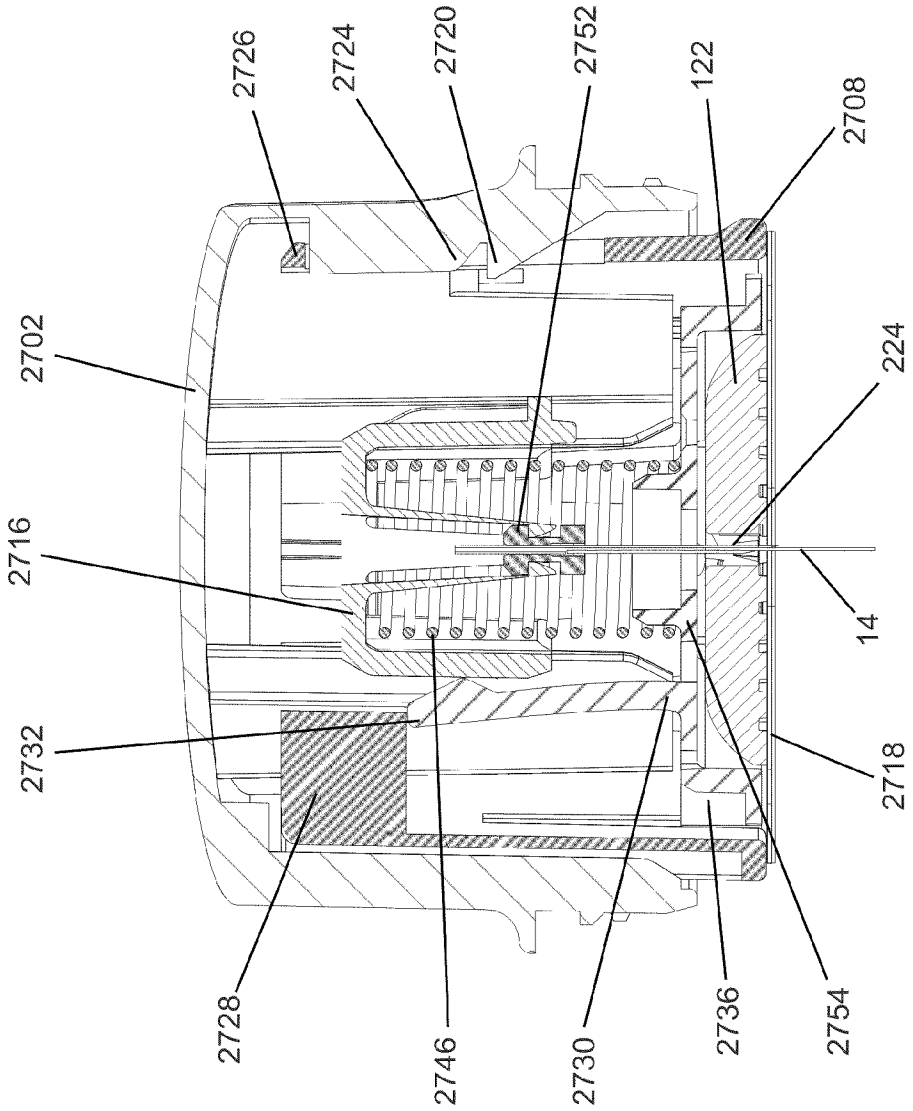
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FIG. 104

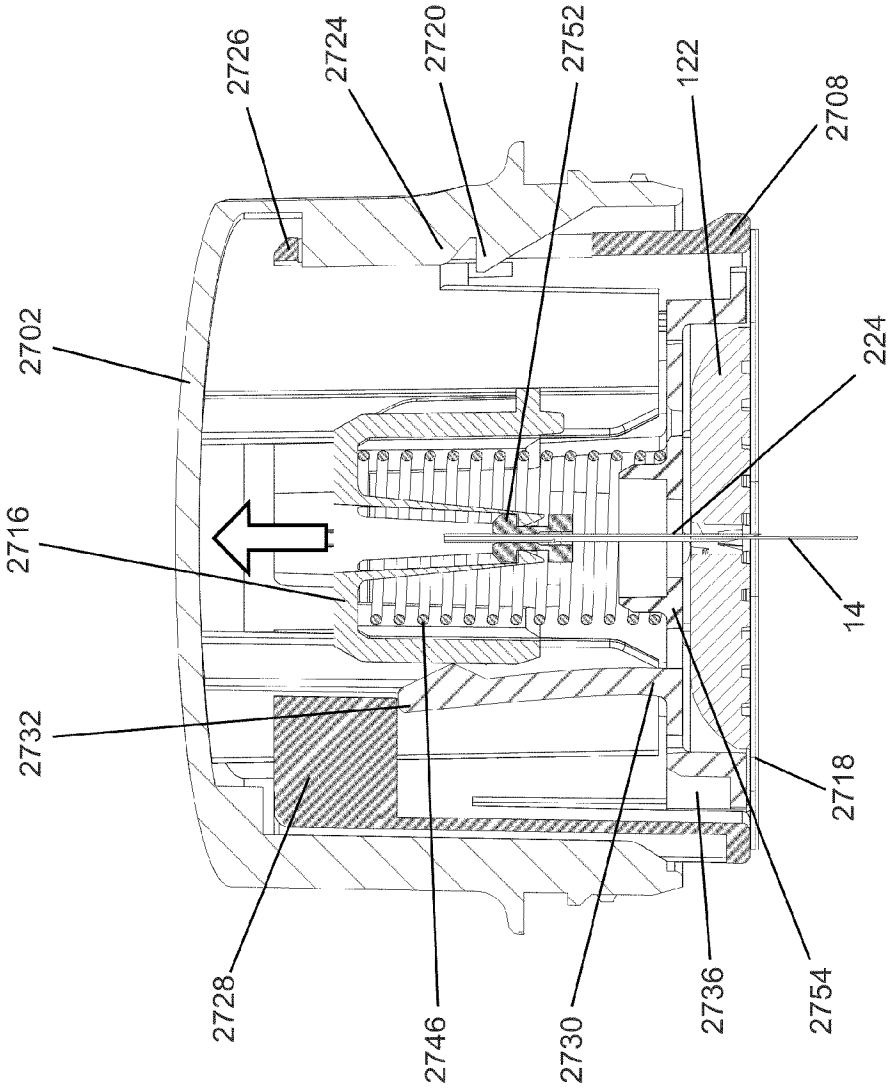
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FIG. 105

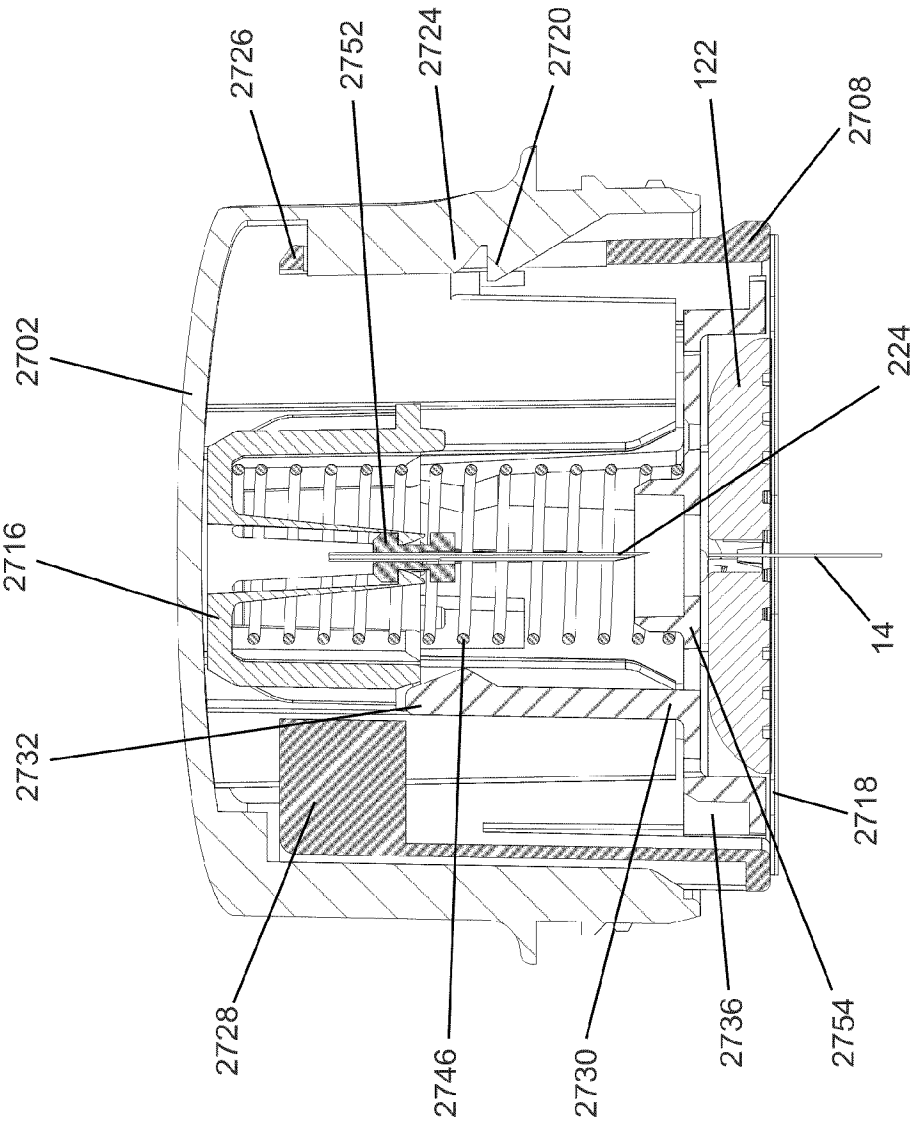
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FIG. 106

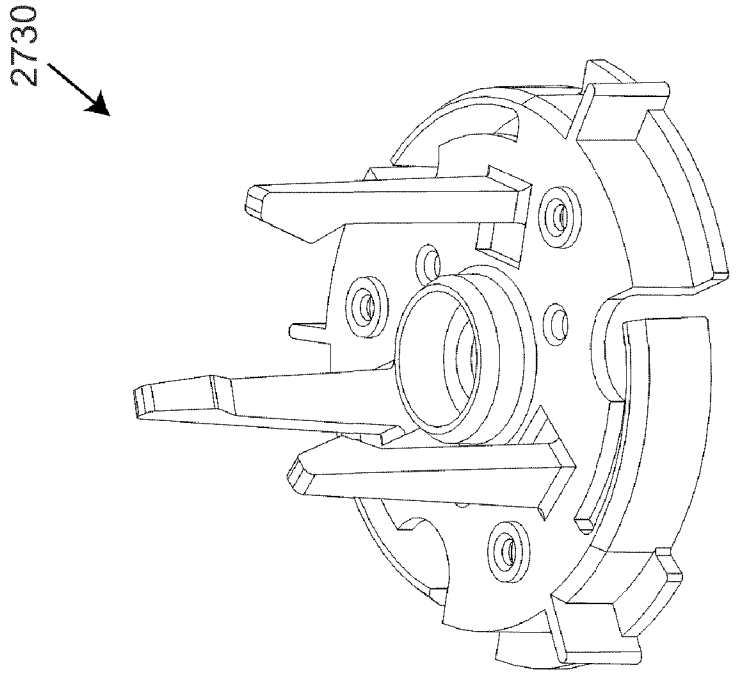

FIG. 108

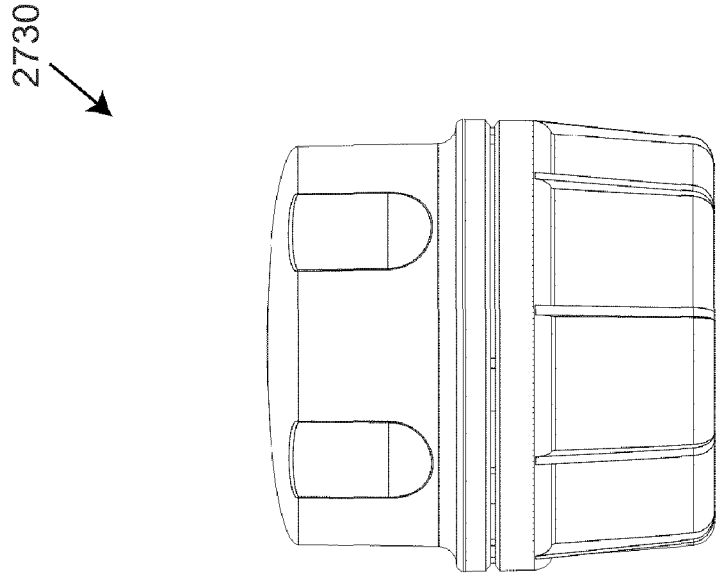

FIG. 107

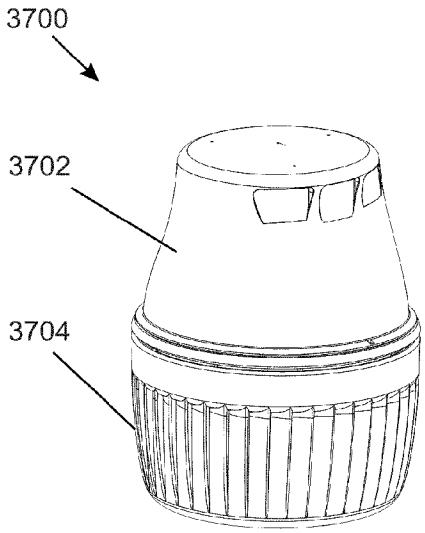

FIG. 109

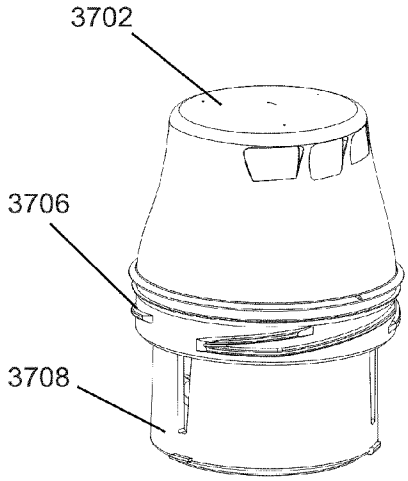

FIG. 110

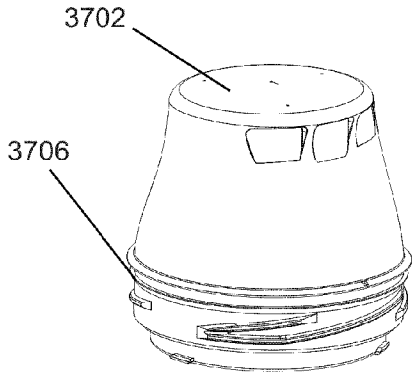

FIG. 111

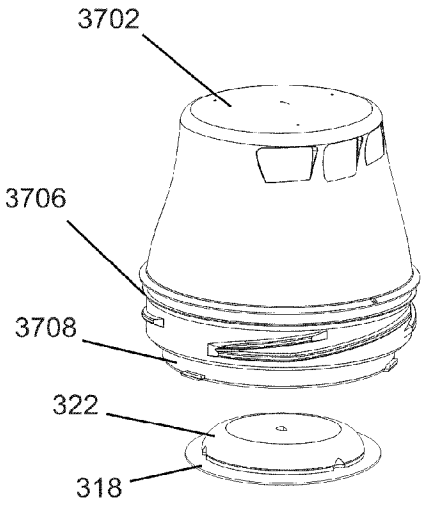

FIG. 112

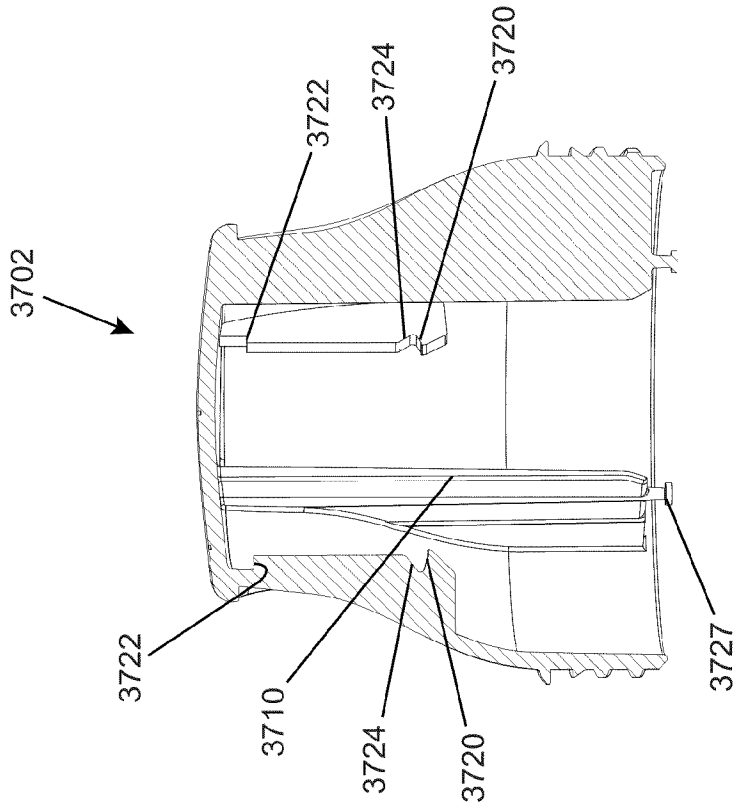

FIG. 114

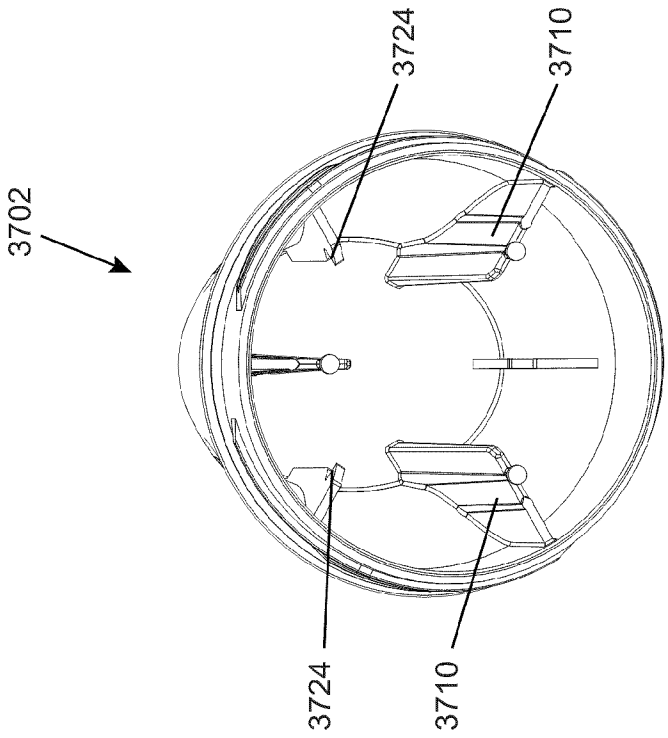

FIG. 113

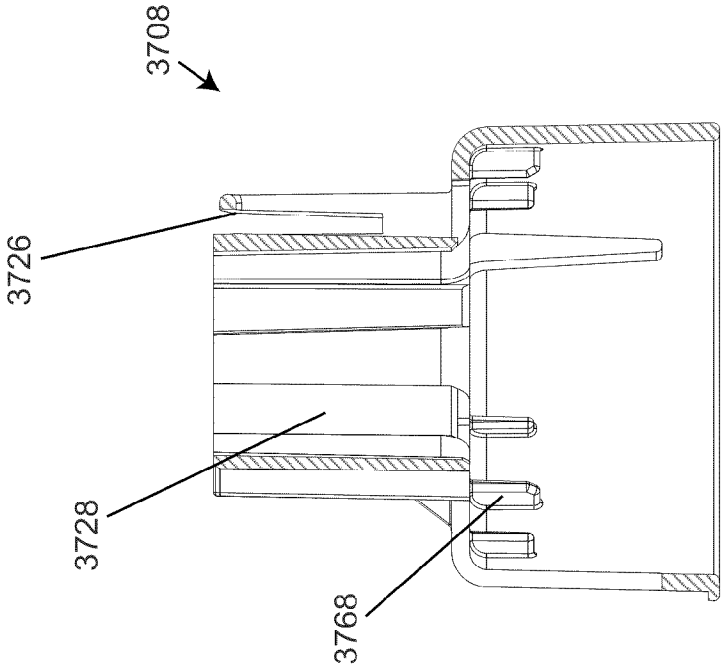

FIG. 116

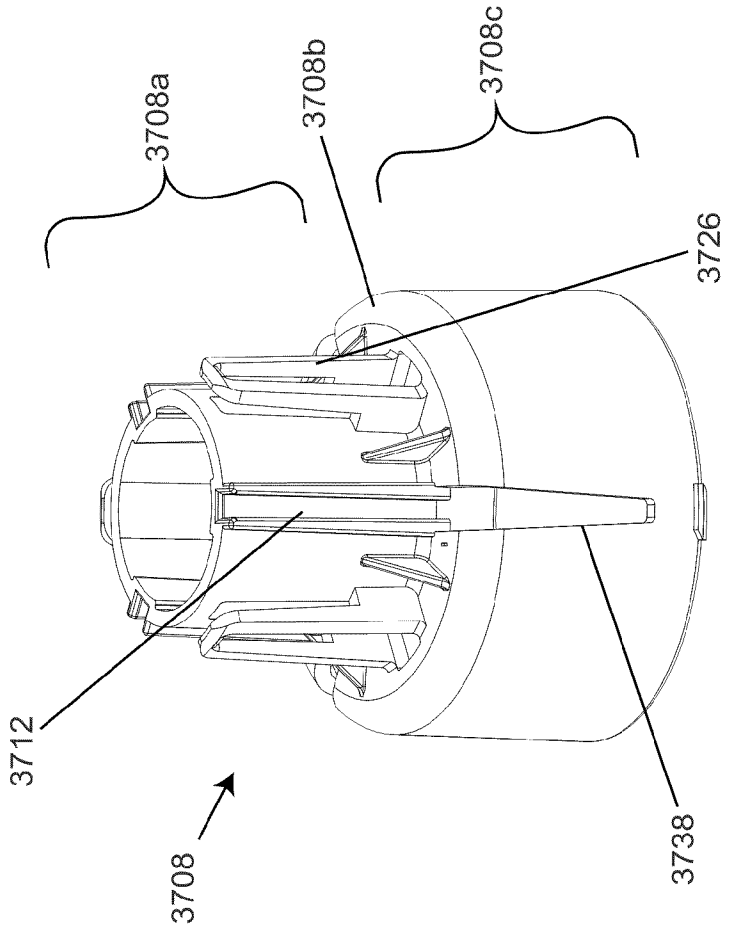

FIG. 115

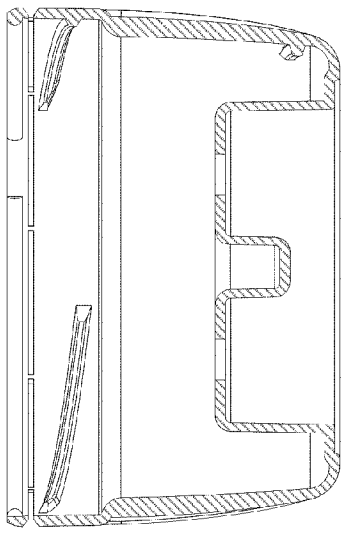

FIG. 119

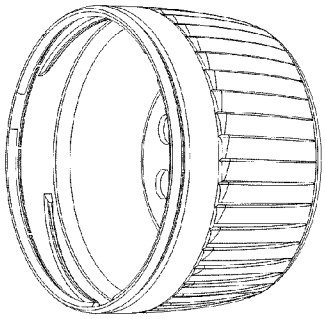

FIG. 117

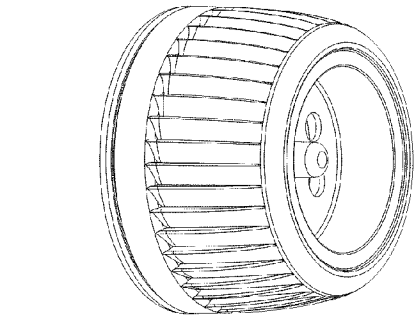

FIG. 118

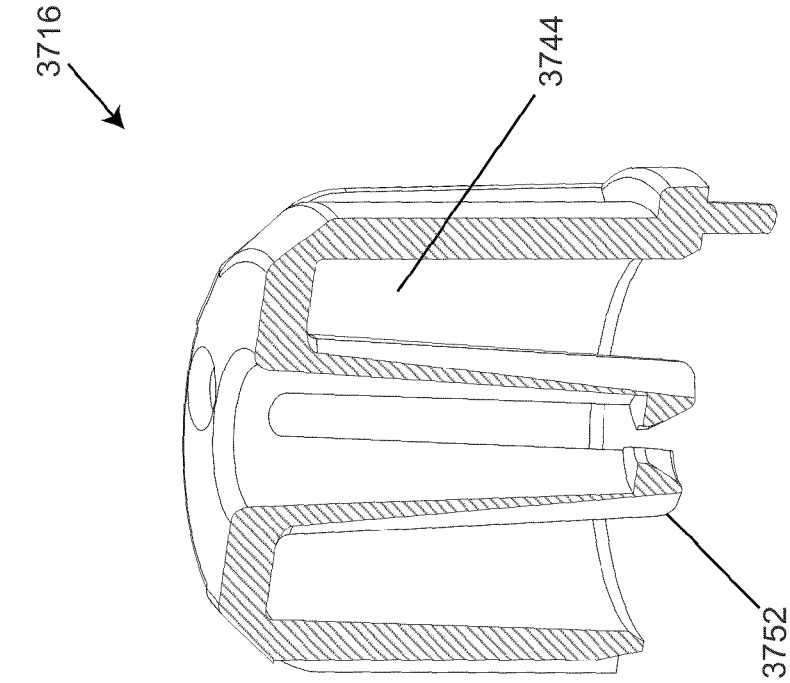

FIG. 121

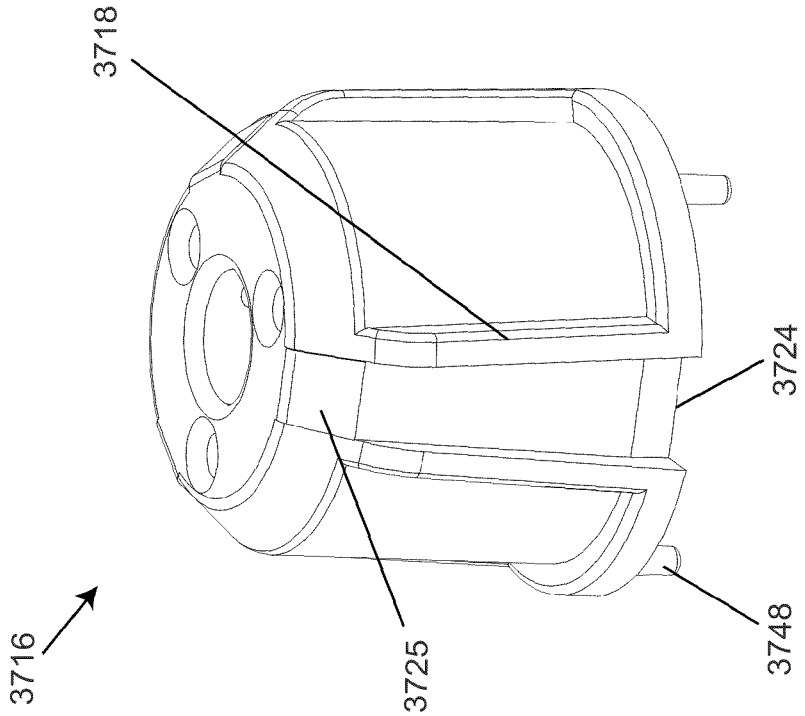

FIG. 120

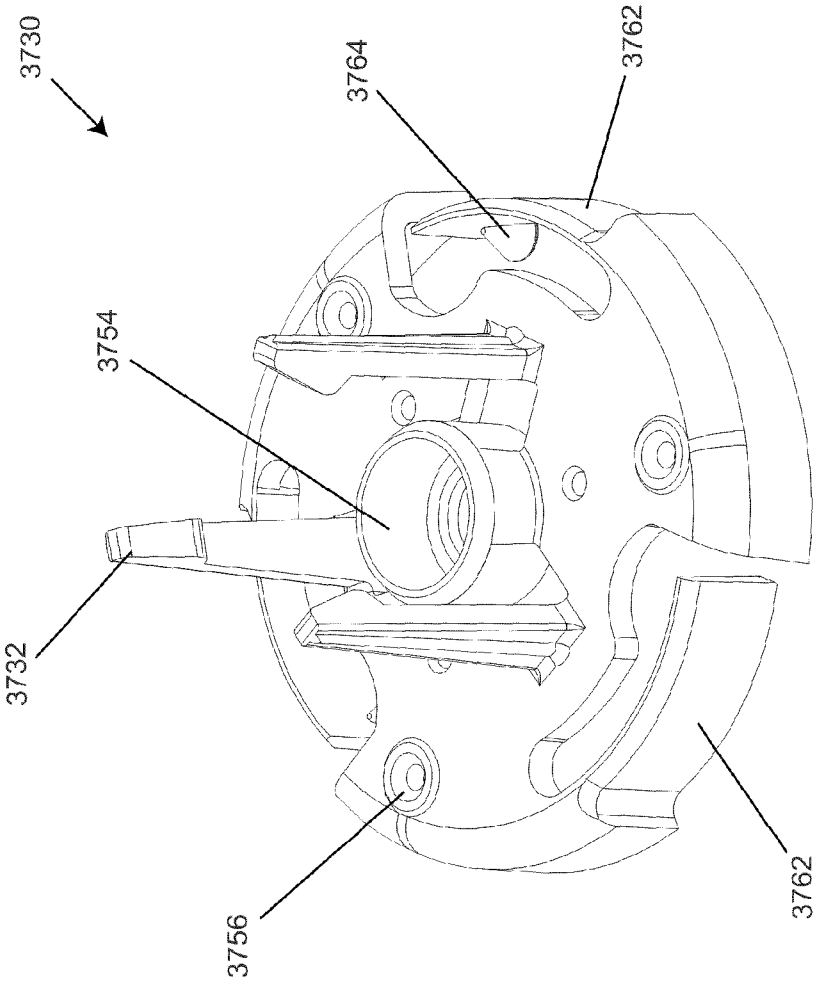

FIG. 122

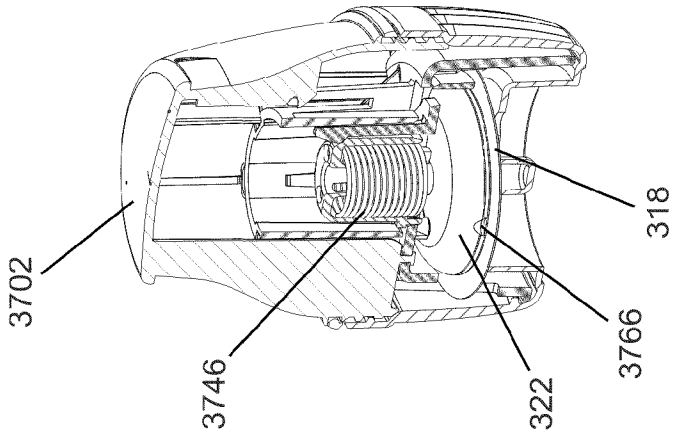

FIG. 125

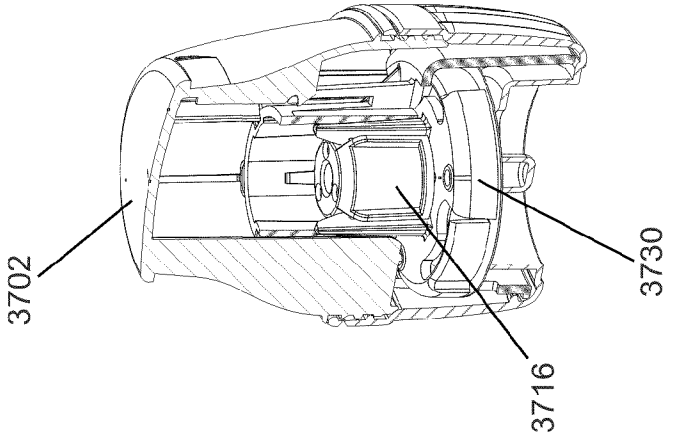

FIG. 124

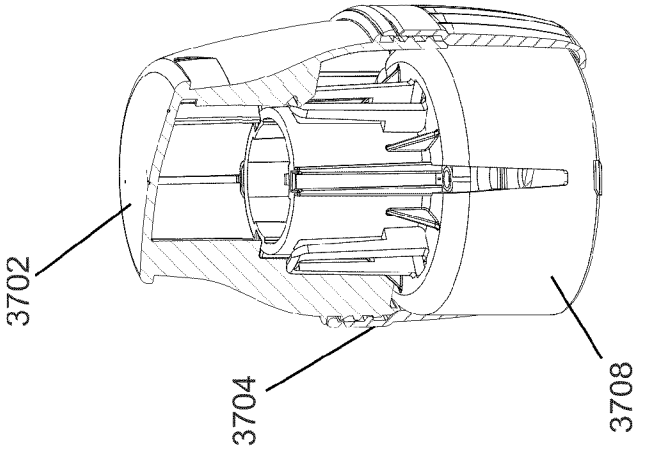

FIG. 123

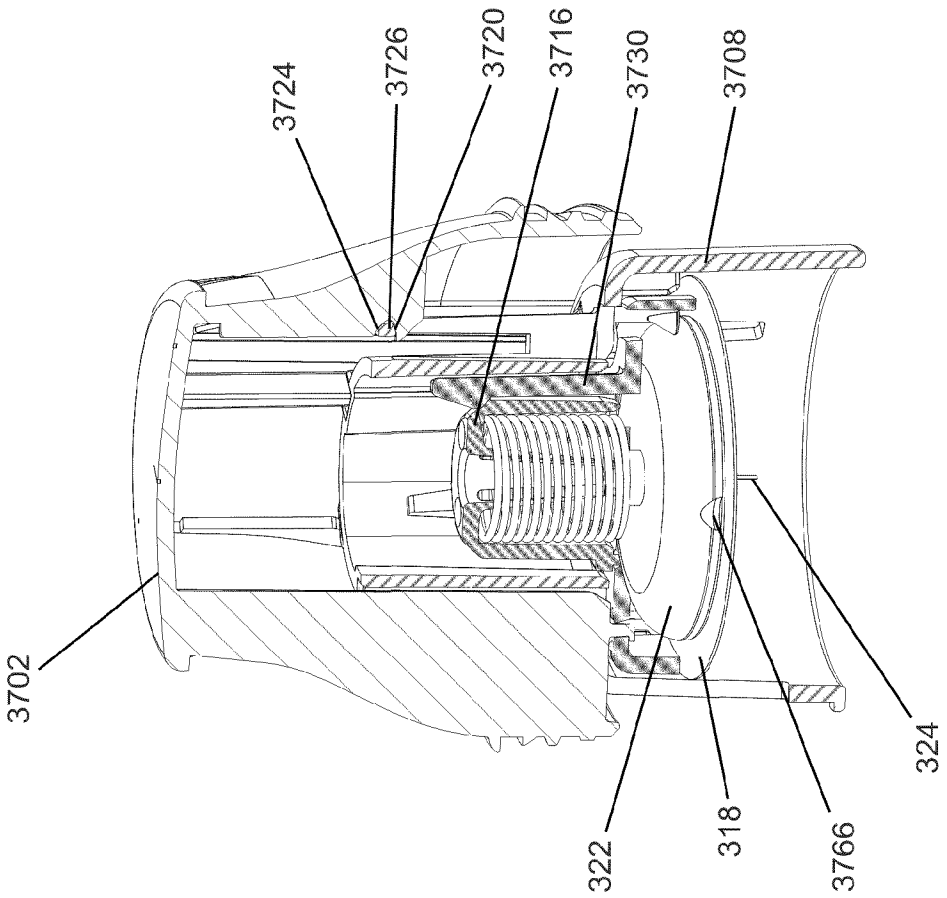

FIG. 126

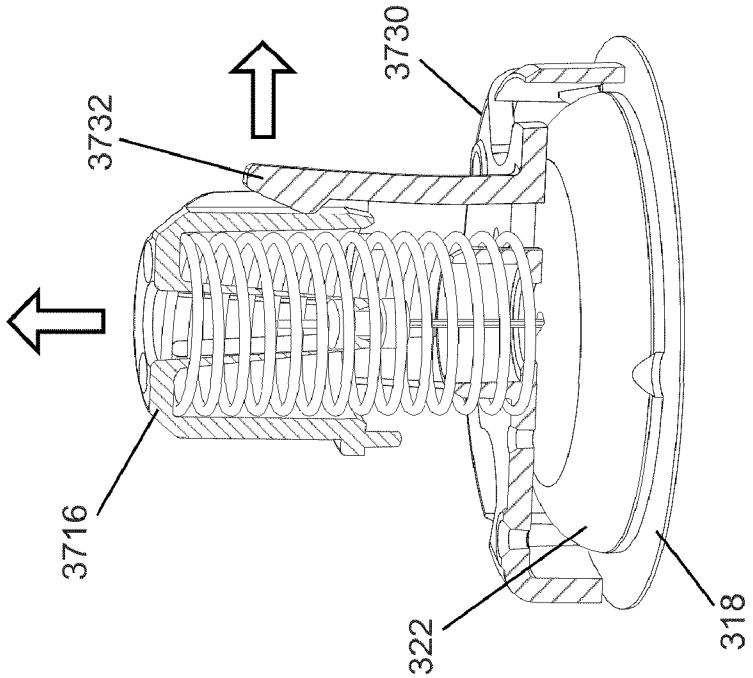

FIG. 128

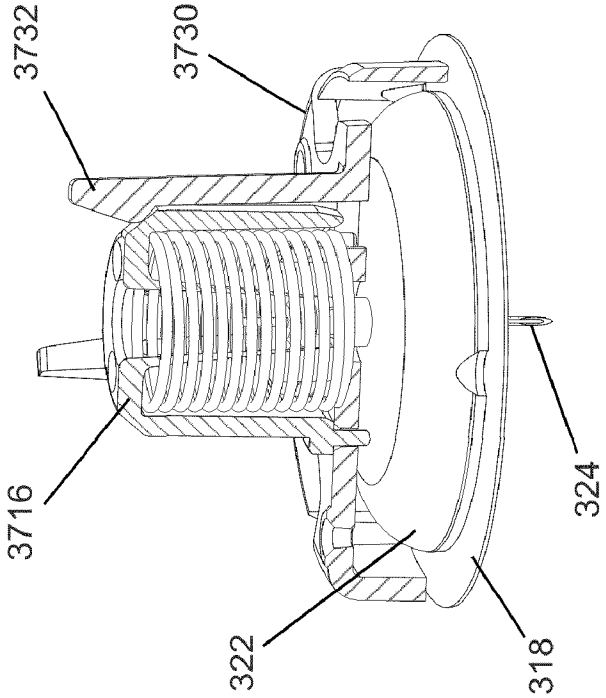

FIG. 127

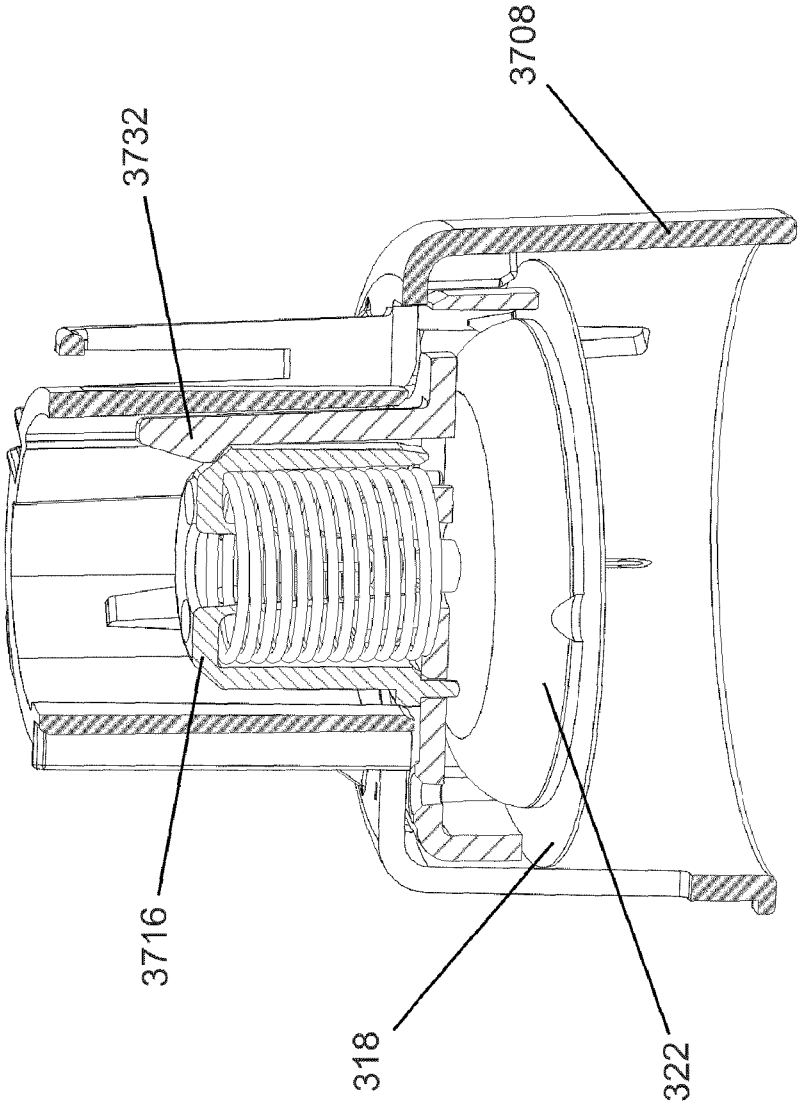

FIG. 129

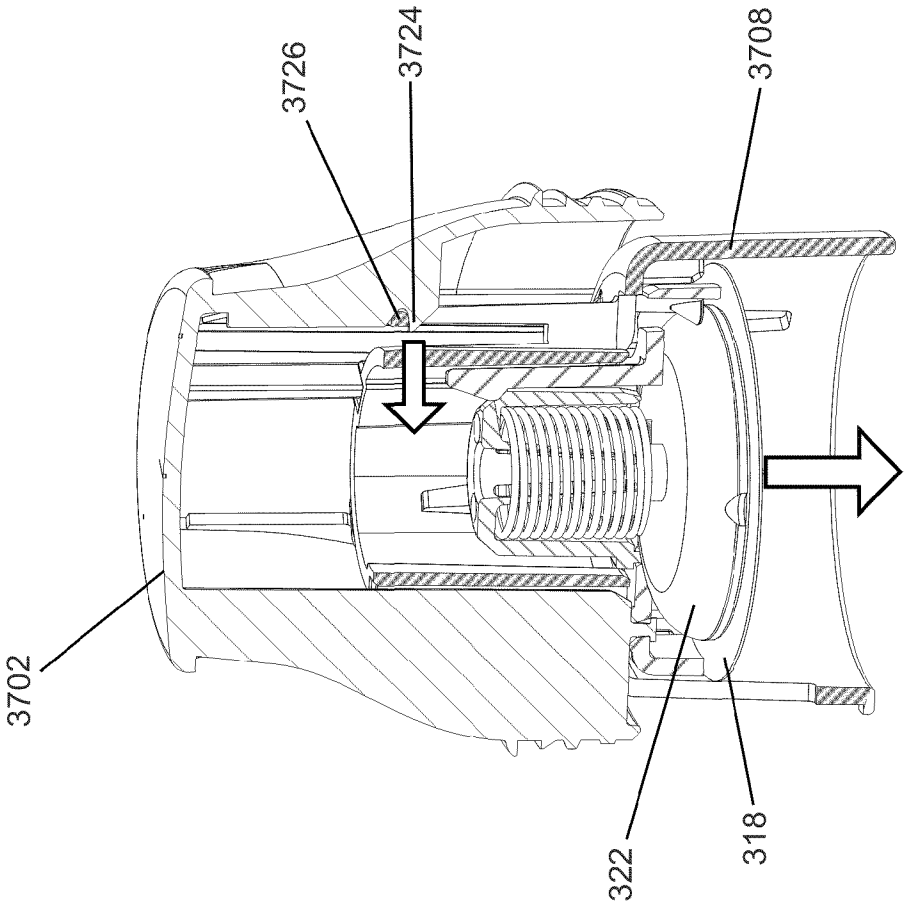

FIG. 130

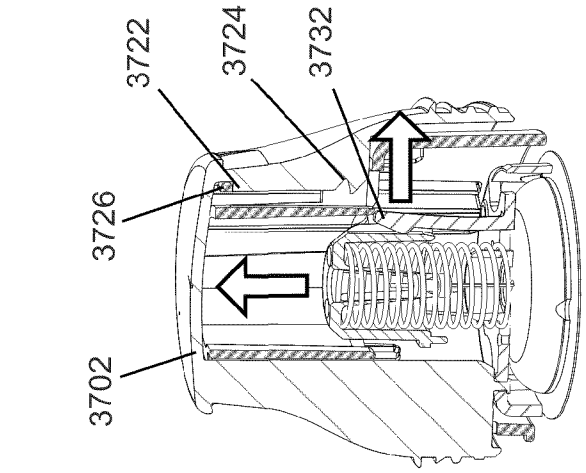

FIG. 133

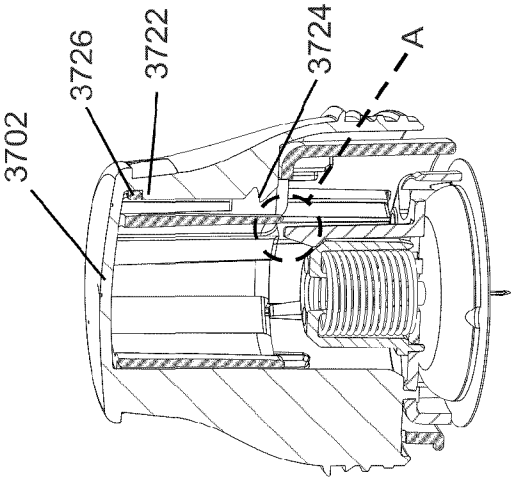

FIG. 132

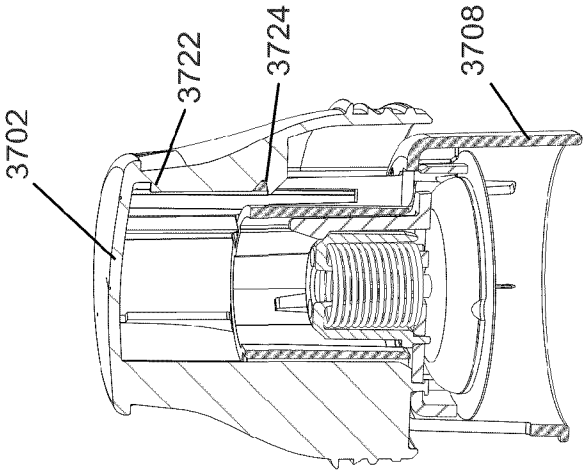

FIG. 131

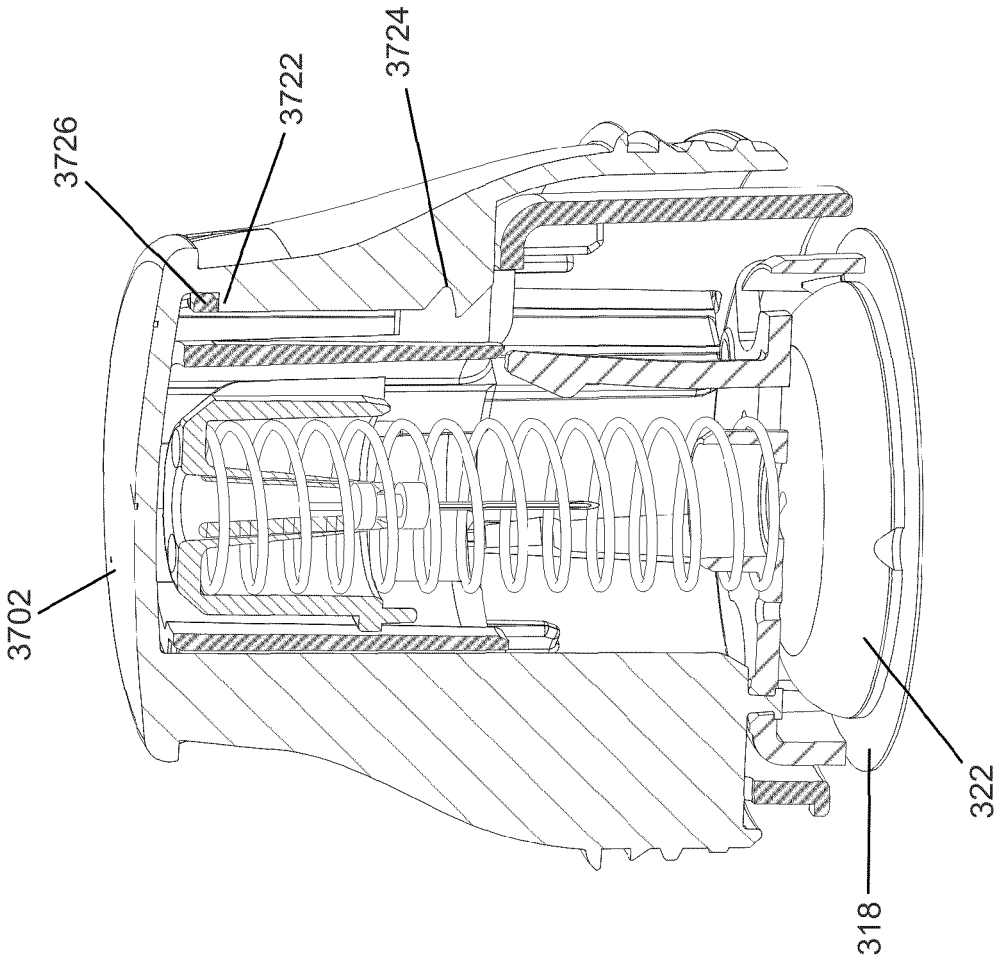

FIG. 134

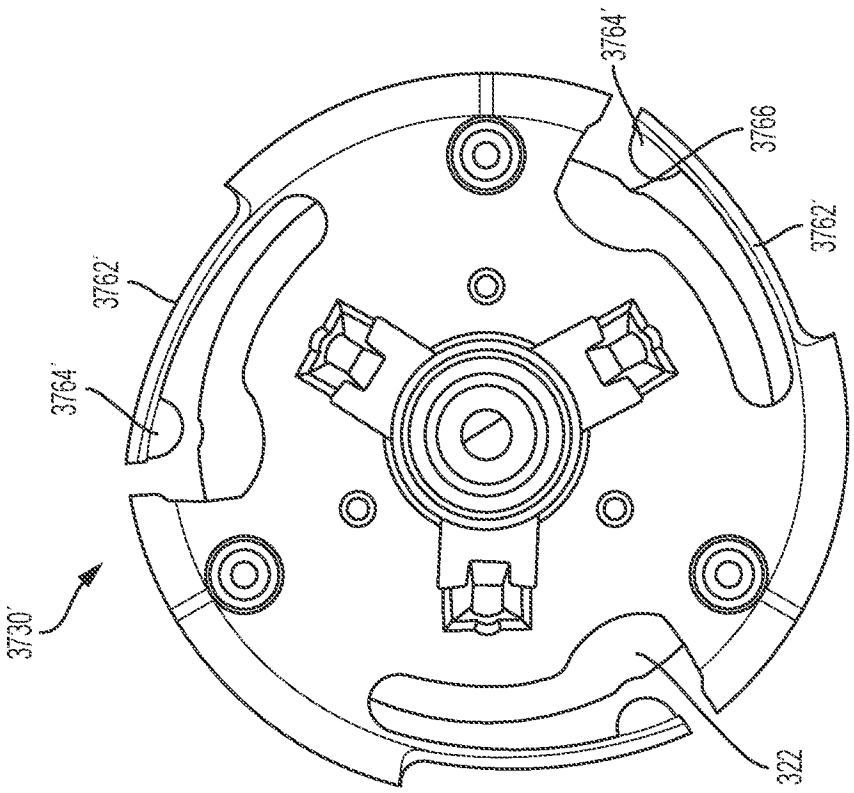

FIG. 136

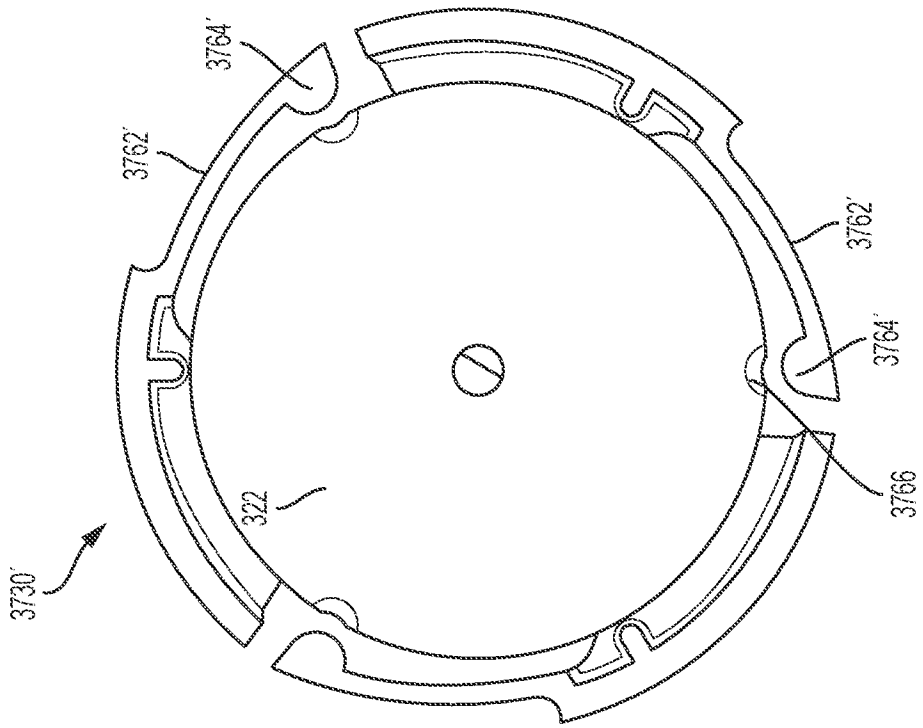

FIG. 135

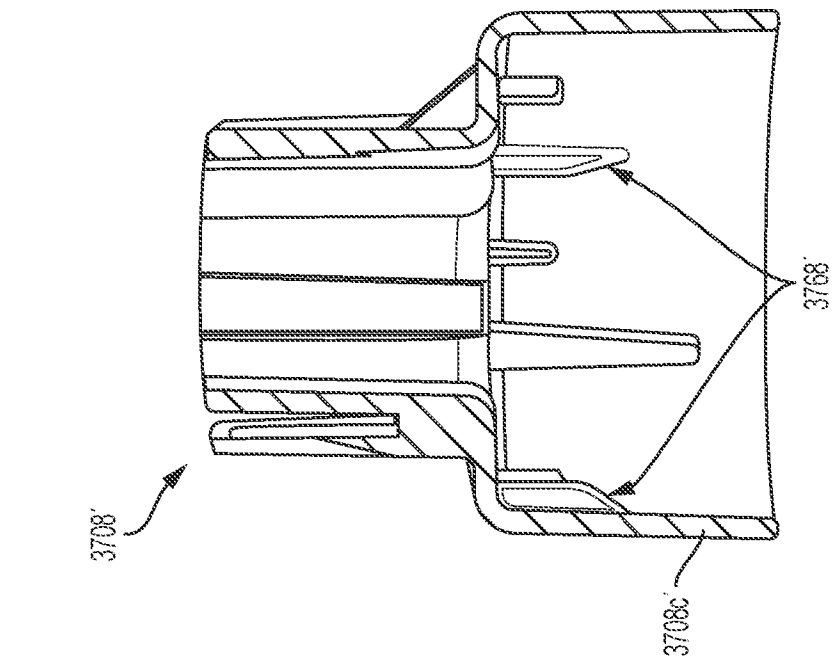

FIG. 138

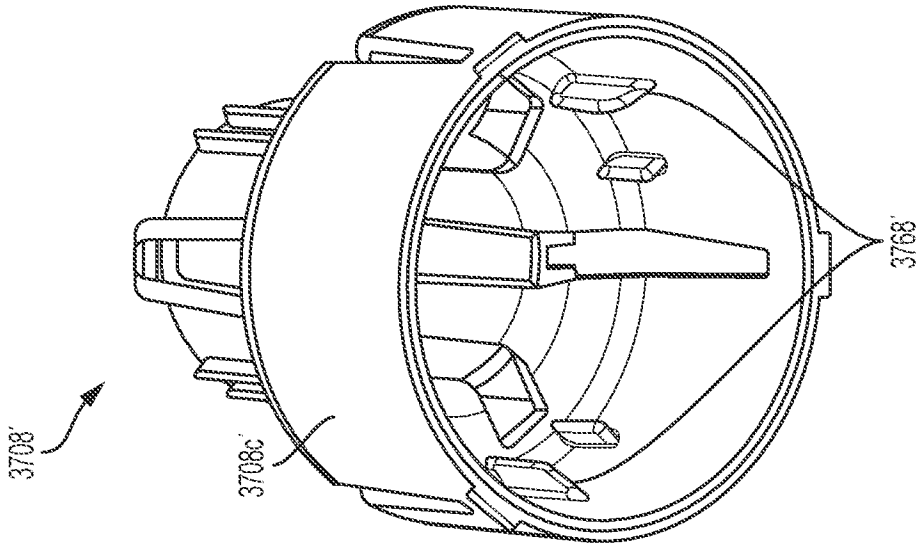

FIG. 137

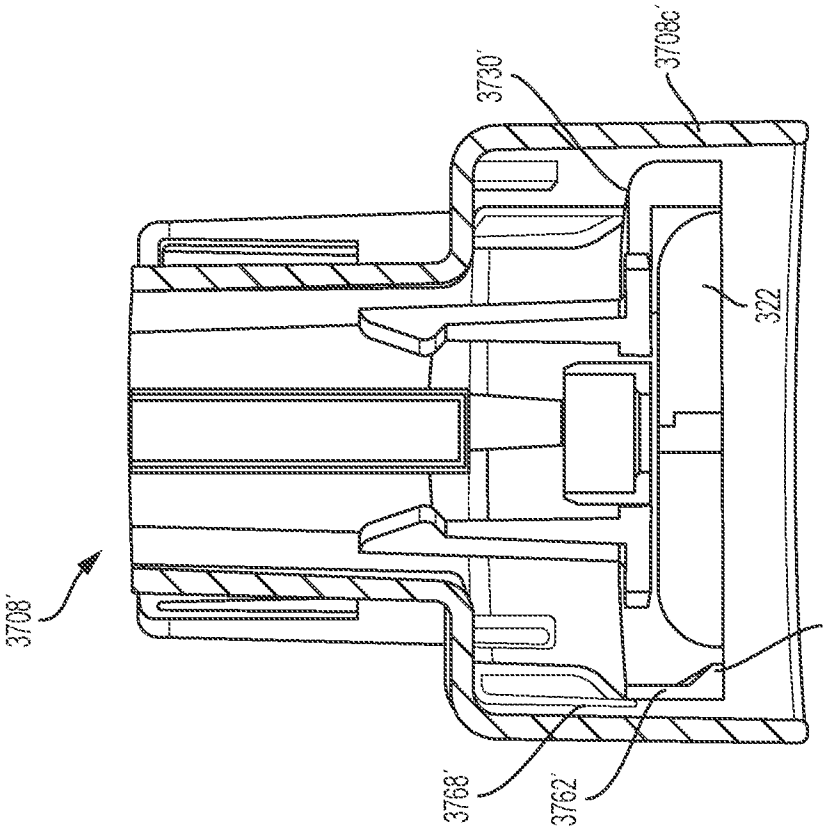

FIG. 140

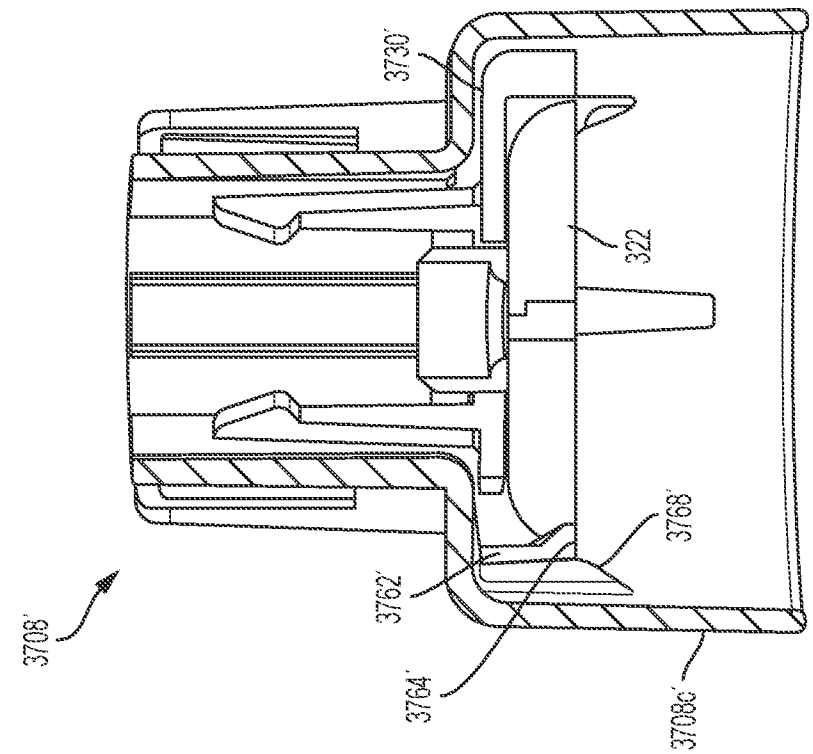

FIG. 139

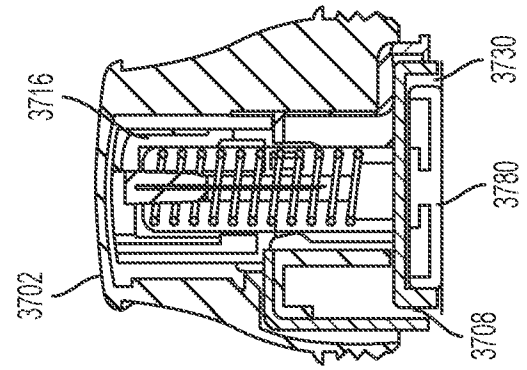

FIG. 144

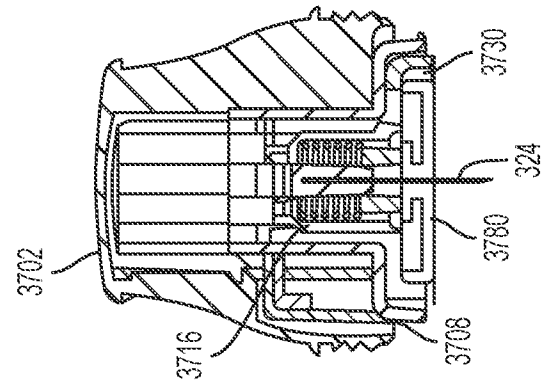

FIG. 143

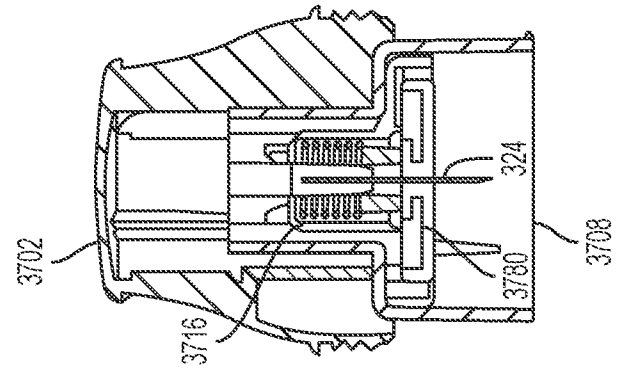

FIG. 142

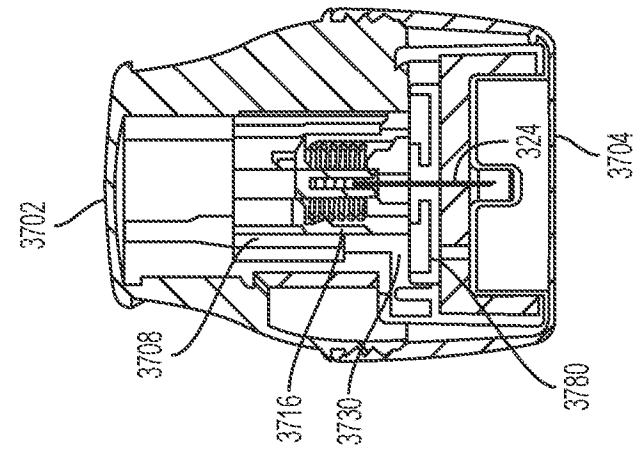

FIG. 141

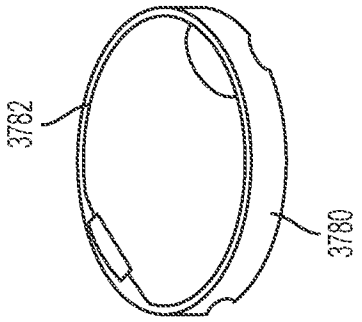

FIG. 147a

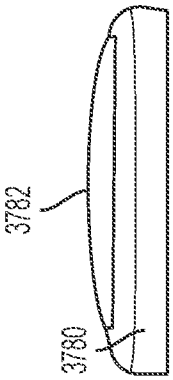

FIG. 147b

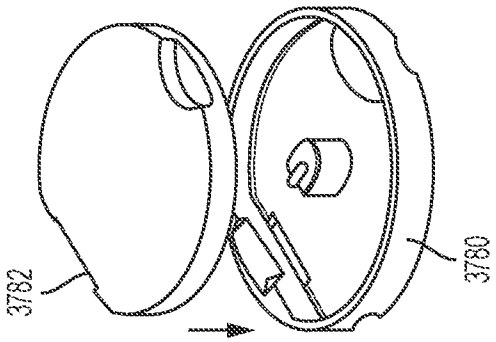

FIG. 146a

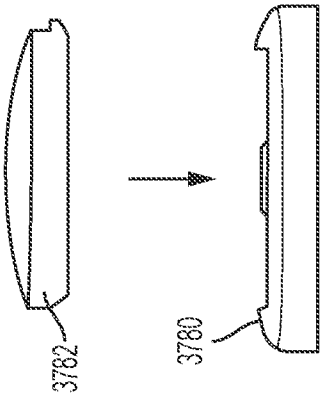

FIG. 146b

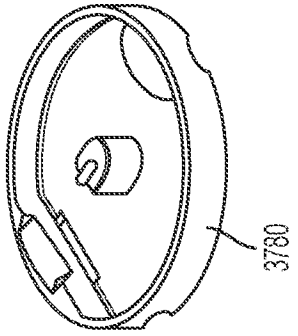

FIG. 145a

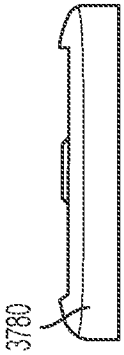

FIG. 145b

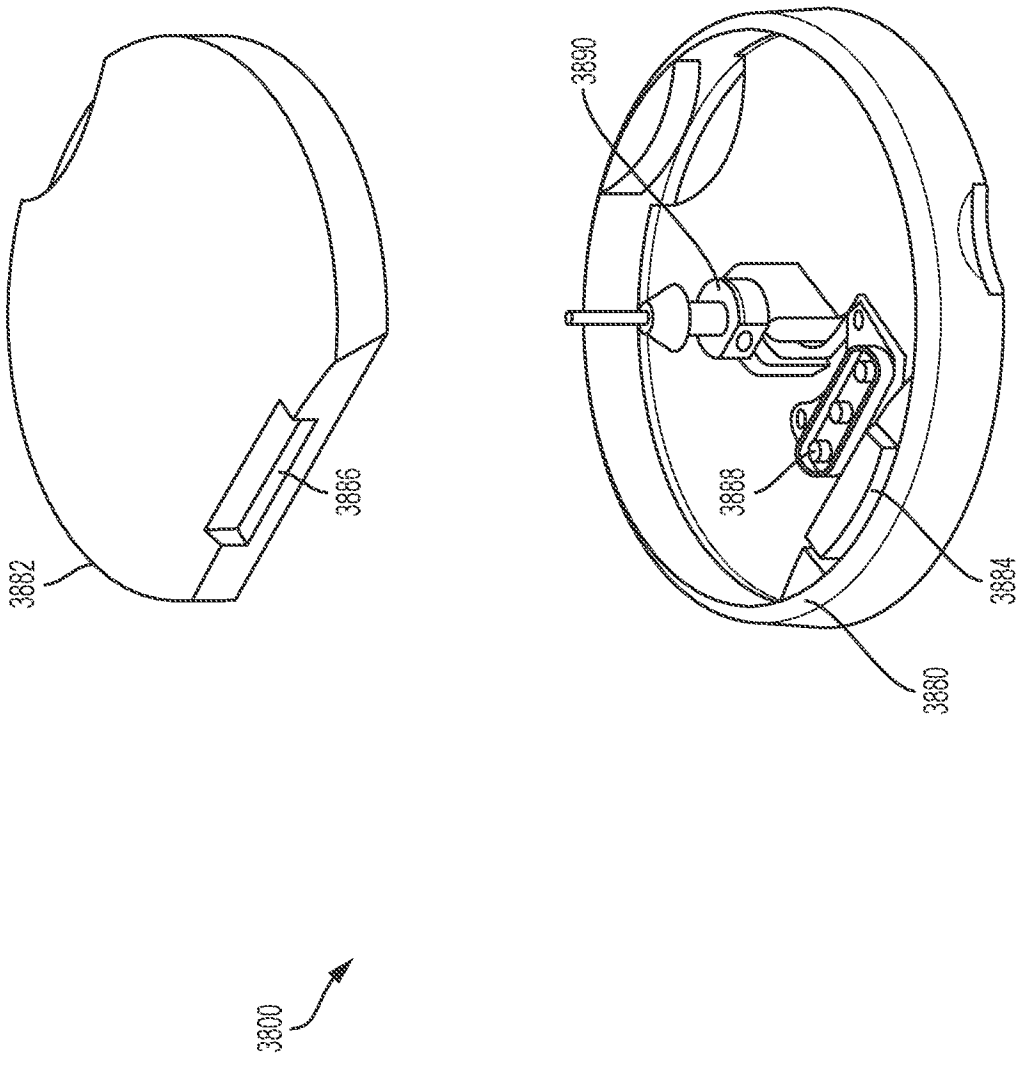

FIG. 148

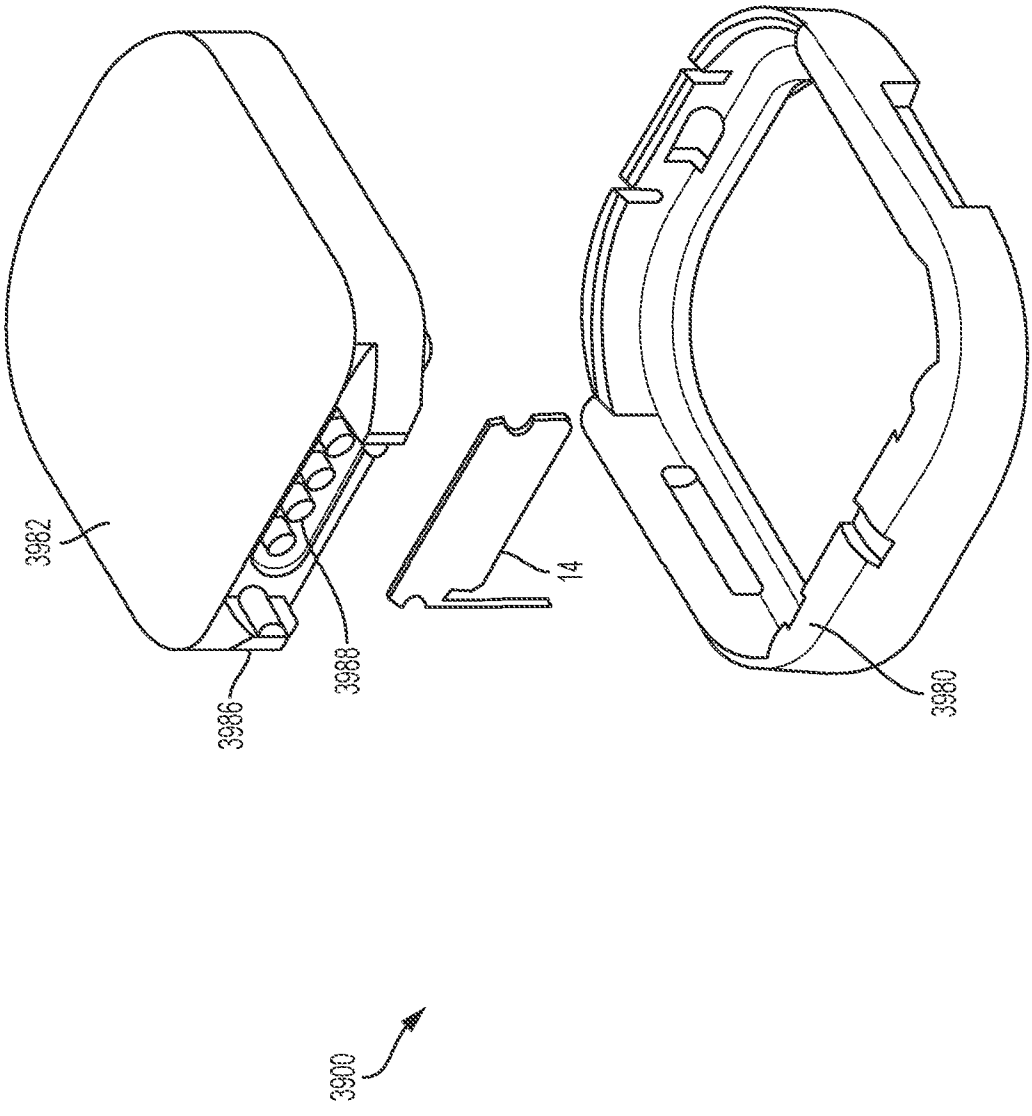

FIG. 149

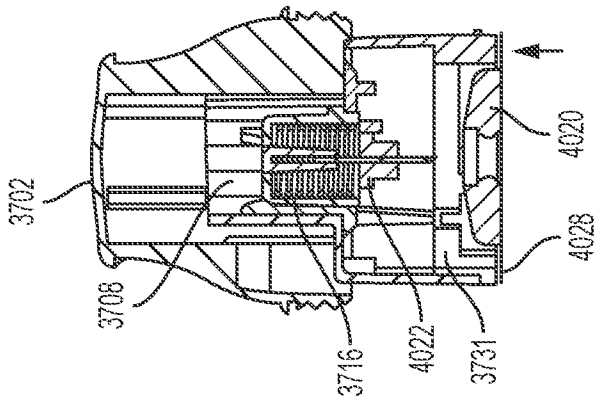

FIG. 153

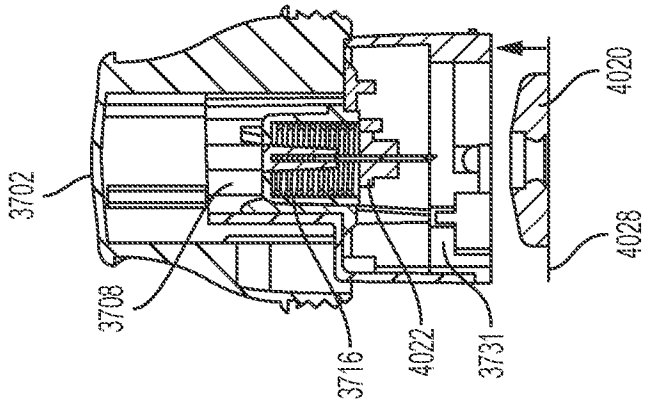

FIG. 152

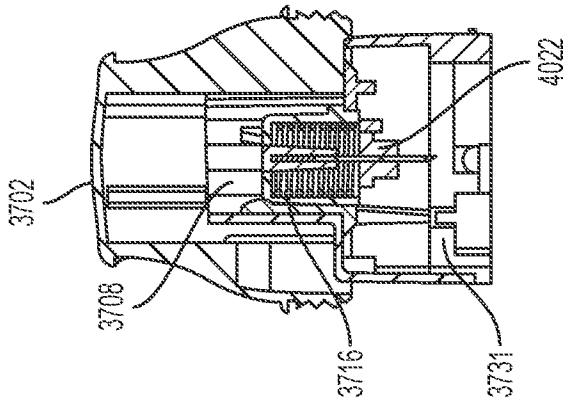

FIG. 151

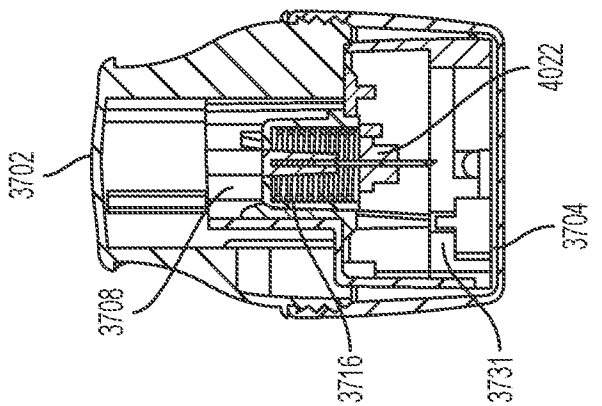

FIG. 150

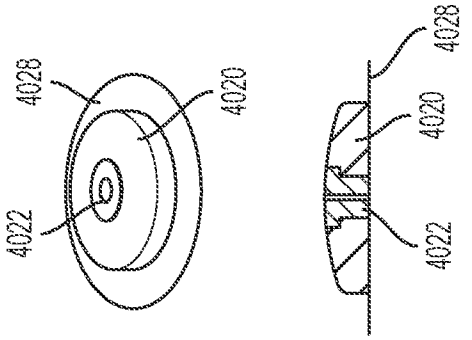

FIG. 156

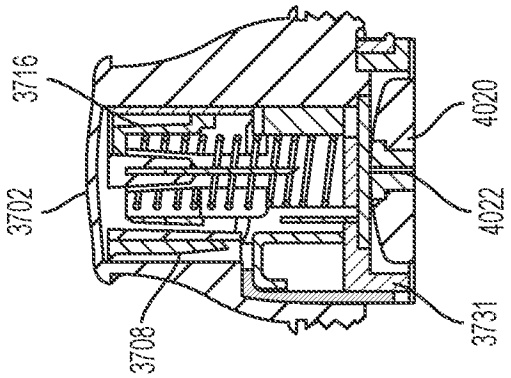

FIG. 155

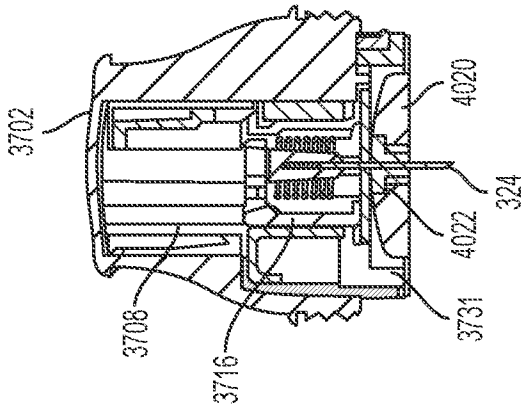

FIG. 154

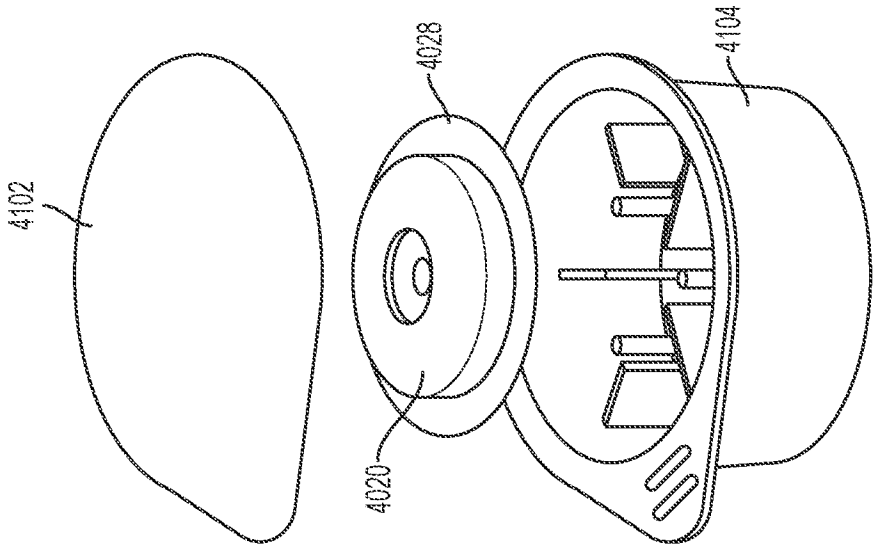

FIG. 158

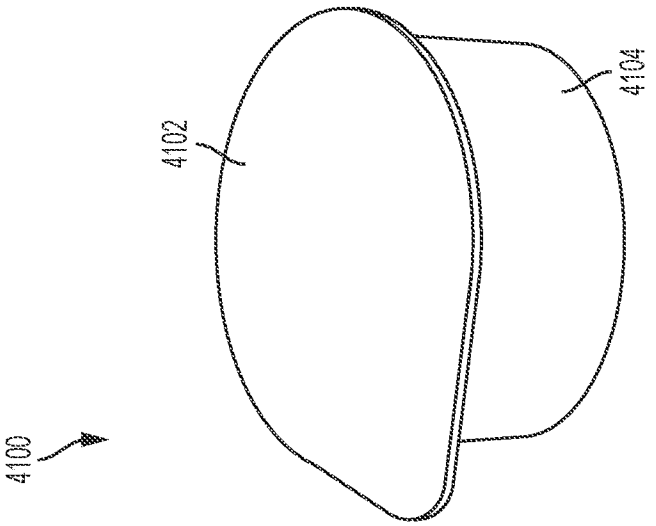

FIG. 157

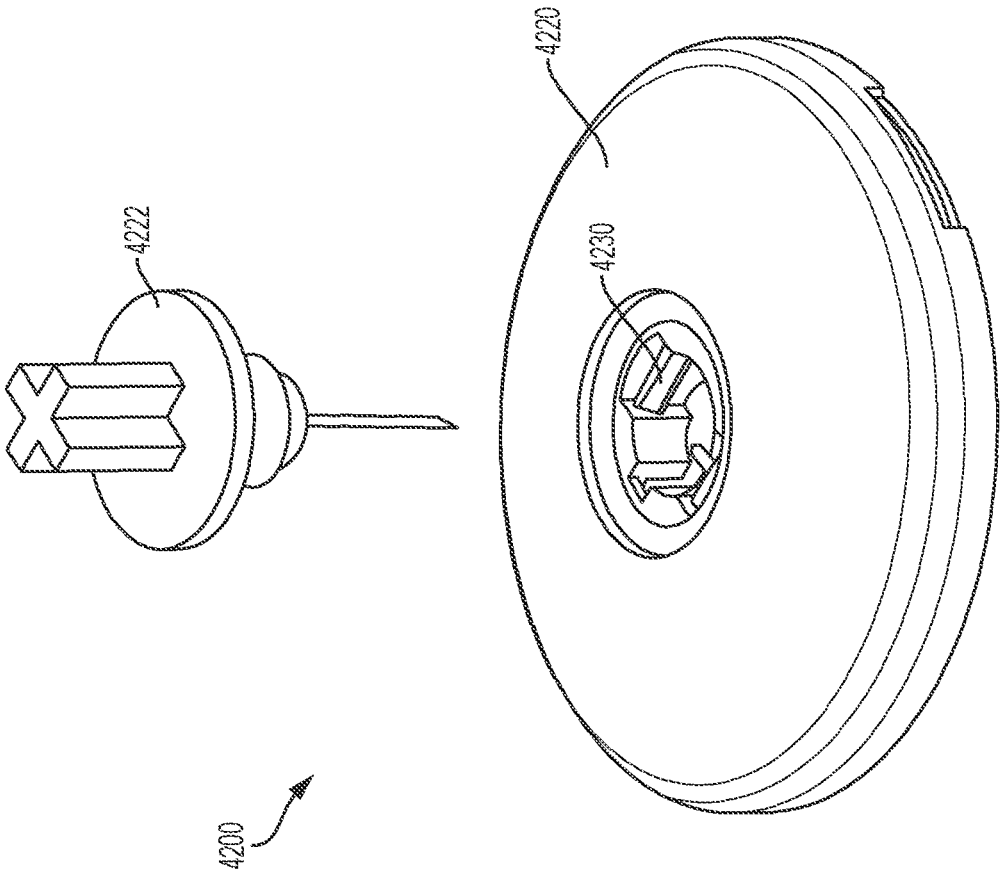

FIG. 159

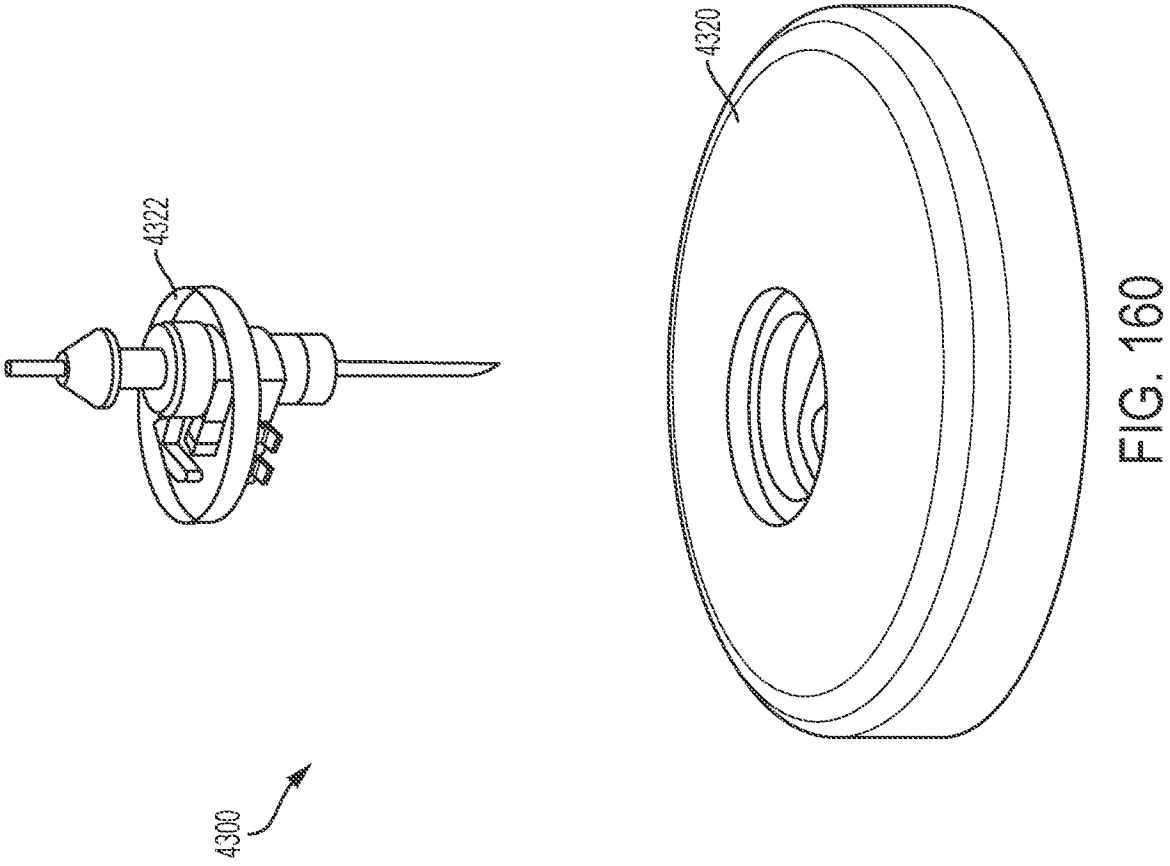

FIG. 160

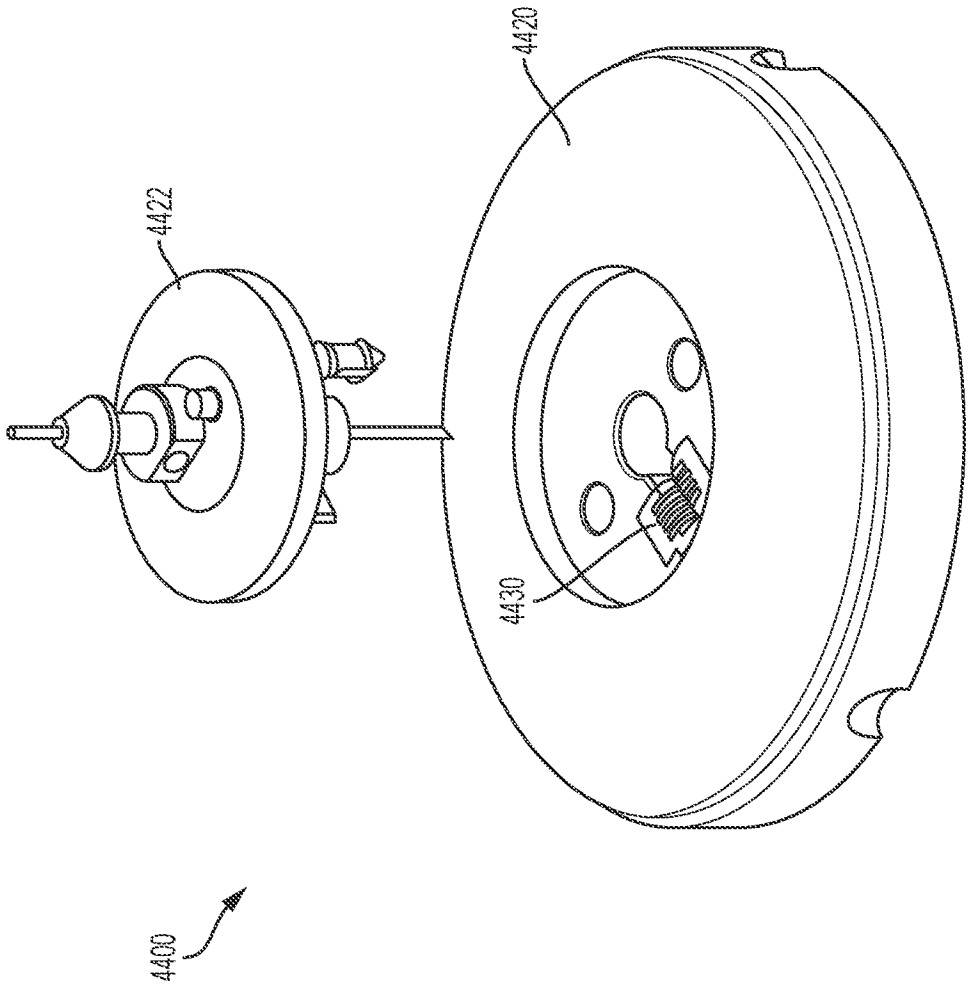

FIG. 161

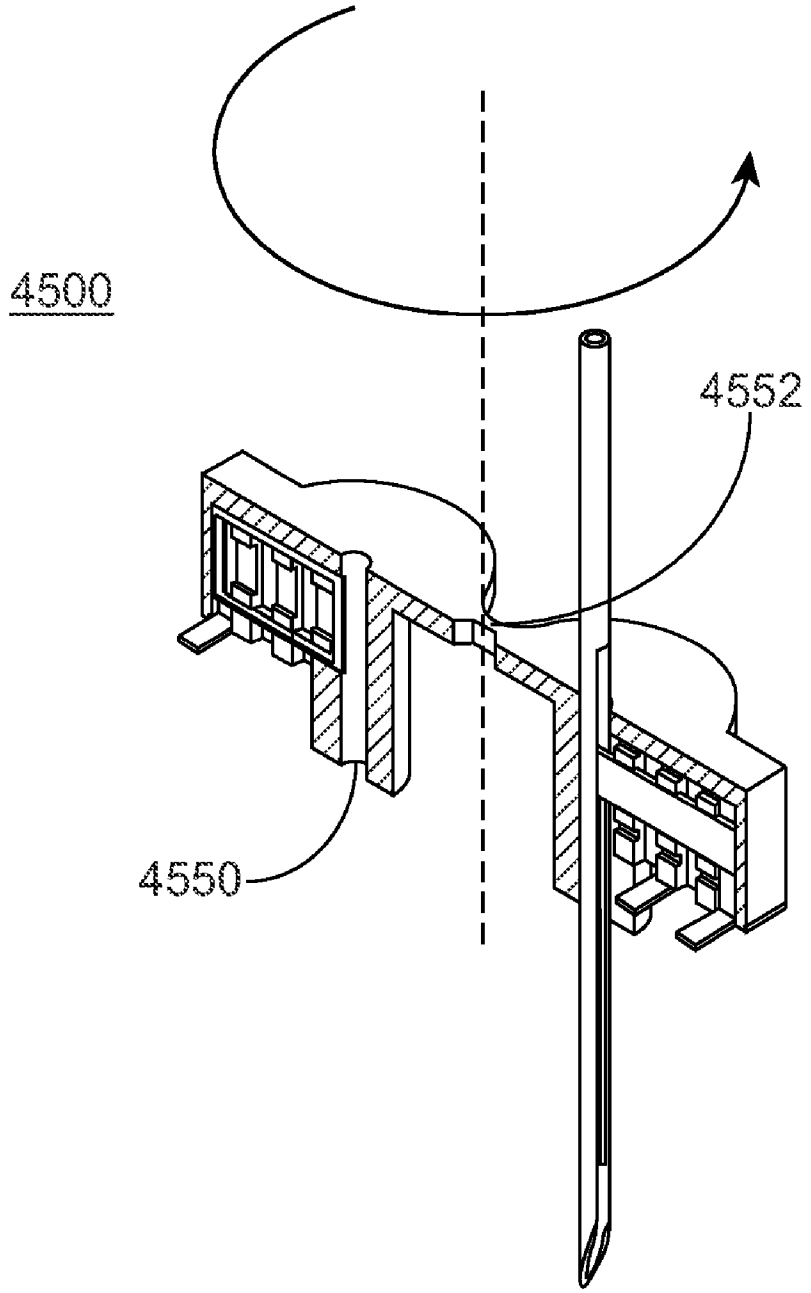

FIG. 162

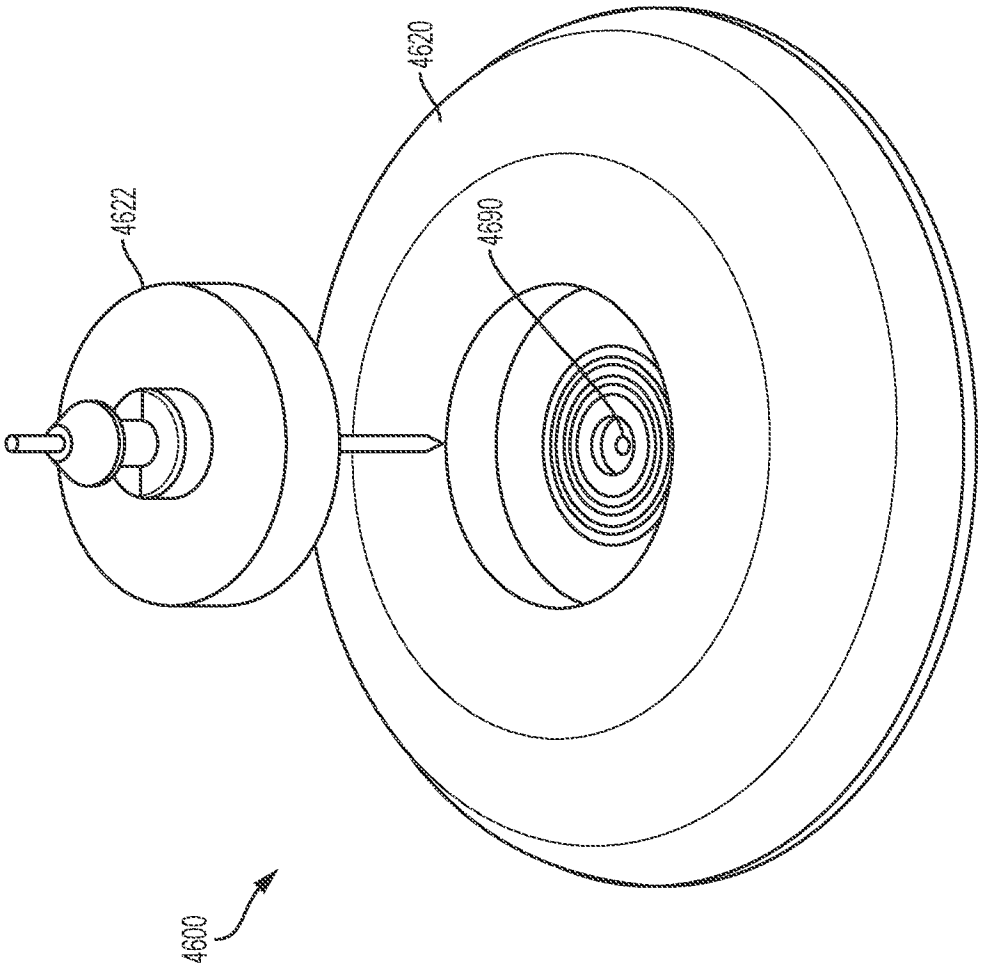

FIG. 163

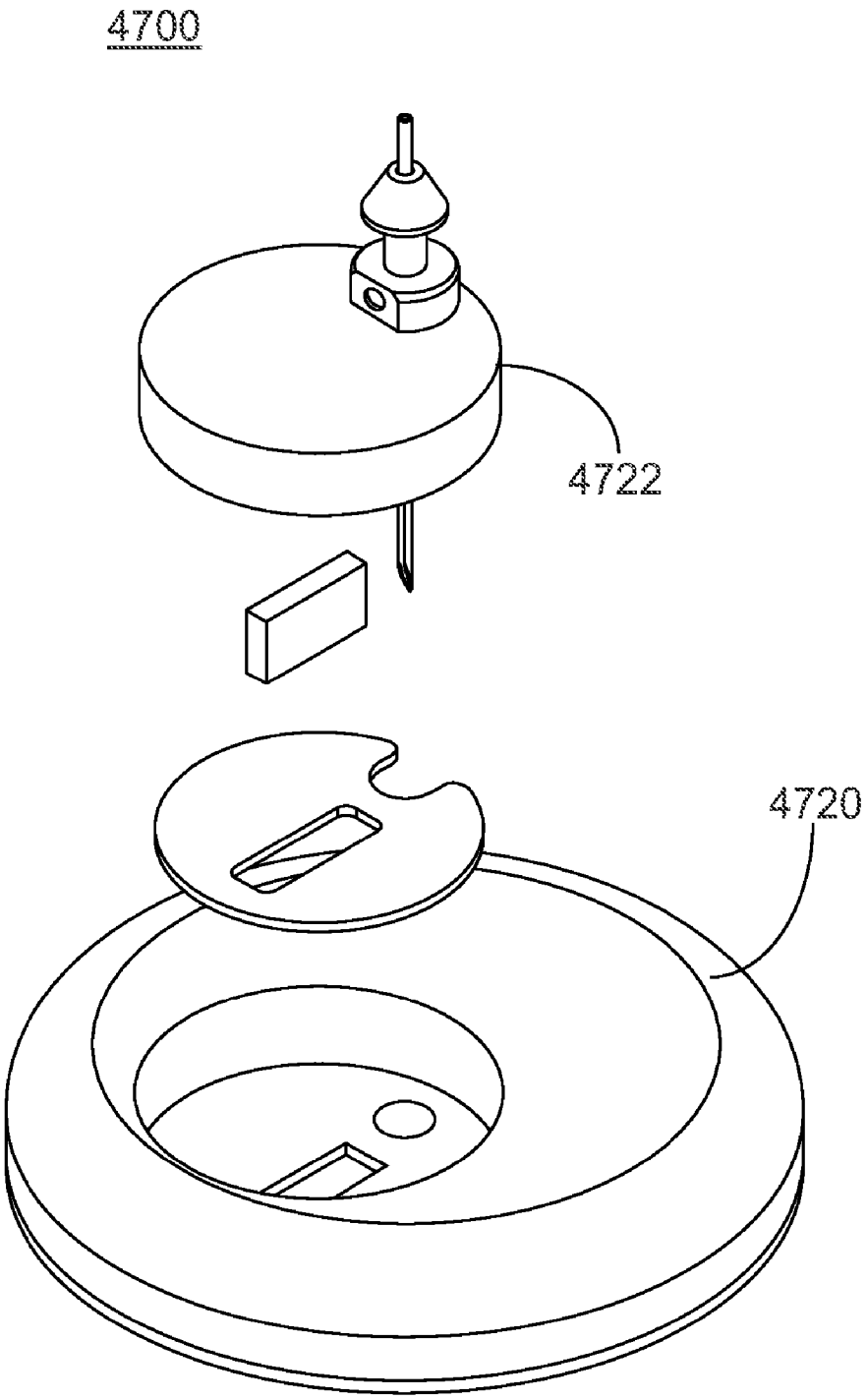

FIG. 164

REMARKS

Claims 26-48 are pending and claims 1-25 have been canceled. Examination of these new claims is respectfully requested. Support for the new claims can be found, for example, in paragraphs [0248] to [0266], and Figures 3, 109-140, and elsewhere throughout the application as filed. No new matter has been introduced.

All citations to claim support are purely for the benefit of the Examiner. It is stressed that the citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

Cancelation of the claims is made without prejudice and solely to advance prosecution of this application and are not intended as a disavowal of any subject matter. Accordingly, by this response, Applicants do not concede that previously pending claims are not patentable.

The right is reserved to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any previously pending claims regardless of whether those claims were amended or cancelled herein. This may entail the pursuit of broader and/or narrower claims, and/or subject matter that was previously relinquished by virtue of argument or amendment.

It is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 432-9993. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: September 11, 2020

Respectfully submitted,

/Glen Liu/

Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660
Attorney for Applicant

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions of the claims in the application.

1-25. (Cancelled)

26. (New) A glucose monitoring assembly, the assembly comprising:

(1) an inserter, comprising:

an inserter housing; and

a sharp, wherein the sharp is configured to insert a portion of a glucose sensor into a subject;

(2) an on body electronics unit, comprising:

an on body electronics unit housing comprising a plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is configured to be detachably engaged to the inserter;

the glucose sensor;

on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level; and

an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject,

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position within the inserter to a distal position, and

wherein the inserter is configured to retract the sharp from the distal position to a retracted position within the inserter.

27. (New) The glucose monitoring assembly of claim 26, wherein the inserter further comprises one or more gripping arms.

28. (New) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are configured to engage the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the one or more gripping arms are configured to disengage from the plurality of recesses when the on body electronics unit is in the distal position.

29. (New) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are biased in an outward direction.

30. (New) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are configured to deflect in an outward direction after the on body electronics unit advances from the proximal position.

31. (New) The glucose monitoring assembly of claim 27, wherein the inserter further comprises one or more interior surfaces configured to hold the one or more gripping arms against the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

32. (New) The glucose monitoring assembly of claim 31, wherein the inserter is configured such that the one or more interior surfaces are not in contact with the one or more gripping arms when the on body electronics unit is in the distal position.

33. (New) The glucose monitoring assembly of claim 27, wherein each of the one or more gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

34. (New) The glucose monitoring assembly of claim 33, where the engagement boss is disposed on a tip portion of the gripping arm.

35. (New) The glucose monitoring assembly of claim 33, wherein the engagement boss comprises a conical shape.

36. (New) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses comprises a concave portion.

37. (New) The glucose monitoring assembly of claim 26, wherein the plurality of recesses are disposed on a side wall of the on body electronics unit housing.

38. (New) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a driver disposed in the inserter housing, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.

39. (New) The glucose monitoring assembly of claim 26, further comprising a cap removably attached to a distal portion of the inserter.

40. (New) The glucose monitoring assembly of claim 36, wherein the cap is removably attached to the distal portion of the inserter by a plurality of threads.

41. (New) The glucose monitoring assembly of claim 36, wherein the cap includes a first interior space, and wherein a section of the glucose sensor and a section of the sharp are housed within the first interior space.

42. (New) The glucose monitoring assembly of claim 38, wherein the first interior space comprises a sterile environment.

43. (New) The glucose monitoring assembly of claim 26, wherein a proximal end of the inserter comprises an inserter handle, wherein a distal end of the inserter comprises a sheath having a distal sheath end configured to be placed on the skin surface of the subject, and wherein the

inserter handle is configured to move in a downward direction toward the skin surface relative to the sheath in response to an application of force on the inserter handle.

44. (New) The glucose monitoring assembly of claim 43, wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter handle.

45. (New) The glucose monitoring assembly of claim 26, wherein the on body electronics unit further comprises a sensor hub,

wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion,

wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

46. (New) The glucose monitoring assembly of claim 26, wherein the on body electronics comprises an aperture, and wherein the sharp extends through the aperture of the on body electronics.

47. (New) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a distal end configured to be placed on the skin surface of the subject before advancement of the on body electronics unit and the sharp.

48. (New) The glucose monitoring assembly of claim 26, wherein the on body electronics are in a low power state, inactive mode, or powered down mode when the on body electronics unit is in the proximal position.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/019,110	Filing Date 09/11/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $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	09/11/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 23	Minus	** 23	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $460 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/EVA V GILLIS/
*** 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8

CONFIRMATION NO. 1087

95508
One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

FORMALITIES LETTER

OC000000120099240

Date Mailed: 09/23/2020

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given **TWO MONTHS** from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings submitted to the Office are not electronically reproducible because portions of figures 1, 14A-14C, 36 are missing and/or blurry.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

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:

Mail Stop Missing Parts
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://sportal.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**.

/vvan/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/019,110

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
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), (i), 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))	23 minus 20 =	* 3			OR	x 100 =	300
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 460 =	0.00
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).						400
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	2420

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
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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
17/019,110	09/11/2020	2812	2420	A0130.0107.01C8	23	1

CONFIRMATION NO. 1087

FILING RECEIPT

95508
One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

OC000000120099239

Date Mailed: 09/23/2020

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)

Manuel Luis Donnay, San Francisco, CA;
Tuan Nguyen, Dublin, CA;
Louis G. Pace, San Carlos, CA;
Peter G. Robinson, Alamo, CA;

Applicant(s)

ABBOTT DIABETES CARE INC., Alameda, CA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 16/002,847 06/07/2018
which is a CON of 13/436,768 03/30/2012 PAT 10010280
which is a CON of 13/071,461 03/24/2011 PAT 9215992
which claims benefit of 61/411,262 11/08/2010
and claims benefit of 61/361,374 07/02/2010
and claims benefit of 61/345,562 05/17/2010
and claims benefit of 61/317,243 03/24/2010

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: No

Permission to Access Search Results: No

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: 09/22/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/019,110**

Projected Publication Date: To Be Determined - pending completion of Corrected Papers

Non-Publication Request: No

Early Publication Request: No

Title

MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

Preliminary Class

438

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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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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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 U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Manuel Luis Donnay et al.

Application No.: 17/019,110 Confirmation No.: 1087

Filed: September 11, 2020 Art Unit: 2812

For: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES Examiner: Not yet assigned

SECOND PRELIMINARY AMENDMENT

EFS Web
Commissioner for Patents

INTRODUCTORY COMMENTS

Prior to examination, please amend the application as follows:

Amendments to the Claims beginning on page 2 of this paper; and

Remarks beginning on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions of the claims in the application.

1-25. (Canceled)

26. (Currently amended) A glucose monitoring assembly, the assembly comprising:

(1) an inserter, comprising:

an inserter housing; and

a sharp, wherein the sharp is configured to insert a portion of a glucose sensor into a subject;

(2) an on body electronics unit, comprising:

an on body electronics unit housing comprising a plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is configured to be detachably engaged to the inserter;

the glucose sensor; and

on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level[[;]], ~~and~~

~~an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject,~~

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position within the inserter to a distal position, and

wherein the inserter is configured to retract the sharp from the distal position to a retracted position within the inserter.

27. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises one or more gripping arms.

28. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are configured to engage the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the one or more gripping arms are configured to disengage from the plurality of recesses when the on body electronics unit is in the distal position.

29. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are biased in an outward direction.

30. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are configured to deflect in an outward direction after the on body electronics unit advances from the proximal position.

31. (Previously presented) The glucose monitoring assembly of claim 27, wherein the inserter further comprises one or more interior surfaces configured to hold the one or more gripping arms against the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

32. (Currently amended) The glucose monitoring assembly of claim 31, wherein the inserter is <u>further</u> configured such that the one or more interior surfaces are not in contact with the one or more gripping arms when the on body electronics unit is in the distal position.

33. (Previously presented) The glucose monitoring assembly of claim 27, wherein each of the one or more gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

34. (Previously presented) The glucose monitoring assembly of claim 33, where the engagement boss is disposed on a tip portion of the gripping arm.

35. (Previously presented) The glucose monitoring assembly of claim 33, wherein the engagement boss comprises a conical shape.

36. (Previously presented) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses comprises a concave portion.

37. (Currently amended) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses [[are]] is disposed on a side wall of the on body electronics unit housing.

38. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a driver disposed in the inserter housing, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.

39. (Previously presented) The glucose monitoring assembly of claim 26, further comprising a cap removably attached to a distal portion of the inserter.

40. (Currently amended) The glucose monitoring assembly of claim [[36]] 39, wherein the cap is removably attached to the distal portion of the inserter by a plurality of threads.

41. (Currently amended) The glucose monitoring assembly of claim [[36]] 39, wherein the cap includes a first interior space, and wherein a section of the glucose sensor and a section of the sharp are housed within the first interior space.

42. (Currently amended) The glucose monitoring assembly of claim [[38]] 41, wherein the first interior space comprises a sterile environment.

43. (Currently amended) The glucose monitoring assembly of claim 26, wherein a proximal end of the inserter comprises an inserter handle, wherein a distal end of the inserter comprises a sheath having a distal sheath end configured to be placed on [[the]] a skin surface of the subject, and wherein the inserter handle is configured to move in a downward direction [[toward]]

towards the skin surface relative to the sheath in response to an application of force on the inserter handle.

44. (Previously presented) The glucose monitoring assembly of claim 43, wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter handle.

45. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics unit further comprises a sensor hub,

wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion,

wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

46. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics comprises an aperture, and wherein the sharp extends through the aperture of the on body electronics.

47. (Currently amended) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a distal end configured to be placed on [[the]] a skin surface of the subject before advancement of the on body electronics unit and the sharp.

48. (Currently amended) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics [[are]] is in a low power state~~, inactive mode, or powered down mode~~ when the on body electronics unit is in the proximal position.

49. (New) The glucose monitoring assembly of claim 26, further comprising an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.

50. (New) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a no power state when the on body electronics unit is in the proximal position.

51. (New) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in an inactive mode when the on body electronics unit is in the proximal position.

REMARKS

Claims 26-51 are pending, of which claims 26, 32, 37, 40-43, and 47-48 have been amended without prejudice, and claims 49-51 have been newly added. Claims 1-25 remain canceled without prejudice. Examination of these pending claims is respectfully requested. No new matter has been introduced.

All citations to claim support are purely for the benefit of the Examiner. It is stressed that the citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

Cancelation of the claims is made without prejudice and solely to advance prosecution of this application and are not intended as a disavowal of any subject matter. Accordingly, by this response, Applicants do not concede that previously pending claims are not patentable.

The right is reserved to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any previously pending claims regardless of whether those claims were amended or cancelled herein. This may entail the pursuit of broader and/or narrower claims, and/or subject matter that was previously relinquished by virtue of argument or amendment.

It is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 432-9993. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: October 2, 2020

Respectfully submitted,

/Glen Liu/

Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660
Attorney for Applicant

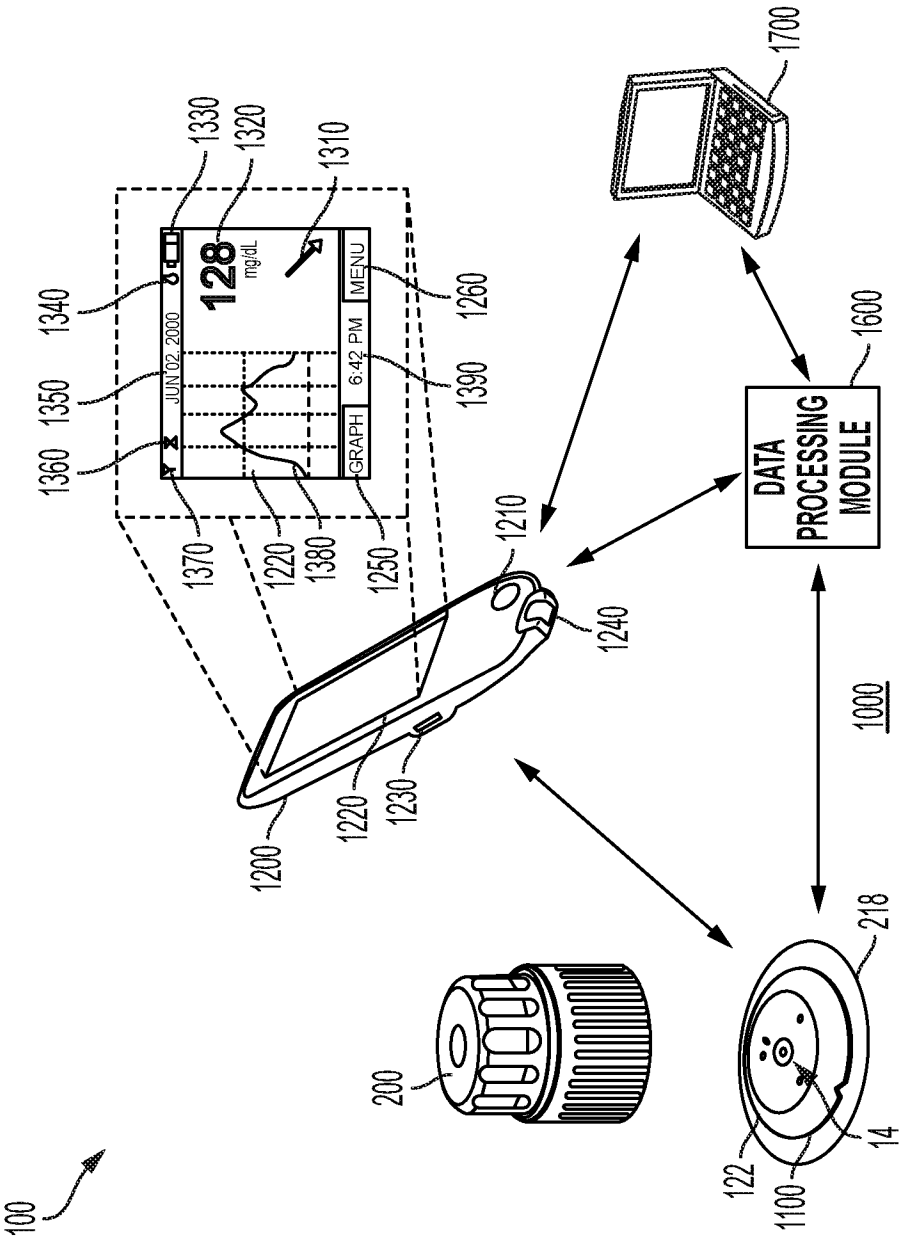
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FIG. 1

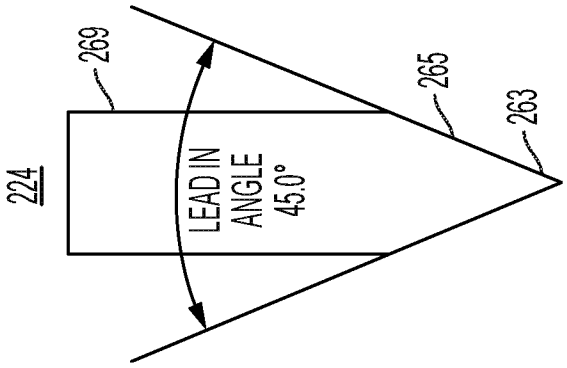

FIG. 14B

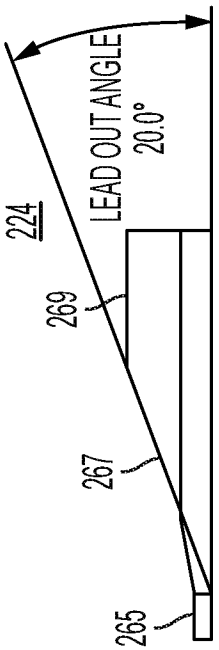

FIG. 14C

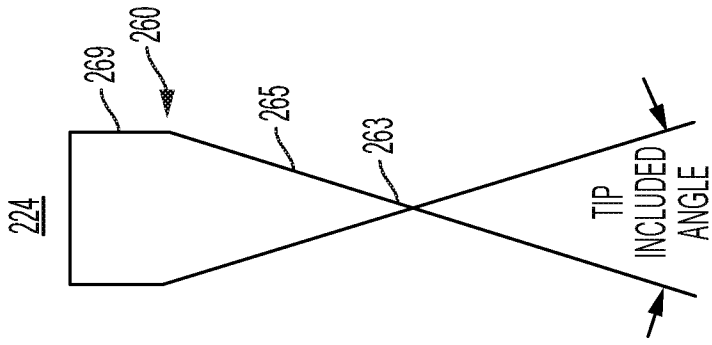

FIG. 14A

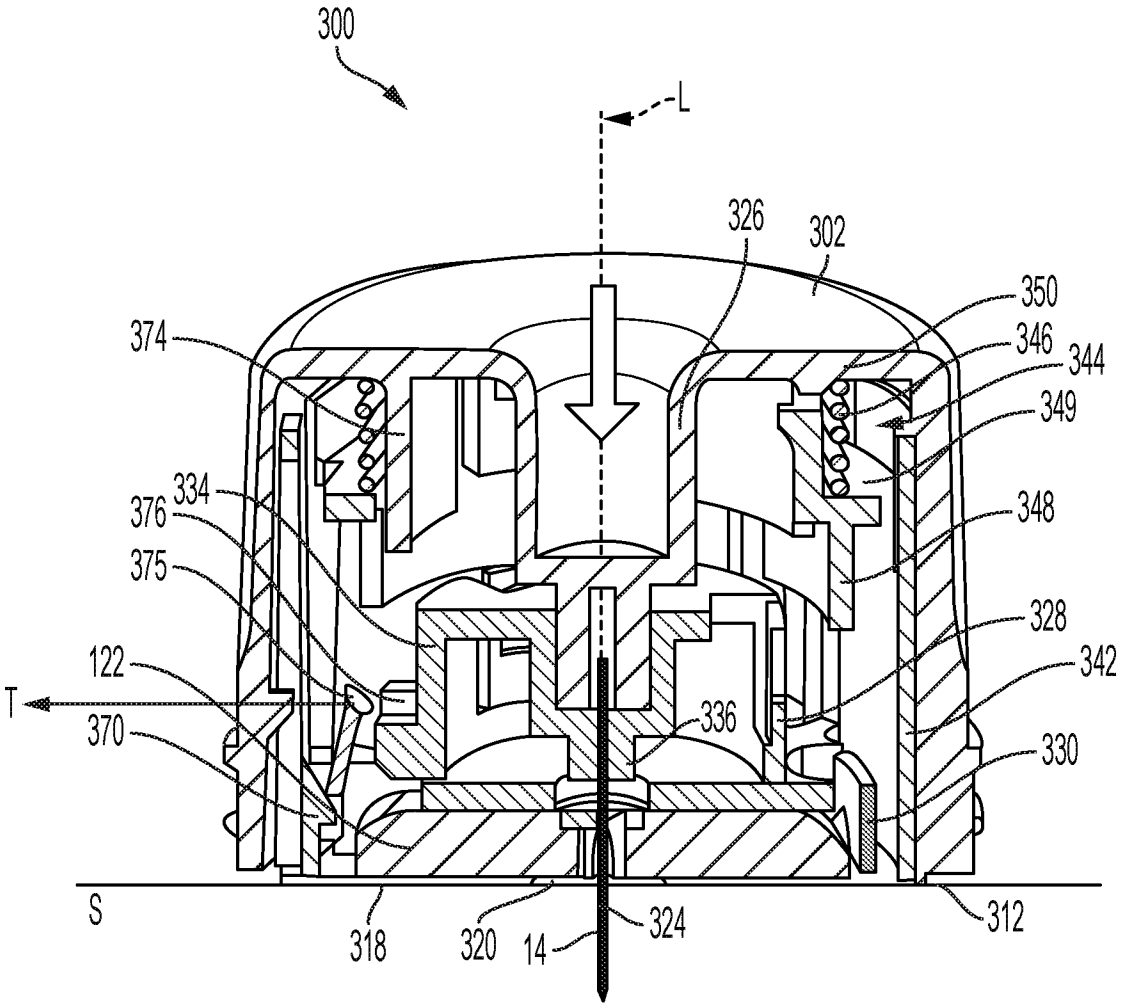
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FIG. 36

Electronic Patent Application Fee Transmittal

Application Number:	17019110
Filing Date:	11-Sep-2020
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Filer:	Glen Liu/Alana Fredericks
Attorney Docket Number:	A0130.0107.01C8

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	3	100	300
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**300**

Electronic Acknowledgement Receipt

EFS ID:	40747739
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	02-OCT-2020
Filing Date:	11-SEP-2020
Time Stamp:	14:25:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$300
RAM confirmation Number	E202002E25354373
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		10297USC16_A0130_0107_01C8_2nd_Preliminary_Amendment.pdf	105914 3033ed6edac8084bc2f9ea915ded394683b30c07	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	8

Warnings:

Information:

2	Drawings-only black and white line drawings	10297USC16_A0130_0107_01C8_Replacement_Figures.pdf	48973 32cd50634df646bd9ae170d1558ab1a85c309070	no	3

Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	30062 7900e44988c96ae438cf4e4bc1c7d684b18d7a39	no	2

Warnings:

Information:

Total Files Size (in bytes):	184949

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.

SCORE Placeholder Sheet for IFW Content

Application Number: 17019110 Document Date: 10/02/2020

The presence of this form in the IFW record indicates that the following document type was received in electronic format on the date identified above. This content is stored in the SCORE database.

Since this was an electronic submission, there is no physical artifact folder, no artifact folder is recorded in PALM, and no paper documents or physical media exist. The TIFF images in the IFW record were created from the original documents that are stored in SCORE.

- Drawing

At the time of document entry (noted above):

- USPTO employees may access SCORE content via DAV or via the SCORE web page.
- External customers may access SCORE content via PAIR using the Supplemental Content tab.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/019,110	Filing Date 09/11/2020	☐ 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), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $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		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	10/02/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 26	Minus	** 23	= 3		x $100 =	300
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	300

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/EVA V GILLIS/
*** 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.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/019,110

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	320
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	700
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	26 minus 20 =	* 6			OR	x 100 =	600
INDEPENDENT CLAIMS (37 CFR 1.16(h))	1 minus 3 =	*				x 480 =	0.00
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).						420
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	2840

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
						TOTAL ADD'L FEE		OR	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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
17/019,110	09/11/2020	2812	2720	A0130.0107.01C8	26	1

CONFIRMATION NO. 1087

UPDATED FILING RECEIPT

95508
One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

OC000000120441367

Date Mailed: 10/07/2020

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)

Manuel Luis Donnay, San Francisco, CA;
Tuan Nguyen, Dublin, CA;
Louis G. Pace, San Carlos, CA;
Peter G. Robinson, Alamo, CA;

Applicant(s)

ABBOTT DIABETES CARE INC., Alameda, CA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 16/002,847 06/07/2018
which is a CON of 13/436,768 03/30/2012 PAT 10010280
which is a CON of 13/071,461 03/24/2011 PAT 9215992
which claims benefit of 61/411,262 11/08/2010
and claims benefit of 61/361,374 07/02/2010
and claims benefit of 61/345,562 05/17/2010
and claims benefit of 61/317,243 03/24/2010

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: No

Permission to Access Search Results: No

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: 09/22/2020

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/019,110**

Projected Publication Date: 01/14/2021

Non-Publication Request: No

Early Publication Request: No

Title

MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

Preliminary Class

438

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.

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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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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8	1087

95508 7590 10/23/2020

One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

EXAMINER	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
10/23/2020	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):

IPdocketing@onellp.com
PAIRgroup@onellp.com
onellpdocketing@onellp.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/019,110	**Applicant(s)** Donnay et al.	
	Examiner CHERYL P GIBSON BAYLOR	**Art Unit** OPET	**AIA (FITF) Status** No

1. THE REQUEST FILED 11 September 2020 IS **GRANTED** .

   The above-identified application has met the requirements for prioritized examination
   - A. ☑ for an original nonprovisional application (Track I).
   - B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:
   - A. filing a **petition for extension of time** to extend the time period for filing a reply;
   - B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;
   - C. filing a **request for continued examination** ;
   - D. filing a notice of appeal;
   - E. filing a request for suspension of action;
   - F. mailing of a notice of allowance;
   - G. mailing of a final Office action;
   - H. completion of examination as defined in 37 CFR 41.102; or
   - I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET	

POWER OF ATTORNEY TO PROSECUTE BEFORE THE USPTO
By Assignee

ABBOTT DIABETES CARE INC., assignee of the application(s) for United States Letters Patent identified in the attached statement under 37 CFR 3.73(c), does revoke all powers of attorney previously given and hereby appoints as its attorneys and/or agents, with full power of substitution and revocation, to prosecute this application and transact all business in the United States Patent and Trademark Office, and in countries other than the United States, and to do all things necessary or appropriate therefor before any competent International Authorities in connection with any international patent application(s) corresponding to the above-identified application, all of the registered practitioners identified by Customer Number **95508**.

ONE LLP
4000 MacArthur Blvd.,
East Tower, Suite 500
Newport Beach, CA 92660
(949)-502-2870

The undersigned, also hereby authorizes and empowers all of the registered practitioners associated with Customer Number 95508 to sign statements under 37 CFR 3.73(b) on behalf of the undersigned to establish the undersigned's right to take actions in applications for United States Letters Patent.

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to the address associated with Customer Number 95508.

The individual whose signature is supplied below is authorized to act on behalf of the assignee.

Full Name of Assignee: ABBOTT DIABETES CARE INC.	
Post Office Address: 1420 Harbor Bay Parkway, Alameda, CA 94502	
Signature of Declarant or Assignee:	Date: 12-30-15
Full Name of Declarant: Susan Tall If Other Than Assignee:	
Title of Declarant: Senior Counsel, Patents & Trademarks	
Address of Declarant: 1420 Harbor Bay Parkway, Alameda, CA 94502	

Electronic Acknowledgement Receipt

EFS ID:	41106517
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	12-NOV-2020
Filing Date:	11-SEP-2020
Time Stamp:	14:15:41
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Assignee showing of ownership per 37 CFR 3.73	A0130_0107_01C8_373Form.pdf	99206 84c399f0fccb0caedda932b75a1b5420633e53df	no	3

Warnings:

Information:					
2	Power of Attorney	Abbott_US_POA.pdf	195275 0f313a77b2b660f04e3b7ddc795affde7278b9e0	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	294481	

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.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: Samuel Mason Curry, et al.

Application No./Patent No.: 17/019,110 Filed/Issue Date: 09/11/2020

Titled: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

ABBOTT DIABETES CARE INC., a CORPORATION

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☑ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 053858, Frame 0315, or for which a copy thereof is attached.

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

   1. From: _____ To: _____

      The document was recorded in the United States Patent and Trademark Office at

      Reel _____, Frame _____, or for which a copy thereof is attached.

   2. From: _____ To: _____

      The document was recorded in the United States Patent and Trademark Office at

      Reel _____, Frame _____, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). 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 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/AIA/96 (08-12)
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STATEMENT UNDER 37 CFR 3.73(c)

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

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5. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

6. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Glen Liu/	11/12/2020
Signature	Date
Glen Liu	75,058
Printed or Typed Name	Title or Registration 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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Manuel Luis Donnay et al.

Application No.: 17/019,110 Confirmation No.: 1087

Filed: September 11, 2020 Art Unit: 3771

For: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES Examiner: Vy Q. Bui

THIRD PRELIMINARY AMENDMENT

EFS Web
Commissioner for Patents

INTRODUCTORY COMMENTS

Prior to examination, please amend the application as follows:

Amendments to the Claims beginning on page 2 of this paper; and

Remarks beginning on page 7 of this paper.

Electronic Patent Application Fee Transmittal

Application Number:	17019110
Filing Date:	11-Sep-2020
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Filer:	Glen Liu/Alana Fredericks
Attorney Docket Number:	A0130.0107.01C8

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	4	100	400
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**400**

Electronic Acknowledgement Receipt

EFS ID:	41130987
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	16-NOV-2020
Filing Date:	11-SEP-2020
Time Stamp:	13:41:57
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$400
RAM confirmation Number	E2020AFD42104575
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		10297USC16_A0130_0107_01C8_Third_Preliminary_Amendment.pdf	106558 2228d9f3f53b969740cb1462a97a483d26999434	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Applicant Arguments/Remarks Made in an Amendment	7	8
	Claims	2	6
	Preliminary Amendment	1	1

Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30194 50d0e2a0c4ad1ff16883d17d03c917b115435621	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	136752		

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.

REMARKS

Claims 26-41 and 43-56 are pending, of which claims 52-56 are newly added. Examination of these pending claims is respectfully requested. Claim 42 has been canceled without prejudice, and claims 1-25 remain canceled without prejudice. Support for the new claims can be found, for example, in paragraphs [0170], [0248] to [0266], and Figures 3, 18, 109-140, and elsewhere throughout the application as filed. No new matter has been introduced.

All citations to claim support are purely for the benefit of the Examiner. It is stressed that the citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

Cancelation of the claims is made without prejudice and solely to advance prosecution of this application and are not intended as a disavowal of any subject matter. Accordingly, by this response, Applicants do not concede that previously pending claims are not patentable.

The right is reserved to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any previously pending claims regardless of whether those claims were amended or cancelled herein. This may entail the pursuit of broader and/or narrower claims, and/or subject matter that was previously relinquished by virtue of argument or amendment.

It is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 444-5970. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: November 16, 2020

Respectfully submitted,

/Glen Liu/

Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660
Attorney for Applicant

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions of the claims in the application.

1-25. (Canceled)

26. (Previously presented) A glucose monitoring assembly, the assembly comprising:

(1) an inserter, comprising:

an inserter housing; and

a sharp, wherein the sharp is configured to insert a portion of a glucose sensor into a subject;

(2) an on body electronics unit, comprising:

an on body electronics unit housing comprising a plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is configured to be detachably engaged to the inserter;

the glucose sensor; and

on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position within the inserter to a distal position, and

wherein the inserter is configured to retract the sharp from the distal position to a retracted position within the inserter.

27. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises one or more gripping arms.

28. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are configured to engage the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the one or more gripping arms are configured to disengage from the plurality of recesses when the on body electronics unit is in the distal position.

29. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are biased in an outward direction.

30. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are configured to deflect in an outward direction after the on body electronics unit advances from the proximal position.

31. (Previously presented) The glucose monitoring assembly of claim 27, wherein the inserter further comprises one or more interior surfaces configured to hold the one or more gripping arms against the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

32. (Previously presented) The glucose monitoring assembly of claim 31, wherein the inserter is further configured such that the one or more interior surfaces are not in contact with the one or more gripping arms when the on body electronics unit is in the distal position.

33. (Previously presented) The glucose monitoring assembly of claim 27, wherein each of the one or more gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

34. (Previously presented) The glucose monitoring assembly of claim 33, where the engagement boss is disposed on a tip portion of the gripping arm.

35. (Previously presented) The glucose monitoring assembly of claim 33, wherein the engagement boss comprises a conical shape.

36. (Previously presented) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses comprises a concave portion.

37. (Previously presented) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses is disposed on a side wall of the on body electronics unit housing.

38. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a driver disposed in the inserter housing, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.

39. (Previously presented) The glucose monitoring assembly of claim 26, further comprising a cap removably attached to a distal portion of the inserter.

40. (Previously presented) The glucose monitoring assembly of claim 39, wherein the cap is removably attached to the distal portion of the inserter by a plurality of threads.

41. (Previously presented) The glucose monitoring assembly of claim 39, wherein the cap includes a first interior space, and wherein a section of the glucose sensor and a section of the sharp are housed within the first interior space.

42. (Canceled)

43. (Previously presented) The glucose monitoring assembly of claim 26, wherein a proximal end of the inserter comprises an inserter handle, wherein a distal end of the inserter comprises a sheath having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter handle is configured to move in a downward direction towards the skin surface relative to the sheath in response to an application of force on the inserter handle.

44. (Previously presented) The glucose monitoring assembly of claim 43, wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter handle.

45. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics unit further comprises a sensor hub,

wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion,

wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

46. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics comprises an aperture, and wherein the sharp extends through the aperture of the on body electronics.

47. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit and the sharp.

48. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit is in the proximal position.

49. (Previously presented) The glucose monitoring assembly of claim 26, further comprising an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.

50. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a no power state when the on body electronics unit is in the proximal position.

51. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in an inactive mode when the on body electronics unit is in the proximal position.

52. (New) The glucose monitoring assembly of claim 47, wherein the distal end of the inserter defines a plane, and wherein a bottom surface of the on body electronics unit is parallel to the plane when the on body electronics unit and the sharp are in the proximal position.

53. (New) The glucose monitoring assembly of claim 26, wherein the on body electronics unit and the sharp are configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position.

54. (New) The glucose monitoring assembly of claim 26, wherein a distance between the on body electronics unit in the proximal position and the on body electronics unit in the distal position is greater than a maximum height of the on body electronics unit.

55. (New) The glucose monitoring assembly of claim 46, wherein the aperture of the on body electronics is a first aperture, wherein the on body electronics unit housing further comprises a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.

56. (New) The glucose monitoring assembly of claim 26, wherein the sharp is further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject.

PTO/SB/06 (09-11)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/019,110	Filing Date 09/11/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $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		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	11/16/2020	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 30	Minus	** 26	= 4		x $100 =	400
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	400

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/EVA V GILLIS/
*** 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.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8

CONFIRMATION NO. 1087

95508
One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

POA ACCEPTANCE LETTER

OC000000121359383

Date Mailed: 11/17/2020

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 11/12/2020.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

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**.

/ytdemisse/

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/019,110	Filing Date 09/11/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $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) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	* 30	Minus	** 26	= 4		x $0 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $0 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
AMENDMENT	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/CARLOTTA B LEE/
*** 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.

PTO/SB/08a (08-03)
Approved for use through 7/31/28. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449A/PTO				*Complete if Known*	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	17/019,110
				Filing Date	September 11, 2020
				First Named Inventor	Manuel Luis Donnay
				Art Unit	3771
(use as many sheets as necessary)				Examiner Name	Vy. Q. Bui
Sheet	1	of	1	Attorney Docket Number	A0130.0107.01C8

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	1	2009/0299301 A1	12-03-2009	Gottleib et al.
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
	11			
	12			
	13			
	14			
	15			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	Foreign Patent Document Country[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
	16				
	17				
	18				
	19				

OFFICE ACTIONS/SEARCH REPORTS

Examiner Initials'	Cite No.[1]	Country	Description	Date of Issuance MM-DD-YYY	T[2]
	20	EP	20195922.8 Extended Search Report	12-16-2020	
	21				
	22				
	23				

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicants unique citation designation number (optional). [2]See Kinds of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4]For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

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 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours 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 are required 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, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450

Electronic Acknowledgement Receipt

EFS ID:	41435611
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	18-DEC-2020
Filing Date:	11-SEP-2020
Time Stamp:	16:18:52
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	10297USC16_A0130_0107_01C8_IDS_Transmittal.pdf	92368 dbdebfbcca1443dd18ce4186914831bdf7248dfa	no	4

Warnings:

Information:					
2	Information Disclosure Statement (IDS) Form (SB08)	10297USC16_A0130_0107_01C8_IDS_1449.pdf	105471 88a6e741a4af3860530713c3f2dd1e9469672750	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
3	Other Reference-Patent/App/Search documents	EP201959228_EESR.pdf	1430557 8731dc73c2bbf046cbd0c2f0b5e7f49cbfd5c511	no	9
Warnings:					
Information:					
		Total Files Size (in bytes):	1628396		

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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.

Docket No.: A0130.0107.01C8
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Manuel Luis Donnay et al.

Application No.: 17/019,110 | Confirmation No.: 1087

Filed: September 11, 2020 | Art Unit: 3771

For: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES | Examiner: Vy Q. Bui

INFORMATION DISCLOSURE STATEMENT (IDS)

EFS Web
Commissioner for Patents

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the 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 this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Timing of Filing of the Information Disclosure Statement:

☒ This IDS is being filed before the First Office Action.

☐ This IDS is being filed after the issuance of the First Office Action but before the issuance of a Final Office Action.

☐ This IDS is being filed after the issuance of a Final Office Action, Ex Parte Quayle Action or Notice of Allowance but before the payment of the Issue Fee.

Certifications:

If checked, the undersigned makes the following statement(s):

☒ Statement under 37 CFR § 1.97(e):

☒ Each item of information contained in this information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement; or

☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.

☐ Statement Under 37 C.F.R. § 1.704(d):

Each item of information contained in this information disclosure statement was cited a counterpart application less than thirty days prior to the filing of this information disclosure statement.

Fee Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):

☐ If checked, the fee of $240.00 set forth in 37 C.F.R. §1.17(p).

Copies of Information:

In accordance with 37 C.F.R. §1.98(a), the following are enclosed:

☒ A legible copy of each document (or relevant portion thereof) cited in the attached PTO/SB/08, except for U.S. patent and U.S. published applications.

☐ With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in § 1.56(c) most

knowledgeable about the content of the information, is attached. This concise explanation is provided by way of:

☐ A translation of the relevant portions of the non-English language information;

☐ A statement explaining the relevant portions of the non-English language information;

☐ A copy [and where not in the English language, a translation] of at least the relevant portion(s) of the communication from _____in which the information was cited; or

☐ This information is contained in the specification of the present application.

☐ In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not enclosed as they were provided in application Serial No. _____, filed _____, which the present application relies upon for an earlier effective filing date under 35 U.S.C. 120.

Materiality:

Whether or not the information and references disclosed in this Information Disclosure Statement is "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Dated: December 18, 2020

Respectfully submitted,

Electronic signature: /Glen Liu/
Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Boulevard
East Tower, Suite 500
(949) 432-9993
Attorney for Applicants

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8

CONFIRMATION NO. 1087

95508
One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

PUBLICATION NOTICE

OC000000122666406

Title:MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

Publication No.US-2021-0007651-A1
Publication Date:01/14/2021

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/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Manuel Luis Donnay et al.

Application No.: 17/019,110 Confirmation No.: 1087

Filed: September 11, 2020 Art Unit: 3600

For: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES Examiner: Not yet assigned

FOURTH PRELIMINARY AMENDMENT

EFS Web
Commissioner for Patents

INTRODUCTORY COMMENTS

Prior to examination, please amend the application as follows:

Amendments to the Claims beginning on page 2 of this paper; and

Remarks beginning on page 8 of this paper.

Electronic Patent Application Fee Transmittal

Application Number:	17019110
Filing Date:	11-Sep-2020
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Filer:	Glen Liu/Alana Fredericks
Attorney Docket Number:	A0130.0107.01C8

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	1202	5	100	500
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**500**

Electronic Acknowledgement Receipt

EFS ID:	41693017
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	20-JAN-2021
Filing Date:	11-SEP-2020
Time Stamp:	13:35:39
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$500
RAM confirmation Number	E20211JD35510714
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		10297USC16_A0130_0107_01C8_Fourth_Preliminary_Amendment.pdf	104856 f8601b3c5b36a473bcaf17a86cb4badd429b71fc	yes	9

Multipart Description/PDF files in .zip description

Document Description	Start	End
Applicant Arguments/Remarks Made in an Amendment	8	9
Claims	2	7
Preliminary Amendment	1	1

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30150 dc060af0ed68a7b326f726f2684d95590e61bd92	no	2

Warnings:

Information:

Total Files Size (in bytes):	135006

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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.

REMARKS

Claims 26-39, 43, and 45-58 are pending, of which claim 43 has been amended without prejudice and claims 57-58 have been newly added. Examination of these pending claims is respectfully requested. Claims 40-41 and 44 have been canceled without prejudice and claims 1-25 and 42 remain canceled without prejudice. Support for the new claims can be found, for example, in Figures 100-106 and elsewhere throughout the application as filed. No new matter has been introduced.

All citations to claim support are purely for the benefit of the Examiner. It is stressed that the citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

Cancelation of the claims is made without prejudice and solely to advance prosecution of this application and are not intended as a disavowal of any subject matter. Accordingly, by this response, Applicants do not concede that previously pending claims are not patentable.

The right is reserved to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any previously pending claims regardless of whether those claims were amended or cancelled herein. This may entail the pursuit of broader and/or narrower claims, and/or subject matter that was previously relinquished by virtue of argument or amendment.

It is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 432-9993. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: January 20, 2021

Respectfully submitted,

/Glen Liu/

Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660
Attorney for Applicant

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions of the claims in the application.

1-25. (Canceled)

26. (Previously presented) A glucose monitoring assembly, the assembly comprising:

(1) an inserter, comprising:

an inserter housing; and

a sharp, wherein the sharp is configured to insert a portion of a glucose sensor into a subject;

(2) an on body electronics unit, comprising:

an on body electronics unit housing comprising a plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is configured to be detachably engaged to the inserter;

the glucose sensor; and

on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position within the inserter to a distal position, and

wherein the inserter is configured to retract the sharp from the distal position to a retracted position within the inserter.

27. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises one or more gripping arms.

28. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are configured to engage the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the one or more gripping arms are configured to disengage from the plurality of recesses when the on body electronics unit is in the distal position.

29. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are biased in an outward direction.

30. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are configured to deflect in an outward direction after the on body electronics unit advances from the proximal position.

31. (Previously presented) The glucose monitoring assembly of claim 27, wherein the inserter further comprises one or more interior surfaces configured to hold the one or more gripping arms against the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

32. (Previously presented) The glucose monitoring assembly of claim 31, wherein the inserter is further configured such that the one or more interior surfaces are not in contact with the one or more gripping arms when the on body electronics unit is in the distal position.

33. (Previously presented) The glucose monitoring assembly of claim 27, wherein each of the one or more gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

34. (Previously presented) The glucose monitoring assembly of claim 33, where the engagement boss is disposed on a tip portion of the gripping arm.

35. (Previously presented) The glucose monitoring assembly of claim 33, wherein the engagement boss comprises a conical shape.

36. (Previously presented) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses comprises a concave portion.

37. (Previously presented) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses is disposed on a side wall of the on body electronics unit housing.

38. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a driver disposed in the inserter housing, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.

39. (Previously presented) The glucose monitoring assembly of claim 26, further comprising a cap removably attached to a distal portion of the inserter.

40-42. (Canceled)

43. (Currently amended) The glucose monitoring assembly of claim 26, wherein a proximal end of the inserter comprises an inserter handle, wherein a distal end of the inserter comprises a sheath having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter handle is configured to move in a downward direction towards the skin surface relative to the sheath in response to an application of force on the inserter handle,

wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter handle.

44. (Canceled)

45. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics unit further comprises a sensor hub,

wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion,
wherein the distal sensor portion is configured to sense a glucose level of the subject,
wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

46. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics comprises an aperture, and wherein the sharp extends through the aperture of the on body electronics.

47. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit and the sharp.

48. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit is in the proximal position.

49. (Previously presented) The glucose monitoring assembly of claim 26, further comprising an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.

50. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a no power state when the on body electronics unit is in the proximal position.

51. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in an inactive mode when the on body electronics unit is in the proximal position.

52. (Previously presented) The glucose monitoring assembly of claim 47, wherein the distal end of the inserter defines a plane, and wherein a bottom surface of the on body electronics unit is parallel to the plane when the on body electronics unit and the sharp are in the proximal position.

53. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics unit and the sharp are configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position.

54. (Previously presented) The glucose monitoring assembly of claim 26, wherein a distance between the on body electronics unit in the proximal position and the on body electronics unit in the distal position is greater than a maximum height of the on body electronics unit.

55. (Previously presented) The glucose monitoring assembly of claim 46, wherein the aperture of the on body electronics is a first aperture, wherein the on body electronics unit housing further comprises a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.

56. (Previously presented) The glucose monitoring assembly of claim 26, wherein the sharp is further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject.

57. (New) The glucose monitoring assembly of claim 37, further comprising a plurality of cut-outs circumferentially disposed on the side wall of the housing, wherein each of the plurality of cut-outs extends vertically along the side wall from a lower end of the side wall to a height below a top exterior surface of a top portion of the on body electronics unit housing.

58. (New) The on-body device of claim 57, wherein each of the plurality of cut-outs comprises a cross-sectional area having a quadrilateral geometry.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/019,110	Filing Date 09/11/2020	☐ To be Mailed

ENTITY: ☑ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $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	01/20/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 30	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	SLIE
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/SHARON M WEST/
*** 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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Manuel Luis Donnay et al.

Application No.: 17/019,110 | Confirmation No.: 1087

Filed: September 11, 2020 | Art Unit: 3791

For: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES | Examiner: Huong Q. Nguyen

FIFTH PRELIMINARY AMENDMENT

EFS Web
Commissioner for Patents

INTRODUCTORY COMMENTS

Prior to examination, please amend the application as follows:

Amendments to the Claims beginning on page 2 of this paper; and

Remarks beginning on page 8 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions of the claims in the application.

1-25. (Canceled)

26. (Currently amended) A glucose monitoring assembly, the assembly comprising:

(1) an inserter, comprising:

an inserter housing; and

a sharp, wherein the sharp is configured to insert a portion of a glucose sensor into a subject;

(2) an on body electronics unit, comprising:

an on body electronics unit housing comprising a plurality of recesses circumferentially disposed thereon, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is ~~configured to be~~ detachably engaged [[to]] with the inserter;

the glucose sensor; and

on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position within the inserter to a distal position, and

wherein the inserter is configured to retract the sharp from the distal position to a retracted position within the inserter.

27. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises one or more gripping arms.

28. (Currently amended) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are configured to ~~engage~~ be engaged with the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the one or more gripping arms are configured to ~~disengage~~ be disengaged from the plurality of recesses when the on body electronics unit is in the distal position.

29. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are biased in an outward direction.

30. (Previously presented) The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are configured to deflect in an outward direction after the on body electronics unit advances from the proximal position.

31. (Previously presented) The glucose monitoring assembly of claim 27, wherein the inserter further comprises one or more interior surfaces configured to hold the one or more gripping arms against the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

32. (Previously presented) The glucose monitoring assembly of claim 31, wherein the inserter is further configured such that the one or more interior surfaces are not in contact with the one or more gripping arms when the on body electronics unit is in the distal position.

33. (Previously presented) The glucose monitoring assembly of claim 27, wherein each of the one or more gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

34. (Previously presented) The glucose monitoring assembly of claim 33, where the engagement boss is disposed on a tip portion of the gripping arm.

35. (Previously presented) The glucose monitoring assembly of claim 33, wherein the engagement boss comprises a conical shape.

36. (Previously presented) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses comprises a concave portion.

37. (Previously presented) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses is disposed on a side wall of the on body electronics unit housing.

38. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a driver disposed in the inserter housing, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.

39. (Previously presented) The glucose monitoring assembly of claim 26, further comprising a cap removably attached to a distal portion of the inserter.

40-42. (Canceled)

43. (Previously presented) The glucose monitoring assembly of claim 26, wherein a proximal end of the inserter comprises an inserter handle, wherein a distal end of the inserter comprises a sheath having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter handle is configured to move in a downward direction towards the skin surface relative to the sheath in response to an application of force on the inserter handle,

wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter handle.

44. (Canceled)

45. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics unit further comprises a sensor hub,

wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion,
wherein the distal sensor portion is configured to sense a glucose level of the subject,
wherein the proximal sensor portion is engaged with the sensor hub, and
wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

46. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics comprises an aperture, and wherein the sharp extends through the aperture of the on body electronics.

47. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit and the sharp.

48. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit is in the proximal position.

49. (Previously presented) The glucose monitoring assembly of claim 26, further comprising an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.

50. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a no power state when the on body electronics unit is in the proximal position.

51. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in an inactive mode when the on body electronics unit is in the proximal position.

52. (Previously presented) The glucose monitoring assembly of claim 47, wherein the distal end of the inserter defines a plane, and wherein a bottom surface of the on body electronics unit is parallel to the plane when the on body electronics unit and the sharp are in the proximal position.

53. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics unit and the sharp are configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position.

54. (Previously presented) The glucose monitoring assembly of claim 26, wherein a distance between the on body electronics unit in the proximal position and the on body electronics unit in the distal position is greater than a maximum height of the on body electronics unit.

55. (Previously presented) The glucose monitoring assembly of claim 46, wherein the aperture of the on body electronics is a first aperture, wherein the on body electronics unit housing further comprises a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.

56. (Previously presented) The glucose monitoring assembly of claim 26, wherein the sharp is further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject.

57. (Currently amended) The glucose monitoring assembly of claim 37, further comprising a plurality of ~~cut-outs~~ notches circumferentially disposed on the side wall of the housing, wherein each of the plurality of ~~cut-outs~~ notches extends vertically along the side wall from a lower end of the side wall to a height below a top exterior surface of a top portion of the on body electronics unit housing.

58. (Currently amended) The on-body device of claim 57, wherein each of the plurality of ~~cut-outs~~ notches comprises a cross-sectional area having a quadrilateral geometry.

REMARKS

Claims 26-39, 43, and 45-58 are pending, of which claims 26, 28, 57, and 58 have been amended without prejudice. Examination of these pending claims is respectfully requested. Claims 1-25, 40-42, and 44 remain canceled without prejudice. Support for the amendments can be found, for example, in Figures 100-106 and elsewhere throughout the application as filed. No new matter has been introduced.

All citations to claim support are purely for the benefit of the Examiner. It is stressed that the citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

Cancelation of the claims is made without prejudice and solely to advance prosecution of this application and are not intended as a disavowal of any subject matter. Accordingly, by this response, Applicants do not concede that previously pending claims are not patentable.

The right is reserved to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any previously pending claims regardless of whether those claims were amended or cancelled herein. This may entail the pursuit of broader and/or narrower claims, and/or subject matter that was previously relinquished by virtue of argument or amendment.

It is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 432-9993. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: January 29, 2021

Respectfully submitted,

/Glen Liu/

Glen Liu
Registration No.: 75,058
ONE LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660
Attorney for Applicant

Electronic Acknowledgement Receipt

EFS ID:	41792895
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	29-JAN-2021
Filing Date:	11-SEP-2020
Time Stamp:	22:29:17
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10297USC16_A0130_0107_01C8_Fifth_Preliminary_Amendment.pdf	106185 258b01c78a4817edf2fc7d2b3fbee653405fe558	yes	9

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	7
	Applicant Arguments/Remarks Made in an Amendment	8	9
Warnings:			
Information:			
	Total Files Size (in bytes):	106185	

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.

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 17/019,110	Filing Date 09/11/2020	☐ 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), (i), or (m))	N/A	N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*		x $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		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	*	Minus	**	=		x $0 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=		x $0 =	
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	

		(Column 1)		(Column 2)	(Column 3)			
AMENDMENT	01/29/2021	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA		RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 29	Minus	** 30	= 0		x $100 =	0
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 3	= 0		x $480 =	0
	☐ Application Size Fee (37 CFR 1.16(s))							
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							
							TOTAL ADD'L FEE	0

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.	LDRC
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".	/EVA V GILLIS/
*** 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.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8	1087

95508 7590 03/23/2021

One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
03/23/2021	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):

IPdocketing@onellp.com
PAIRgroup@onellp.com
onellpdocketing@onellp.com

Office Action Summary	Application No. 17/019,110	Applicant(s) Donnay et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status No

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

Period for Reply

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

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

Status

1)☑ Responsive to communication(s) filed on 1/29/2021.

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

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

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

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

Disposition of Claims*

5) ☑ Claim(s) 26-39,43 and 45-56 is/are pending in the application.

5a) Of the above claim(s) 57-58 is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 26-39,43 and 45-56 is/are rejected.

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

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

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

Application Papers

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

11)☑ The drawing(s) filed on 09/11/2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the claims dated 1/29/2021. After an interview with applicant on 3/12/2021, claims 57-58 are hereby withdrawn. Claims 26-39, 43, and 45-56 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application is being examined under the pre-AIA first to invent provisions.

Claim Interpretation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

No claim elements are interpreted under 112 sixth paragraph.

Claim Rejections - 35 USC § 112

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

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

Claims 28-30 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

In regard to Claim 28, the limitation "the one or more gripping arms are configured to be engaged with the plurality of recesses" is unclear because it is unclear if the claims intends

when only one gripping arm exists, if the one gripping arm is engaged with each of the plurality of recesses, or if each arm is engaged with each recess. While the latter interpretation is used in the claims below, clarification is requested.

In regard to Claim 29-30, the recitation of "outward" is indefinite because the term has not been defined relative to any structure. Therefore, it is unclear if outward means outside of the device, distally, or laterally, or any other possible direction/interpretation. Clarification is requested.

In regard to Claim 30, the recitation of "the one or more gripping arms are configured to deflect in an outward direction after the on body electronics unit advances" is indefinite because multiple interpretations are present. The claim suggestions that the moving of the body electronics unit as it advances causes the gripping arms to deflect outward. However, it is know that structural features cause the outward deflection of the arms, while the on body electronics unit is advanced, but the advancing is not the cause. Since the claim can be interpreted either way, it is indefinite. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of pre-AIA 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 –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim(s) 26, 36-39, 43, and 46-56 is/are rejected under pre-AIA 35 U.S.C. 102(e) as being anticipated by Thomas et al (US Pub No. 20100198034).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under pre-AIA 35 U.S.C. 102(e). This rejection under pre-AIA 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor or joint inventors (i.e., the inventive entity) of this application and is thus not the invention "by another," or if the same invention is not being claimed, by an appropriate showing under 37 CFR 1.131(a).

In regard to Claim 26, Thomas et al disclose a glucose monitoring assembly, the assembly comprising:

(1) an inserter, comprising:

an inserter housing 1210, best seen in Figure 12A-F; and

a sharp 1260, wherein the sharp is configured to insert a portion of a glucose sensor 1020, 1280 into a subject, best seen in Figure 2, 10A, and 12A-F (0072-0073; 0131, 0137-0142);

(2) an on body electronics unit, comprising:

an on body electronics unit housing 1010 comprising a plurality of recesses circumferentially disposed thereon (recess in the middle and one on right side, Figure 10B, at least one is circumferentially disposed), wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter, best seen in Figure 10A-B and 12A-F (0131-0132);

the glucose sensor 1020, 1280, best seen in Figure 10A-B; and

on body electronics 1030, 1270 coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, best seen in Figure 10A-B (0131-0132), and

wherein the on body electronics includes a processor 102, memory (0102), a power supply (0102), and wireless communication circuitry, i.e. RF, configured to wirelessly communicate data indicative of a glucose level (0055, 0068, 0102, 0159),

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position within the inserter to a distal position, best seen in Figure 12A-F (0137-0142), and

wherein the inserter is configured to retract the sharp from the distal position to a retracted position within the inserter (0140).

36. The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses comprises a concave portion, best seen in Figure 10B.

37. The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses is disposed on a side wall of the on body electronics unit housing, wherein the surface with the two recesses is considered a side wall, best seen in Figure 10B.

38. The glucose monitoring assembly of claim 26, wherein the inserter further comprises a driver 1250 disposed in the inserter housing 1210, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position, best seen in Figure 12A-F (0137-0142).

39. The glucose monitoring assembly of claim 26, further comprising a cap 1220 removably attached to a distal portion of the inserter, best seen in Figure 12A (0137-0142).

43. The glucose monitoring assembly of claim 26, wherein a proximal end of the inserter comprises an inserter handle (top of 1210), wherein a distal end of the inserter comprises a sheath having a distal sheath end configured to be placed on a skin surface of the subject, best seen in Figure 12B, and wherein the inserter handle is configured to move in a downward direction (arrow 1240) towards the skin surface relative to the sheath in response to an application of force on the inserter handle, best seen in Figure 12C-E, wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter handle (0137-0142).

45. The glucose monitoring assembly of claim 26, wherein the on body electronics unit 1030 further comprises a sensor hub (middle of Figure 10B), wherein the glucose sensor comprises a distal sensor portion 1020 and a proximal sensor portion (connected to 1030), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion, best seen in Figure 10A-B (0130-0131).

46. The glucose monitoring assembly of claim 26, wherein the on body electronics 1030 comprises an aperture, best seen in Figure 10A, and wherein the sharp 1260 extends through the aperture of the on body electronics 1270, best seen in Figure 12C-F (0137-0142).

47. The glucose monitoring assembly of claim 26, wherein the inserter further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit 1270 and the sharp 1260, best seen in Figure 12A-B (0137-0142).

48. The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit is in the proximal position, i.e. power is only activated once the sensor and on body electronics are contacted by the skin in the distal position, and not the proximal position (0075, 0078, 0080, 0102, 0103, 0121, 0142, 0143-0144, 0147-0154, 0156).

49. The glucose monitoring assembly of claim 26, further comprising an adhesive portion 1290 configured to secure the on body electronics unit housing to a skin surface of the subject, best seen in Figure 12G (0140).

50. The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a no power state when the on body electronics unit is in the proximal position, i.e. power is only activated once the sensor and on body electronics are contacted by the skin in the distal position, and not the proximal position (0075, 0078, 0080, 0102, 0103, 0121, 0142, 0143-0144, 0147-0154, 0156).

51. The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in an inactive mode when the on body electronics unit is in the proximal position, i.e. power is only activated once the sensor and on body electronics are contacted by the skin in the distal position, and not the proximal position (0075, 0078, 0080, 0102, 0103, 0121, 0142, 0143-0144, 0147-0154, 0156).

52. The glucose monitoring assembly of claim 47, wherein the distal end of the inserter defines a plane, and wherein a bottom surface of the on body electronics unit is parallel to the plane when the on body electronics unit 1270 and the sharp 1260 are in the proximal position, best seen in Figure 12C.

53. The glucose monitoring assembly of claim 26, wherein the on body electronics unit 1270 and the sharp 1260 are configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position, best seen in Figure 12A-F.

54. The glucose monitoring assembly of claim 26, wherein a distance between the on body electronics unit 1270 in the proximal position and the on body electronics unit in the distal position is greater than a maximum height of the on body electronics unit, best seen in Figure 12C-F

55. The glucose monitoring assembly of claim 46, wherein the aperture of the on body electronics is a first aperture, wherein the on body electronics unit housing 1010 further comprises a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture – Figure !0A-B shows the central aperture extending through the housing 1010, and wherein the sharp 1260 extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position, best seen in Figure 12A-F (0137-0142).

56. The glucose monitoring assembly of claim 26, wherein the sharp 1260 is further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject, best seen in Figure 12A-F.

Claim Rejections - 35 USC § 103

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

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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

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

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

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

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

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claims 27 and 29-30 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over Thomas et al in view of Funderburk et al (US Pat No. 7381184).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under pre-AIA 35 U.S.C. 102(e). This rejection under pre-AIA 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131(a); or (3) an oath or declaration under 37 CFR 1.131(c) stating that the application and reference are currently owned by the same party and that the inventor or joint inventors (i.e., the inventive entity) named in the application is the prior inventor under pre-AIA 35 U.S.C. 104 as in effect on March 15, 2013, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a rejection under pre-AIA 35 U.S.C. 103(a). See MPEP §§ 2146 *et seq*.

In regard to Claim 27, Thomas et al disclose the invention above but do not expressly disclose one or more gripping arms. Funderburk et al teach that it is well-known in the art to provide an analogous glucose monitoring system inserter comprising gripping arms 412 which are used to maintain or drive the insertion of the sensor as required during operation, best seen in Figure 20-23 (Col.15: 14-Col.16: 40).

29. The glucose monitoring assembly of claim 27, wherein the one or more gripping arms are biased in an outward direction, best seen in Figure 20-23.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Thomas et al such that there is included one or more gripping arms as taught by Funderburk et al to effectively enable the drive portion of the device to be maintained or driven as necessary during the sensor insertion process, such that in combination, the one or more gripping arms are configured to deflect in an outward direction after the on body electronics unit advances from the proximal position (Claim 30).

Claims 28 and 31-35 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over Thomas et al in view of Funderburk et al, further in view of Yodfat et al (US Pub No. 20100137695), and Cole et al (US Pub No. 20080058830).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under pre-AIA 35 U.S.C. 102(e). This rejection under pre-AIA 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131(a); or (3) an oath or declaration under 37 CFR 1.131(c) stating that the application and reference are currently owned by the same party

and that the inventor or joint inventors (i.e., the inventive entity) named in the application is the prior inventor under pre-AIA 35 U.S.C. 104 as in effect on March 15, 2013, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a rejection under pre-AIA 35 U.S.C. 103(a). See MPEP §§ 2146 *et seq*.

Thomas et al as modified disclose the invention above but do not expressly disclose the one or more gripping arms having an engagement boss to engage the plurality of recesses.

In regard to Claim 28 and 33, Funderburk et al teach that it is well-known in the art to provide an analogous glucose monitoring system inserter comprising an engagement boss 352 (Figure 26B shows it protrudes) configured to engage a recess 350 connected to sensor 314 when in the proximal position, configured to disengage from the plurality of recesses when the on body electronics unit is in the distal position, the engagement between the boss and recess used to releasably hold the sensor in the correction position during insertion, best seen in Figure 25-26 (Col.14: 9-18; Col.17: 1-17).

In regard to Claim 31-32, Funderburk et al disclose the analogous inserter comprises one or more interior surfaces (Figure 16, 25-26) configured to hold the one or more engagement bosses against the recess of the sensor when the on body electronics unit is in the proximal position, and configured such that the one or more interior surfaces are not in contact with the engagement boss when the on body electronics unit is in the distal position, since at that point, the sensor will have been implanted and thus released from the inserter, best seen in Figure 16 and 25-26 (Col.14: 9-18; Col.17: 1-17).

35. Funderburk et al disclose the engagement boss 353 comprises a conical shape, best seen in Figure 26B.

However, Funderburk et al do not disclose the engagement boss on a gripping arm.

Yodfat et al teach that it is well-known in the art to provide a connecting mechanism comprising at least one arm 30 (Figure 6a, each end) that is releasably engaged with a plurality of recesses (near element 44, Figure 6A, each side), as an effective connecting mechanism, shown in figure 6B.

Cole et al teach that it is well-known in the art to use gripping arms 312a,b to effectively releasably engage with an analogous implanted sensor 301 to enable the sensor to be held in a desired position, best seen in Figure 13b-c (0113-0117).

In regard to Claim 34, Cole et al also teach that the gripping arm has an engagement boss at a tip portion to contact the sensor, best seen in Figure 13b-c. Thus, Cole et al teach that it is well known to use gripping arms to releasably engage with an implanted sensor.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the invention of Thomas et al as modified such that a conical engagement boss is engaged with a recess is provided, as taught by Funderburk et al, to effectively releasably engage with the sensor during insertion (i.e. in proximal position) until the distal position at insertion, such that the engagement boss is provided on the tip of a plurality of gripping arms, as taught by both Yodfat et al and Cole et al, to provide an equally as effective means of holding the sensor in the proper position during insertion, such that since Thomas et al already discloses the recesses, said gripping arms with the engagement boss at the tip would engage the plurality of recesses on the on body electronics unit housing, to effectively hold the

on body electronics unit in the proper position proximally (already taught by Thomas et al) until its insertion into the patient at the distal position (already taught by Thomas et al), such that in combination, the one or more gripping arms are configured to engage the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and wherein the one or more gripping arms are configured to disengage from the plurality of recesses when the on body electronics unit is in the distal position, wherein each of the one or more gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

Conclusion

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

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

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

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

H.Q. NGUYEN
Examiner
Art Unit 3791

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791

Applicant-Initiated Interview Summary	**Application No.** 17/019,110	**Applicant(s)** Donnay et al.		
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (First Inventor to File) Status** No	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
Huong Q NGUYEN	Examiner	WebEx/Video Conference
Glen Liu	Attorney of Record	

Date of Interview: 12 March 2021

Issues Discussed:

Other

Applicant wishes to cancel/withdrawn Claims 57-58. Therefore, said claims will not be examined.

/H Q NGUYEN/ Examiner, Art Unit 3791	/DEVIN B HENSON/ Primary Examiner, Art Unit 3791

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

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

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

Notice of References Cited	Application/Control No. 17/019,110	Applicant(s)/Patent Under Reexamination Donnay et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20100198034-A1	08-2010	Thomas; Christopher Allen	C12Q1/001	600/365
*	B	US-20100137695-A1	06-2010	Yodfat; Ofer	A61M5/158	600/345
*	C	US-20080058830-A1	03-2008	Cole; Mark S.	A61F2/1664	606/107
	D					
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	Art Unit
	Huong Q NGUYEN	3791

CPC - Searched*		
Symbol	Date	Examiner
A61B5/14503,1473,14865,6849,14532	03/13/2021	HQN
A61B2560/063	03/13/2021	HQN
A61B17/3468	03/13/2021	HQN
A61M2005/1585	03/13/2021	HQN
A61B5/15144,15113,15186,15188,1519,15192,15194	03/13/2021	HQN
A61B2017/347	03/13/2021	HQN

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
EAST search history	03/13/2021	HQN
Inventor search	03/13/2021	HQN

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	Art Unit
	Huong Q NGUYEN	3791

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	Art Unit
	Huong Q NGUYEN	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/29/2021								
	26	✓								
	27	✓								
	28	✓								
	29	✓								
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	57	✓								
	58	✓								

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	15	"019110".ap.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 12:23
S2	2	"4637403".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 12:29
S3	5	("20080319414" | "20150141776" | "20160058474").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 12:29
S4	18	"327052".ap.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 12:31
S5	18	Frey-Stephan$.in. and patch	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2021/03/13 12:31

			IBM_TDB			
S6	17	Frey-Stephan$.in. and patch and process$5	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 12:31
S7	6	(("5299571") or ("20100022863") or ("20120226122") or ("20130256289")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:21
S8	9	("20080242961" | "20090171179" | "4294258" | "20100198033" | "7985203" | "20080140009" | "7519408" | "20040138588").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:22
S9	510	abbott.as. and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:23
S10	400	(sensor with electronics) same glucose same ((implant$5 insert$5) with skin)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:24
S11	8	600/584.ccls. and ((hole aperture opening) same electronic same sensor)	US-PGPUB; USPAT;	OR	OFF	2021/03/13 13:45

			USOCR; FPRS; EPO; JPO; IBM_TDB			
S12	186	lancet and nguyen.xa.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:46
S13	149	yodfat-ofer$.in. and infusion and skin and securable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 14:37
S14	46	Donnay-Manuel$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:37
S15	29	Nguyen-Tuan$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:37
S16	96	Pace-Louis$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:38

S17	55	Robinson-Peter$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:38
S18	107	S14 S15 S16 S17	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:38
S19	70	S18 not S9	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:39
S20	26	(US-20080009805-$ | US-20100030111-$ | US-20080031941-$ | US-20050101912-$ | US-20050131347-$ | US-20040133164-$ | US-20050173245-$ | US-20040204687-$ | US-20080255440-$ | US-20100324392-$ | US-16176370-$ | US-1704889-$ | US-20040133164-$ | US-20040204687-$ | US-20050101912-$ | US-20050131347-$ | US-20050173245-$ | US-20080009805-$ | US-20080031941-$ | US-20080255440-$ | US-20100030111-$ | US-20100324392-$ | US-5527288-$ | US-6102896-$ | US-7407493-$ | US-7699807-$ | US-7850652-$ | US-7896844-$ | US-7955297-$ | US-7985203-$ | US-8172805-$ | US-8262618-$ | US-8409145-$ | US-8870822-$ | US-8880138-$ | US-9295786-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:23
S21	1	"20090299301".DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2021/03/13 16:23

			IBM_TDB			
S22	138	(US-4970145-$ | US-4974929-$ | US-4986271-$ | US-4994167-$ | US-5001054-$ | US-5035860-$ | US-5036860-$ | US-5050612-$ | US-5058592-$ | US-5070535-$ | US-5082550-$ | US-5082786-$ | US-5089112-$ | US-5095904-$ | US-5101814-$ | US-5108564-$ | US-5109850-$ | US-5120420-$ | US-5126034-$ | US-5133856-$ | US-5135003-$ | US-5141868-$ | US-5161532-$ | US-5165407-$ | US-5174291-$ | US-5190041-$ | US-5192416-$ | US-5198367-$ | US-5202261-$ | US-5205920-$ | US-5208154-$ | US-5209229-$ | US-5217595-$ | US-5229282-$ | US-5250439-$ | US-5262035-$ | US-5262305-$ | US-5264103-$ | US-5264104-$ | US-5264106-$ | US-5271815-$ | US-5279294-$ | US-5284156-$ | US-5286362-$ | US-5286364-$ | US-5288636-$ | US-5293546-$ | US-5320098-$ | US-5320725-$ | US-5322063-$ | US-5337747-$ | US-5352348-$ | US-5356786-$ | US-5368028-$ | US-5372133-$ | US-5376251-$ | US-5378628-$ | US-5387327-$ | US-5390671-$ | US-5391250-$ | US-5395504-$ | US-5400782-$ | US-5411647-$ | US-5431160-$ | US-5437999-$ | US-5469846-$ | US-5491474-$ | US-5494562-$ | US-5496453-$ | US-5497772-$ | US-5531878-$ | US-5545191-$ | US-5560357-$ | US-5562713-$ | US-5565085-$ | US-5567302-$ | US-5568806-$ | US-5569186-$ | US-5582184-$ | US-5582697-$ | US-5582698-$ | US-5586553-$ | US-5589326-$ | US-5593852-$ | US-5596150-$ | US-5617851-$ | US-5628890-$ | US-5651869-$ | US-5660163-$ | US-5665222-$ | US-5670031-$ | US-5680858-$ | US-5682233-$ | US-5695623-$ | US-5708247-$ | US-5711297-$ | US-5711861-$ | US-5711862-$ | US-5741211-$ | US-5771001-$ | US-5791344-$ | US-5800420-$ | US-5807375-$ | US-5820551-$ | US-5820622-$ | US-5822715-$ | US-5827184-$ | US-5840020-$ | US-5842983-$ | US-5885211-$ | US-5899855-$ | US-5954643-$ | US-5954685-$ | US-5957854-$ | US-5964993-$ | US-5971922-$ | US-5972199-$ | US-6001067-$ | US-6024699-$ | US-6093172-$ | US-6103033-$ | US-6120676-$ | US-6122351-$ | US-6134461-$ | US-6143164-$ | US-6175752-$ | US-6338790-$ | US-6368141-$ | US-6368274-$ | US-6409740-$ | US-6695860-$ | US-6699188-$ | US-6746582-$ | US-6770030-$ | US-6936006-$ | US-6990366-$ | US-7381184-$ | US-RE32947-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:44
S23	53	(US-20030002682-$ | US-20080004512-$ | US-20070027381-$ | US-20080027474-$ | US-20080033318-$ | US-20060036139-$ | US-	US-PGPUB; USPAT;	OR	OFF	2021/03/13 16:44

		20070038044-$ | US-20040064133-$ | US-20080064941-$ | US-20080065646-$ | US-20090069658-$ | US-20030078560-$ | US-20080086044-$ | US-20050090850-$ | US-20090102678-$ | US-20080112848-$ | US-20020130042-$ | US-20040133164-$ | US-20080133702-$ | US-20060155317-$ | US-20030155656-$ | US-0158207-$ | US-0173741-$ | US-0188731-$ | US-0189939-$ | US-0212766-$ | US-0244368-$ | US-0249922-$ | US-20060264888-$ | US-20080269673-$ | US-20080275313-$ | US-20080283396-$ | US-20020130042-$ | US-20030002682-$ | US-20030078560-$ | US-20030155656-$ | US-20040064133-$ | US-20040133164-$ | US-20040158207-$ | US-20050090850-$ | US-20060036139-$ | US-20060155317-$ | US-20060189939-$ | US-20060264888-$ | US-20070027381-$ | US-20070038044-$ | US-20070173741-$ | US-20070244368-$ | US-20070249922-$ | US-20080004512-$ | US-20080027474-$ | US-20080033318-$ | US-20080064941-$ | US-20080065646-$ | US-20080086044-$ | US-20080112848-$ | US-20080133702-$ | US-20080188731-$ | US-20080269673-$ | US-20080275313-$ | US-20080283396-$ | US-20090069658-$ | US-20090102678-$ | US-20090212766-$ | US-3260656-$ | US-3653841-$ | US-3719564-$ | US-3776832-$).did.	USOCR; FPRS; EPO; JPO; IBM_TDB			
S24	119	(US-3837339-$ | US-3926760-$ | US-3972320-$ | US-3979274-$ | US-4008717-$ | US-4016866-$ | US-4055175-$ | US-4059406-$ | US-4076596-$ | US-4098574-$ | US-4100048-$ | US-4129128-$ | US-4151845-$ | US-4168205-$ | US-4172770-$ | US-4178916-$ | US-4206755-$ | US-4224125-$ | US-4240438-$ | US-4247297-$ | US-4340458-$ | US-4352960-$ | US-4356074-$ | US-4365637-$ | US-4366033-$ | US-4375399-$ | US-4384586-$ | US-4390621-$ | US-4401122-$ | US-4404066-$ | US-4418148-$ | US-4427770-$ | US-4431004-$ | US-4436094-$ | US-4440175-$ | US-4450842-$ | US-4458686-$ | US-4461691-$ | US-4469110-$ | US-4477314-$ | US-4484987-$ | US-4522690-$ | US-4524114-$ | US-4526661-$ | US-4534356-$ | US-4538616-$ | US-4543955-$ | US-4545382-$ | US-4552840-$ | US-4560534-$ | US-4571292-$ | US-4573994-$ | US-4581336-$ | US-4595011-$ | US-4619754-$ | US-4627445-$ | US-4627908-$ | US-4633878-$ | US-4637403-$ | US-4650547-$ | US-4654197-$ | US-4655880-$ | US-4655885-$ | US-4671288-$ | US-4679562-$ | US-4680268-$ | US-4682602-$ | US-4684537-$ | US-4685463-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:44

		US-4703756-$ | US-4711245-$ | US-4717673-$ | US-4721601-$ | US-4721677-$ | US-4726378-$ | US-4726716-$ | US-4731726-$ | US-4757022-$ | US-4758323-$ | US-4759371-$ | US-4759828-$ | US-4764416-$ | US-4776944-$ | US-4781798-$ | US-4784736-$ | US-4795707-$ | US-4796634-$ | US-4805624-$ | US-4813424-$ | US-4815469-$ | US-4820399-$ | US-4822337-$ | US-4830959-$ | US-4832797-$ | US-4840893-$ | US-4848351-$ | US-4871351-$ | US-4871440-$ | US-4874500-$ | US-4890620-$ | US-4894137-$ | US-4897162-$ | US-4897173-$ | US-4909908-$ | US-4911794-$ | US-4917800-$ | US-4919141-$ | US-4919767-$ | US-4923586-$ | US-4927516-$ | US-4934369-$ | US-4935105-$ | US-4935345-$ | US-4938860-$ | US-4944299-$ | US-4950378-$ | US-4953552-$ | US-4954129-$ | US-4969468-$).DID.				
S25	9	("20080269774" | "5873879" | "4950288" | "20080058830" | "20020026241").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:58
S26	16	"649323".ap.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:00
S27	1	"20120238857".did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:12
S28	45	(US-3123790-$ | US-3581062-$ | US-3670727-$ | US-3949388-$ | US-4036749-$ | US-4120292-$ | US-4245634-$ | US-4294258-$ | US-4327725-$ | US-4344438-$ | US-4349728-$ | US-4373527-$ | US-4425920-$ | US-4478976-$ | US-4494950-$ | US-4509531-$ | US-4527240-$ | US-4619793-$ | US-4627842-$ | US-4685466-$ | US-4698057-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2021/03/13 17:25

		US-4711247-$ | US-4729672-$ | US-4749985-$ | US-4755173-$ | US-4777953-$ | US-4779618-$ | US-4781683-$ | US-4854322-$ | US-4895147-$ | US-4921199-$ | US-4925268-$ | US-4988341-$ | US-4995402-$ | US-4401400-$ | US-5000180-$ | US-5013161-$ | US-5019974-$ | US-5035860-$ | US-5047044-$ | US-5055171-$ | US-5106365-$ | US-5108889-$ | US-5122925-$).DID.	IBM_TDB			
S29	91	(US-5140985-$ | US-5234835-$ | US-5238729-$ | US-5246867-$ | US-5264105-$ | US-5285792-$ | US-5293877-$ | US-5299571-$ | US-5340722-$ | US-5342789-$ | US-5360404-$ | US-5372427-$ | US-5379238-$ | US-5408999-$ | US-5425361-$ | US-5431921-$ | US-5462645-$ | US-5472317-$ | US-5489414-$ | US-5507288-$ | US-5509410-$ | US-5514718-$ | US-5551427-$ | US-5575563-$ | US-5584813-$ | US-5601435-$ | US-5609575-$ | US-5613978-$ | US-5628310-$ | US-5632557-$ | US-5640954-$ | US-5653239-$ | US-5665071-$ | US-5711001-$ | US-5733044-$ | US-5735285-$ | US-5749656-$ | US-5766131-$ | US-5772586-$ | US-5779665-$ | US-5851197-$ | US-5865804-$ | US-5924979-$ | US-5925021-$ | US-5931814-$ | US-5948006-$ | US-5951521-$ | US-5961451-$ | US-5965380-$ | US-5987353-$ | US-5995860-$ | US-6017335-$ | US-6022368-$ | US-6026321-$ | US-6027459-$ | US-6049727-$ | US-6068399-$ | US-6083710-$ | US-6088608-$ | US-6091975-$ | US-6091976-$ | US-6117290-$ | US-6119028-$ | US-6121009-$ | US-6121611-$ | US-6159147-$ | US-6162611-$ | US-6200265-$ | US-6212416-$ | US-6219574-$ | US-6248067-$ | US-6254536-$ | US-6254586-$ | US-6275717-$ | US-6283761-$ | US-6283982-$ | US-6284478-$ | US-6293925-$ | US-6295506-$ | US-6306104-$ | US-6309884-$ | US-6329161-$ | US-6348640-$ | US-6359444-$ | US-6360888-$ | US-6366794-$ | US-6377828-$ | US-6379301-$ | US-6413393-$ | US-6418332-$ | US-6424847-$).did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:25
S30	105	(US-6427088-$ | US-6437679-$ | US-6440068-$ | US-6478736-$ | US-6484045-$ | US-6484046-$ | US-6514718-$ | US-6520326-$ | US-6522927-$ | US-6551494-$ | US-6554798-$ | US-6558320-$ | US-6558321-$ | US-6560471-$ | US-6561978-$ | US-6562001-$ | US-6564105-$ | US-6565509-$ | US-6571128-$ | US-6572566-$ | US-6576101-$ | US-6577899-$ | US-6579690-$ | US-6585644-$ | US-6589229-$ | US-6591125-$ | US-6595919-$ | US-6605200-$ | US-6605201-$ | US-6607509-$ | US-6610012-$ | US-6633772-$ | US-6635014-$ | US-6648821-$ | US-6654625-$ | US-6659948-$ | US-6666849-$ | US-6668196-$ | US-6676290-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:25

		US-6687546-$ | US-6689056-$ | US-6694191-$ | US-6702857-$ | US-6733446-$ | US-6740075-$ | US-6741877-$ | US-6758810-$ | US-6790178-$ | US-6809653-$ | US-6810290-$ | US-6811533-$ | US-6811534-$ | US-6813519-$ | US-6837858-$ | US-6837885-$ | US-6849052-$ | US-6854882-$ | US-6862465-$ | US-6873268-$ | US-6881551-$ | US-6892085-$ | US-6895265-$ | US-6931327-$ | US-6932894-$ | US-6942518-$ | US-6950708-$ | US-6958705-$ | US-6959211-$ | US-6968294-$ | US-6971274-$ | US-6974437-$ | US-6990366-$ | US-6997907-$ | US-6998247-$ | US-7003336-$ | US-7003340-$ | US-7003341-$ | US-7024245-$ | US-7025743-$ | US-7041068-$ | US-7041468-$ | US-7052483-$ | US-7056302-$ | US-7074307-$ | US-7081195-$ | US-7097637-$ | US-7098803-$ | US-7108778-$ | US-7110803-$ | US-7113821-$ | US-7134999-$ | US-7136689-$ | US-7171274-$ | US-7190988-$ | US-7192450-$ | US-7198606-$ | US-7207974-$ | US-7226978-$ | US-7276029-$ | US-7278983-$ | US-7297151-$ | US-7299082-$ | US-7310544-$ | US-7318816-$ | US-7324012-$).DID.				
S31	81	(US-7329239-$ | US-7335294-$ | US-7340287-$ | US-7340309-$ | US-7354420-$ | US-7364592-$ | US-7366556-$ | US-7379765-$ | US-7402153-$ | US-7416541-$ | US-7424318-$ | US-7455663-$ | US-7460898-$ | US-7467003-$ | US-7471972-$ | US-7494465-$ | US-7497827-$ | US-7519408-$ | US-7583990-$ | US-7591801-$ | US-7599726-$ | US-7613491-$ | US-7615007-$ | US-7632228-$ | US-7637868-$ | US-7640048-$ | US-7651596-$ | US-7654956-$ | US-7657297-$ | US-7666149-$ | US-7682338-$ | US-7697967-$ | US-7711402-$ | US-7713574-$ | US-7715893-$ | US-7727147-$ | US-7731657-$ | US-7736344-$ | US-7763042-$ | US-7822454-$ | US-20060009727-$ | US-20020013538-$ | US-20020019022-$ | US-20020022855-$ | US-20020023852-$ | US-20020042090-$ | US-20020057993-$ | US-20020066764-$ | US-20020076966-$ | US-20020082487-$ | US-20020103499-$ | US-20020106709-$ | US-20020119711-$ | US-20020128594-$ | US-20020154050-$ | US-20020161288-$ | US-20020165462-$ | US-20020198444-$ | US-20030023317-$ | US-20030023461-$ | US-20030032867-$ | US-20030032874-$ | US-20030042137-$ | US-20030060753-$ | US-20030065308-$ | US-20030069510-$ | US-20030078481-$ | US-20030083686-$ | US-20030097092-$ | US-20030100040-$ | US-20030109775-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:26

		20030134347-$ | US-20030135333-$ | US-20030144581-$ | US-20030144608-$ | US-20030168338-$ | US-20030176933-$ | US-20030187338-$ | US-20030199790-$ | US-20030199910-$ | US-20030212379-$).did.				
S32	82	(US-20030217966-$ | US-20030225361-$ | US-20040010207-$ | US-20040011671-$ | US-20040040840-$ | US-20040045879-$ | US-20040054263-$ | US-20040064068-$ | US-20040096959-$ | US-20040106858-$ | US-20040106859-$ | US-20040116865-$ | US-20040116866-$ | US-20040122353-$ | US-20040122489-$ | US-20040133164-$ | US-20040135684-$ | US-20040138588-$ | US-20040147996-$ | US-20040152622-$ | US-20040167801-$ | US-20040171921-$ | US-20040176672-$ | US-20040186362-$ | US-20040186365-$ | US-20040193090-$ | US-20040199059-$ | US-20040204687-$ | US-20040210122-$ | US-20040225338-$ | US-20040236200-$ | US-20040236251-$ | US-20040254433-$ | US-20040254434-$ | US-20040267300-$ | US-20050003470-$ | US-20050004494-$ | US-20050010269-$ | US-20050027177-$ | US-20050027180-$ | US-20050031689-$ | US-20050043598-$ | US-20050070819-$ | US-20050085872-$ | US-20050090607-$ | US-20050106713-$ | US-20050112169-$ | US-20050114068-$ | US-20050121322-$ | US-20050131346-$ | US-20050143635-$ | US-20050154410-$ | US-20050165404-$ | US-20050176136-$ | US-20050182306-$ | US-20050187720-$ | US-20050192557-$ | US-20050195930-$ | US-20050197554-$ | US-20050199494-$ | US-20050203360-$ | US-20050222518-$ | US-20050239154-$ | US-20050239156-$ | US-20050241957-$ | US-20050245795-$ | US-20050245799-$ | US-20050245844-$ | US-20050277164-$ | US-20050287620-$ | US-20060001538-$ | US-20060004303-$ | US-20060010098-$ | US-20060015020-$ | US-20060015024-$ | US-20060016700-$ | US-20060019327-$ | US-20060020186-$ | US-20060020187-$ | US-20060020188-$ | US-20060020189-$ | US-20060020190-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:26
S33	85	(US-20060020191-$ | US-20060020192-$ | US-20060036140-$ | US-20060036141-$ | US-20060036142-$ | US-20060036143-$ | US-20060036144-$ | US-20060036145-$ | US-20060047220-$ | US-20060129173-$ | US-20060155210-$ | US-20060166629-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/13 17:26

		20060173444-$ | US-20060189863-$ | US-20060195029-$ | US-20060200181-$ | US-20060200970-$ | US-20060222566-$ | US-20060226985-$ | US-20060247508-$ | US-20060253086-$ | US-20060258929-$ | US-20060276724-$ | US-20060287591-$ | US-20070016381-$ | US-20070060814-$ | US-20070073129-$ | US-20070078320-$ | US-20070078321-$ | US-20070078322-$ | US-20070088377-$ | US-20070106135-$ | US-20070110124-$ | US-20070123819-$ | US-20070149875-$ | US-20070163880-$ | US-20070173706-$ | US-20070191701-$ | US-20070203407-$ | US-20070203966-$ | US-20070235331-$ | US-20070244398-$ | US-20080004573-$ | US-20080009692-$ | US-20080009805-$ | US-20080017522-$ | US-20080021666-$ | US-20080029391-$ | US-20080033254-$ | US-20080033268-$ | US-20080039702-$ | US-20080045824-$ | US-20080064937-$ | US-20080064944-$ | US-20080071156-$ | US-20080083617-$ | US-20080086042-$ | US-20080086273-$ | US-20080097246-$ | US-20080108942-$ | US-20080114280-$ | US-20080119707-$ | US-20080161664-$ | US-20080167578-$ | US-20080183061-$ | US-20080183399-$ | US-20080189051-$ | US-20080194935-$ | US-20080194936-$ | US-20080194937-$ | US-20080194938-$ | US-20080195232-$ | US-20080195967-$ | US-20080197024-$ | US-20080200788-$ | US-20080200789-$ | US-20080200791-$ | US-20080200897-$ | US-20080208025-$ | US-20080214481-$ | US-20080214915-$ | US-20080214918-$ | US-20080228051-$ | US-20080228054-$ | US-20080242961-$).did.	JPO; IBM_TDB			
S34	69	(US-20080262469-$ | US-20080283396-$ | US-20080287764-$ | US-20080287765-$ | US-20080287766-$ | US-20080294096-$ | US-20080296155-$ | US-20080300476-$ | US-20080306368-$ | US-20080306434-$ | US-20080306435-$ | US-20080306444-$ | US-20090012379-$ | US-20090018424-$ | US-20090030294-$ | US-20090036758-$ | US-20090036763-$ | US-20090036915-$ | US-20090043181-$ | US-20090043182-$ | US-20090043525-$ | US-20090043541-$ | US-20090043542-$ | US-20090045055-$ | US-20090054866-$ | US-20090062633-$ | US-20090062635-$ | US-20090076356-$ | US-20090076359-$ | US-20090076360-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:27

		20090076361-$ | US-20090082693-$ | US-20090099436-$ | US-20090105569-$ | US-20090124877-$ | US-20090124878-$ | US-20090124879-$ | US-20090124964-$ | US-20090124979-$ | US-20090131768-$ | US-20090131769-$ | US-20090131776-$ | US-20090131777-$ | US-20090137886-$ | US-20090137887-$ | US-20090143659-$ | US-20090143660-$ | US-20090156919-$ | US-20090156924-$ | US-20090163790-$ | US-20090163791-$ | US-20090171182-$ | US-20090178459-$ | US-20090182217-$ | US-20090192366-$ | US-20090192380-$ | US-20090192722-$ | US-20090192724-$ | US-20090192745-$ | US-20090192751-$ | US-20090198215-$ | US-20090203981-$ | US-20090204341-$ | US-20090216103-$ | US-20090240120-$ | US-20090240128-$ | US-20090240193-$ | US-20090242399-$ | US-20090242425-$).DID.				
S35	61	(US-20090247855-$ | US-20090247856-$ | US-20090259201-$ | US-20090259202-$ | US-20090270765-$ | US-20090287073-$ | US-20090287074-$ | US-20090292184-$ | US-20090292185-$ | US-20090299155-$ | US-20090299156-$ | US-20090299162-$ | US-20090299276-$ | US-20100010324-$ | US-20100010331-$ | US-20100010332-$ | US-20100016687-$ | US-20100016698-$ | US-20100022855-$ | US-20100022863-$ | US-20100030038-$ | US-20100030053-$ | US-20100030484-$ | US-20100030485-$ | US-20100036215-$ | US-20100036216-$ | US-20100036222-$ | US-20100036223-$ | US-20100036225-$ | US-20100036281-$ | US-20100041971-$ | US-20100045465-$ | US-20100049014-$ | US-20100049024-$ | US-20100063373-$ | US-20100069728-$ | US-20100076283-$ | US-20100081908-$ | US-20100081910-$ | US-20100087724-$ | US-20100096259-$ | US-20100099970-$ | US-20100099971-$ | US-20100100113-$ | US-20100106088-$ | US-20100119693-$ | US-20100121169-$ | US-20100168677-$ | US-20100324392-$ | US-20100331647-$ | US-20110021889-$ | US-20110046456-$ | US-20110082484-$ | US-20110106126-$ | US-20110257521-$ | US-20110288574-$ | US-20110319729-$ | US-20120123385-$ | US-20120184909-$ | US-20120296327-$ | US-20130047981-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:27

S36	948	S20 S21 S22 S23 S24 S28 S29 S30 S31 S32 S33 S34 S35	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:28
S37	390	S36 and (sensor with electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:30
S38	351	S37 not (S9 S10)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:30
S39	217	S38 and (insert$5 with sensor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:31
S40	14,590	A61B5/14503,1473,14865,6849.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:36
S41	1,112	A61B2560/063.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2021/03/13 17:36

			JPO; IBM_TDB			
S42	10,711	A61B17/3468.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:37
S43	25,187	S40 S41 S42	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:37
S44	45,210	A61B5/14532.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:38
S45	5,048	A61M2005/1585.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:42
S47	11,078	A61B5/15144,15113,15186,15188,1519,15192,15194.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:47
S48	3,608	A61B2017/347.cpc.	US-PGPUB;	OR	ON	2021/03/13 17:47

			USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB			
S52	29,666	S43 S45	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:57
S57	9,851	S52 and S44	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:04
S58	1,762	S57 and (sensor and electronics) and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:04
S59	1	S58 and S48	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:05
S60	43	S58 and S47	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2021/03/13 18:08

			IBM_TDB			
S61	11	S48 and (sensor and electronics) and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:09
S62	23	S48 and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:10
S63	7	(US-20050158207-$ | US-20070173741-$ | US-20080188731-$ | US-20060189939-$ | US-20090212766-$ | US-20070244368-$ | US-20070249922-$).did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 18:43

3/13/2021 9:10:01 PM
C:\Users\hnguyen50\Documents\EAST\Workspaces\cases FY 2021\Second Quarter\17019110 inserting device for implantable sensor abbott.wsp

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	1	of	13

Complete if Known	
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
	1	3,260,656	07-12-1966	Ross Jr.
	2	3,653,841	04-04-1972	Klein
	3	3,719,564	03-06-1973	Lilly, Jr. et al.
	4	3,776,832	12-04-1973	Oswin et al.
	5	3,837,339	09-24-1974	Aisenberg et al.
	6	3,926,760	12-16-1975	Allen et al.
	7	3,972,320	08-03-1976	Kalman
	8	3,979,274	09-07-1976	Newman
	9	4,008,717	02-22-1977	Kowarski
	10	4,016,866	04-12-1977	Lawton
	11	4,055,175	10-25-1977	Clemens et al.
	12	4,059,406	11-22-1977	Fleet
	13	4,076,596	02-28-1978	Connery et al.
	14	4,098,574	07-04-1978	Dappen
	15	4,100,048	07-11-1978	Pompei et al.
	16	4,129,128	12-12-1978	McFarlane
	17	4,151,845	05-01-1979	Clemens
	18	4,168,205	09-18-1979	Danninger et al.
	19	4,172,770	10-30-1979	Semersky et al.
	20	4,178,916	12-18-1979	McNamara
	21	4,206,755	06-10-1980	Klein
	22	4,224,125	09-23-1980	Nakamura et al.
	23	4,240,438	12-23-1980	Updike et al.
	24	4,247,297	01-27-1981	Berti et al.
	25	4,340,458	07-20-1982	Lerner et al.
	26	4,352,960	10-05-1982	Dormer et al.
	27	4,356,074	10-26-1982	Johnson
	28	4,365,637	12-28-1982	Johnson
	29	4,366,033	12-28-1982	Richter et al.
	30	4,375,399	03-01-1983	Havas et al.
	31	4,384,586	05-24-1983	Christiansen
	32	4,390,621	06-28-1983	Bauer

Examiner Signature	/H Q NGUYEN/	Date Considered	03/13/2021

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Sheet 2 of 13

Complete if Known	
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

	33	4,401,122	08-30-1983	Clark Jr.
	34	4,404,066	09-13-1983	Johnson
	35	4,418,148	11-29-1983	Oberhardt
	36	4,427,770	01-24-1984	Chen et al.
	37	4,431,004	02-14-1984	Bessman et al.
	38	4,436,094	03-13-1984	Cerami
	39	4,440,175	04-03-1984	Wilkins
	40	4,450,842	05-29-1984	Zick et al.
	41	4,458,686	07-10-1984	Clark Jr.
	42	4,461,691	07-24-1984	Frank
	43	4,469,110	09-04-1984	Slama
	44	4,477,314	10-16-1984	Richter et al.
	45	4,484,987	11-27-1984	Gough
	46	4,522,690	06-11-1985	Venkatasetty
	47	4,524,114	06-18-1985	Samuels et al.
	48	4,526,661	07-02-1985	Steckhan et al.
	49	4,534,356	08-13-1985	Papadakis
	50	4,538,616	09-03-1985	Rogoff
	51	4,543,955	10-01-1985	Schroeppel
	52	4,545,382	10-08-1985	Higgins et al.
	53	4,552,840	11-12-1985	Riffer
	54	4,560,534	12-24-1985	Kung et al.
	55	4,571,292	02-18-1986	Liu et al.
	56	4,573,994	03-04-1986	Fischell et al.
	57	4,581,336	04-08-1986	Malloy et al.
	58	4,595,011	06-17-1986	Phillips
	59	4,619,754	10-28-1986	Niki et al.
	60	4,627,445	12-09-1986	Garcia et al.
	61	4,627,908	12-09-1986	Miller
	62	4,633,878	01-06-1987	Bombardieri
	63	4,637,403	01-20-1987	Garcia et al.
	64	4,650,547	03-17-1987	Gough
	65	4,654,197	03-31-1987	Lilja et al.
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Examiner Signature	/H Q NGUYEN/	Date Considered	03/13/2021

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Sheet	3	of	13

Complete if Known	
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

	67	4,655,885	04-07-1987	Hill et al.
	68	4,671,288	06-09-1987	Gough
	69	4,679,562	07-14-1987	Luksha
	70	4,680,268	07-14-1987	Clark Jr.
	71	4,682,602	07-28-1987	Prohaska
	72	4,684,537	08-04-1987	Graetzel et al.
	73	4,685,463	08-11-1987	Williams
	74	4,703,756	11-03-1987	Gough et al.
	75	4,711,245	12-08-1987	Higgins et al.
	76	4,717,673	01-05-1988	Wrighton et al.
	77	4,721,601	01-26-1988	Wrighton et al.
	78	4,721,677	01-26-1988	Clark Jr.
	79	4,726,378	02-23-1988	Kaplan
	80	4,726,716	02-23-1988	McGuire
	81	4,731,726	03-15-1988	Allen III
	82	4,757,022	07-12-1988	Shults et al.
	83	4,758,323	07-19-1988	Davis et al.
	84	4,759,371	07-26-1988	Franetzki
	85	4,759,828	07-26-1988	Young et al.
	86	4,764,416	08-16-1988	Ueyama et al.
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	88	4,781,798	11-01-1988	Gough
	89	4,784,736	11-15-1988	Lonsdale et al.
	90	4,795,707	01-03-1989	Niiyama et al.
	91	4,796,634	01-10-1989	Huntsman et al.
	92	4,805,624	02-21-1989	Yao et al.
	93	4,813,424	03-21-1989	Wilkins
	94	4,815,469	03-28-1989	Cohen et al.
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	96	4,822,337	04-18-1989	Newhouse et al.
	97	4,830,959	05-16-1989	McNeil et al.
	98	4,832,797	05-23-1989	Vadgama et al.
	99	RE 32,947	06-13-1989	Dormer et al.
	100	4,840,893	06-20-1989	Hill et al.

Examiner Signature	/H Q NGUYEN/	Date Considered	03/13/2021

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Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

	101	4,848,351	07-18-1989	Finch
	102	4,871,351	10-03-1989	Feingold
	103	4,871,440	10-03-1989	Nagata et al.
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	112	4,919,141	04-24-1990	Zier et al.
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	116	4,934,369	06-19-1990	Maxwell
	117	4,935,105	06-19-1990	Churchouse
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	119	4,938,860	07-03-1990	Wogoman
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	122	4,953,552	09-04-1990	DeMarzo
	123	4,954,129	09-04-1990	Giuliani et al.
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	127	4,986,271	01-22-1991	Wilkins
	128	4,994,167	02-19-1991	Shults et al.
	129	5,001,054	03-19-1991	Wagner
	130	5,035,860	07-30-1991	Kleingeld et al.
	131	5,036,860	08-06-1991	Leigh et al.
	132	5,050,612	09-24-1991	Matsumura
	133	5,058,592	10-22-1991	Whisler
	134	5,070,535	12-03-1991	Hochmair et al.

Examiner Signature	/H Q NGUYEN/	Date Considered	03/13/2021

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 13

Complete if Known	
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 6 of 13

Complete if Known	
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	7	of	13

Complete if Known	
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

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Sheet 8 of 13

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Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

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Sheet 9 of 13

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Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	A0130.0107.01C8

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Examiner Initials	Cite No.[1]	Foreign Patent Document Country[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T[6]
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	300				

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				Filing Date	September 11, 2020
				First Named Inventor	Manuel Luis Donnay
				Art Unit	To be assigned
(use as many sheets as necessary)				Examiner Name	To be assigned
Sheet	10	of	13	Attorney Docket Number	A0130.0107.01C8

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(use as many sheets as necessary)				Examiner Name	To be assigned
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Sheet	12	of	13	Attorney Docket Number	A0130.0107.01C8

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FOREIGN PATENT DOCUMENTS

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OFFICE ACTIONS/SEARCH REPORTS

Examiner Initials'	Cite No.[1]	Country	Description	Date of Issuance MM-DD-YYY	T[2]
	36	EP	16176370.1 Extended Search Report	12-07-2016	
	37	JP	2016-44196 Office Action	04-11-2017	Y
	38				
	39				
	40				

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
17/019,110	09/11/2020	600	3791	A0130.0107.01C8

APPLICANTS

ABBOTT DIABETES CARE INC., Alameda, CA;

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Manuel Luis Donnay, San Francisco, CA;
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**** CONTINUING DATA ***************************

This application is a CON of 16/002,847 06/07/2018
which is a CON of 13/436,768 03/30/2012 PAT 10010280
which is a CON of 13/071,461 03/24/2011 PAT 9215992
which claims benefit of 61/411,262 11/08/2010
and claims benefit of 61/361,374 07/02/2010
and claims benefit of 61/345,562 05/17/2010
and claims benefit of 61/317,243 03/24/2010

**** FOREIGN APPLICATIONS ***************************

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09/22/2020

Foreign Priority claimed ❑ Yes ☑ No 35 USC 119(a-d) conditions met ❑ Yes ☑ No Verified and Acknowledged /Hnguyen / Examiner's Signature	❑ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	99	26	1

ADDRESS

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Newport Beach, CA 92660
UNITED STATES

TITLE

MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

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	Complete if Known
Application Number	To be assigned
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned

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Application Number	To be assigned
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First Named Inventor	Manuel Luis Donnay
Art Unit	To be assigned
Examiner Name	To be assigned

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				Application Number	To be assigned
				Filing Date	September 11, 2020
				First Named Inventor	Manuel Luis Donnay
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	19	of	20	Attorney Docket No: A0130.0107.01C8	

NON PATENT LITERATURE DOCUMENTS			
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				Filing Date	September 11, 2020
				First Named Inventor	Manuel Luis Donnay
				Art Unit	To be assigned
				Examiner Name	To be assigned
Sheet	20	of	20	Attorney Docket No: A0130.0107.01C8	

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Sheet 1 of 1

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Application Number	17/019,110
Filing Date	September 11, 2020
First Named Inventor	Manuel Luis Donnay
Art Unit	3771
Examiner Name	Vy. Q. Bui
Attorney Docket Number	A0130.0107.01C8

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.[1]	U.S. Patent Document Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
/H.Q.N/	1	2009/0299301 A1	12-03-2009	Gottleib et al.
	2			
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	16				
	17				
	18				
	19				

OFFICE ACTIONS/SEARCH REPORTS

Examiner Initials'	Cite No.[1]	Country	Description	Date of Issuance MM-DD-YYY	T[2]
/H.Q.N/	20	EP	20195922.8 Extended Search Report	12-16-2020	
	21				
	22				
	23				

Examiner Signature	/H Q NGUYEN/	Date Considered	03/12/2021

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Application Serial No: 17/019,110

Attorney Docket No: A0130.0107.01C8
Customer Number: 95508
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8	1087

95508 7590 05/17/2021

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EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
05/17/2021	ELECTRONIC

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Applicant-Initiated Interview Summary	**Application No.** 17/019,110	**Applicant(s)** Donnay et al.		
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (First Inventor to File) Status** No	**Page** 1 of 2

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
Huong Q NGUYEN	Examiner	Telephonic
Devin Henson	Primary Examiner	
Glen Liu	Attorney of Record	

Date of Interview: 29 April 2021

Issues Discussed:

35 U.S.C. 112

The 112 issues presented in the office action were discussed.

35 U.S.C. 102

The examiner's interpretation of Thomas et al was discussed, in particular, with regard to the recesses on the on body electronics unit housing.

35 U.S.C. 103

Funderburk et al was also discussed and the differences between the reference's teachings of the sensor housing that attaches to a sensor with a recess.

☑ Attachment

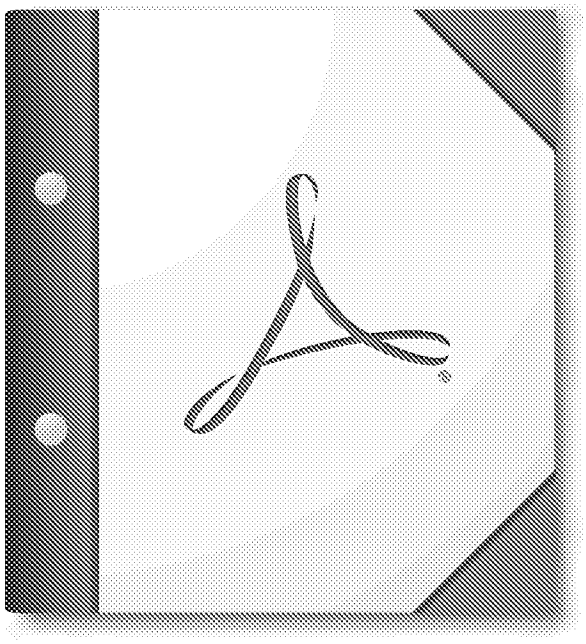
/H Q NGUYEN/ Examiner, Art Unit 3791	/DEVIN B HENSON/ Primary Examiner, Art Unit 3791

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

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete

and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Manuel Luis Donnay et al.

Application No.: 17/019,110 | Confirmation No.: 1087

Filed: September 11, 2020 | Art Unit: 3791

For: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES | Examiner: Huong Q. Nguyen

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

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INTRODUCTORY COMMENTS

In response to the Non-Final Office Action dated March 23, 2021 ("3/23/21 NFOA"), please see the following:

Amendments to the Claims beginning on page 2 of this paper; and

Remarks beginning on page 8 of this paper.

Electronic Acknowledgement Receipt

EFS ID:	42761630
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	19-MAY-2021
Filing Date:	11-SEP-2020
Time Stamp:	11:37:48
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no

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Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		10297USC16_A0130_0107_01C8_Response_to_NFOA_dated_3_23_2021.pdf	232462 a32c44fd9f318aeba3d0ce1142160a52ae56ec6f	yes	14

	Multipart Description/PDF files in .zip description		
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	Applicant Arguments/Remarks Made in an Amendment	8	14
	Claims	2	7
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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

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New International Application Filed with the USPTO as a Receiving Office

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REMARKS

Reconsideration is respectfully requested. Claims 26-39, 43, 45-56, and 59-61 are pending, of which claims 26-33, 52, and 54 have been amended without prejudice, and claims 59-61 are newly added. Claims 57-58 have been canceled without prejudice, and claims 1-25 remain canceled without prejudice. Support for the new claims and the amendments can be found, for example, in paragraphs [0257], [0265]-[0266], as well as Figures 122, 125-126, and 135-138, and elsewhere throughout U.S. Publ. No. 2021/0007651 ("the '651 Publication").[1] No new matter has been introduced.

For the reasons set forth below, Applicants respectfully submit that all pending claims are allowable.

TELEPHONIC INTERVIEW OF APRIL 29, 2021

The Applicants express thanks to Examiner Nguyen and Examiner Henson for participating in a telephonic interview on April 29, 2021. As summarized below, the following subjects were discussed during the interview.

First, the parties discussed the pending rejections under Section 112, second paragraph. *See* 3/23/21 NFOA at 4-5. In particular, the Applicants proposed the following claim amendments: replacing the term "one or more gripping arms" with "a plurality of gripping arms" (claims 27-33); replacing the term "outward" to "radially outward" (claims 29-30); and replacing the term "after the on body electronics unit advances" to "when the each interior surface of the plurality of interior surfaces is not in contact with the corresponding gripping arm of the plurality of gripping arms" (claim 30). The Examiners indicated that the proposed claim amendments appeared to overcome the rejections under Section 112, second paragraph.

Second, the parties discussed the pending rejections under Section 102. In particular, the parties discussed Figure 10B of U.S. Publ. No. 2010/0198034 ("Thomas"), which is relied on for the alleged disclosure of "an on body electronics unit housing comprising a plurality of recesses circumferentially disposed thereon," as recited in independent claim 26. *See* 3/23/21 NFOA at 6.

[1] All citations are provided purely for the benefit of the Examiner. These citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

Applicants noted that the purported "recesses" shown in Figure 10B are part of the sensor electronics 1030 – and are not circumferentially disposed on the on body electronics unit housing 1010. *See also* Thomas at paras. [0130] to [0132]. Examiner Henson further suggested capturing the "circumferentially" concept by instead using the substitute phrase "on a periphery."

The Examiners' guidance is appreciated. For the sole purpose of advancing prosecution, and without conceding to the merits of the rejections under Section 112, dependent claims 27-33 have been amended as discussed during the interview. Furthermore, for the sole purpose of advancing prosecution, and without conceding to the merits of the rejection under Section 102, independent claim 26 has been amended to recite "a plurality of recesses disposed on a **periphery of the on body electronics unit housing**," as suggested by Examiner Henson. Accordingly, it is respectfully submitted that the pending claims are in condition for allowance.

REJECTIONS UNDER SECTION 112

Claims 28-30 were rejected under pre-AIA 35 U.S.C. §112, second paragraph, as allegedly being indefinite. *See* 3/23/21 NFOA at 4-5. For the sole purpose of advancing prosecution, and without conceding the merits of the Section 112 rejection, claims 28-30 have been amended, as follows (with emphasis added):

> 28. The glucose monitoring assembly of claim 27, wherein **each gripping arm of the plurality of gripping arms** is configured to be engaged with **a corresponding recess of the plurality of recesses** of the on body electronics unit housing when the on body electronics unit is in the proximal position, and
>
> wherein **the each gripping arm of the plurality of gripping arms** is configured to be disengaged from **the corresponding recess of the plurality of recesses** when the on body electronics unit is in the distal position.
>
> 29. The glucose monitoring assembly of claim 27, wherein **each gripping arm of the plurality of gripping arms** is biased in **radially outward direction**.
>
> 30. The glucose monitoring assembly of claim 32, wherein **the each gripping arm of the plurality of gripping arms** is configured to deflect in a **radially outward**

direction when the each interior surface of the plurality of interior surfaces is not in contact with the corresponding gripping arm of the plurality of gripping arms.[2]

In view of the above amendments (which were discussed during the interview on April 29, 2021), it is respectfully submitted that claims 28-30 are not indefinite. Accordingly, it is respectfully requested that the Section 112 rejections be withdrawn.

REJECTIONS UNDER SECTION 102 AND 103

Claims 26, 36-39, 43, and 46-50 were rejected under pre-AIA 35 U.S.C. §102(e) as being allegedly anticipated by Thomas. *See* 3/23/21 NFOA at 5-10.

In addition, claims 27 and 29-30 were rejected under pre-AIA 35 U.S.C. §103(a) as being allegedly unpatentable over Thomas in view of U.S. Patent No. 7,381,184 ("Funderburk"). *Id.* at 11-13. In addition, claims 28 and 31-35 were rejected under pre-AIA 35 U.S.C. §103(a) as being allegedly unpatentable over Thomas and Funderburk, and further in view of U.S. Publ. No. 2010/0137695 ("Yodfat") and U.S. Publ. No. 2008/0058830 ("Cole"). *Id.* at 13-16.

It is respectfully submitted that Thomas does not anticipate independent claim 26 because it does not teach each and every limitation recited in the claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."). Independent claim 26, as amended, recites as follows (with emphasis added):

> 26. A glucose monitoring assembly, the assembly comprising:
>
> (1) an inserter, comprising:
>
> an inserter housing; and
>
> a sharp, wherein the sharp is configured to insert a portion of a glucose sensor into a subject;
>
> (2) an on body electronics unit, comprising:
>
> **an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing**, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter;
>
> the glucose sensor; and

[2] Dependent claims 27, 31, 32, and 33 have also been amended to maintain consistency with the amendments made to claims 28-30.

on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position within the inserter to a distal position, and

wherein the inserter is configured to retract the sharp from the distal position to a retracted position within the inserter.

The 3/23/21 NFOA cites to Figure 10B of Thomas for the alleged disclosure of "an on body electronics unit housing comprising a plurality of recesses circumferentially disposed thereon," as previously recited in claim 26. *See* 3/23/21 NFOA at 6. However, as shown below, the purported "recesses" in Figure 10B (circled in red) are located in sensor electronics 1030 that are enclosed within the on body electronics unit housing, and are not "disposed on a periphery of the on body electronics unit housing," as recited in amended claim 26.

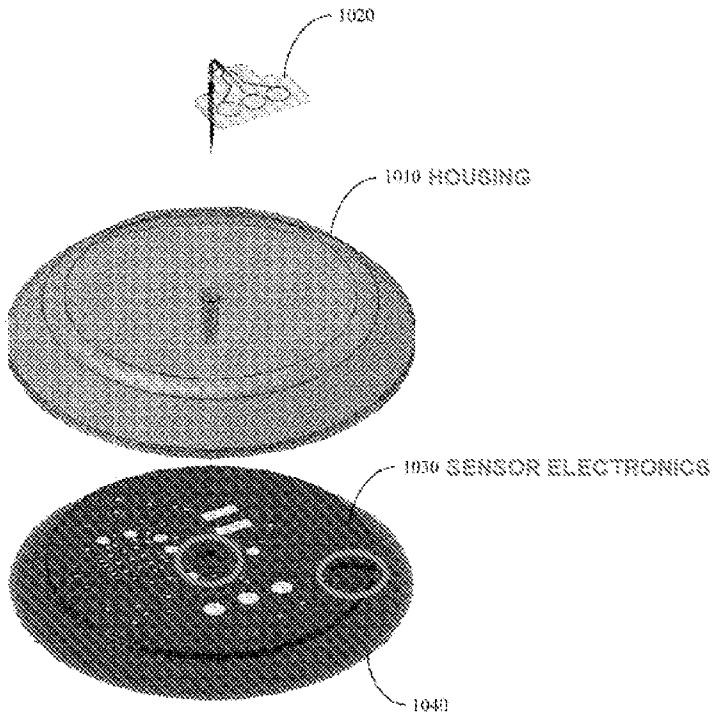

FIGURE 10B

Additionally, Thomas is silent on the limitation, "wherein the plurality of recesses is detachably engaged with the inserter." The 3/23/21 NFOA relies on Figures 12A-F of Thomas, in part, for the alleged disclosure of this limitation. However, neither Figures 12A-F, nor the

corresponding portion of Thomas's specification at paragraphs [0137] to [0141], describe that the plurality of purported "recesses" in Figures 10B – which are part of sensor electronics 1030 – are detachably engaged with the inserter.[3]

Accordingly, it is respectfully submitted that Thomas does not anticipate independent claim 26, as amended. For the same reasons, it is also respectfully submitted that Thomas does not anticipate dependent claim 37, which recites "wherein each of the plurality of recesses is disposed **on a side wall of the on body electronics unit housing**." Accordingly, the Applicants therefore respectfully request withdrawal of the Section 102 rejections to claims 26 and 37, as well as to any claims that depend therefrom.

The Section 103 rejections in the 3/23/21 NFOA rely on Thomas for the same alleged teachings on which the Section 102 rejection is based. *See* 3/23/21 NFOA at 11-16. Thus, for the same reasons that Thomas does not anticipate independent claim 26, Thomas also does not render obvious any of the dependent claims. It is therefore respectfully requested that the Section 103 rejections also be withdrawn.

NEW CLAIMS 59-61

Dependent claims 59-61 are newly added. New claim 59 recites the glucose monitoring assembly of claim 27, "wherein the inserter further comprises an interior surface configured to hold each gripping arm of the plurality of gripping arms against a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position." New claim 60 depends from claim 59, and further recites: "wherein the inserter is further configured such that the interior surface is not in contact with the each gripping arm of the plurality

[3] During the interview of April 29, 2021, Examiner Nguyen stated that Thomas might be combinable with Funderburk, under Section 103(a), to teach the limitation, "an on body electronics unit housing comprising a plurality of recesses circumferentially disposed thereon." In particular, Examiner Nguyen cited to sensor dimple 350 in Figure 25 of Funderburk as the purported "recess." Applicants respectfully disagree. Neither Thomas nor Funderburk teach or describe a plurality of recesses disposed **on a periphery of the on body electronics unit housing**, as recited in amended independent claim 26. The purported "recesses" in the cited references are disposed on, respectively, sensor electronics 1030 in Figure 10B of Thomas, and sensor 314 in Figure 25 of Funderburk.

Indeed, inserter kit 300 shown in Figure 16 of Funderburk has no electronics and, consequently, also does not have an on body electronics unit housing. As can be seen in Figures 15, 29, and 30 of Funderburk, transmitter 330 (which is the electronics) is coupled with a mount after the inserter has been removed. As such, Funderburk does not teach, describe, or suggest an inserter engaging an on body electronics unit housing with recesses disposed on the periphery, let alone using gripping arms to do so (as required by some of the dependent claims).

of gripping arms when the on body electronics unit is in the distal position." New claim 61 depends from claim 60, and further recites: "wherein the each gripping arm of the plurality of gripping arms is configured to deflect in a radially outward direction when the interior surface is not in contact with the each gripping arm of the plurality of gripping arms."

Support for the new claims can be found, for example, at paragraphs [0257] and [0266], as well as Figures 122 and 137-138 of the '651 Publication. It is respectfully submitted that the cited references, whether considered individually or in a proper combination, do not teach, describe, or suggest the limitations of new claims 59-61. Consequently, for at least the reasons stated above, it is respectfully submitted that new claims 59-61 are allowable.

CONCLUSION

Amendments to and/or cancellations of the claims are made without prejudice and solely to clarify the issues before the Examiner and/or to advance prosecution of this application and do not constitute a *de facto* acquiescence to any objection and/or rejection. Accordingly, this response does not concede that previously pending claims are not patentable.

The right is reserved to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any previously pending claims regardless of whether those claims were amended or cancelled herein. This may entail the pursuit of broader claims, narrower claims, and subject matter that was previously relinquished by virtue of argument or amendment.

Any silence with regard to the rejections of and/or objections to certain dependent claims constitutes a recognition that such are moot based on amendments or remarks made with respect to the independent claim from which the dependent claims depend. Such silence does not constitute a *de facto* acquiescence to any objection and/or rejection.

It is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 432-9993. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: May 19, 2021

Respectfully submitted,

/Glen Liu/

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AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions of the claims in the application.

1-25. (Canceled)

26. (Currently amended) A glucose monitoring assembly, the assembly comprising:

(1) an inserter, comprising:

an inserter housing; and

a sharp, wherein the sharp is configured to insert a portion of a glucose sensor into a subject;

(2) an on body electronics unit, comprising:

an on body electronics unit housing comprising a plurality of recesses ~~circumferentially~~ disposed ~~thereon~~ on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter;

the glucose sensor; and

on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position within the inserter to a distal position, and

wherein the inserter is configured to retract the sharp from the distal position to a retracted position within the inserter.

27. (Currently amended) The glucose monitoring assembly of claim 26, wherein the inserter further comprises ~~one or more~~ a plurality of gripping arms.

28. (Currently amended) The glucose monitoring assembly of claim 27, wherein ~~the one or more~~ each gripping arm of the plurality of gripping arms [[are]] is configured to be engaged with

a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the ~~one or more~~ each gripping arm of the plurality of gripping arms [[are]] is configured to be disengaged from the corresponding recess of the plurality of recesses when the on body electronics unit is in the distal position.

29. (Currently amended) The glucose monitoring assembly of claim 27, wherein ~~the one or more~~ each gripping arm of the plurality of gripping arms [[are]] is biased in [[an]] radially outward direction.

30. (Currently amended) The glucose monitoring assembly of claim [[27]] 32, wherein the ~~one or more~~ each gripping arm of the plurality of gripping arms [[are]] is configured to deflect in [[an]] a radially outward direction ~~after the on body electronics unit advances from the proximal position~~ when the each interior surface of the plurality of interior surfaces is not in contact with the corresponding gripping arm of the plurality of gripping arms.

31. (Currently amended) The glucose monitoring assembly of claim 27, wherein the inserter further comprises ~~one or more~~ a plurality of interior surfaces, wherein each interior surface of the plurality of interior surfaces is configured to hold ~~the one or more~~ a corresponding gripping arm of the plurality of gripping arms against a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

32. (Currently amended) The glucose monitoring assembly of claim 31, wherein the inserter is further configured such that the ~~one or more~~ each interior surface of the plurality of interior surfaces [[are]] is not in contact with the ~~one or more~~ corresponding gripping arm of the plurality of gripping arms when the on body electronics unit is in the distal position.

33. (Currently amended) The glucose monitoring assembly of claim 27, wherein each ~~of the one or more~~ gripping arm of the plurality of gripping arms comprises an engagement boss

configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

34. (Previously presented) The glucose monitoring assembly of claim 33, where the engagement boss is disposed on a tip portion of the gripping arm.

35. (Previously presented) The glucose monitoring assembly of claim 33, wherein the engagement boss comprises a conical shape.

36. (Previously presented) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses comprises a concave portion.

37. (Previously presented) The glucose monitoring assembly of claim 26, wherein each of the plurality of recesses is disposed on a side wall of the on body electronics unit housing.

38. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a driver disposed in the inserter housing, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.

39. (Previously presented) The glucose monitoring assembly of claim 26, further comprising a cap removably attached to a distal portion of the inserter.

40-42. (Canceled)

43. (Previously presented) The glucose monitoring assembly of claim 26, wherein a proximal end of the inserter comprises an inserter handle, wherein a distal end of the inserter comprises a sheath having a distal sheath end configured to be placed on a skin surface of the subject, and wherein the inserter handle is configured to move in a downward direction towards the skin surface relative to the sheath in response to an application of force on the inserter handle,

wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter handle.

44. (Canceled)

45. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics unit further comprises a sensor hub,

wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion,

wherein the distal sensor portion is configured to sense a glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

46. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics comprises an aperture, and wherein the sharp extends through the aperture of the on body electronics.

47. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit and the sharp.

48. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit is in the proximal position.

49. (Previously presented) The glucose monitoring assembly of claim 26, further comprising an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.

50. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a no power state when the on body electronics unit is in the proximal position.

51. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in an inactive mode when the on body electronics unit is in the proximal position.

52. (Currently amended) The glucose monitoring assembly of claim 47, wherein the distal end of the inserter defines a plane, and wherein a bottom surface of the on body electronics unit housing is parallel to the plane when the on body electronics unit and the sharp are in the proximal position.

53. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics unit and the sharp are configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position.

54. (Currently amended) The glucose monitoring assembly of claim 26, wherein a distance between the on body electronics unit housing when the on body electronics unit is in the proximal position and the on body electronics unit housing when the on body electronics unit is in the distal position is greater than a maximum height of the on body electronics unit housing.

55. (Previously presented) The glucose monitoring assembly of claim 46, wherein the aperture of the on body electronics is a first aperture, wherein the on body electronics unit housing further comprises a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.

56. (Previously presented) The glucose monitoring assembly of claim 26, wherein the sharp is further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject.

57-58. (Canceled)

59. (New) The glucose monitoring assembly of claim 27, wherein the inserter further comprises an interior surface configured to hold each gripping arm of the plurality of gripping arms against a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

60. (New) The glucose monitoring assembly of claim 59, wherein the inserter is further configured such that the interior surface is not in contact with the each gripping arm of the plurality of gripping arms when the on body electronics unit is in the distal position.

61. (New) The glucose monitoring assembly of claim 60, wherein the each gripping arm of the plurality of gripping arms is configured to deflect in a radially outward direction when the interior surface is not in contact with the each gripping arm of the plurality of gripping arms.

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

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

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

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Office Action Summary	Application No. 17/019,110	Applicant(s) Donnay et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status No

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

Period for Reply

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

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

Status

1)☑ Responsive to communication(s) filed on 5/19/2021.

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

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

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

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

Disposition of Claims*

5) ☑ Claim(s) 26-39,43,45-56 and 59-61 is/are pending in the application.

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

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 26-39,43,45-56 and 59-61 is/are rejected.

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

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

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

Application Papers

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

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

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

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

Priority under 35 U.S.C. § 119

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

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

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

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

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

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

Attachment(s)

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

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

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

4) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the amendment filed 5/19/2021. Claims 26-39, 43, 45-56, and 59-61 remain pending and under prosecution.

Claim Rejections - 35 USC § 112

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

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

Claims 58-61 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

In regard to Claim 59, the recitation of "an interior surface configured to hold each gripping arm of the plurality of gripping arms against a corresponding recess" is indefinite because it is unclear if one interior surface is used to hold each gripping arm or if there is one interior surface for each gripping arm, i.e. as recited in newly amended Claim 31. While the latter interpretation is used, clarification is requested.

Claim Rejections - 35 USC § 103

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

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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

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

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

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

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

This application currently names joint inventors. In considering patentability of the claims under pre-AIA 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of pre-AIA 35 U.S.C. 103(c) and potential pre-AIA 35 U.S.C. 102(e), (f) or (g) prior art under pre-AIA 35 U.S.C. 103(a).

Claims 26, 36-39, 43, and 46-56 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over Thomas et al (US Pub No. 20100198034) in view of Brister et al (US Pub No. 20080242961) – cited by applicant.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under pre-AIA 35 U.S.C. 102(e). This rejection under pre-AIA 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131(a); or (3) an oath or declaration under 37 CFR 1.131(c) stating that the application and reference are currently owned by the same party and that the inventor or joint inventors (i.e., the inventive entity) named in the application is the prior inventor under pre-AIA 35 U.S.C. 104 as in effect on March 15, 2013, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a rejection under pre-AIA 35 U.S.C. 103(a). See MPEP §§ 2146 *et seq*.

In regard to Claim 26, Thomas et al disclose a glucose monitoring assembly, the assembly comprising:

(1) an inserter, comprising:

an inserter housing 1210, best seen in Figure 12A-F; and

a sharp 1260, wherein the sharp is configured to insert a portion of a glucose sensor 1020, 1280 into a subject, best seen in Figure 2, 10A, and 12A-F (0072-0073; 0131, 0137-0142);

(2) an on body electronics unit, comprising:

an on body electronics unit housing 1010 comprising at least one recess disposed thereon (recess in the middle Figure 10B), wherein the recess is detachably engaged with the inserter, best seen in Figure 10A-B and 12A-F (0131-0132);

the glucose sensor 1020, 1280, best seen in Figure 10A-B; and

on body electronics 1030, 1270 coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, best seen in Figure 10A-B (0131-0132), and

wherein the on body electronics includes a processor 102, memory (0102), a power supply (0102), and wireless communication circuitry, i.e. RF, configured to wirelessly communicate data indicative of a glucose level (0055, 0068, 0102, 0159),

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position within the inserter to a distal position, best seen in Figure 12A-F (0137-0142), and

wherein the inserter is configured to retract the sharp from the distal position to a retracted position within the inserter (0140).

However, Thomas et al do not expressly disclose the on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit

housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess.

Brister et al teach that it is well-known in the art to provide an analogous glucose monitoring assembly comprising an on body electronics unit housing 24 to house electronics 16 and sensor assembly 26, comprising a plurality of recesses, i.e. 1) left side of Figure 3/Figure 11B; Figure 12C that forms a "lip" for a bottom of electronics 16 (Figure 12C); 2) right side of Figure 3/11A (two channels with a post in between, each channel considered a recess) for tabs 120 of electronics 16, best seen in Figure 12A-C (0240), the plurality of recesses disposed on a periphery of the on body electronics unit housing, best seen in Figure 3 and 12A-C, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess as seen in Figure 3, 11A-B, and 12A-C, to effectively retain the electronics with the sensor assembly.

Brister et al also teach plurality of recesses as part of latches 30 (at least two) on a periphery of the on body electronics unit housing 24, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess (latches 30 are on opposite sides), to releasably couple the body electronics unit housing 24 to the applicator 60 during insertion of the sensor, best seen in Figure 2, 8D, 8I, 11A (0100, 0210).

36. Brister et al disclose the glucose monitoring assembly of claim 26, wherein each of the plurality of recesses comprises a concave portion, best seen in Figure 3, 8D, 8I, 11A-B, and 12A-C.

37. Brister et al disclose the glucose monitoring assembly of claim 26, wherein each of the plurality of recesses is disposed on a side wall of the on body electronics unit housing 24,

wherein the surface with the two recesses is considered a side wall, best seen in Figure 3, 8D, 8I, 11A-B, and 12A-C.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Thomas et al such that the on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, to effectively retain the electronics with the sensor or releasably couple the inserter with the on body electronics unit housing for insertion of the sensor, as taught by Brister et al.

38. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein the inserter further comprises a driver 1250 disposed in the inserter housing 1210, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position, best seen in Figure 12A-F (0137-0142).

39. Thomas et al disclose the glucose monitoring assembly of claim 26, further comprising a cap 1220 removably attached to a distal portion of the inserter, best seen in Figure 12A (0137-0142).

43. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein a proximal end of the inserter comprises an inserter handle (top of 1210), wherein a distal end of the inserter comprises a sheath having a distal sheath end configured to be placed on a skin surface of the subject, best seen in Figure 12B, and wherein the inserter handle is configured to move in a downward direction (arrow 1240) towards the skin surface relative to the sheath in

response to an application of force on the inserter handle, best seen in Figure 12C-E, wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter handle (0137-0142).

45. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein the on body electronics unit 1030 further comprises a sensor hub (middle of Figure 10B), wherein the glucose sensor comprises a distal sensor portion 1020 and a proximal sensor portion (connected to 1030), wherein the distal sensor portion is configured to sense a glucose level of the subject, wherein the proximal sensor portion is engaged with the sensor hub, and wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion, best seen in Figure 10A-B (0130-0131).

46. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein the on body electronics 1030 comprises an aperture, best seen in Figure 10A, and wherein the sharp 1260 extends through the aperture of the on body electronics 1270, best seen in Figure 12C-F (0137-0142).

47. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein the inserter further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit 1270 and the sharp 1260, best seen in Figure 12A-B (0137-0142).

48. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit is in the proximal position, i.e. power is only activated once the sensor and on body electronics

are contacted by the skin in the distal position, and not the proximal position (0075, 0078, 0080, 0102, 0103, 0121, 0142, 0143-0144, 0147-0154, 0156).

49. Thomas et al disclose the glucose monitoring assembly of claim 26, further comprising an adhesive portion 1290 configured to secure the on body electronics unit housing to a skin surface of the subject, best seen in Figure 12G (0140).

50. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a no power state when the on body electronics unit is in the proximal position, i.e. power is only activated once the sensor and on body electronics are contacted by the skin in the distal position, and not the proximal position (0075, 0078, 0080, 0102, 0103, 0121, 0142, 0143-0144, 0147-0154, 0156).

51. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in an inactive mode when the on body electronics unit is in the proximal position, i.e. power is only activated once the sensor and on body electronics are contacted by the skin in the distal position, and not the proximal position (0075, 0078, 0080, 0102, 0103, 0121, 0142, 0143-0144, 0147-0154, 0156).

52. Thomas et al disclose the glucose monitoring assembly of claim 47, wherein the distal end of the inserter defines a plane, and wherein a bottom surface of the on body electronics unit is parallel to the plane when the on body electronics unit 1270 and the sharp 1260 are in the proximal position, best seen in Figure 12C.

53. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein the on body electronics unit 1270 and the sharp 1260 are configured to advance in a linear direction

when advancing from the proximal position within the inserter to the distal position, best seen in Figure 12A-F.

54. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein a distance between the on body electronics unit 1270 in the proximal position and the on body electronics unit in the distal position is greater than a maximum height of the on body electronics unit, best seen in Figure 12C-F

55. Thomas et al disclose the glucose monitoring assembly of claim 46, wherein the aperture of the on body electronics is a first aperture, wherein the on body electronics unit housing 1010 further comprises a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture – Figure 10A-B shows the central aperture extending through the housing 1010, and wherein the sharp 1260 extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position, best seen in Figure 12A-F (0137-0142).

56. Thomas et al disclose the glucose monitoring assembly of claim 26, wherein the sharp 1260 is further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject, best seen in Figure 12A-F.

Claims 27 and 29 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over Thomas et al in view of Brister et al, further in view of Funderburk et al (US Pat No. 7381184).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under pre-AIA 35

U.S.C. 102(e). This rejection under pre-AIA 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131(a); or (3) an oath or declaration under 37 CFR 1.131(c) stating that the application and reference are currently owned by the same party and that the inventor or joint inventors (i.e., the inventive entity) named in the application is the prior inventor under pre-AIA 35 U.S.C. 104 as in effect on March 15, 2013, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a rejection under pre-AIA 35 U.S.C. 103(a). See MPEP §§ 2146 *et seq*.

In regard to Claim 27, Thomas et al in combination with Brister et al disclose the invention above but do not expressly disclose a plurality of gripping arms. Funderburk et al teach that it is well-known in the art to provide an analogous glucose monitoring system inserter comprising a plurality of gripping arms 412 which are used to maintain or drive the insertion of the sensor as required during operation, best seen in Figure 20-23 (Col.15: 14-Col.16: 40).

29. Funderburk et al disclose the glucose monitoring assembly of claim 27, wherein the plurality of gripping arms are biased in an outward direction, best seen in Figure 20-23.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Thomas et al as modified by Brister et al such that there is included a plurality of gripping arms as taught by Funderburk et al to effectively enable the drive portion of the device to be maintained or driven as necessary during the sensor insertion process, such that in combination, the plurality of gripping arms are configured to deflect in an outward direction after the on body electronics unit advances from the proximal position (Claim 30).

Claims 28, 30-35, and 59-61 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being obvious over Thomas et al in view of Brister et al and Funderburk et al, further in view of Yodfat et al (US Pub No. 20100137695), and Cole et al (US Pub No. 20080058830).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under pre-AIA 35 U.S.C. 102(e). This rejection under pre-AIA 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131(a); or (3) an oath or declaration under 37 CFR 1.131(c) stating that the application and reference are currently owned by the same party and that the inventor or joint inventors (i.e., the inventive entity) named in the application is

the prior inventor under pre-AIA 35 U.S.C. 104 as in effect on March 15, 2013, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under pre-AIA 35 U.S.C. 103(c) as prior art in a rejection under pre-AIA 35 U.S.C. 103(a). See MPEP §§ 2146 *et seq*.

Thomas et al as modified disclose the invention above but do not expressly disclose the plurality of gripping arms having an engagement boss to engage the plurality of recesses.

In regard to Claim 28 and 33, Funderburk et al teach that it is well-known in the art to provide an analogous glucose monitoring system inserter comprising an engagement boss 352 (Figure 26B shows it protrudes) configured to engage a recess 350 connected to sensor 314 when in the proximal position, configured to disengage from the plurality of recesses when the on body electronics unit is in the distal position, the engagement between the boss and recess used to releasably hold the sensor in the correction position during insertion, best seen in Figure 25-26 (Col.14: 9-18; Col.17: 1-17).

In regard to Claim 30-32 and 59-61, Funderburk et al disclose the analogous inserter comprises a plurality of interior surfaces (Figure 16, 25-26) configured to hold the one or more engagement bosses against the recess of the sensor when the on body electronics unit is in the proximal position, and configured such that the one or more interior surfaces are not in contact with the engagement boss when the on body electronics unit is in the distal position, since at that point, the sensor will have been implanted and thus released from the inserter, best seen in Figure 16 and 25-26 (Col.14: 9-18; Col.17: 1-17), such that the engagement bosses are configured to deflect in a radially outward direction after the on body electronics unit advances

from the proximal position when the each interior surface of the plurality of interior surfaces is not in contact with the engagement boss, best seen in Figure 20-23 as an effective mechanism to releasably couple two components together in the proximal position vs the distal position in the inserter (Col.15: 14-col.16: 40).

35. Funderburk et al disclose the engagement boss 353 comprises a conical shape, best seen in Figure 26B.

However, Funderburk et al do not disclose the engagement boss on a gripping arm.

Yodfat et al teach that it is well-known in the art to provide a connecting mechanism comprising at least one arm 30 (Figure 6a, each end) that is releasably engaged with a plurality of recesses (near element 44, Figure 6A, each side), as an effective connecting mechanism, shown in figure 6B.

Cole et al teach that it is well-known in the art to use gripping arms 312a,b to effectively releasably engage with an analogous implanted sensor 301 to enable the sensor to be held in a desired position, best seen in Figure 13b-c (0113-0117).

In regard to Claim 34, Cole et al also teach that the gripping arm has an engagement boss at a tip portion to contact the sensor, best seen in Figure 13b-c. Thus, Cole et al teach that it is well known to use gripping arms to releasably engage with an implanted sensor.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to modify the invention of Thomas et al as modified such that a conical engagement boss is engaged with a recess is provided, as taught by Funderburk et al, to effectively releasably engage with the sensor during insertion (i.e. in proximal position) until the distal position at insertion, such that the engagement boss is provided on the tip of a plurality

of gripping arms, as taught by both Yodfat et al and Cole et al, to provide an equally as effective means of holding the sensor in the proper position during insertion, such that since Thomas et al in combination with Brister et al already discloses the recesses on the on body electronics unit housing, said gripping arms with the engagement boss at the tip would engage a corresponding recess of the plurality of recesses on the on body electronics unit housing, to effectively hold the on body electronics unit in the proper position proximally (already taught by Thomas et al) until its insertion into the patient at the distal position (already taught by Thomas et al), such that in combination, each gripping arm is configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and wherein each gripping arm is configured to disengage from corresponding recess of the plurality of recesses when the on body electronics unit is in the distal position, each gripping arm of the plurality of gripping arms is configured to deflect in a radially outward direction after the on body electronics unit advances from the proximal position when each interior surface of the plurality of interior surfaces is not in contact with the corresponding gripping arm of the plurality of gripping arms, as taught by Funderburk et al to effectively provide a mechanism to facilitate the releasable coupling of the gripping arms to the on body electronics unit (also taught by Thomas et al), wherein each of the plurality of gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

Response to Arguments

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

The previous 112 rejections are withdrawn in light of applicant's amendments.

Conclusion

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

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

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

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

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

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

H.Q. NGUYEN
Examiner
Art Unit 3791

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	Art Unit
	Huong Q NGUYEN	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	01/29/2021	05/19/2021							
	26	✓	✓							
	27	✓	✓							
	28	✓	✓							
	29	✓	✓							
	30	✓	✓							
	31	✓	✓							
	32	✓	✓							
	33	✓	✓							
	34	✓	✓							
	35	✓	✓							
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	39	✓	✓							
	40	-	-							
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	42	-	-							
	43	✓	✓							
	44	-	-							
	45	✓	✓							
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	54	✓	✓							
	55	✓	✓							
	56	✓	✓							
	57	✓	-							
	58	✓	-							
	59		✓							
	60		✓							
	61		✓							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	Art Unit
	Huong Q NGUYEN	3791

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61B5/14503,1473,14865,6849,14532	03/13/2021	HQN
A61B2560/063	03/13/2021	HQN
A61B17/3468	03/13/2021	HQN
A61M2005/1585	03/13/2021	HQN
A61B5/15144,15113,15186,15188,1519,15192,15194	03/13/2021	HQN
A61B2017/347	03/13/2021	HQN
A61B5/1411,15029,150282,15107,15117	06/04/2021	HQN
Updated	06/04/2021	HQN

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
600	583-584	06/04/2021	HQN

* 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**
EAST search history	03/13/2021	HQN
Inventor search	03/13/2021	HQN
Updated	06/04/2021	HQN
Updated	06/04/2021	HQN

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	17/019,110	Donnay et al.
	Examiner	Art Unit
	Huong Q NGUYEN	3791

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

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CONFIRMATION NO. 1087

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
17/019,110	09/11/2020	600	3791	A0130.0107.01C8

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**** CONTINUING DATA ***************************

This application is a CON of 16/002,847 06/07/2018
which is a CON of 13/436,768 03/30/2012 PAT 10010280
which is a CON of 13/071,461 03/24/2011 PAT 9215992
which claims benefit of 61/411,262 11/08/2010
and claims benefit of 61/361,374 07/02/2010
and claims benefit of 61/345,562 05/17/2010
and claims benefit of 61/317,243 03/24/2010

**** FOREIGN APPLICATIONS ***************************

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09/22/2020

Foreign Priority claimed ❑ Yes ☑ No 35 USC 119(a-d) conditions met ❑ Yes ☑ No Verified and Acknowledged /Hnguyen / Examiner's Signature	❑ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		CA	99	26	1

ADDRESS

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UNITED STATES

TITLE

MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

FILING FEE RECEIVED		
3620	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	❑ All Fees ❑ 1.16 Fees (Filing) ❑ 1.17 Fees (Processing Ext. of time) ❑ 1.18 Fees (Issue) ❑ Other _____ ❑ Credit

BIB (Rev. 05/07).

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	15	"019110".ap.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 12:23
S2	2	"4637403".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 12:29
S3	5	("20080319414" | "20150141776" | "20160058474").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 12:29
S4	18	"327052".ap.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 12:31
S5	18	Frey-Stephan$.in. and patch	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2021/03/13 12:31

			IBM_TDB			
S6	17	Frey-Stephan$.in. and patch and process$5	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 12:31
S7	6	(("5299571") or ("20100022863") or ("20120226122") or ("20130256289")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:21
S8	9	("20080242961" | "20090171179" | "4294258" | "20100198033" | "7985203" | "20080140009" | "7519408" | "20040138588").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:22
S9	510	abbott.as. and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:23
S10	400	(sensor with electronics) same glucose same ((implant$5 insert$5) with skin)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:24
S11	8	600/584.ccls. and ((hole aperture opening) same electronic same sensor)	US-PGPUB; USPAT;	OR	OFF	2021/03/13 13:45

			USOCR; FPRS; EPO; JPO; IBM_TDB			
S12	186	lancet and nguyen.xa.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 13:46
S13	149	yodfat-ofer$.in. and infusion and skin and securable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 14:37
S14	46	Donnay-Manuel$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:37
S15	29	Nguyen-Tuan$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:37
S16	96	Pace-Louis$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:38

S17	55	Robinson-Peter$.in. and (sensor same electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:38
S18	107	S14 S15 S16 S17	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:38
S19	70	S18 not S9	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 15:39
S20	26	(US-20080009805-$ | US-20100030111-$ | US-20080031941-$ | US-20050101912-$ | US-20050131347-$ | US-20040133164-$ | US-20050173245-$ | US-20040204687-$ | US-20080255440-$ | US-20100324392-$ | US-16176370-$ | US-1704889-$ | US-20040133164-$ | US-20040204687-$ | US-20050101912-$ | US-20050131347-$ | US-20050173245-$ | US-20080009805-$ | US-20080031941-$ | US-20080255440-$ | US-20100030111-$ | US-20100324392-$ | US-5527288-$ | US-6102896-$ | US-7407493-$ | US-7699807-$ | US-7850652-$ | US-7896844-$ | US-7955297-$ | US-7985203-$ | US-8172805-$ | US-8262618-$ | US-8409145-$ | US-8870822-$ | US-8880138-$ | US-9295786-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:23
S21	1	"20090299301".DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2021/03/13 16:23

			IBM_TDB			
S22	138	(US-4970145-$ | US-4974929-$ | US-4986271-$ | US-4994167-$ | US-5001054-$ | US-5035860-$ | US-5036860-$ | US-5050612-$ | US-5058592-$ | US-5070535-$ | US-5082550-$ | US-5082786-$ | US-5089112-$ | US-5095904-$ | US-5101814-$ | US-5108564-$ | US-5109850-$ | US-5120420-$ | US-5126034-$ | US-5133856-$ | US-5135003-$ | US-5141868-$ | US-5161532-$ | US-5165407-$ | US-5174291-$ | US-5190041-$ | US-5192416-$ | US-5198367-$ | US-5202261-$ | US-5205920-$ | US-5208154-$ | US-5209229-$ | US-5217595-$ | US-5229282-$ | US-5250439-$ | US-5262035-$ | US-5262305-$ | US-5264103-$ | US-5264104-$ | US-5264106-$ | US-5271815-$ | US-5279294-$ | US-5284156-$ | US-5286362-$ | US-5286364-$ | US-5288636-$ | US-5293546-$ | US-5320098-$ | US-5320725-$ | US-5322063-$ | US-5337747-$ | US-5352348-$ | US-5356786-$ | US-5368028-$ | US-5372133-$ | US-5376251-$ | US-5378628-$ | US-5387327-$ | US-5390671-$ | US-5391250-$ | US-5395504-$ | US-5400782-$ | US-5411647-$ | US-5431160-$ | US-5437999-$ | US-5469846-$ | US-5491474-$ | US-5494562-$ | US-5496453-$ | US-5497772-$ | US-5531878-$ | US-5545191-$ | US-5560357-$ | US-5562713-$ | US-5565085-$ | US-5567302-$ | US-5568806-$ | US-5569186-$ | US-5582184-$ | US-5582697-$ | US-5582698-$ | US-5586553-$ | US-5589326-$ | US-5593852-$ | US-5596150-$ | US-5617851-$ | US-5628890-$ | US-5651869-$ | US-5660163-$ | US-5665222-$ | US-5670031-$ | US-5680858-$ | US-5682233-$ | US-5695623-$ | US-5708247-$ | US-5711297-$ | US-5711861-$ | US-5711862-$ | US-5741211-$ | US-5771001-$ | US-5791344-$ | US-5800420-$ | US-5807375-$ | US-5820551-$ | US-5820622-$ | US-5822715-$ | US-5827184-$ | US-5840020-$ | US-5842983-$ | US-5885211-$ | US-5899855-$ | US-5954643-$ | US-5954685-$ | US-5957854-$ | US-5964993-$ | US-5971922-$ | US-5972199-$ | US-6001067-$ | US-6024699-$ | US-6093172-$ | US-6103033-$ | US-6120676-$ | US-6122351-$ | US-6134461-$ | US-6143164-$ | US-6175752-$ | US-6338790-$ | US-6368141-$ | US-6368274-$ | US-6409740-$ | US-6695860-$ | US-6699188-$ | US-6746582-$ | US-6770030-$ | US-6936006-$ | US-6990366-$ | US-7381184-$ | US-RE32947-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:44
S23	53	(US-20030002682-$ | US-20080004512-$ | US-20070027381-$ | US-20080027474-$ | US-20080033318-$ | US-20060036139-$ | US-	US-PGPUB; USPAT;	OR	OFF	2021/03/13 16:44

		20070038044-$ | US-20040064133-$ | US-20080064941-$ | US-20080065646-$ | US-20090069658-$ | US-20030078560-$ | US-20080086044-$ | US-20050090850-$ | US-20090102678-$ | US-20080112848-$ | US-20020130042-$ | US-20040133164-$ | US-20080133702-$ | US-20060155317-$ | US-20030155656-$ | US-0158207-$ | US-0173741-$ | US-0188731-$ | US-0189939-$ | US-0212766-$ | US-0244368-$ | US-0249922-$ | US-20060264888-$ | US-20080269673-$ | US-20080275313-$ | US-20080283396-$ | US-20020130042-$ | US-20030002682-$ | US-20030078560-$ | US-20030155656-$ | US-20040064133-$ | US-20040133164-$ | US-20040158207-$ | US-20050090850-$ | US-20060036139-$ | US-20060155317-$ | US-20060189939-$ | US-20060264888-$ | US-20070027381-$ | US-20070038044-$ | US-20070173741-$ | US-20070244368-$ | US-20070249922-$ | US-20080004512-$ | US-20080027474-$ | US-20080033318-$ | US-20080064941-$ | US-20080065646-$ | US-20080086044-$ | US-20080112848-$ | US-20080133702-$ | US-20080188731-$ | US-20080269673-$ | US-20080275313-$ | US-20080283396-$ | US-20090069658-$ | US-20090102678-$ | US-20090212766-$ | US-3260656-$ | US-3653841-$ | US-3719564-$ | US-3776832-$).did.	USOCR; FPRS; EPO; JPO; IBM_TDB			
S24	119	(US-3837339-$ | US-3926760-$ | US-3972320-$ | US-3979274-$ | US-4008717-$ | US-4016866-$ | US-4055175-$ | US-4059406-$ | US-4076596-$ | US-4098574-$ | US-4100048-$ | US-4129128-$ | US-4151845-$ | US-4168205-$ | US-4172770-$ | US-4178916-$ | US-4206755-$ | US-4224125-$ | US-4240438-$ | US-4247297-$ | US-4340458-$ | US-4352960-$ | US-4356074-$ | US-4365637-$ | US-4366033-$ | US-4375399-$ | US-4384586-$ | US-4390621-$ | US-4401122-$ | US-4404066-$ | US-4418148-$ | US-4427770-$ | US-4431004-$ | US-4436094-$ | US-4440175-$ | US-4450842-$ | US-4458686-$ | US-4461691-$ | US-4469110-$ | US-4477314-$ | US-4484987-$ | US-4522690-$ | US-4524114-$ | US-4526661-$ | US-4534356-$ | US-4538616-$ | US-4543955-$ | US-4545382-$ | US-4552840-$ | US-4560534-$ | US-4571292-$ | US-4573994-$ | US-4581336-$ | US-4595011-$ | US-4619754-$ | US-4627445-$ | US-4627908-$ | US-4633878-$ | US-4637403-$ | US-4650547-$ | US-4654197-$ | US-4655880-$ | US-4655885-$ | US-4671288-$ | US-4679562-$ | US-4680268-$ | US-4682602-$ | US-4684537-$ | US-4685463-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:44

		US-4703756-$ | US-4711245-$ | US-4717673-$ | US-4721601-$ | US-4721677-$ | US-4726378-$ | US-4726716-$ | US-4731726-$ | US-4757022-$ | US-4758323-$ | US-4759371-$ | US-4759828-$ | US-4764416-$ | US-4776944-$ | US-4781798-$ | US-4784736-$ | US-4795707-$ | US-4796634-$ | US-4805624-$ | US-4813424-$ | US-4815469-$ | US-4820399-$ | US-4822337-$ | US-4830959-$ | US-4832797-$ | US-4840893-$ | US-4848351-$ | US-4871351-$ | US-4871440-$ | US-4874500-$ | US-4890620-$ | US-4894137-$ | US-4897162-$ | US-4897173-$ | US-4909908-$ | US-4911794-$ | US-4917800-$ | US-4919141-$ | US-4919767-$ | US-4923586-$ | US-4927516-$ | US-4934369-$ | US-4935105-$ | US-4935345-$ | US-4938860-$ | US-4944299-$ | US-4950378-$ | US-4953552-$ | US-4954129-$ | US-4969468-$).DID.				
S25	9	("20080269774" | "5873879" | "4950288" | "20080058830" | "20020026241").PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 16:58
S26	16	"649323".ap.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:00
S27	1	"20120238857".did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:12
S28	45	(US-3123790-$ | US-3581062-$ | US-3670727-$ | US-3949388-$ | US-4036749-$ | US-4120292-$ | US-4245634-$ | US-4294258-$ | US-4327725-$ | US-4344438-$ | US-4349728-$ | US-4373527-$ | US-4425920-$ | US-4478976-$ | US-4494950-$ | US-4509531-$ | US-4527240-$ | US-4619793-$ | US-4627842-$ | US-4685466-$ | US-4698057-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2021/03/13 17:25

		US-4711247-$ | US-4729672-$ | US-4749985-$ | US-4755173-$ | US-4777953-$ | US-4779618-$ | US-4781683-$ | US-4854322-$ | US-4895147-$ | US-4921199-$ | US-4925268-$ | US-4988341-$ | US-4995402-$ | US-4401400-$ | US-5000180-$ | US-5013161-$ | US-5019974-$ | US-5035860-$ | US-5047044-$ | US-5055171-$ | US-5106365-$ | US-5108889-$ | US-5122925-$).DID.	IBM_TDB			
S29	91	(US-5140985-$ | US-5234835-$ | US-5238729-$ | US-5246867-$ | US-5264105-$ | US-5285792-$ | US-5293877-$ | US-5299571-$ | US-5340722-$ | US-5342789-$ | US-5360404-$ | US-5372427-$ | US-5379238-$ | US-5408999-$ | US-5425361-$ | US-5431921-$ | US-5462645-$ | US-5472317-$ | US-5489414-$ | US-5507288-$ | US-5509410-$ | US-5514718-$ | US-5551427-$ | US-5575563-$ | US-5584813-$ | US-5601435-$ | US-5609575-$ | US-5613978-$ | US-5628310-$ | US-5632557-$ | US-5640954-$ | US-5653239-$ | US-5665071-$ | US-5711001-$ | US-5733044-$ | US-5735285-$ | US-5749656-$ | US-5766131-$ | US-5772586-$ | US-5779665-$ | US-5851197-$ | US-5865804-$ | US-5924979-$ | US-5925021-$ | US-5931814-$ | US-5948006-$ | US-5951521-$ | US-5961451-$ | US-5965380-$ | US-5987353-$ | US-5995860-$ | US-6017335-$ | US-6022368-$ | US-6026321-$ | US-6027459-$ | US-6049727-$ | US-6068399-$ | US-6083710-$ | US-6088608-$ | US-6091975-$ | US-6091976-$ | US-6117290-$ | US-6119028-$ | US-6121009-$ | US-6121611-$ | US-6159147-$ | US-6162611-$ | US-6200265-$ | US-6212416-$ | US-6219574-$ | US-6248067-$ | US-6254536-$ | US-6254586-$ | US-6275717-$ | US-6283761-$ | US-6283982-$ | US-6284478-$ | US-6293925-$ | US-6295506-$ | US-6306104-$ | US-6309884-$ | US-6329161-$ | US-6348640-$ | US-6359444-$ | US-6360888-$ | US-6366794-$ | US-6377828-$ | US-6379301-$ | US-6413393-$ | US-6418332-$ | US-6424847-$).did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:25
S30	105	(US-6427088-$ | US-6437679-$ | US-6440068-$ | US-6478736-$ | US-6484045-$ | US-6484046-$ | US-6514718-$ | US-6520326-$ | US-6522927-$ | US-6551494-$ | US-6554798-$ | US-6558320-$ | US-6558321-$ | US-6560471-$ | US-6561978-$ | US-6562001-$ | US-6564105-$ | US-6565509-$ | US-6571128-$ | US-6572566-$ | US-6576101-$ | US-6577899-$ | US-6579690-$ | US-6585644-$ | US-6589229-$ | US-6591125-$ | US-6595919-$ | US-6605200-$ | US-6605201-$ | US-6607509-$ | US-6610012-$ | US-6633772-$ | US-6635014-$ | US-6648821-$ | US-6654625-$ | US-6659948-$ | US-6666849-$ | US-6668196-$ | US-6676290-$ |	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:25

		US-6687546-$ | US-6689056-$ | US-6694191-$ | US-6702857-$ | US-6733446-$ | US-6740075-$ | US-6741877-$ | US-6758810-$ | US-6790178-$ | US-6809653-$ | US-6810290-$ | US-6811533-$ | US-6811534-$ | US-6813519-$ | US-6837858-$ | US-6837885-$ | US-6849052-$ | US-6854882-$ | US-6862465-$ | US-6873268-$ | US-6881551-$ | US-6892085-$ | US-6895265-$ | US-6931327-$ | US-6932894-$ | US-6942518-$ | US-6950708-$ | US-6958705-$ | US-6959211-$ | US-6968294-$ | US-6971274-$ | US-6974437-$ | US-6990366-$ | US-6997907-$ | US-6998247-$ | US-7003336-$ | US-7003340-$ | US-7003341-$ | US-7024245-$ | US-7025743-$ | US-7041068-$ | US-7041468-$ | US-7052483-$ | US-7056302-$ | US-7074307-$ | US-7081195-$ | US-7097637-$ | US-7098803-$ | US-7108778-$ | US-7110803-$ | US-7113821-$ | US-7134999-$ | US-7136689-$ | US-7171274-$ | US-7190988-$ | US-7192450-$ | US-7198606-$ | US-7207974-$ | US-7226978-$ | US-7276029-$ | US-7278983-$ | US-7297151-$ | US-7299082-$ | US-7310544-$ | US-7318816-$ | US-7324012-$).DID.				
S31	81	(US-7329239-$ | US-7335294-$ | US-7340287-$ | US-7340309-$ | US-7354420-$ | US-7364592-$ | US-7366556-$ | US-7379765-$ | US-7402153-$ | US-7416541-$ | US-7424318-$ | US-7455663-$ | US-7460898-$ | US-7467003-$ | US-7471972-$ | US-7494465-$ | US-7497827-$ | US-7519408-$ | US-7583990-$ | US-7591801-$ | US-7599726-$ | US-7613491-$ | US-7615007-$ | US-7632228-$ | US-7637868-$ | US-7640048-$ | US-7651596-$ | US-7654956-$ | US-7657297-$ | US-7666149-$ | US-7682338-$ | US-7697967-$ | US-7711402-$ | US-7713574-$ | US-7715893-$ | US-7727147-$ | US-7731657-$ | US-7736344-$ | US-7763042-$ | US-7822454-$ | US-20060009727-$ | US-20020013538-$ | US-20020019022-$ | US-20020022855-$ | US-20020023852-$ | US-20020042090-$ | US-20020057993-$ | US-20020066764-$ | US-20020076966-$ | US-20020082487-$ | US-20020103499-$ | US-20020106709-$ | US-20020119711-$ | US-20020128594-$ | US-20020154050-$ | US-20020161288-$ | US-20020165462-$ | US-20020198444-$ | US-20030023317-$ | US-20030023461-$ | US-20030032867-$ | US-20030032874-$ | US-20030042137-$ | US-20030060753-$ | US-20030065308-$ | US-20030069510-$ | US-20030078481-$ | US-20030083686-$ | US-20030097092-$ | US-20030100040-$ | US-20030109775-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:26

		20030134347-$ | US-20030135333-$ | US-20030144581-$ | US-20030144608-$ | US-20030168338-$ | US-20030176933-$ | US-20030187338-$ | US-20030199790-$ | US-20030199910-$ | US-20030212379-$).did.				
S32	82	(US-20030217966-$ | US-20030225361-$ | US-20040010207-$ | US-20040011671-$ | US-20040040840-$ | US-20040045879-$ | US-20040054263-$ | US-20040064068-$ | US-20040096959-$ | US-20040106858-$ | US-20040106859-$ | US-20040116865-$ | US-20040116866-$ | US-20040122353-$ | US-20040122489-$ | US-20040133164-$ | US-20040135684-$ | US-20040138588-$ | US-20040147996-$ | US-20040152622-$ | US-20040167801-$ | US-20040171921-$ | US-20040176672-$ | US-20040186362-$ | US-20040186365-$ | US-20040193090-$ | US-20040199059-$ | US-20040204687-$ | US-20040210122-$ | US-20040225338-$ | US-20040236200-$ | US-20040236251-$ | US-20040254433-$ | US-20040254434-$ | US-20040267300-$ | US-20050003470-$ | US-20050004494-$ | US-20050010269-$ | US-20050027177-$ | US-20050027180-$ | US-20050031689-$ | US-20050043598-$ | US-20050070819-$ | US-20050085872-$ | US-20050090607-$ | US-20050106713-$ | US-20050112169-$ | US-20050114068-$ | US-20050121322-$ | US-20050131346-$ | US-20050143635-$ | US-20050154410-$ | US-20050165404-$ | US-20050176136-$ | US-20050182306-$ | US-20050187720-$ | US-20050192557-$ | US-20050195930-$ | US-20050197554-$ | US-20050199494-$ | US-20050203360-$ | US-20050222518-$ | US-20050239154-$ | US-20050239156-$ | US-20050241957-$ | US-20050245795-$ | US-20050245799-$ | US-20050245844-$ | US-20050277164-$ | US-20050287620-$ | US-20060001538-$ | US-20060004303-$ | US-20060010098-$ | US-20060015020-$ | US-20060015024-$ | US-20060016700-$ | US-20060019327-$ | US-20060020186-$ | US-20060020187-$ | US-20060020188-$ | US-20060020189-$ | US-20060020190-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:26
S33	85	(US-20060020191-$ | US-20060020192-$ | US-20060036140-$ | US-20060036141-$ | US-20060036142-$ | US-20060036143-$ | US-20060036144-$ | US-20060036145-$ | US-20060047220-$ | US-20060129173-$ | US-20060155210-$ | US-20060166629-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	OFF	2021/03/13 17:26

		20060173444-$ | US-20060189863-$ | US-20060195029-$ | US-20060200181-$ | US-20060200970-$ | US-20060222566-$ | US-20060226985-$ | US-20060247508-$ | US-20060253086-$ | US-20060258929-$ | US-20060276724-$ | US-20060287591-$ | US-20070016381-$ | US-20070060814-$ | US-20070073129-$ | US-20070078320-$ | US-20070078321-$ | US-20070078322-$ | US-20070088377-$ | US-20070106135-$ | US-20070110124-$ | US-20070123819-$ | US-20070149875-$ | US-20070163880-$ | US-20070173706-$ | US-20070191701-$ | US-20070203407-$ | US-20070203966-$ | US-20070235331-$ | US-20070244398-$ | US-20080004573-$ | US-20080009692-$ | US-20080009805-$ | US-20080017522-$ | US-20080021666-$ | US-20080029391-$ | US-20080033254-$ | US-20080033268-$ | US-20080039702-$ | US-20080045824-$ | US-20080064937-$ | US-20080064944-$ | US-20080071156-$ | US-20080083617-$ | US-20080086042-$ | US-20080086273-$ | US-20080097246-$ | US-20080108942-$ | US-20080114280-$ | US-20080119707-$ | US-20080161664-$ | US-20080167578-$ | US-20080183061-$ | US-20080183399-$ | US-20080189051-$ | US-20080194935-$ | US-20080194936-$ | US-20080194937-$ | US-20080194938-$ | US-20080195232-$ | US-20080195967-$ | US-20080197024-$ | US-20080200788-$ | US-20080200789-$ | US-20080200791-$ | US-20080200897-$ | US-20080208025-$ | US-20080214481-$ | US-20080214915-$ | US-20080214918-$ | US-20080228051-$ | US-20080228054-$ | US-20080242961-$).did.	JPO; IBM_TDB			
S34	69	(US-20080262469-$ | US-20080283396-$ | US-20080287764-$ | US-20080287765-$ | US-20080287766-$ | US-20080294096-$ | US-20080296155-$ | US-20080300476-$ | US-20080306368-$ | US-20080306434-$ | US-20080306435-$ | US-20080306444-$ | US-20090012379-$ | US-20090018424-$ | US-20090030294-$ | US-20090036758-$ | US-20090036763-$ | US-20090036915-$ | US-20090043181-$ | US-20090043182-$ | US-20090043525-$ | US-20090043541-$ | US-20090043542-$ | US-20090045055-$ | US-20090054866-$ | US-20090062633-$ | US-20090062635-$ | US-20090076356-$ | US-20090076359-$ | US-20090076360-$ | US-	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:27

		20090076361-$ | US-20090082693-$ | US-20090099436-$ | US-20090105569-$ | US-20090124877-$ | US-20090124878-$ | US-20090124879-$ | US-20090124964-$ | US-20090124979-$ | US-20090131768-$ | US-20090131769-$ | US-20090131776-$ | US-20090131777-$ | US-20090137886-$ | US-20090137887-$ | US-20090143659-$ | US-20090143660-$ | US-20090156919-$ | US-20090156924-$ | US-20090163790-$ | US-20090163791-$ | US-20090171182-$ | US-20090178459-$ | US-20090182217-$ | US-20090192366-$ | US-20090192380-$ | US-20090192722-$ | US-20090192724-$ | US-20090192745-$ | US-20090192751-$ | US-20090198215-$ | US-20090203981-$ | US-20090204341-$ | US-20090216103-$ | US-20090240120-$ | US-20090240128-$ | US-20090240193-$ | US-20090242399-$ | US-20090242425-$).DID.				
S35	61	(US-20090247855-$ | US-20090247856-$ | US-20090259201-$ | US-20090259202-$ | US-20090270765-$ | US-20090287073-$ | US-20090287074-$ | US-20090292184-$ | US-20090292185-$ | US-20090299155-$ | US-20090299156-$ | US-20090299162-$ | US-20090299276-$ | US-20100010324-$ | US-20100010331-$ | US-20100010332-$ | US-20100016687-$ | US-20100016698-$ | US-20100022855-$ | US-20100022863-$ | US-20100030038-$ | US-20100030053-$ | US-20100030484-$ | US-20100030485-$ | US-20100036215-$ | US-20100036216-$ | US-20100036222-$ | US-20100036223-$ | US-20100036225-$ | US-20100036281-$ | US-20100041971-$ | US-20100045465-$ | US-20100049014-$ | US-20100049024-$ | US-20100063373-$ | US-20100069728-$ | US-20100076283-$ | US-20100081908-$ | US-20100081910-$ | US-20100087724-$ | US-20100096259-$ | US-20100099970-$ | US-20100099971-$ | US-20100100113-$ | US-20100106088-$ | US-20100119693-$ | US-20100121169-$ | US-20100168677-$ | US-20100324392-$ | US-20100331647-$ | US-20110021889-$ | US-20110046456-$ | US-20110082484-$ | US-20110106126-$ | US-20110257521-$ | US-20110288574-$ | US-20110319729-$ | US-20120123385-$ | US-20120184909-$ | US-20120296327-$ | US-20130047981-$).DID.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:27

S36	948	S20 S21 S22 S23 S24 S28 S29 S30 S31 S32 S33 S34 S35	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 17:28
S37	390	S36 and (sensor with electronics)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:30
S38	351	S37 not (S9 S10)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:30
S39	217	S38 and (insert$5 with sensor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:31
S40	14,590	A61B5/14503,1473,14865,6849.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:36
S41	1,112	A61B2560/063.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO;	OR	ON	2021/03/13 17:36

			JPO; IBM_TDB			
S42	10,711	A61B17/3468.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:37
S43	25,187	S40 S41 S42	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:37
S44	45,210	A61B5/14532.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:38
S45	5,048	A61M2005/1585.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:42
S47	11,078	A61B5/15144,15113,15186,15188,1519,15192,15194.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:47
S48	3,608	A61B2017/347.cpc.	US-PGPUB;	OR	ON	2021/03/13 17:47

			USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB			
S52	29,666	S43 S45	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 17:57
S57	9,851	S52 and S44	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:04
S58	1,762	S57 and (sensor and electronics) and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:04
S59	1	S58 and S48	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:05
S60	43	S58 and S47	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2021/03/13 18:08

			IBM_TDB			
S61	11	S48 and (sensor and electronics) and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:09
S62	23	S48 and (sensor with (insert$5) with (needle sharp$5 pierc$5 punctur$5))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/13 18:10
S63	7	(US-20050158207-$ | US-20070173741-$ | US-20080188731-$ | US-20060189939-$ | US-20090212766-$ | US-20070244368-$ | US-20070249922-$).did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/13 18:43
S68	5	(("20080114280") or ("20040204687") or ("20100324392") or ("20040133164")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/22 22:44
S89	7	"9402544".pn.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/03/25 19:39
S90	3,906	A61B5/1411.cpc.	US-PGPUB; USPAT;	OR	ON	2021/03/25 22:17

			USOCR; FPRS; EPO; JPO; IBM_TDB			
S91	2,049	A61B5/15029,150282.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/25 22:23
S92	8,552	A61B5/15107,15117.cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/25 22:23
S93	11,837	S90 S91 S92	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/25 23:21
S94	386	S93 and ((snap detent) with spring)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	ON	2021/03/25 23:21
S96	4	"9215992".did.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/05/08 19:42

S97	1,274	600/583.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/05/08 20:51
S98	121	600/583.ccls. and bulge	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; IBM_TDB	OR	OFF	2021/05/10 15:29

6/4/2021 7:34:32 AM
C:\Users\hnguyen50\Documents\EAST\Workspaces\cases FY 2021\Second Quarter\17019110 inserting device for implantable sensor abbott.wsp

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/019,110	09/11/2020	Manuel Luis Donnay	A0130.0107.01C8	1087

95508 7590 11/09/2021

One LLP
4000 MacArthur Blvd.
East Tower, Suite 500
Newport Beach, CA 92660

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
11/09/2021	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):

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Applicant-Initiated Interview Summary	**Application No.** 17/019,110	**Applicant(s)** Donnay et al.		
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (First Inventor to File) Status** No	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
Huong Q NGUYEN	Examiner	Telephonic
Devin Henson	Primary Examiner	
Glen Liu	Attorney of Record	

Date of Interview: 26 October 2021

Issues Discussed:

35 U.S.C. 103

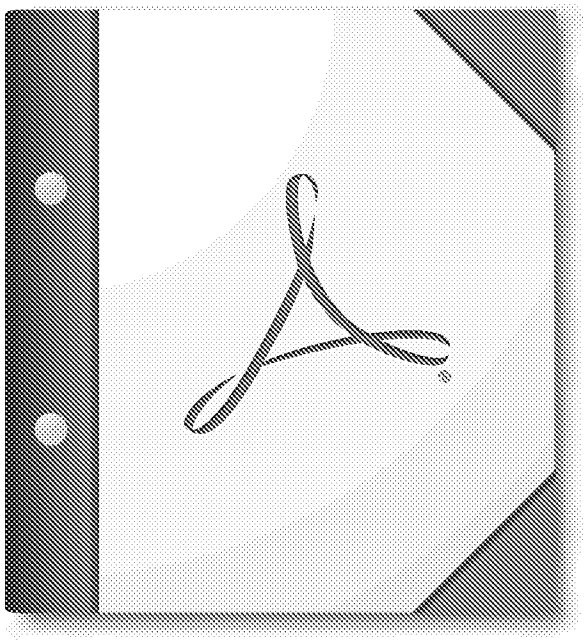
The examiner's interpretation of the prior art was discussed. Applicant elaborated upon the differences between the instant invention and the prior art. Applicant indicated that an affidavit to establish the date of the invention would be submitted to remove Thomas et al as a reference in the 103 rejection.

/H Q NGUYEN/ Examiner, Art Unit 3791	/DEVIN B HENSON/ Primary Examiner, Art Unit 3791

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

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview.

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



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Electronic Acknowledgement Receipt

EFS ID:	44330411
Application Number:	17019110
International Application Number:	
Confirmation Number:	1087
Title of Invention:	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
First Named Inventor/Applicant Name:	Manuel Luis Donnay
Customer Number:	95508
Filer:	Glen Liu/Alana Fredericks
Filer Authorized By:	Glen Liu
Attorney Docket Number:	A0130.0107.01C8
Receipt Date:	19-NOV-2021
Filing Date:	11-SEP-2020
Time Stamp:	15:46:40
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	NPL_Morak.pdf	2086347 4f0d821ff543a571185bd565dd3f3dfabf87e485	no	7

Warnings:

Information:					
2	Non Patent Literature	NPL_Movassaghi.pdf	185985 7fb827a33487b774acc0bad639f8a3ccac3732f5	no	6
Warnings:					
Information:					
3	Non Patent Literature	NPL_Passey.pdf	1669092 c355e0f900bfce425f2b63a173aa309cfc58cf66	no	9
Warnings:					
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4	Non Patent Literature	NPL_Sandham.pdf	185760 c070fb4838a2b8ac0a63a4e243302d153eae75fe	no	4
Warnings:					
Information:					
5	Non Patent Literature	NPL_Sparacino.pdf	654824 904458e2b9ca811dcae7b833816400a60c3cd4ef	no	7
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6	Non Patent Literature	NPL_Townsend.pdf	872722 80300fb319b29f70f1c46f112377128 4fa832b65	no	26
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7	Non Patent Literature	US60587787.pdf	9817947 5698e3c02bfb3eed737442301c3766ce4e7aa2e7	no	69
Warnings:					
Information:					
8	Non Patent Literature	US60606334.pdf	5455726 0ad1f121a215fcf30beb1f918600cd6ebd028836	no	38
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Information:					

9	Non Patent Literature	NPL_Wang.pdf	334852 7b0cfafa4efea2a77dbf3dbf7b9edb17b48a0e68	no	17
Warnings:					
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10	Non Patent Literature	NPL_ZC_Connector.pdf	321099 fada7628473ca633565c72577a1099388e02224c	no	2
Warnings:					
Information:					
11	Non Patent Literature	NPL_ZS_Connector.pdf	283988 549985b7882487ea090092fc75e62869fb802d64	no	2
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			Total Files Size (in bytes):	21868342	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for 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.

PTO/SB/30EFS (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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REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	17/019,110	Filing Date	2020-09-11	Docket Number (if applicable)	A0130.0107.01C8	Art Unit	3791
First Named Inventor	Manuel Luis Donnay			Examiner Name	Huong Q. Nguyen		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____ (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

☒ The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 505201

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

Applicant Signature

PTO/SB/30EFS (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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Signature of Registered U.S. Patent Practitioner			
Signature	/Glen Liu/	Date (YYYY-MM-DD)	2021-11-19
Name	Glen Liu	Registration Number	75058

This collection of information is required by 37 CFR 1.114. 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 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.

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

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

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

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

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

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

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

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Manuel Luis Donnay et al.

Application No.: 17/019,110 | Confirmation No.: 1087

Filed: September 11, 2020 | Art Unit: 3791

For: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES | Examiner: Huong Q. Nguyen

SUBMISSION TO ACCOMPANY RCE UNDER 37 C.F.R. § 1.114

EFS Web
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INTRODUCTORY COMMENTS

In response to the Final Office Action dated June 9, 2021 ("6/9/21 FOA"), please see the following:

Amendments to the Claims beginning on page 2 of this paper; and

Remarks beginning on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all previous versions of the claims in the application.

1-25. (Canceled)

26. (Currently amended) A glucose monitoring assembly, the assembly comprising:

(1) an inserter[[,]] comprising[[:]]

~~an inserter housing; and~~

a ~~sharp, wherein the~~ sharp [[is]] configured to insert a portion of a glucose sensor into a subject; and

(2) an on body electronics unit, comprising:

an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter;

the glucose sensor; and

on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,

wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position, and

wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

27. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a plurality of gripping arms.

28. (Currently amended) The glucose monitoring assembly of claim 27, wherein each gripping arm of the plurality of gripping arms is configured to be engaged with a corresponding

recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position, and

wherein the each gripping arm of the plurality of gripping arms is further configured to be disengaged from the corresponding recess of the plurality of recesses when the on body electronics unit is in the distal position.

29. (Currently amended) The glucose monitoring assembly of claim 27, wherein each gripping arm of the plurality of gripping arms is biased in a radially outward direction.

30. (Currently amended) The glucose monitoring assembly of claim 32, wherein the ~~each~~ corresponding gripping arm of the plurality of gripping arms is configured to deflect in a radially outward direction when the each interior surface of the plurality of interior surfaces is not in contact with the corresponding gripping arm of the plurality of gripping arms.

31. (Previously presented) The glucose monitoring assembly of claim 27, wherein the inserter further comprises a plurality of interior surfaces, wherein each interior surface of the plurality of interior surfaces is configured to hold a corresponding gripping arm of the plurality of gripping arms against a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

32. (Previously presented) The glucose monitoring assembly of claim 31, wherein the inserter is further configured such that the each interior surface of the plurality of interior surfaces is not in contact with the corresponding gripping arm of the plurality of gripping arms when the on body electronics unit is in the distal position.

33. (Previously presented) The glucose monitoring assembly of claim 27, wherein each gripping arm of the plurality of gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing when the on body electronics unit is in the proximal position.

34. (Currently amended) The glucose monitoring assembly of claim 33, [[where]] wherein the engagement boss is disposed on a tip portion of the gripping arm.

35. (Previously presented) The glucose monitoring assembly of claim 33, wherein the engagement boss comprises a conical shape.

36. (Currently amended) The glucose monitoring assembly of claim 26, wherein each recess of the plurality of recesses comprises a concave portion.

37. (Currently amended) The glucose monitoring assembly of claim 26, wherein each recess of the plurality of recesses is disposed on a side wall of the on body electronics unit housing.

38. (Currently amended) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a driver disposed in the inserter ~~housing~~, wherein the driver is configured to apply a force that retracts the sharp after the sharp reaches the distal position.

39. (Previously presented) The glucose monitoring assembly of claim 26, further comprising a cap removably attached to a distal portion of the inserter.

40-42. (Canceled)

43. (Currently amended) The glucose monitoring assembly of claim 26, ~~wherein a proximal end of the inserter comprises an inserter handle,~~ wherein ~~a distal end of~~ the inserter further comprises an inserter housing and a sheath ~~having a distal sheath end configured to be placed on a skin surface of the subject~~, and wherein the inserter ~~handle~~ housing is configured to move in a downward direction towards the skin surface relative to the sheath in response to an application of force on the inserter ~~handle~~ housing, and

wherein the sheath is configured to remain stationary relative to the skin surface in response to the application of force on the inserter ~~handle~~ housing.

44. (Canceled)

45. (Currently amended) The glucose monitoring assembly of claim 26, wherein the on body electronics unit further comprises a sensor hub,

wherein the glucose sensor comprises a distal sensor portion and a proximal sensor portion,

wherein the distal sensor portion is configured to sense [[a]] the glucose level of the subject,

wherein the proximal sensor portion is engaged with the sensor hub, and

wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.

46. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics comprises an aperture, and wherein the sharp extends through the aperture of the on body electronics.

47. (Previously presented) The glucose monitoring assembly of claim 26, wherein the inserter further comprises a distal end configured to be placed on a skin surface of the subject before advancement of the on body electronics unit and the sharp.

48. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a low power state when the on body electronics unit is in the proximal position.

49. (Previously presented) The glucose monitoring assembly of claim 26, further comprising an adhesive portion configured to secure the on body electronics unit housing to a skin surface of the subject.

50. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in a no power state when the on body electronics unit is in the proximal position.

51. (Previously presented) The glucose monitoring assembly of claim 26, wherein at least a portion of the on body electronics is in an inactive mode when the on body electronics unit is in the proximal position.

52. (Previously presented) The glucose monitoring assembly of claim 47, wherein the distal end of the inserter defines a plane, and wherein a bottom surface of the on body electronics unit housing is parallel to the plane when the on body electronics unit and the sharp are in the proximal position.

53. (Previously presented) The glucose monitoring assembly of claim 26, wherein the on body electronics unit and the sharp are configured to advance in a linear direction when advancing from the proximal position within the inserter to the distal position.

54. (Previously presented) The glucose monitoring assembly of claim 26, wherein a distance between the on body electronics unit housing when the on body electronics unit is in the proximal position and the on body electronics unit housing when the on body electronics unit is in the distal position is greater than a maximum height of the on body electronics unit housing.

55. (Previously presented) The glucose monitoring assembly of claim 46, wherein the aperture of the on body electronics is a first aperture, wherein the on body electronics unit housing further comprises a top surface and a bottom surface, wherein the top surface comprises a second aperture, wherein the bottom surface comprises a third aperture, and wherein the sharp extends through the first aperture, the second aperture, and the third aperture when the on body electronics unit is in the proximal position.

56. (Previously presented) The glucose monitoring assembly of claim 26, wherein the sharp is further configured to pierce a skin surface of the subject at an angle substantially perpendicular to the skin surface of the subject.

57-61. (Canceled)

REMARKS

Reconsideration is respectfully requested. Claims 26-39, 43, and 45-56 are pending, of which claims 26, 28-30, 34, 36-38, 43, and 45 have been amended without prejudice. Claims 59-61 have been canceled without prejudice, and claims 1-25, 40-42, 44, and 57-58 remain canceled without prejudice. Support for the new claims and the amendments can be found, for example, in paragraphs [0257], [0265]-[0266], as well as Figures 122, 125-126, and 135-138, and elsewhere throughout U.S. Publ. No. 2021/0007651 ("the '651 Publication").[1] No new matter has been introduced.

For the reasons set forth below, it is respectfully submitted that the pending claims are allowable.

TELEPHONIC INTERVIEW OF OCTOBER 26, 2021

Examiners Nguyen and Henson are thanked for taking the time to participate in a telephonic interview on October 26, 2021. During the interview, the parties discussed the pending rejections in the 6/9/21 FOA. In particular, the parties first discussed the pending rejections under Section 112, second paragraph. Next, the parties discussed the pending Section 103 rejections and, in particular: (1) the application of U.S. Publ. No. 2008/0242961 ("Brister") to the pending claims, and (2) the disqualification of U.S. Publ. No. 2010/0198034 ("Thomas") as prior art under the pre-AIA §103(c) exclusion (also known as the "common ownership exception").

The Examiners' guidance is appreciated. For the sole purpose of advancing prosecution, and without conceding to the merits of the rejections, claims 59-61 have been canceled without prejudice. Accordingly, it is respectfully submitted that the Section 112 rejections are mooted. Further, with respect to the Section 103 rejections, a statement regarding the common ownership of Thomas is being submitted herewith for purposes of disqualifying Thomas as prior art. Accordingly, it is respectfully submitted that all pending claims are in condition for allowance.

[1] All citations are provided purely for the benefit of the Examiner. These citations are only examples and in no way constitute an exhaustive recitation of all written and depicted support for the claims. Additional support can be found elsewhere, including citations from both the specification and figures that are not stated, as well as the knowledge of those of ordinary skill in the art. These citations in no way constitute a disclaimer that the claim covers only that subject matter which is cited herein and in no way define the inventive subject matter as being only that which is cited herein.

REJECTIONS UNDER SECTION 112, SECOND PARAGRAPH

Claims 59-61 were rejected under pre-AIA 35 U.S.C. §112, second paragraph, as allegedly being indefinite.[2] *See* 6/9/21 FOA at 2. As stated above, for the sole purpose of advancing prosecution, and without conceding the merits of the Section 112 rejections, claims 59-61 have been canceled without prejudice. Accordingly, it is respectfully submitted that the rejections are mooted, and withdrawal of the Section 112 rejections is respectfully requested.

REJECTIONS UNDER SECTION 103

Claims 26, 36-39, 43, and 46-56 were rejected under pre-AIA 35 U.S.C. §103(a) as being allegedly unpatentable over Thomas in view of Brister. *See* 6/9/21 FOA at 4-10.

Claims 27 and 29 were rejected under pre-AIA 35 U.S.C. §103(a) as being allegedly unpatentable over Thomas in view of Brister, and further in view of U.S. Patent No. 7,381,184 ("Funderburk"). *Id.* at 10-12.

Claims 28, 30-35, and 59-61 were rejected under pre-AIA 35 U.S.C. §103(a) as being allegedly unpatentable over Thomas in view of Brister and Funderburk, and further in view of U.S. Publ. No. 2010/0137695 ("Yodfat") and U.S. Publ. No. 2008/0058830 ("Cole"). *Id.* at 12-15.

For the reasons set forth below, it is respectfully submitted that the cited references, whether considered individually or in a proper combination, do not render the pending claims obvious.

A. Thomas Does Not Qualify as Prior Art Under Pre-AIA Section 103(c)(1)

It is respectfully submitted that Thomas is not prior art to the pending claims under pre-AIA §103(a) due to the common ownership exception of pre-AIA §103(c)(1), which states:

> Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

MPEP section 706.02(1)(2), part II provides that a statement on behalf of the Applicant(s) to the effect that the application and the reference were, at the time the invention was made, owned by,

[2] The 6/9/21 FOA states, at page 2, that "Claims 58-61 are rejected under … 35 U.S.C. 112 (pre-AIA), second paragraph …." However, claim 58 was canceled in the Response to Non-Final Office Action dated May 19, 2021.

or subject to an obligation of assignment to, the same organization is sufficient evidence to qualify for the pre-AIA §103(c) exclusion. The requisite statement follows:

> This Application, having Serial No. 17/019,110, and the relied upon prior art reference, having U.S. Publ. No. 2010/0198034 (Thomas), were, at the time the presently claimed inventions of Application 17/019,110 were made,[3] commonly owned by Abbott Diabetes Care Inc.

Accordingly, it is respectfully submitted that Thomas is not prior art under the common ownership exception of pre-AIA §103(c)(1).

B. The Subject Matter of the Pending Claims Was Conceived Before the Critical Date of Thomas and Diligently Reduced to Practice Thereafter

In further support of the pre-AIA §103(c) exclusion in the instant case, the attached Joint Declaration Under 37 C.F.R. §1.131 ("Joint Declaration"), Exhibits 1-8, and Appendices A and B, are being submitted herewith to antedate the publication date of Thomas, which is cited as prior art under pre-AIA 35 U.S.C. §103(a). *See* 6/9/21 FOA at 4.

For example, the Joint Declaration and Exhibits 1-2 show that the subject matter of the pending claims was conceived before August 5, 2010, the publication date of Thomas.[4] *See* Joint Declaration at ¶¶ 3, 10-19 and Exhibits 1-2. In addition, Appendix A is a chart summarizing the sample support for the conception of each limitation of each claim before August 5, 2010.

In addition, the Joint Declaration and Exhibits 3-7 show that, following conception, reasonably continuous diligence was exercised in reducing the claimed subject matter to practice. *See* Joint Declaration at ¶¶ 3, 20-27 and Exhibits 3-7. In particular, Exhibits 3-7 demonstrate reasonably continuous diligence in reducing to practice the claimed subject matter from at least just prior to August 5, 2010 to November 8, 2010. *Id.* In addition, Appendix B is a chart summarizing the sample support from Exhibit 8 for the reduction to practice of each limitation of each claim by no later than November 8, 2010. *See also* Joint Declaration at ¶¶ 28-32 and Exhibit 8.

---

[3] For at least the reasons set forth below, Thomas can only be considered prior art under pre-AIA 35 U.S.C. §102(e). *See also* 6/9/21 FOA at 4 ("Based upon the earlier effective U.S. filing date of [Thomas], it constitutes prior art under pre-AIA 35 U.S.C. 102(e).").

[4] The Joint Declaration being submitted herewith includes, at the end of the document, the signatures of the inventors, respectively: Peter G. Robinson, Tuan Nguyen, Manuel Luis Donnay, and Louis G. Pace.

In view of the foregoing, Thomas can only be considered prior art under pre-AIA 35 U.S.C. §102(e). Moreover, as stated earlier, Thomas was, at the time the presently claimed subject matter was made, commonly owned by the present assignee, Abbott Diabetes Care Inc. Accordingly, Thomas is not properly citable as prior art under pre-AIA 35 U.S.C. §103(a). For these reasons, withdrawal of the Section 103 rejections is respectfully requested.

C. The Cited References Do Not Teach, Describe, or Suggest the Limitations of Independent Claim 26

Even assuming *arguendo* that Thomas qualified as prior art – which it does not – it still would not render independent claim 26 unpatentable under Section 103, whether considered individually or in a proper combination with Brister.

Independent claim 26 recites, as follows (with emphasis added):

> 26. A glucose monitoring assembly, the assembly comprising:
>
> (1) an inserter comprising a sharp configured to insert a portion of a glucose sensor into a subject; and
>
> (2) an on body electronics unit, comprising:
>
> ***an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter***;
>
> the glucose sensor; and
>
> on body electronics coupled with the glucose sensor, wherein the on body electronics is disposed within the on body electronics unit housing, and wherein the on body electronics includes a processor, memory, a power supply, and wireless communication circuitry configured to wirelessly communicate data indicative of a glucose level,
>
> wherein the inserter is configured to advance the on body electronics unit and the sharp from a proximal position entirely within the inserter to a distal position, and
>
> wherein the inserter is further configured to retract the sharp from the distal position to a retracted position entirely within the inserter.

It is respectfully submitted that the cited references, whether considered individually or in a proper combination, do not teach, describe, or suggest "an on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess, and wherein the plurality of recesses is detachably engaged with the inserter," as recited in claim 26.

As an initial matter, the 6/9/21 FOA acknowledges that Thomas does not disclose "the on body electronics unit housing comprising a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess." 6/9/21 FOA at 5-6. For at least this reason, Thomas is deficient.

Instead, the 6/9/21 FOA cites to various portions of Brister for the alleged teaching of these limitations. It is respectfully submitted that Brister does not rectify the deficiency of Thomas for at least the following two sample reasons.

First, the 6/9/21 FOA relies on base 24 of Brister for the alleged disclosure of the "on body electronics unit housing" of claim 26. *See* 6/9/21 FOA at 6. However, as shown below in FIG. 3 of Brister, base 24 is actually a part of a mounting unit 14 that is separate from the electronics unit 16.

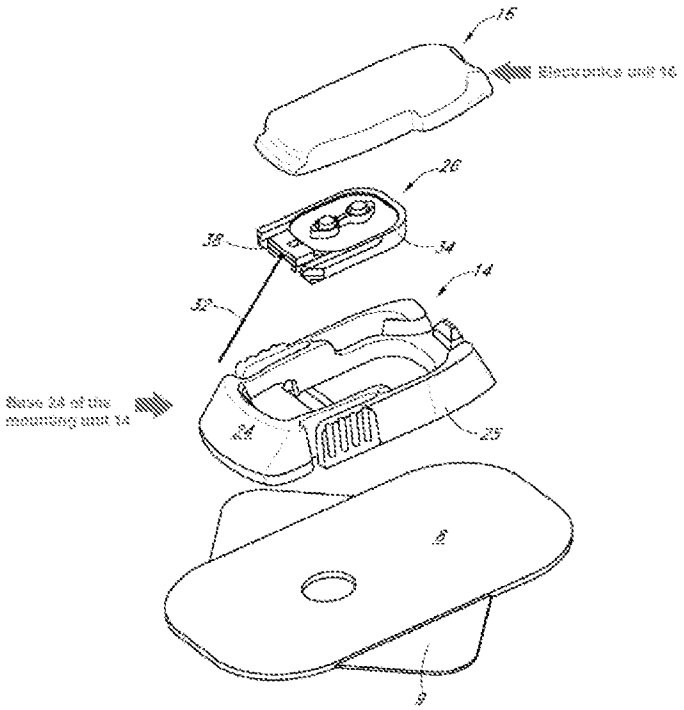

FIG. 3

Moreover, base 24 cannot be the "on body electronics unit housing" of the pending claims because the pending claims require that the on body electronics unit, which includes the on body electronics unit housing, to be advanced from a proximal position entirely within an inserter to a distal position. By contrast, the mounting unit 14 of Brister, which includes base 24, is disposed at the end of applicator 12 and does not "advance from a proximal position entirely within the inserter to a distal position," as recited in claim 26. *See* Brister at paras. [0205] to [0211]; FIGS. 8B to 8D. Furthermore, electronics unit 16 of Brister is placed into mounting unit 14 after the applicator 12 is removed. *See* Brister at para. [0102] ("After insertion of the sensor using the applicator 12, and subsequent release of the applicator 12 from the mounting unit 14 … the electronics unit 16 is configured to releasably mate with the mounting unit …"). In other words, the electronics unit 16 does not "advance from a proximal position entirely within the inserter to a distal position," as required by claim 26.

Second, the 6/9/21 FOA relies on various features of base 24 in Brister for the alleged disclosure of the "plurality of recesses" of the pending claims. *See* 6/9/21 FOA at 6. In particular, the 6/9/21 FOA cites to Figures 3, 11A-B, and 12A-C of Brister, and alleges that: (1) the "'lip' for a bottom of electronics 16," and (2) the "two channels with a post in between, each channel considered a recess … for tabs 120 of electronics 16" disclose the "plurality of recesses" of the pending claims. *See* 6/9/21 FOA at 6; Brister at FIGS. 11A and 12C (circled in red below). However, claim 26 recites, *inter alia*, that the plurality of recesses is detachably engaged with the inserter. By contrast, as acknowledged in the 6/9/21 FOA, these cited features of Brister are utilized to retain electronics unit 16 "with the sensor assembly." They are not detachably engaged with the inserter as recited in claim 26. Moreover, they are not part of an on body electronics unit housing that is advanced from a proximal position entirely within the inserter to a distal position as recited in claim 26.

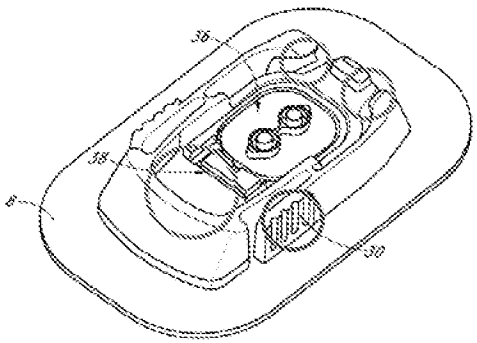

FIG. 11A

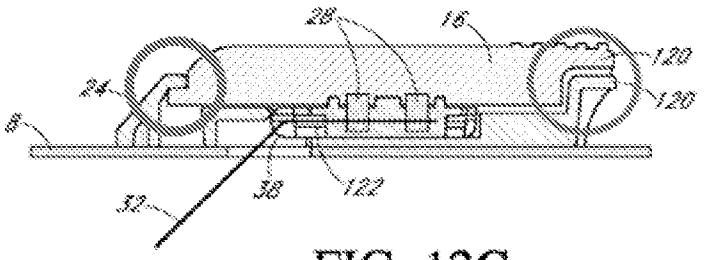

FIG. 12C

As an alternative theory, the 6/9/21 FOA cites to features depicted on the release latches 30 (circled above in blue) for the alleged disclosure of the "plurality of recesses" of the pending claims. However, independent claim 26 requires the "plurality of recesses" to be "disposed on a periphery of the on body electronics unit housing," and release latches 30 are not an on body electronics unit housing. Also, the release latches 30 are not advanced from a proximal position entirely within the inserter to a distal position, as recited in independent claim 26. Finally, independent claim 26 recites that the plurality of recesses is "detachably engaged with the inserter." In Brister, however, the release latches 30 do not detachably engage with applicator 12. Brister states, at paragraph [0100], that "applicator body base 60 is snap fit into the mounting unit 14." By contrast, release latches 30, are disposed on the outside of the mounting unit 14, as shown in FIG. 11A above. In other words, the features shown on release latches 30 do not engage – detachably or not – with applicator 12.

For at least the foregoing reasons, it is respectfully submitted that the cited references, whether considered individually or in a proper combination, fail to teach, describe, or suggest, all of the limitations of independent claim 26. Accordingly, it is respectfully requested that the Section 103 rejection to claim 26, as well as the rejections to the claims that depend therefrom, be withdrawn.

D. The Cited References Do Not Teach, Describe, or Suggest the Limitations of Dependent Claims 28, 31, and 33

It is respectfully submitted that the cited references, whether considered individually or in a proper combination, further fail to teach, describe, or suggest all of the limitations of dependent claims 28, 31, and 33. In particular, the cited references fail to teach or describe at least the following pertinent limitations from each of the aforementioned dependent claims:

- **Claim 28**: "wherein each gripping arm of the plurality of gripping arms is configured to be engaged with a corresponding recess of the plurality of recesses of the on body electronics unit housing …"
- **Claim 31**: "wherein each interior surface of the plurality of interior surfaces is configured to hold a corresponding gripping arm of the plurality of gripping arms against a corresponding recess of the plurality of recesses of the on body electronics unit housing …"
- **Claim 33**: "wherein each gripping arm of the plurality of gripping arms comprises an engagement boss configured to engage with a corresponding recess of the plurality of recesses of the on body electronics unit housing …"

The 6/9/21 FOA cites to Funderburk for the alleged disclosure of each of the aforementioned limitations. More specifically, the 6/9/21 FOA cites to the "laterally extending barbed fingers 412" of Funderburk for the alleged disclosure of "a plurality of gripping arms." *See* 6/9/21 FOA at 11; Funderburk at Col. 15:14-59 and FIGS. 20-23. However, as shown in FIG. 20 of Funderburk (below), the laterally extending barbed fingers 412 of Funderburk do not engage with a plurality of recesses of an on body electronics unit housing, as recited in dependent claims 28 and 33. Similarly, the laterally extending barbed fingers 412 of Funderburk are not held by a plurality of interior surfaces against a plurality of recesses of an on body electronics unit housing, as recited in dependent claim 31.

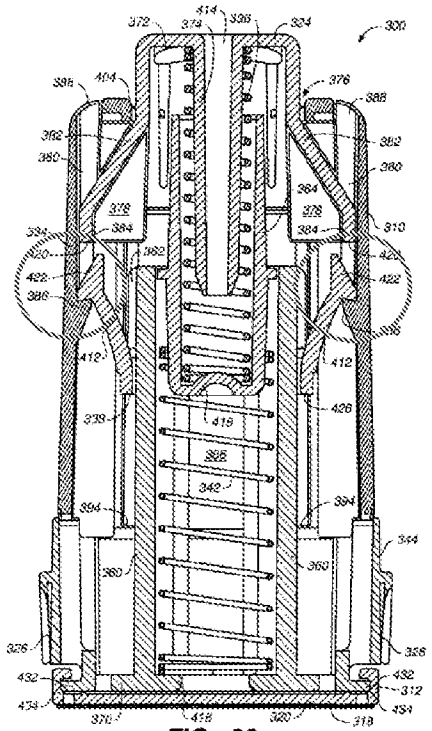

FIG. 20

For at least the foregoing reasons, it is respectfully submitted that the cited references, whether considered individually or in a proper combination, fail to teach, describe, or suggest all of the limitations of dependent claims 28, 31, and 33. Accordingly, it is respectfully requested that the Section 103 rejections to dependent claims 28, 31, and 33, as well as the rejections to the claims that depend therefrom, be withdrawn.

CONCLUSION

Amendments to and/or cancellations of the claims are made without prejudice and solely to clarify the issues before the Examiner and/or to advance prosecution of this application and do not constitute a *de facto* acquiescence to any objection and/or rejection. Accordingly, this response does not concede that previously pending claims are not patentable.

The right is reserved to pursue claims to any subject matter supported by the disclosure of this application in one or more continuation and/or divisional applications at a later time, including the subject matter of any previously pending claims regardless of whether those claims were amended or cancelled herein. This may entail the pursuit of broader claims, narrower claims, and subject matter that was previously relinquished by virtue of argument or amendment.

Any silence with regard to the rejections of and/or objections to certain dependent claims constitutes a recognition that such are moot based on amendments or remarks made with respect to the independent claim from which the dependent claims depend. Such silence does not constitute a *de facto* acquiescence to any objection and/or rejection.

It is respectfully submitted that all claims are in allowable form. In the event that the Examiner deems that a discussion would be helpful in advancing prosecution, the Examiner is invited to call the undersigned at (949) 432-9993. The USPTO is hereby authorized to charge any outstanding fees to Deposit Account No. 50-5201.

Dated: November 19, 2021

Respectfully submitted,

/Glen Liu/

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Manuel Luis Donnay et al.

Application No.: 17/019,110 Confirmation No.: 1087

Filed: September 11, 2020 Art Unit: 3791

For: MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES Examiner: Huong Q. Nguyen

JOINT DECLARATION UNDER 37 C.F.R. § 1.131

We, the undersigned, declare as follows:

1. Each of us is a named inventor of the above-identified patent application, U.S. Patent Application Serial No. 17/019,110 ("the '110 Application"), filed on September 11, 2020. We understand that the '110 Application is currently assigned to Abbott Diabetes Care Inc. ("ADCI" or "the Applicant").

2. We hereby submit this joint declaration in support of the Applicant's Submission to Accompany Request for Continued Examination Under 37 C.F.R. §1.114, including antedating U.S. Pat. Appl. Publ. No. 2010/0198034 A1 ("the '034 Publication" or "Thomas"). We understand that the '034 Publication has a publication date of August 5, 2010.

3. We have reviewed the pending claims in the '110 Application. As explained in further detail below, the subject matter of the pending claims was conceived in the United States before August 5, 2010. Also, as explained in further detail below, the subject matter of the pending claims was reduced to practice by no later than November 8, 2010, and diligence was continuously exercised from at least just before August 5, 2010 to November 8, 2010.

4. In connection with the making of this joint declaration, we reviewed documents and records referenced in this joint declaration to refresh our recollections of events and dates. In particular, we reviewed **Exhibits 1-8** attached hereto. **Exhibits 1-8** are true and correct copies of

records associated with a product development project of ADCI on which we worked. We understand that some of the exhibits (e.g., **Exhibits 2-7**) have been modified to remove (i.e., "redact") certain information on those exhibits, as reflected by the black boxes in **Exhibit 2**, and the boxes containing the word "Redacted" in **Exhibits 3-7**. We further understand that the redaction is consistent with Section 715.07 of the Manual of Patent Examining Procedure of the United States Patent and Trademark Office ("USPTO"). We have examined unredacted copies of **Exhibits 2-7**, as well as the attached redacted versions.

A. The Glucose Monitoring Assembly Project

5. The subject matter of the pending claims relates to a major product development project of ADCI that was in progress during the 2010 calendar year for a new glucose monitoring assembly ("GMA"), comprising: (1) an inserter and (2) an on body electronics unit that included a glucose sensor and on body electronics. For purposes of this declaration, this product development project shall be referred to, hereinafter, as "the GMA Project."

6. Each of us worked on the GMA Project in the United States, along with others, while employed at ADCI during, at least, the 2010 calendar year.

7. In addition, as sometimes occurs with product development projects at ADCI, one or more patent applications were filed in connection with the GMA Project.

8. For example, **Exhibit 1** is a true and correct copy of a U.S. Provisional Patent Application having Serial No. 61/361,374 ("the '374 Provisional"). The '374 Provisional was prepared and filed, at least in part, in connection with the GMA Project. The '374 Provisional is entitled, "MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES," and has a filing date of July 2, 2010.

9. As another example, **Exhibit 8** is a true and correct copy of a U.S. Provisional Patent Application having Serial No. 61/411,262 ("the '262 Provisional"). The '262 Provisional was also prepared and filed, at least in part, in connection with the GMA Project. The '262 Provisional is entitled, "MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES," and has a filing date of November 8, 2010.

B. The Subject Matter of the Pending Claims of the '110 Application Was Conceived in the United States Before August 5, 2010

10. The subject matter of the pending claims in the '110 Application was conceived in the United States before August 5, 2010, as shown by the sample documents cited herein.

11. **Exhibit 1** is the '374 Provisional. As stated above, the '374 Provisional was filed with the USPTO on July 2, 2010 and includes disclosure relating to the GMA Project.

12. For example, Figures 73 through 73O of the '374 Provisional depict an example embodiment of a glucose monitoring assembly. One of those figures – Figure 73H – is shown below with some labels added for context:

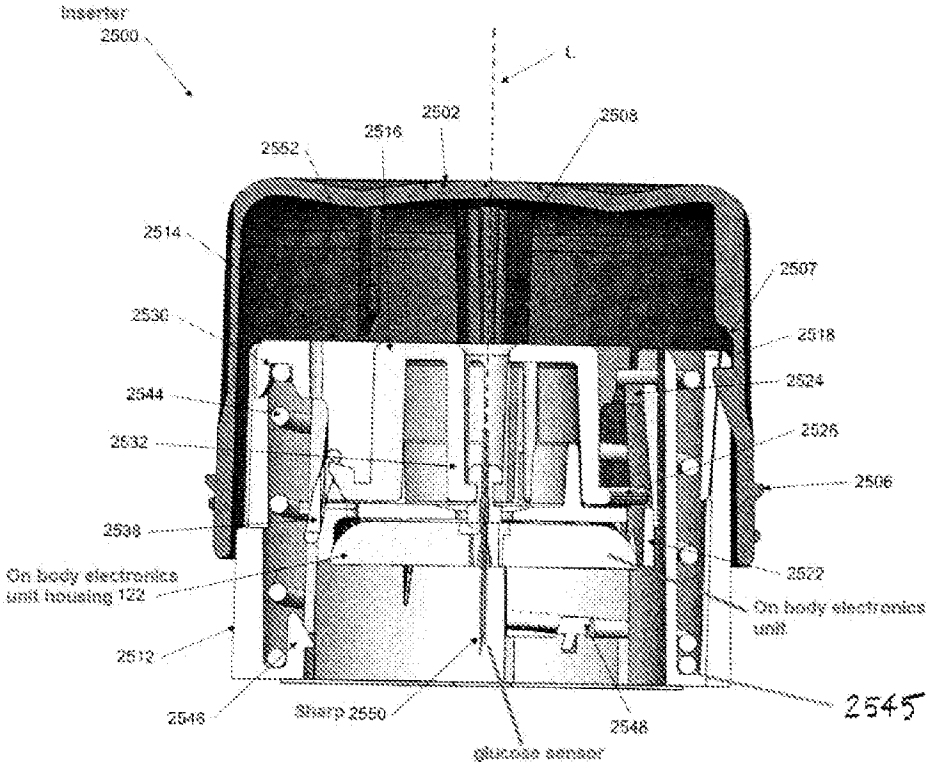


FIG. 73H

13. Another sample figure from the '374 Provisional (i.e., Figure 23) depicts some on body electronics unit details (labels added):

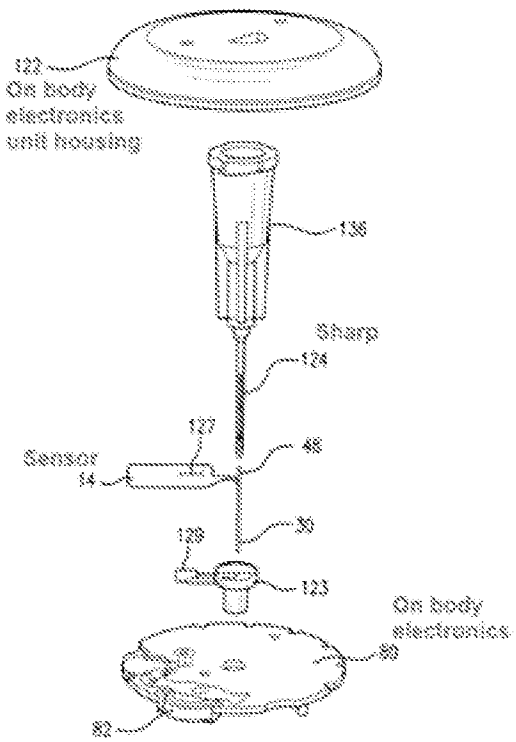
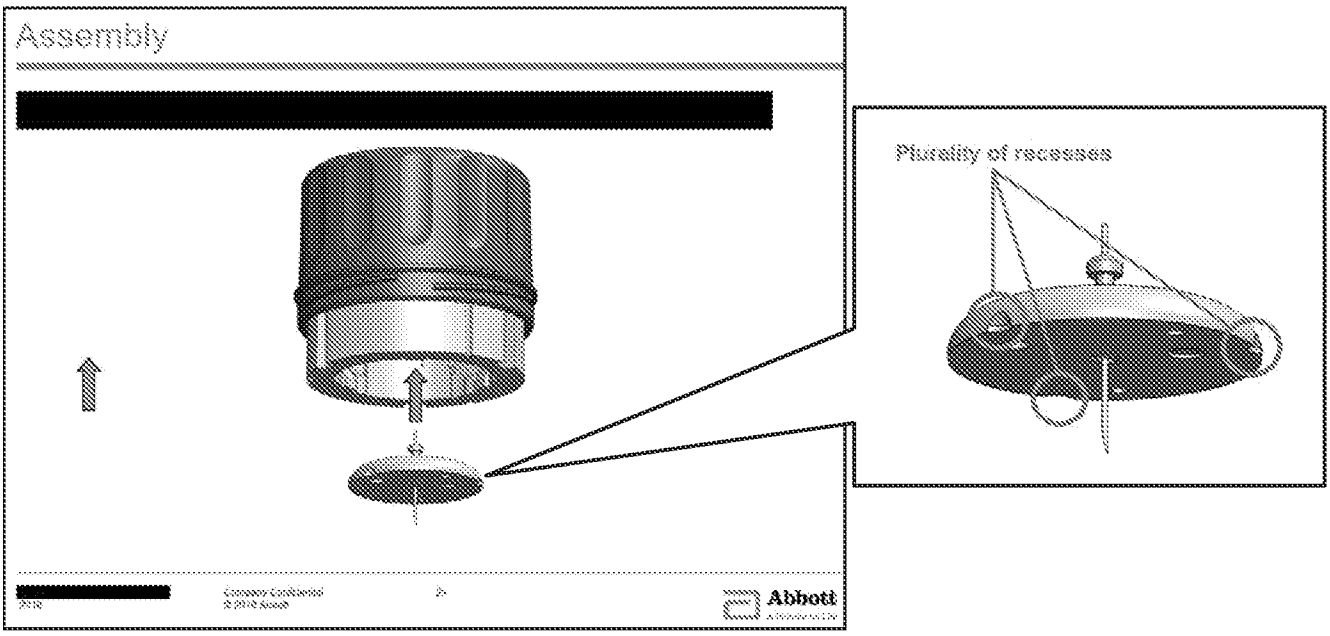


FIG.23

14. **Exhibit 1** discloses other relevant information as reflected by the sample cites in **Appendix A**.

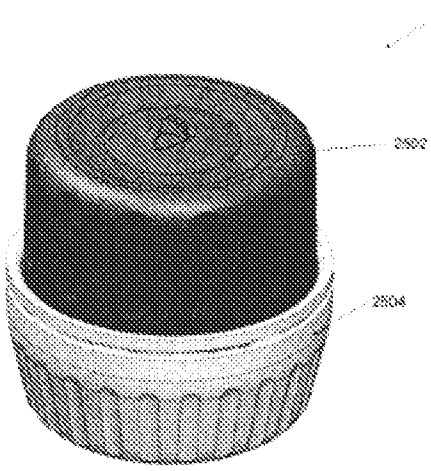
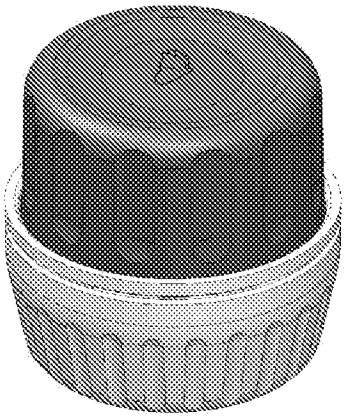
15. **Exhibit 2** is a redacted version of a true and correct copy of a PowerPoint presentation by Manuel Donnay, relating to the GMA Project, and dated April 27, 2010 ("the 4/27/2010 PowerPoint"). The 4/27/2010 PowerPoint is a presentation that reflects an example inserter embodiment of the GMA Project that was conceived prior to August 5, 2010.

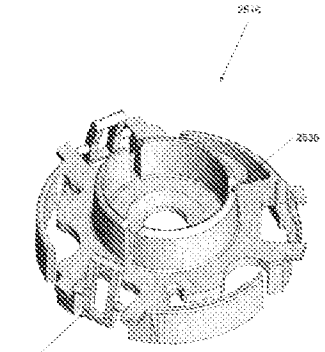
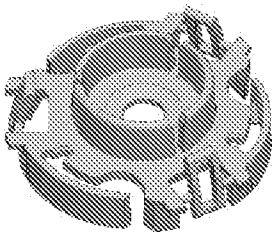
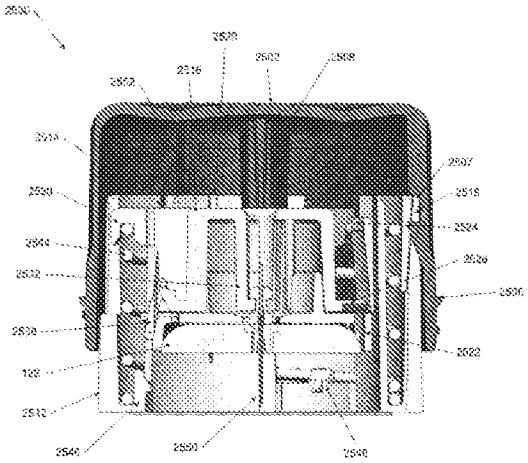
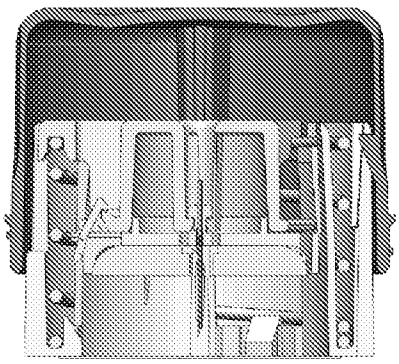
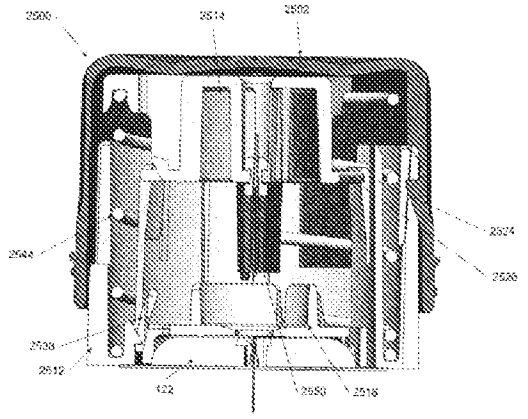
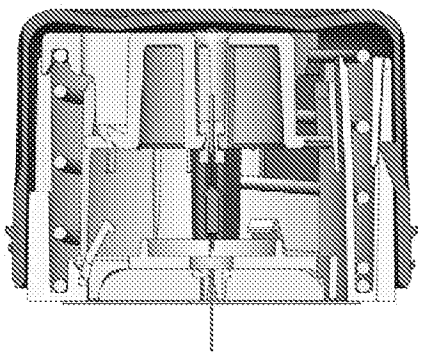
16. For example, Page 21 of the 4/27/2010 PowerPoint, as shown below (with labels added), depicts a plurality of recesses disposed on a periphery of the on body electronics unit housing, wherein the plurality of recesses comprises a first recess in a spaced relation to a second recess.



17. **Exhibit 2** discloses other relevant information as reflected by the sample cites in **Appendix A**.

18. Both the '374 Provisional and the 4/27/2010 PowerPoint were made in connection with the GMA Project. Here are sample side-by-side images from **Exhibits 1** and **2** showing the related embodiment:

Figures from Exhibit 1 (the '374 Provisional)	**Excerpts from Exhibit 2 (the 4/27/2010 PowerPoint)**
 FIG. 73	 **Exhibit 2** at 2.

Figures from Exhibit 1 (the '374 Provisional)	Excerpts from Exhibit 2 (the 4/27/2010 PowerPoint)
 FIG. 73F	
 FIG. 73I	 **Exhibit 2** at 5.
 FIG. 73M	 **Exhibit 2** at 8.

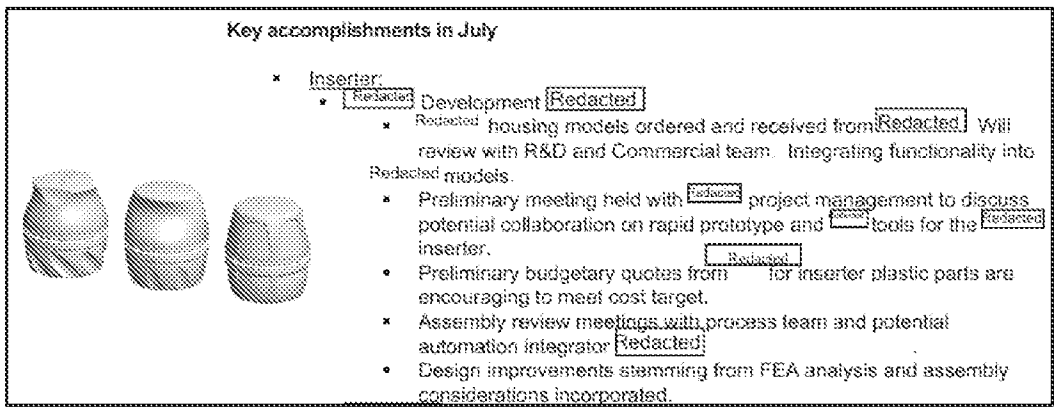
19. **Appendix A** is a demonstrative exhibit, prepared by the Applicant's counsel, that summarizes sample support from the '374 Provisional and the 4/27/2010 PowerPoint, showing that the subject matter of the pending claims was conceived in the United States before August 5, 2010.

C. Work Was Continuously and Diligently Performed From at Least Just Before August 5, 2010 to November 8, 2010

20. Furthermore, in connection with the GMA Project, work on the subject matter of the pending claims in the '110 Application was performed diligently from, at least, a time just before August 5, 2010 through, at least, November 8, 2010. This diligence is reflected, for example, in **Exhibits 3-7**. As explained in detail below, **Exhibits 3-7** are redacted versions of progress reports relating mostly to the GMA Project for each month from just before August 5, 2010 to November 8, 2010 (i.e., **Exhibits 3-7** are monthly reports for July through November 2010). These reports reflect and summarize the continuous work for each month on various aspects of the GMA Project.

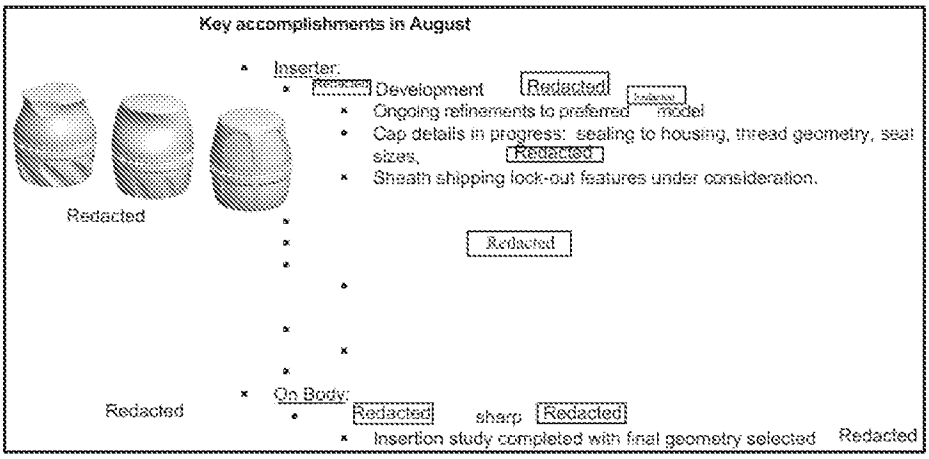
21. **Exhibits 3-7** speak for themselves as to the diligent and ongoing work performed just before August 5, 2010 until at least November 8, 2010. For ease of reference, sample excerpts from those **Exhibits** are highlighted below.

22. For example, **Exhibit 3** is a redacted version of a true and correct copy of a progress report dated July 30, 2010 and reflects work performed in connection with the GMA Project throughout July 2010. Here is a sample excerpt from **Exhibit 3**:

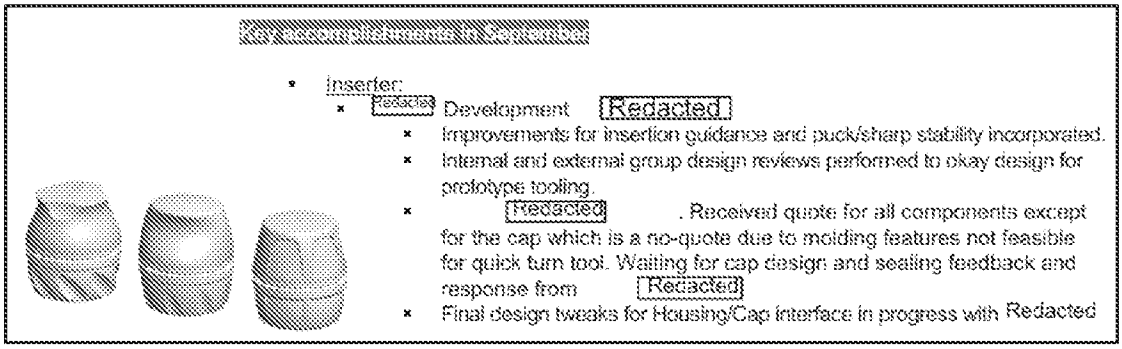

Key accomplishments in July

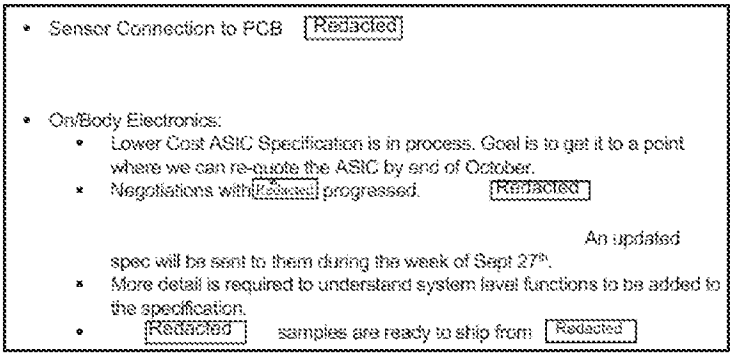
- Inserter:
  - Redacted Development Redacted
    - Redacted housing models ordered and received from Redacted. Will review with R&D and Commercial team. Integrating functionality into Redacted models.
    - Preliminary meeting held with Redacted project management to discuss potential collaboration on rapid prototype and Redacted tools for the Redacted inserter.
    - Preliminary budgetary quotes from Redacted for inserter plastic parts are encouraging to meet cost target.
    - Assembly review meetings with process team and potential automation integrator Redacted
    - Design improvements stemming from FEA analysis and assembly considerations incorporated.

23. As another example, **Exhibit 4** is a redacted version of a true and correct copy of a progress report dated August 27, 2010 and reflects work performed in connection with the GMA Project throughout August 2010. Here is a sample excerpt from **Exhibit 4**:

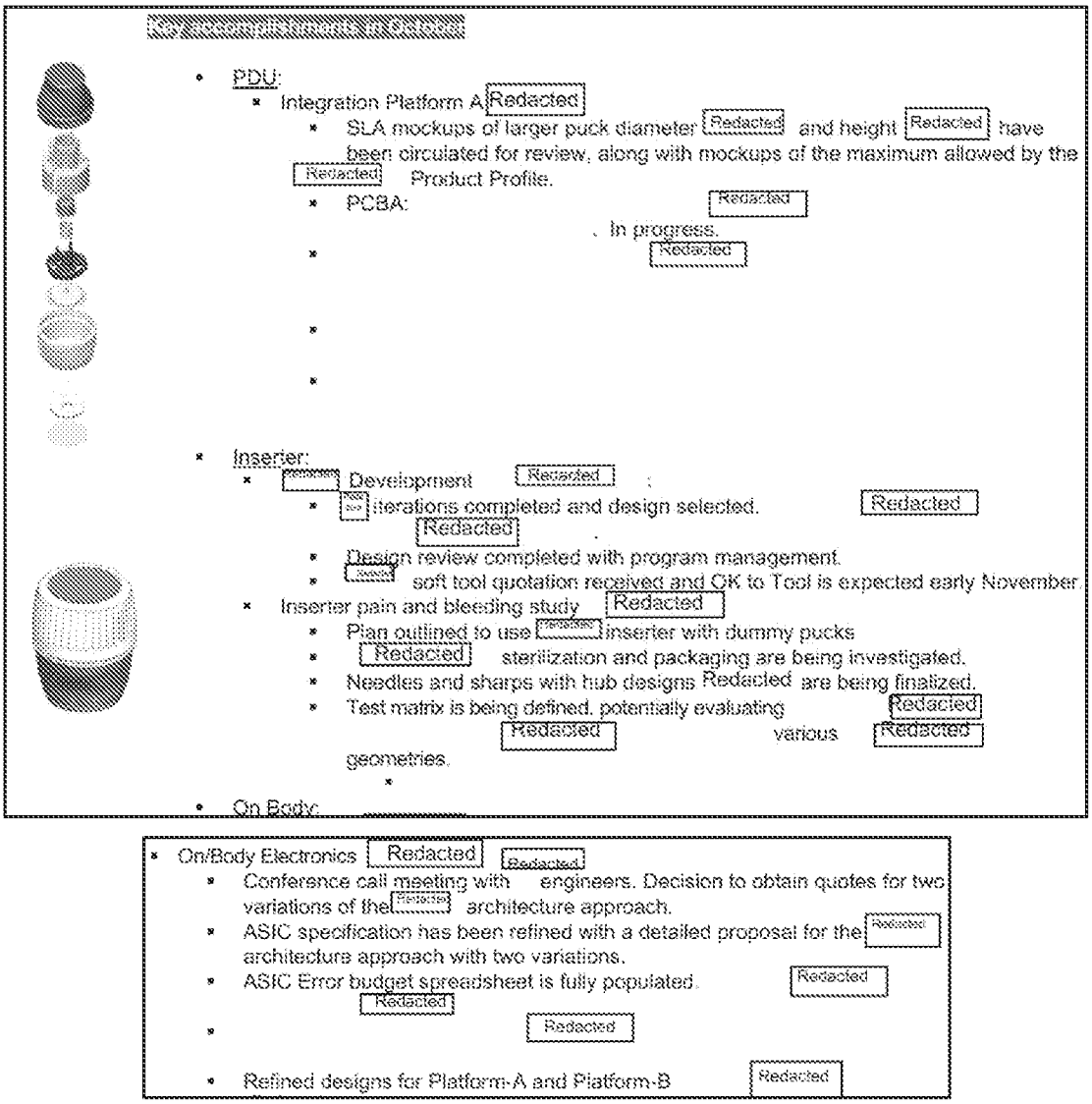


24. As another example, **Exhibit 5** is a redacted version of a true and correct copy of a progress report dated September 30, 2010 and reflects work done throughout September 2010. Here are sample excerpts from **Exhibit 5**:

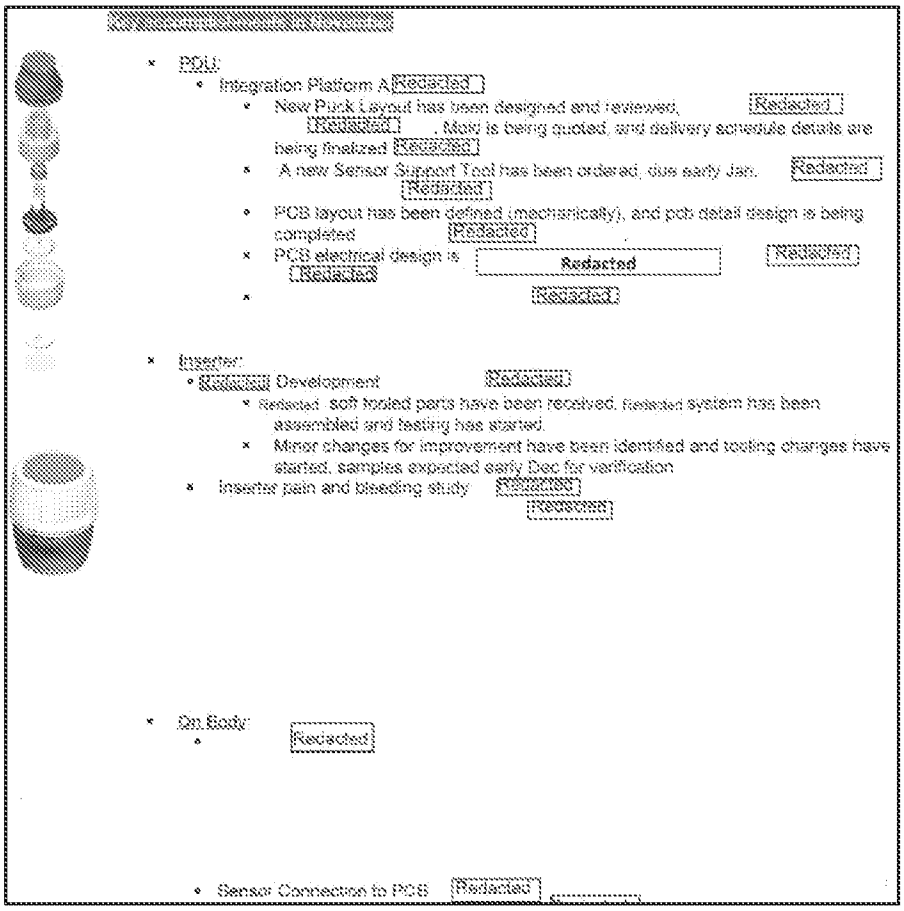


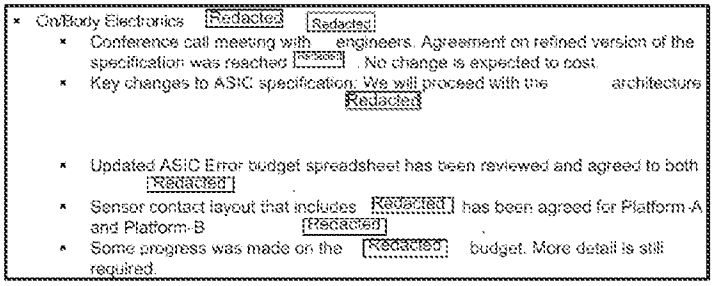


25. As another example, **Exhibit 6** is a redacted version of a true and correct copy of a progress report dated October 28, 2010 and reflects work done throughout October 2010. Here are sample excerpts from **Exhibit 6**:



26. As another example, **Exhibit** 7 is a redacted version of a true and correct copy of a progress report dated December 5, 2010 and reflects work done throughout November 2010. Here are sample excerpts from **Exhibit** 7:





27. In summary, these monthly GMA Project progress reports, at **Exhibits 3-7**, reflect continuous and diligent work from just before August 5, 2010 to at least November 8, 2010.

D. The Subject Matter of the Pending Claims Was Reduced to Practice By No Later Than November 8, 2010

28. Finally, the subject matter of the pending claims in the '110 Application was reduced to practice in the United States by no later than November 8, 2010, as evidenced by **Exhibit 8**. We understand that one way that "reduction to practice" can be shown is by the disclosure of every claim

element in a patent application. We further understand that this form of reduction to practice is sometimes called "constructive reduction to practice."

29. **Exhibit 8**, or the '262 Provisional, shows that the pending claims were reduced to practice by no later than November 8, 2010. As stated above, the '262 Provisional was filed with the USPTO on November 8, 2010 and includes disclosure relating to the GMA Project.

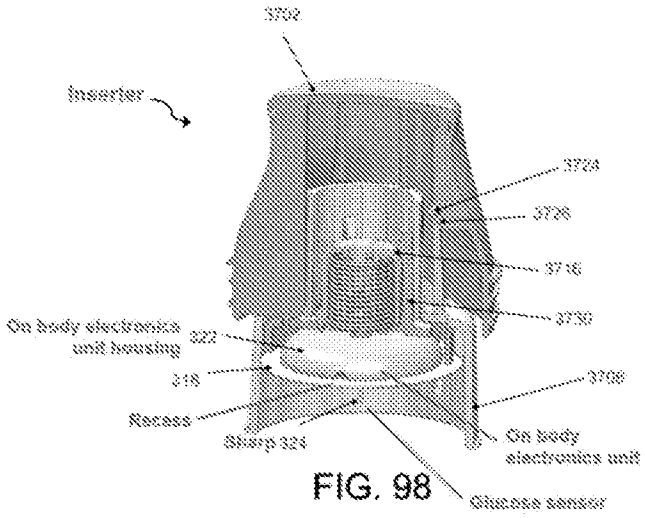


FIG. 98

31. **Exhibit 8** discloses other relevant information as reflected by the sample cites in **Appendix B**.

32. **Appendix B** is a demonstrative exhibit, prepared by the Applicant's counsel, that summarizes sample support from the '262 Provisional showing that the subject matter of the pending claims was reduced to practice in the United States by no later than November 8, 2010.

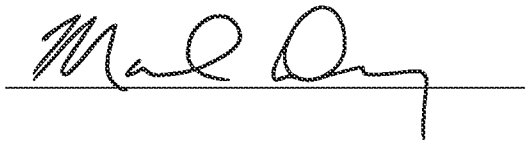
33. We further declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code, § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 09-Nov-2021 Signed:

Dated: 09 NOV 2021

Signed:

Dated: 11/15/2021

Signed: 

Dated: 11/16/2021 Signed:

EXHIBIT 2

[redacted] Mechanical Inserter

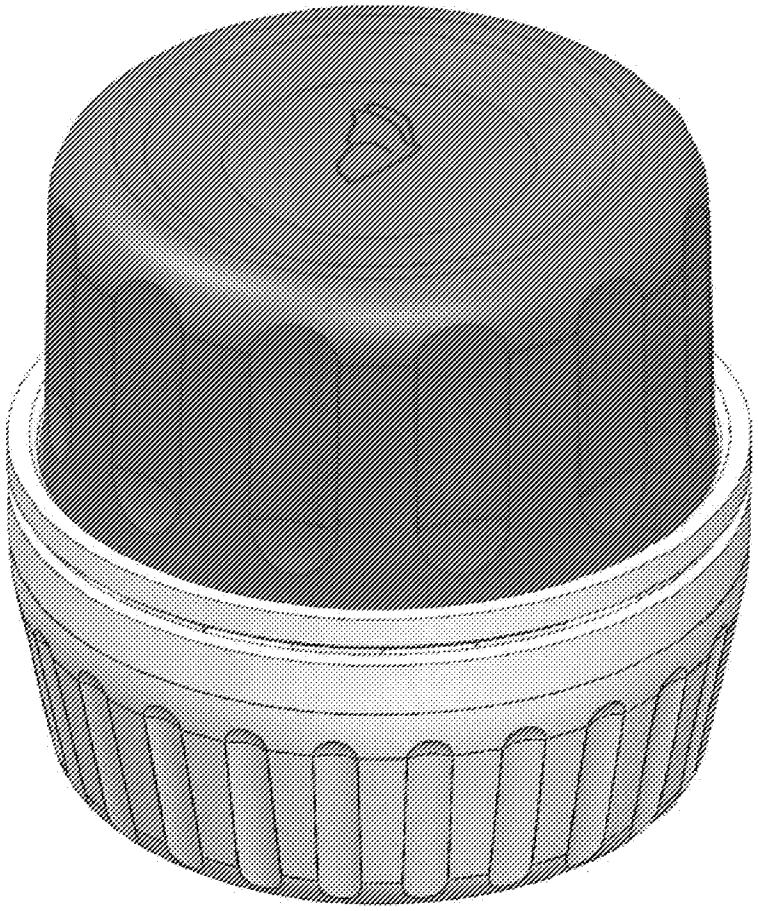
April 27, 2010:

Manuel Donnay

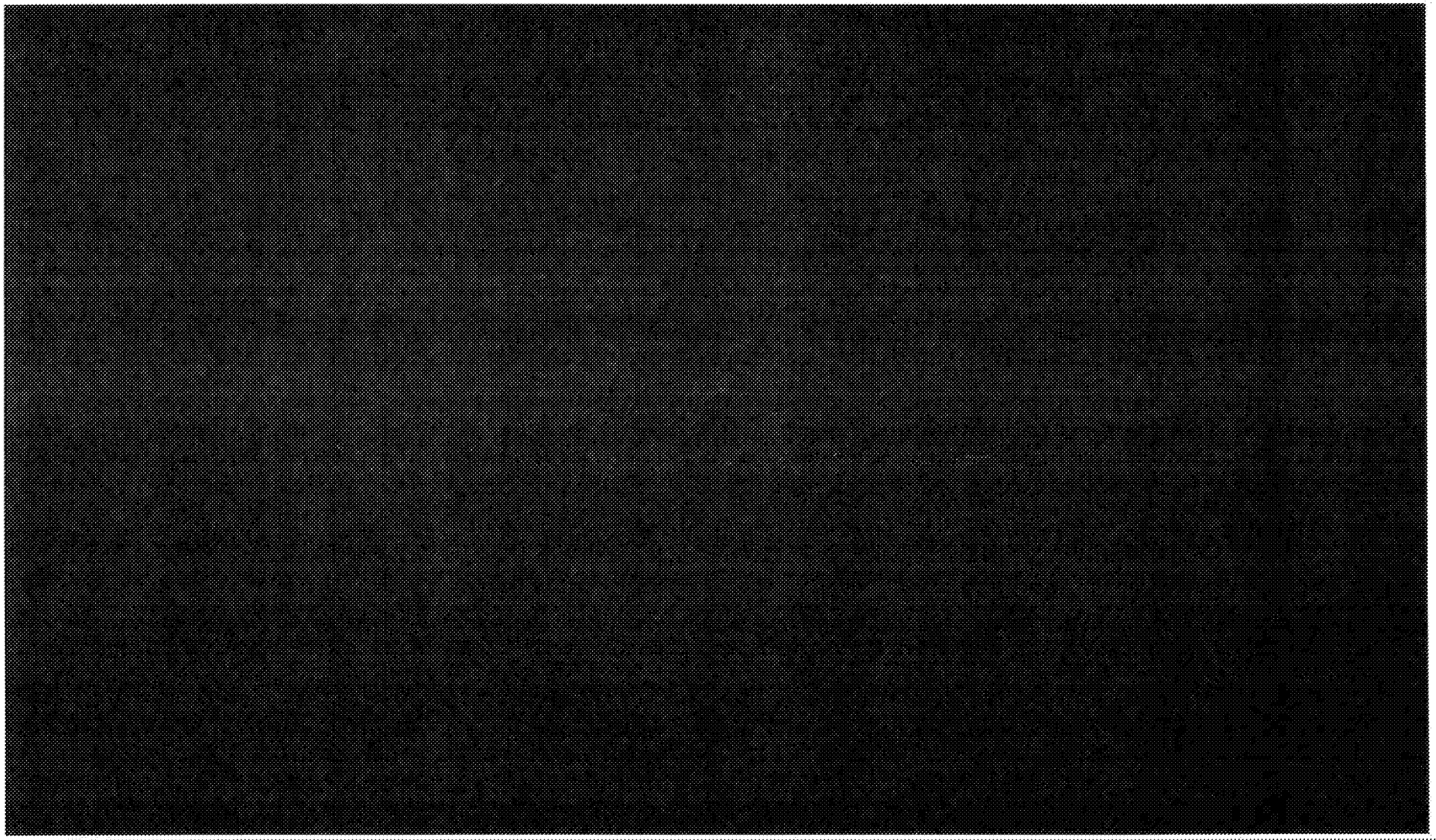
Abbott
A Promise for Life

Agenda

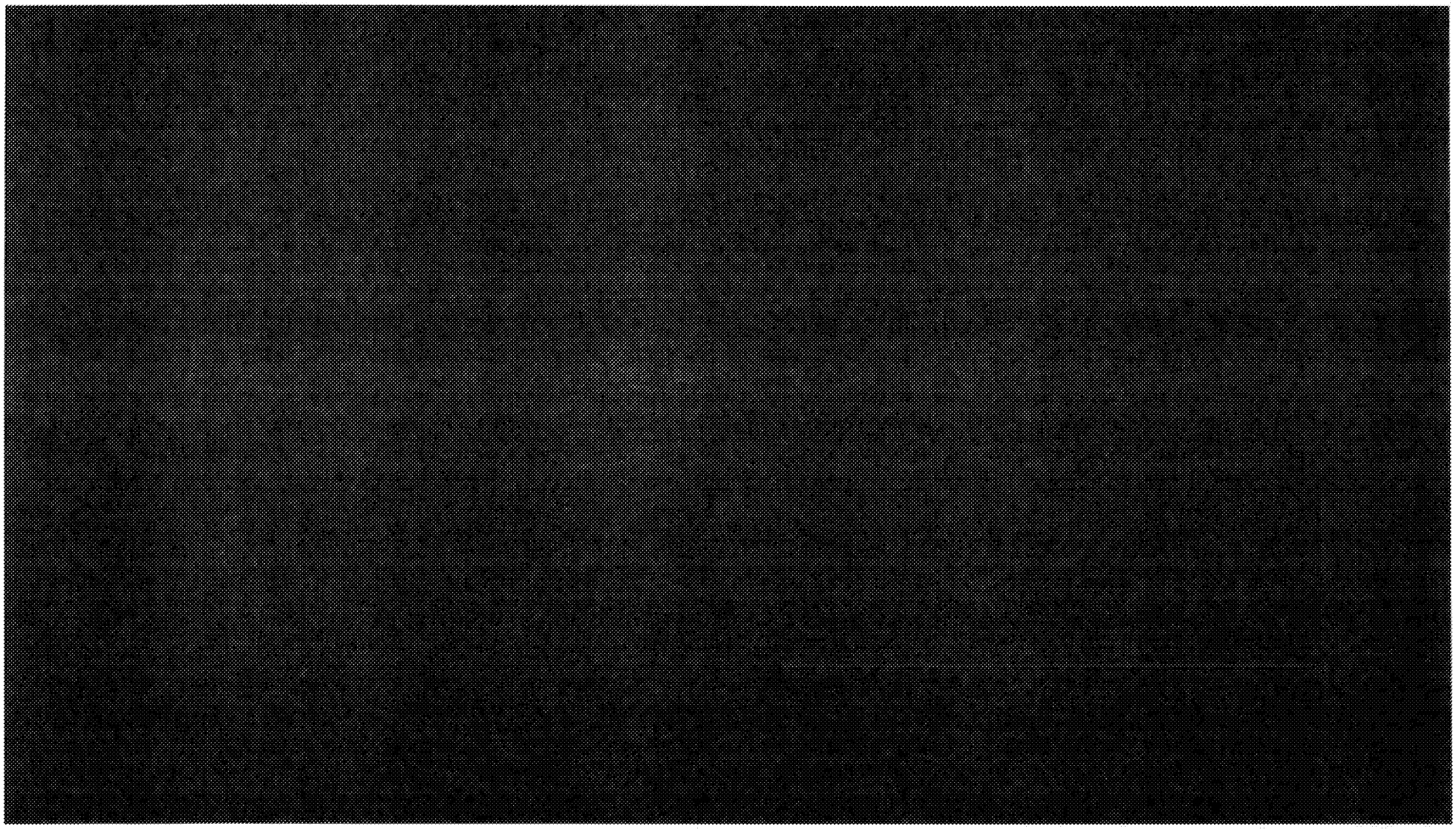
- Parts Overview
- How It Works
- Part Feature Specifics
- Assembly



Parts Overview

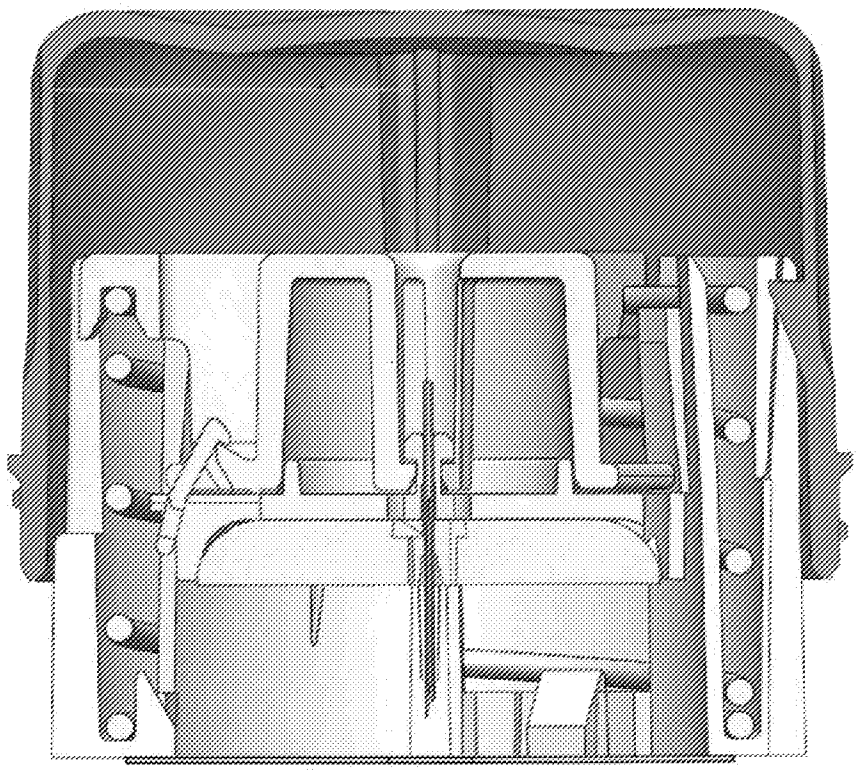


How It Works



How It Works

[redacted]



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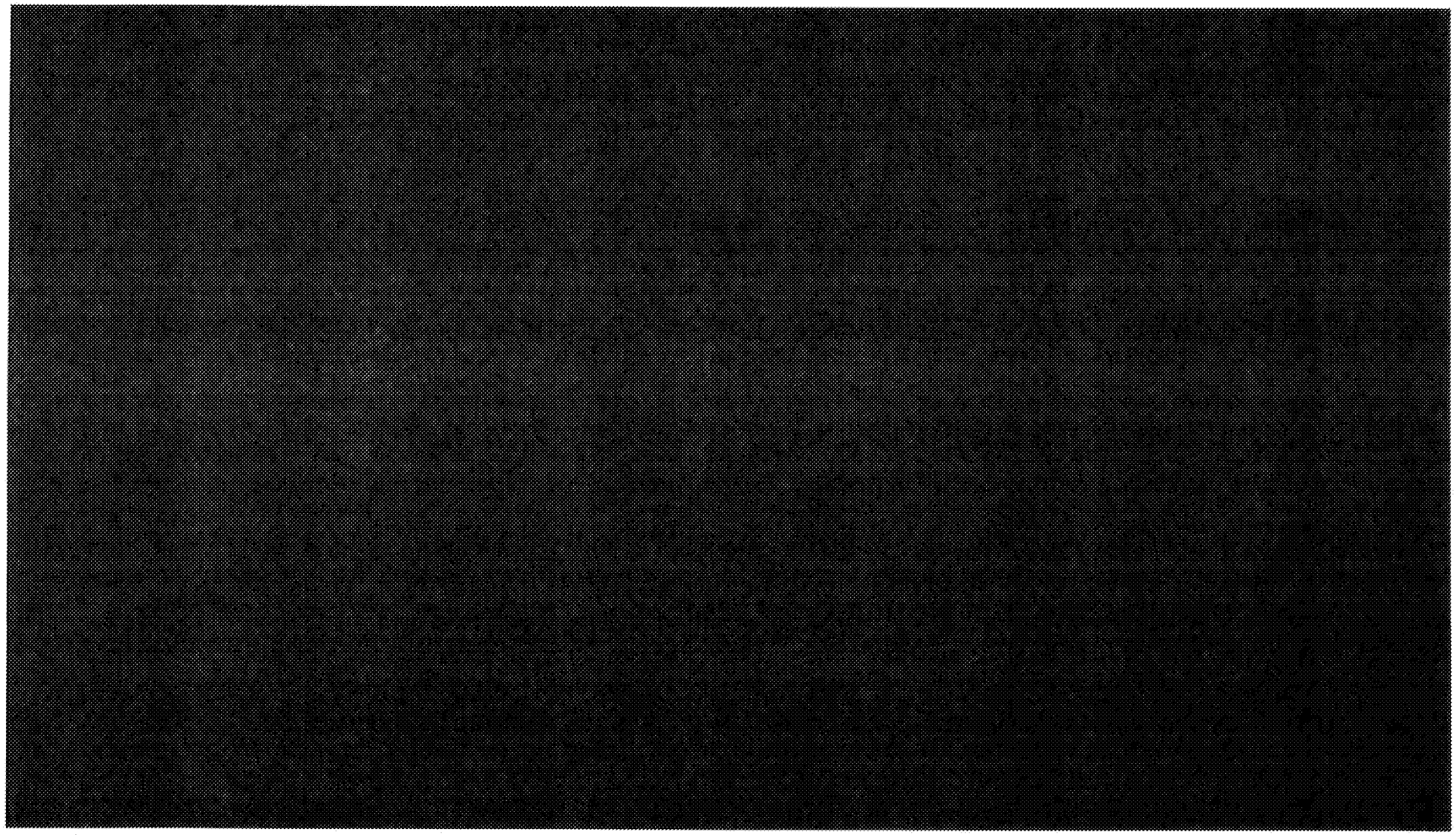
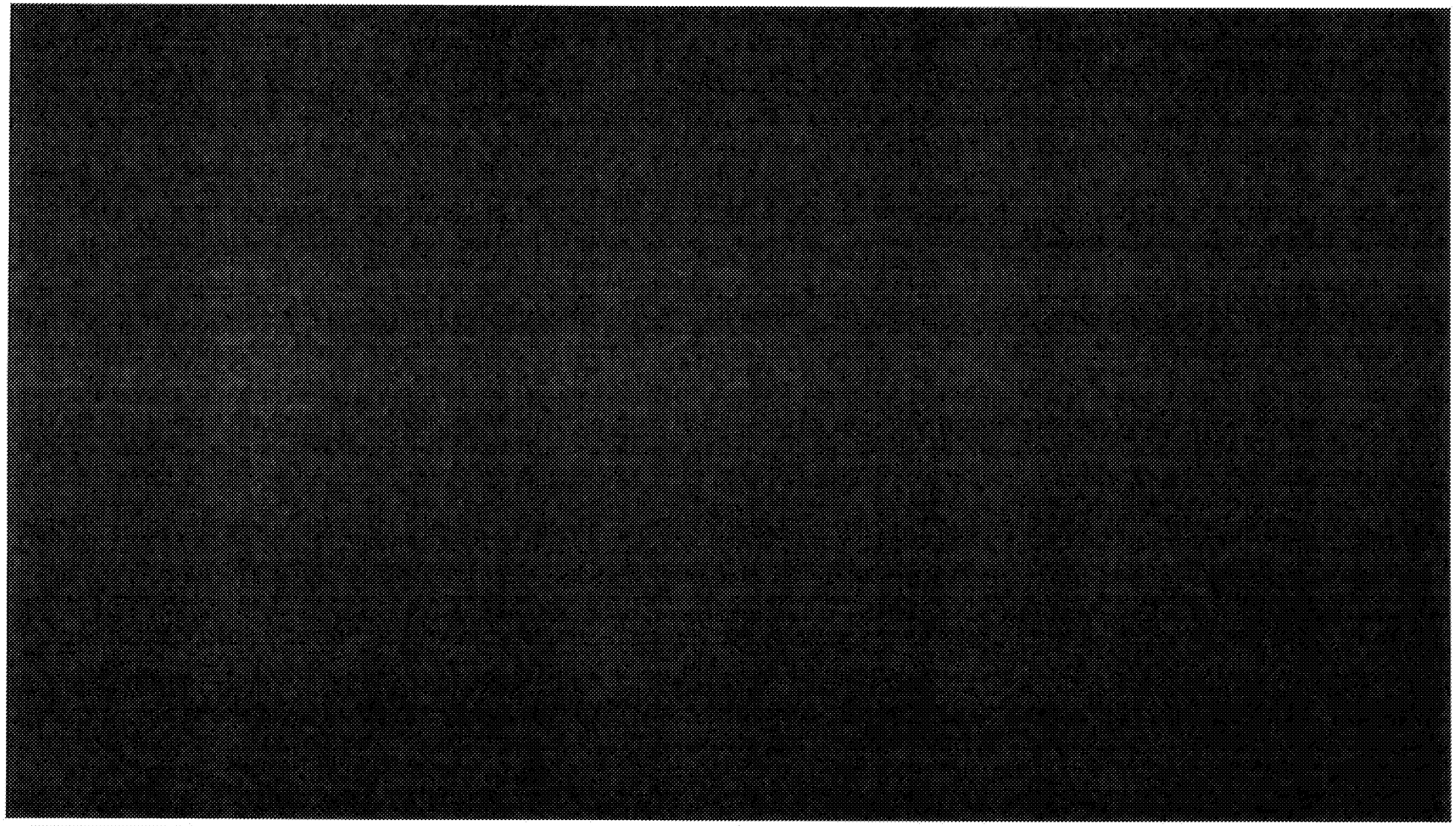
How It Works



How It Works



How It Works

[redacted]

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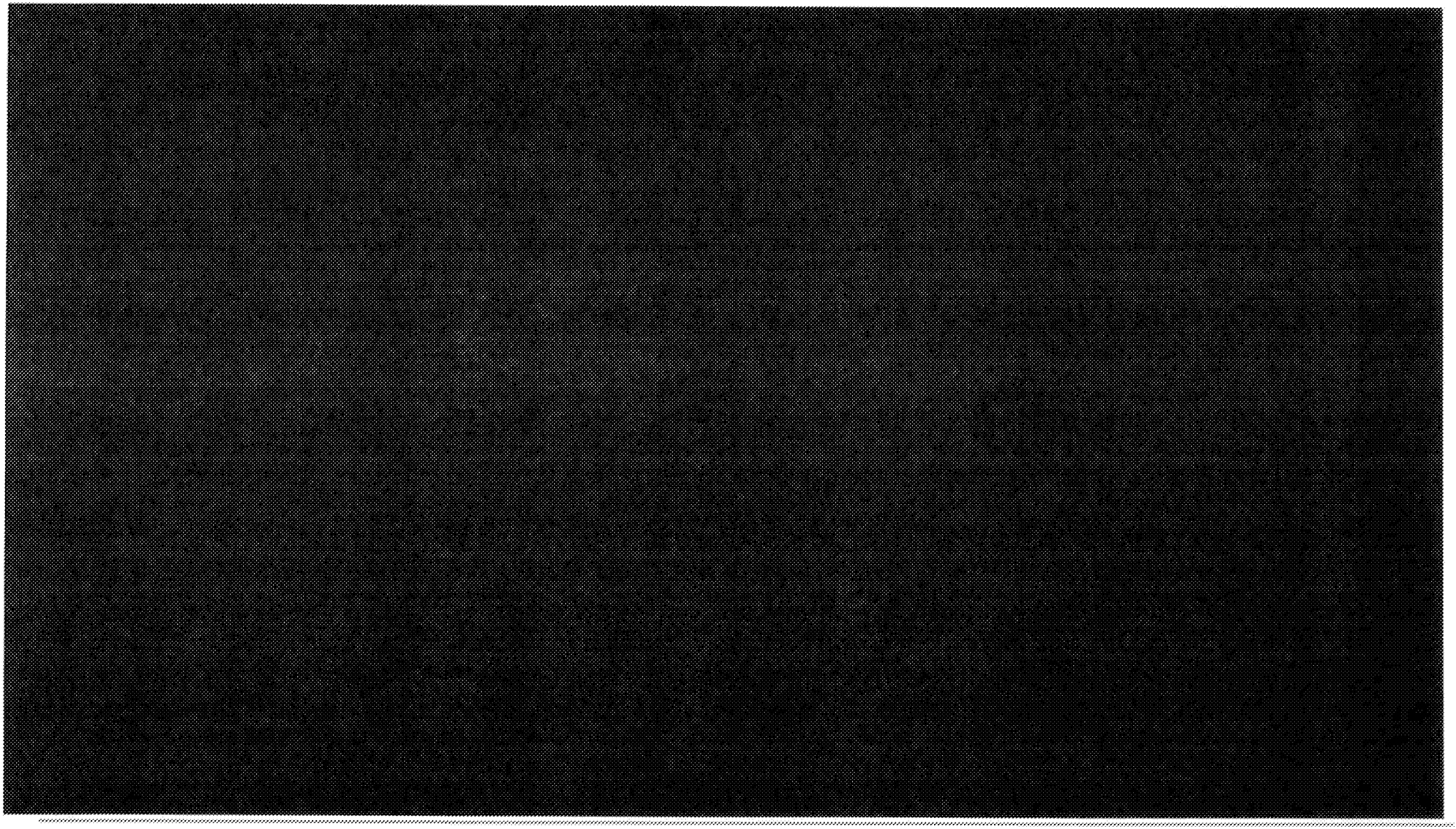
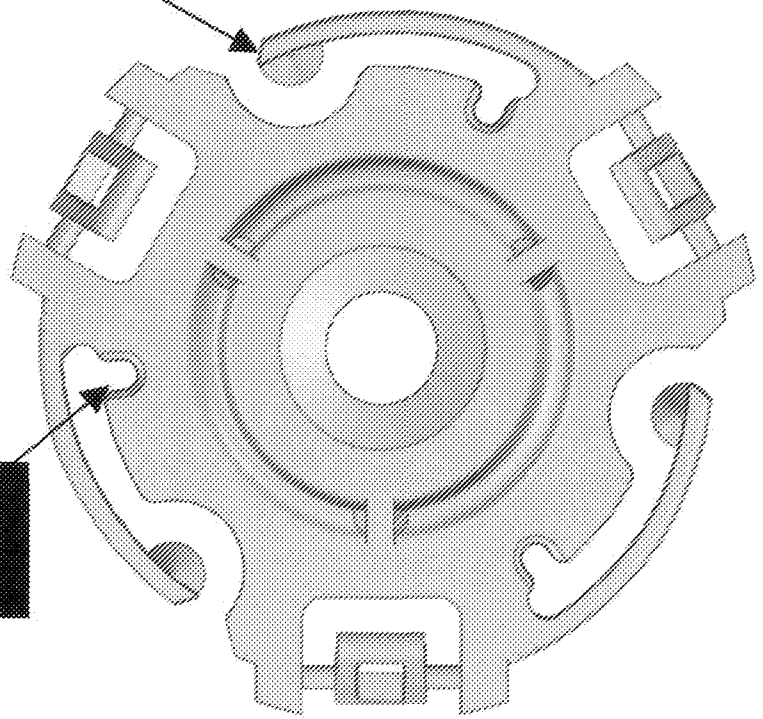
How It Works



Part Features: [redacted]

[redacted]

[redacted]



Part Features:

[redacted]

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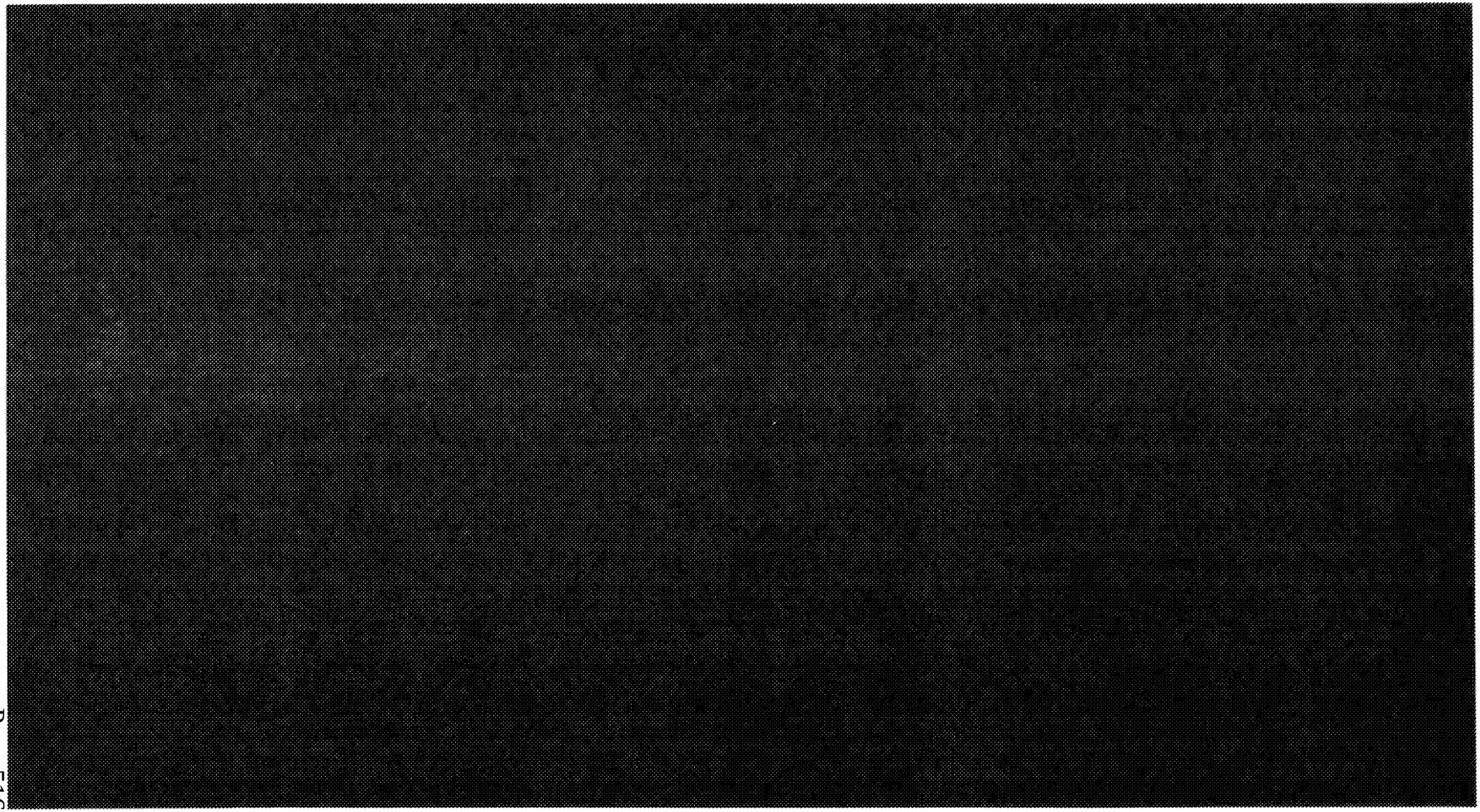
Part Features: [redacted]



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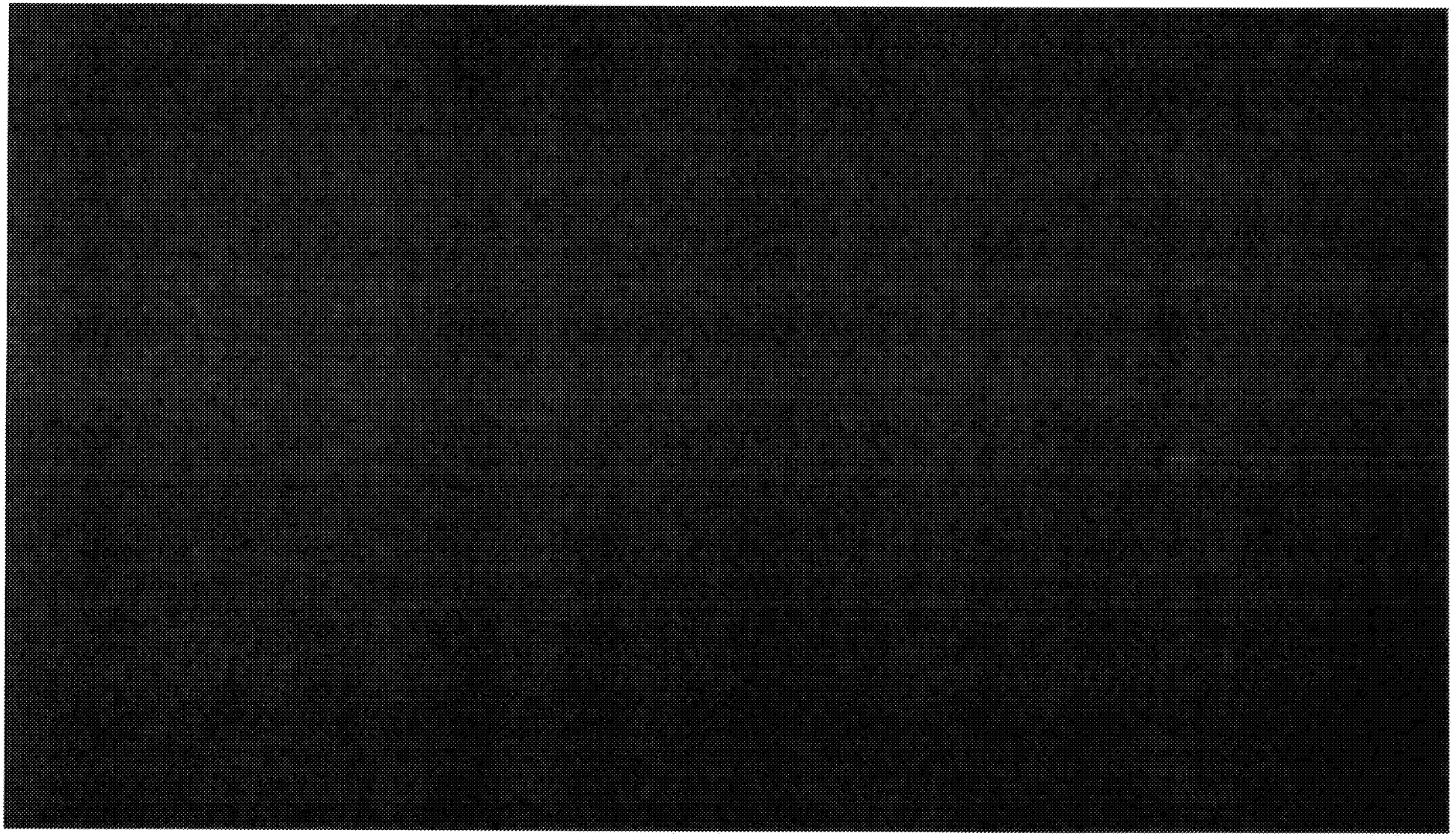
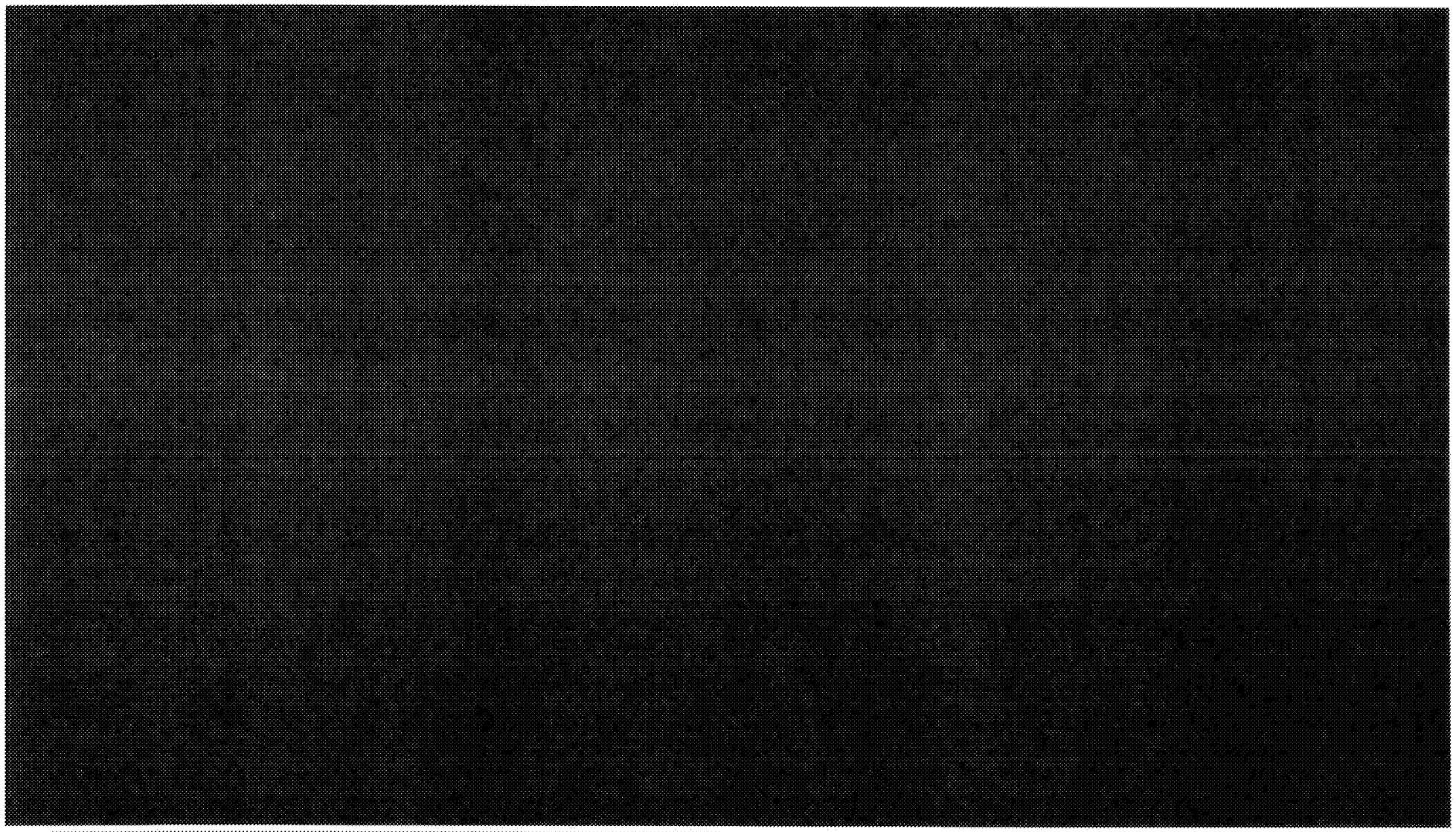
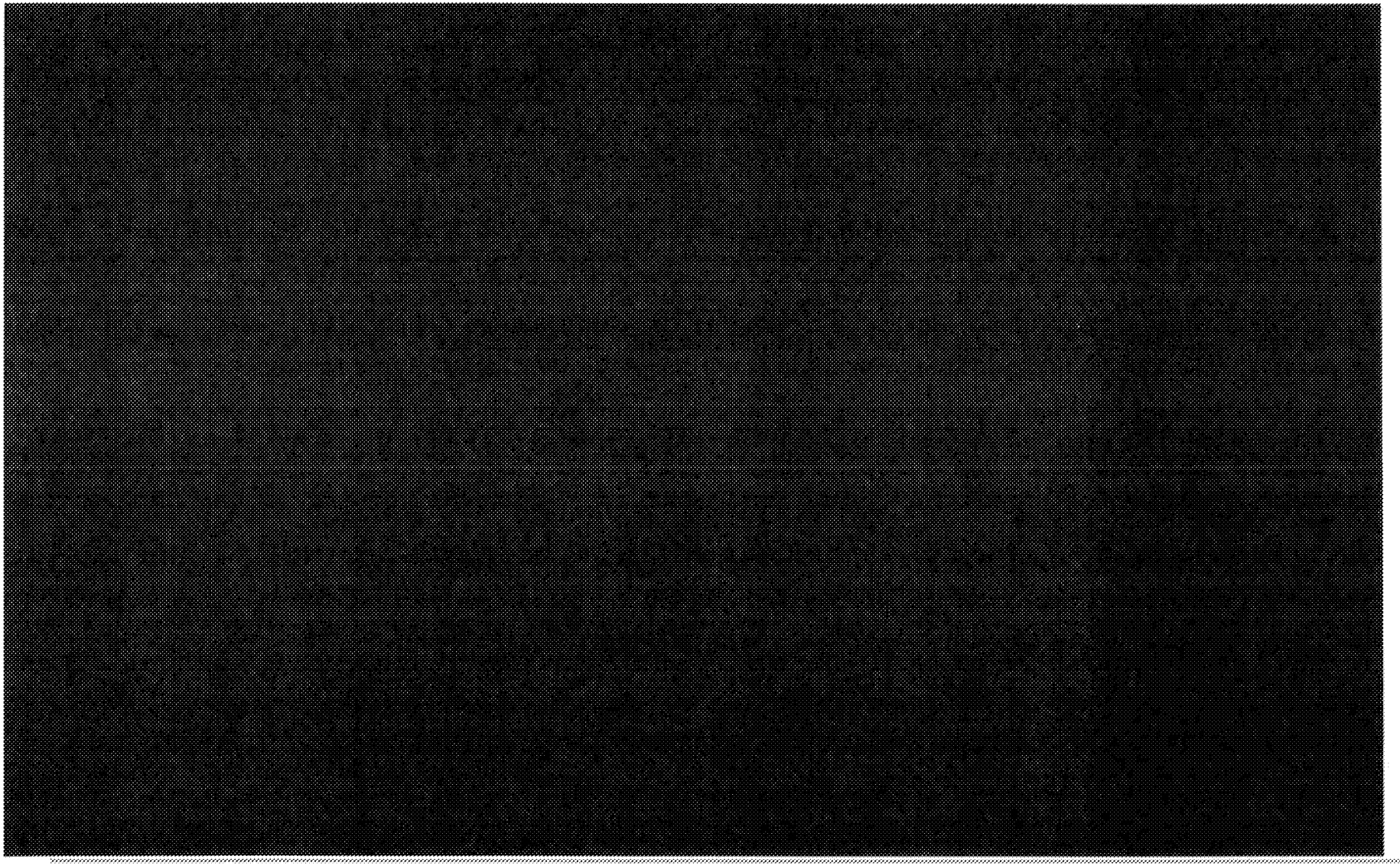

[redacted]

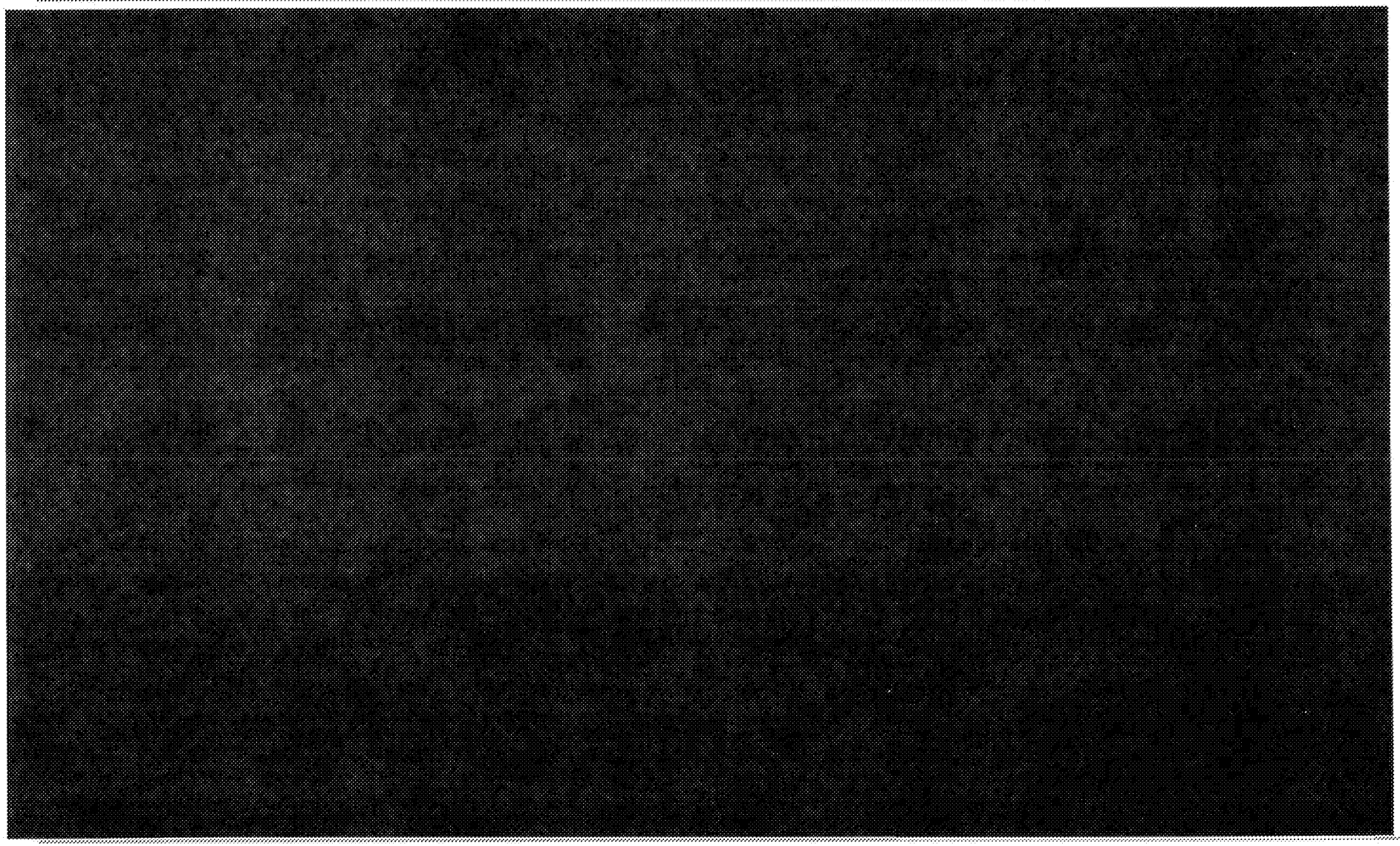
Part Features: [redacted]



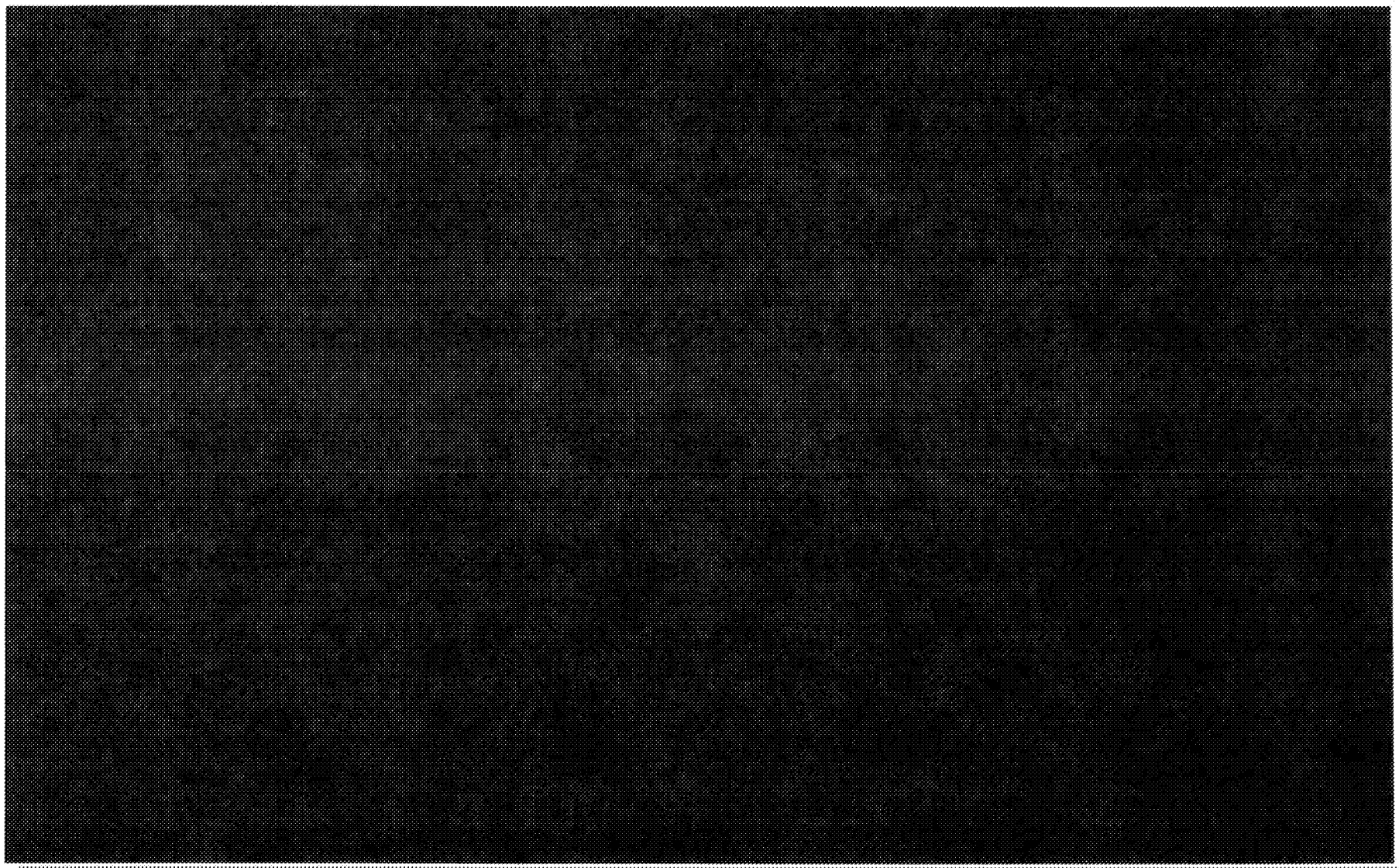
Part Features: [redacted]



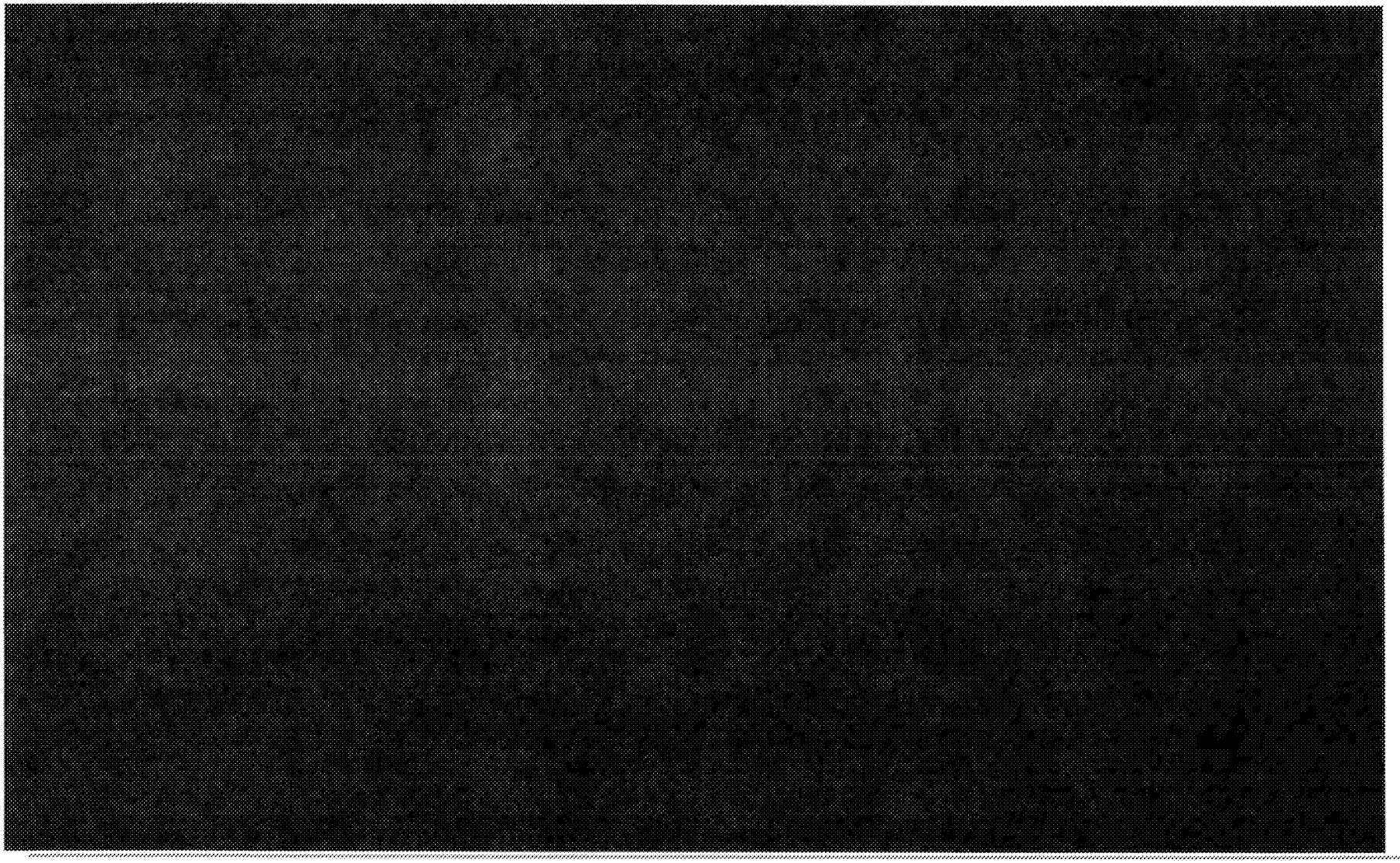
Part Features: [redacted]



Assembly



Assembly



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Assembly

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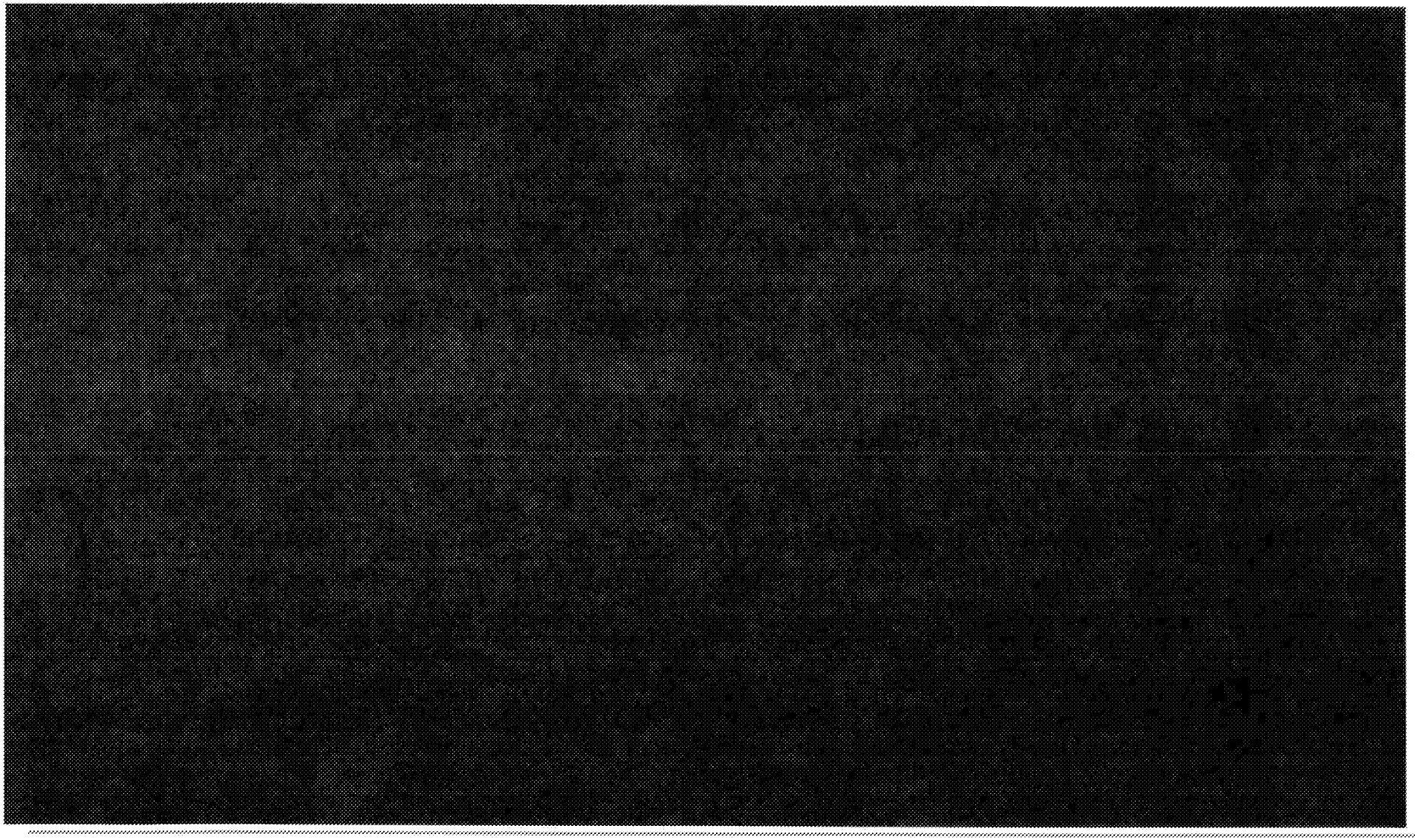
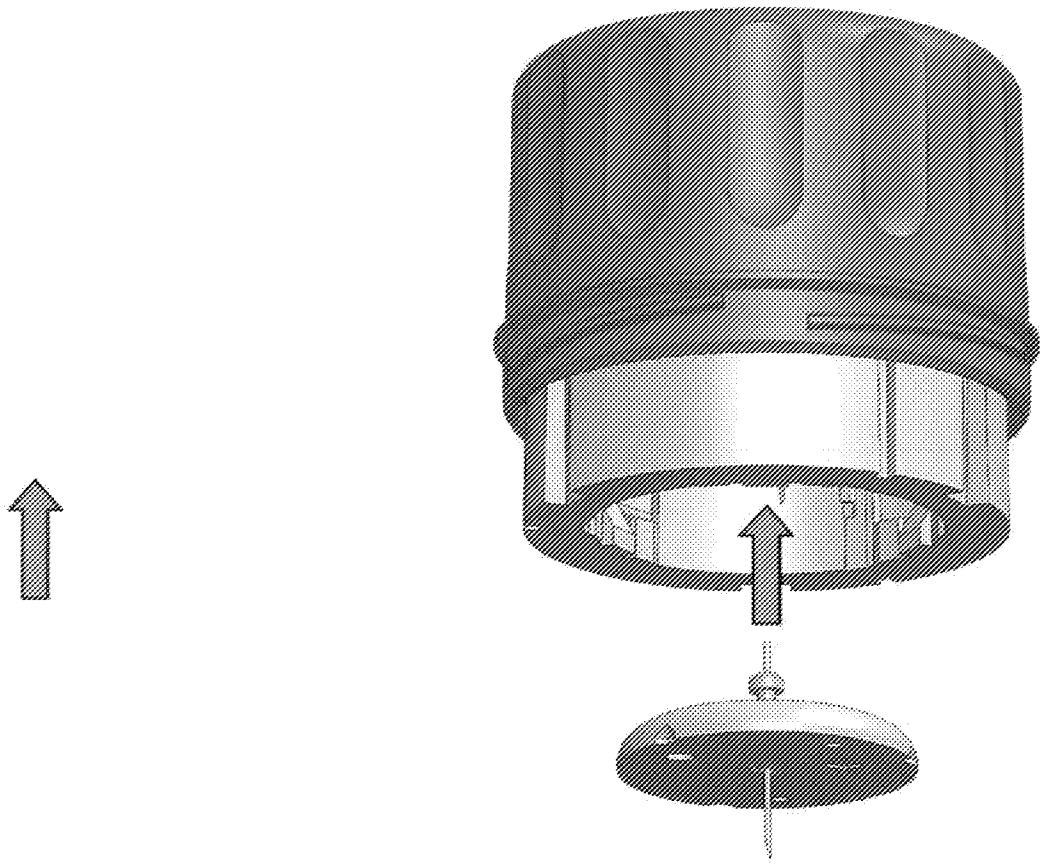
Assembly



Assembly



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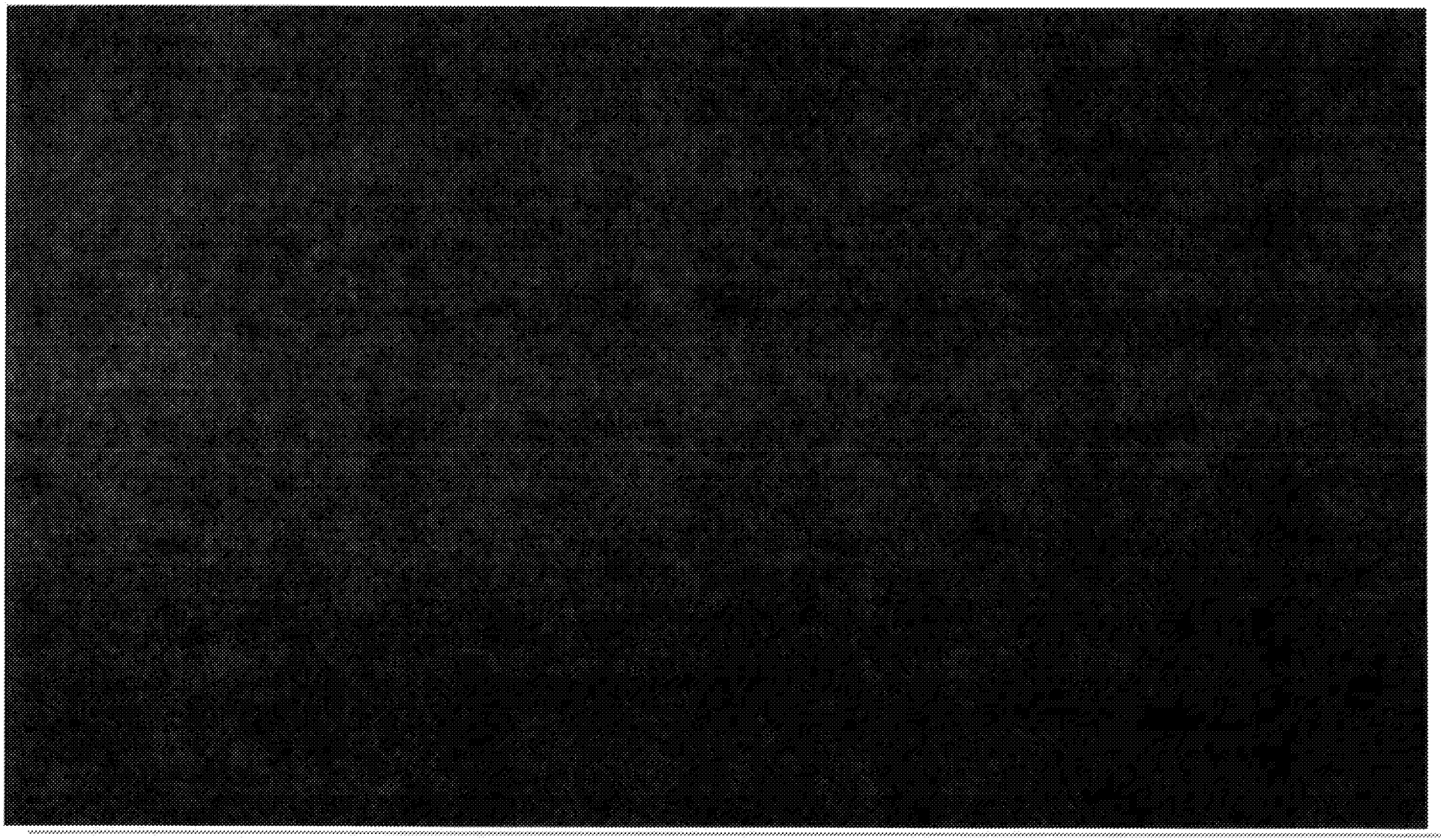
Assembly



Assembly

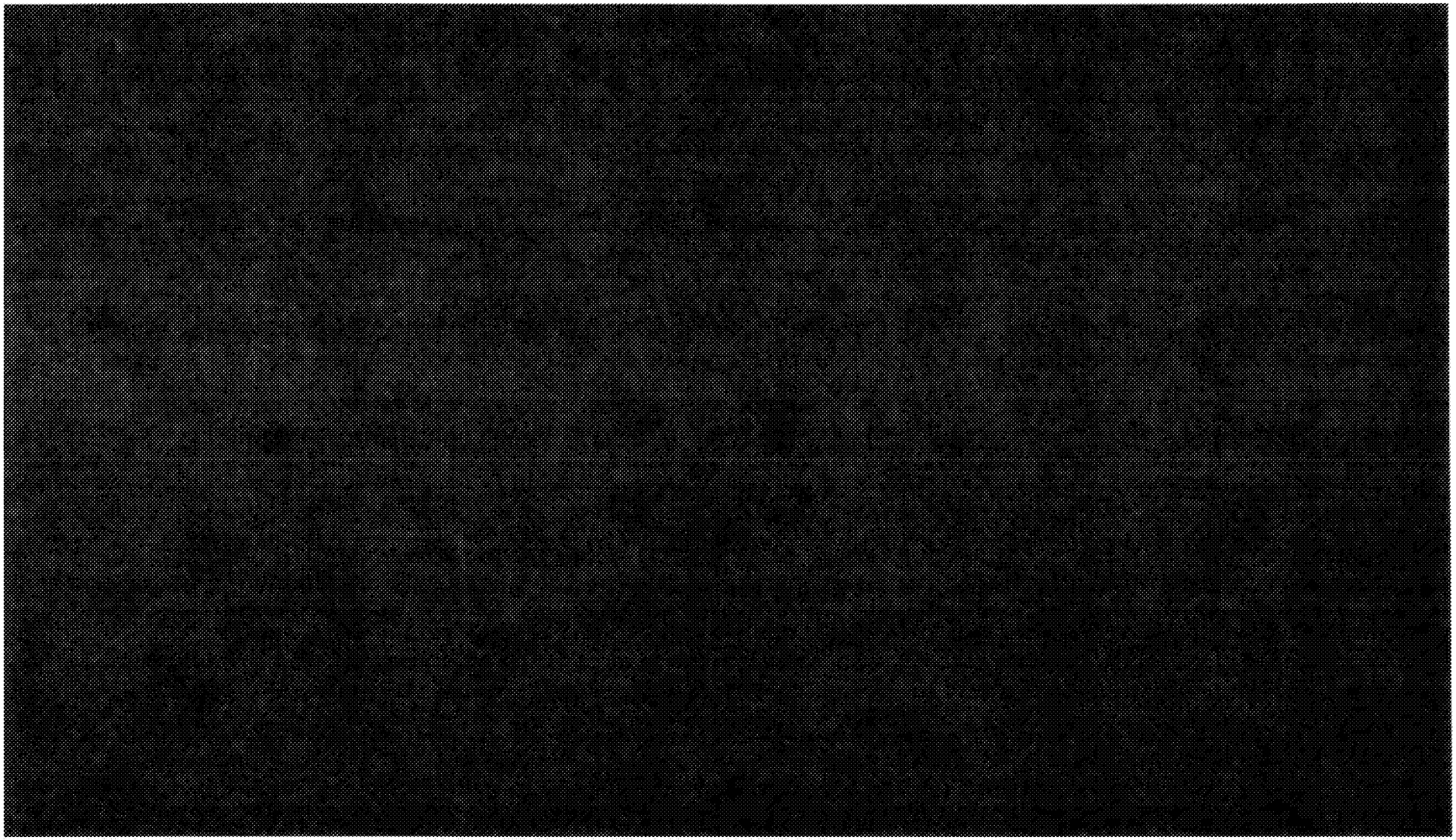


EXHIBIT 3

To: Redacted

From: Tuan Nguyen

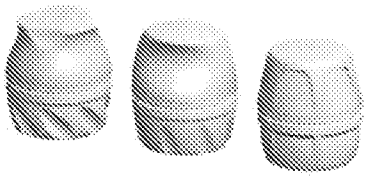
CC: Lou Pace, Redacted

Date: 30 July 2010

Re: Redacted Inserter and Advanced Process Status report

Key accomplishments in July

- Inserter:
  - Redacted Development Redacted
    - Redacted housing models ordered and received from Redacted Will review with R&D and Commercial team. Integrating functionality into Redacted models.
    - Preliminary meeting held with Redacted project management to discuss potential collaboration on rapid prototype and Redacted tools for the Redacted inserter.
    - Preliminary budgetary quotes from Redacted for inserter plastic parts are encouraging to meet cost target.
    - Assembly review meetings with process team and potential automation integrator Redacted
    - Design improvements stemming from FEA analysis and assembly considerations incorporated.
  - Redacted
    - Redacted



- On Body:
  - Sharp Redacted

Redacted

Needle: Redacted

- Adhesive Patch Redacted
  - Drawings updated: Redacted

Redacted

Redacted

- Sensor A Redacted
- Sensor B Redacted
- Sensor C Redacted
- Redacted
- Advanced Process:
  - Sterilization: Redacted
- Redacted

Redacted

Redacted

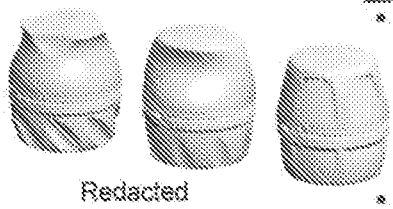
EXHIBIT 4

Abbott
Diabetes Care

To:	Redacted
From:	Tuan Nguyen
CC:	Lou Pace, Redacted
Date:	27 Aug 2010
Re:	Redacted Inserter and Advanced Process Status report

Key accomplishments in August

- Inserter:
  - Redacted Development Redacted Redacted
    - Ongoing refinements to preferred model
    - Cap details in progress: sealing to housing, thread geometry, seal sizes, Redacted
    - Sheath shipping lock-out features under consideration.



Redacted

  - Redacted
  - On Body:
    - Redacted sharp Redacted
    - Insertion study completed with final geometry selected Redacted

Redacted

Redacted

- Adhesive Patch Redacted
- Redacted
- Redacted
- Redacted
- Sensor Connection to PCB Redacted

Redacted

- Redacted

Redacted

- Redacted

- Redacted
  - Redacted
    - Sensor A – Redacted
    - Sensor B – Redacted
    - Sensor C – Redacted
  - Redacted

- Redacted

- Redacted

- Advanced Process Redacted
    - Sterilization:

Redacted

Redacted

Redacted

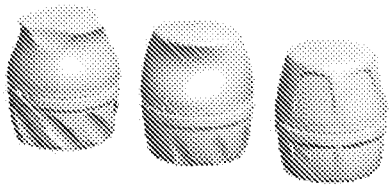
EXHIBIT 5

Abbott
Diabetes Care

To:	Redacted
From:	Tuan Nguyen
CC:	Lou Pace; Redacted
Date:	30 Sep 2010
Re:	Redacted PDU and Advanced Process Status report

Key accomplishments in September

- Inserter:
  - Redacted Development Redacted
    - Improvements for insertion guidance and puck/sharp stability incorporated.
    - Internal and external group design reviews performed to okay design for prototype tooling.
    - Redacted . Received quote for all components except for the cap which is a no-quote due to molding features not feasible for quick turn tool. Waiting for cap design and sealing feedback and response from Redacted
    - Final design tweaks for Housing/Cap interface in progress with Redacted
  - Redacted



Redacted

- On Body:
  - Redacted sharp Redacted
    - Final geometry selected is Redacted
      Next round of parts will include the selected design plus proposed design improvements Redacted and manufacturing improvements Redacted
  - Redacted
    -
      - Cost estimate Redacted
      -
  - Adhesive Patch Redacted
  - Redacted

Redacted

- Sensor Connection to PCB Redacted

- On/Body Electronics:
  - Lower Cost ASIC Specification is in process. Goal is to get it to a point where we can re-quote the ASIC by end of October.
  - Negotiations with Redacted progressed. Redacted An updated spec will be sent to them during the week of Sept 27th.
  - More detail is required to understand system level functions to be added to the specification.
  - Redacted samples are ready to ship from Redacted
- Redacted
- Redacted
  - Sensor A – Redacted
  - Sensor B – Redacted
  - Sensor C – Redacted
- Redacted

Redacted

- Advanced Process Redacted
  - Sterilization:

Redacted

Redacted

Redacted

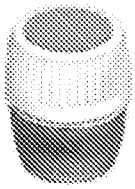
Redacted

EXHIBIT 6

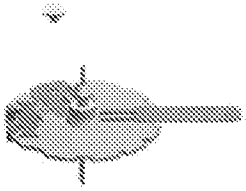
To: Redacted
From: Tuan Nguyen
CC: Lou Pace; Redacted
Date: 28 Oct 2010
Re: Redacted PDU and Advanced Process Status report

Key accomplishments in period:

- PDU:
  - Integration Platform A Redacted
    - SLA mockups of larger puck diameter Redacted and height Redacted have been circulated for review, along with mockups of the maximum allowed by the Redacted Product Profile.
    - PCBA: Redacted . In progress.
    - Redacted
    -
    -
- Inserter:
  - Redacted Development Redacted :
    - Redacted iterations completed and design selected. Redacted Redacted
    - Design review completed with program management.
    - Redacted soft tool quotation received and OK to Tool is expected early November.
  - Inserter pain and bleeding study Redacted
    - Plan outlined to use Redacted inserter with dummy pucks
    - Redacted sterilization and packaging are being investigated.
    - Needles and sharps with hub designs Redacted are being finalized.
    - Test matrix is being defined, potentially evaluating Redacted Redacted various Redacted geometries.
    -
- On Body:
  - Redacted



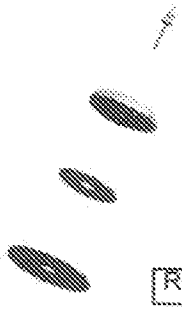
- Sensor Connection to PCB [Redacted]



[Redacted]

- [Redacted] sharp [Redacted]

- [Redacted]



- Adhesive Patch [Redacted]

[Redacted]

- [Redacted]

- [Redacted]

- [Redacted]

Redacted

- On/Body Electronics Redacted Redacted
  - Conference call meeting with engineers. Decision to obtain quotes for two variations of the Redacted architecture approach.
  - ASIC specification has been refined with a detailed proposal for the Redacted architecture approach with two variations.
  - ASIC Error budget spreadsheet is fully populated. Redacted
  - Redacted Redacted
  - Refined designs for Platform-A and Platform-B Redacted Redacted
- Redacted

- Redact Sensor A –
- Sensor B –
- Sensor C –

Redacted Redacted Redacted Redacted

- Advanced Process Redacted

Redacted

Sterilization:

Redacted

Redacted

Redacted

EXHIBIT 7

To: Redacted

From: Tuan Nguyen

CC: Lou Pace; Redacted

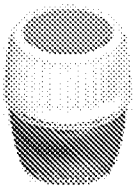
Date: Dec 5 2010

Re: Redacted PDU and Advanced Process Status report

Key accomplishments in December

- PDU:
  - Integration Platform A Redacted
    - New Puck Layout has been designed and reviewed, Redacted Redacted . Mold is being quoted, and delivery schedule details are being finalized Redacted
    - A new Sensor Support Tool has been ordered, due early Jan. Redacted Redacted
    - PCB layout has been defined (mechanically), and pcb detail design is being completed Redacted
    - PCB electrical design is Redacted Redacted Redacted
    - Redacted

- Inserter:
  - Redacted Development Redacted
    - Redacted soft tooled parts have been received. Redacted system has been assembled and testing has started.
    - Minor changes for improvement have been identified and tooling changes have started, samples expected early Dec for verification
  - Inserter pain and bleeding study Redacted Redacted



- On Body:
  - Redacted

- Sensor Connection to PCB Redacted
  - Redacted

Redacted

- Redacted sharp Redacted
  Redacted

- Adhesive Patch Redacted
  - Study completed

Redacted
Redacted

Redacted

- On/Body Electronics Redacted Redacted
  - Conference call meeting with engineers. Agreement on refined version of the specification was reached Redacted . No change is expected to cost.
  - Key changes to ASIC specification: We will proceed with the architecture Redacted
  - Updated ASIC Error budget spreadsheet has been reviewed and agreed to both Redacted
  - Sensor contact layout that includes Redacted has been agreed for Platform-A and Platform-B Redacted
  - Some progress was made on the Redacted budget. More detail is still required.
  - Redacted
- Redacted

Redacted

- Redacted Sensor A – Redacted
- Redacted Sensor B – Redacted

- Sensor C – Redacted
- Redacted

- Advanced Process Redacted

Redacted Sterilization:

Redacted

Redacted

Redacted

Redacted

EXHIBIT 8

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
61/411,262	11/08/2010		760	031312-06899		

CONFIRMATION NO. 1235

90259
Hughes Hubbard and Reed LLP
One Battery Park Plaza
New York, NY 10004

FILING RECEIPT

OC000000044682354

Date Mailed: 12/01/2010

Receipt is acknowledged of this provisional patent application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, 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 Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections 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**

Applicant(s)

Manuel L. Donnay, San Francisco, CA;

Power of Attorney:
David Schalk--60527

If Required, Foreign Filing License Granted: 11/24/2010

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 61/411,262**

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

Title

MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

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

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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 (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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PTO/SB/16 (11-08)
Approved for use through 09/30/2010 OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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Provisional Application for Patent Cover Sheet

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c)

Inventor(s)

Inventor 1 — Remove

Given Name	Middle Name	Family Name	City	State	Country i
Manuel	L.	Donnay	San Francisco	CA	US

All Inventors Must Be Listed – Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. — Add

Title of Invention	MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES
Attorney Docket Number (if applicable)	031312-06899

Correspondence Address

Direct all correspondence to (select one):

(•) The address corresponding to Customer Number	( ) Firm or Individual Name
Customer Number	90259

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

(•) No.

( ) Yes, the name of the U.S. Government agency and the Government contract number are:

PTO/SB/16 (11-08)
Approved for use through 09/30/2010 OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number

Entity Status

Applicant claims small entity status under 37 CFR 1.27

◯ Yes, applicant qualifies for small entity status under 37 CFR 1.27

◉ No

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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 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 CFR1.14). 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.

Signature

Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/David Schalk/			Date (YYYY-MM-DD)	2010-11-08
First Name	David	Last Name	Schalk	Registration Number (If appropriate)	60527

This collection of information is required by 37 CFR 1.51. 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 8 hours 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. **This form can only be used when in conjunction with EFS-Web. If this form is mailed to the USPTO, it may cause delays in handling the provisional application.**

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

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

MEDICAL DEVICE INSERTERS AND PROCESSES OF INSERTING AND USING MEDICAL DEVICES

BACKGROUND OF THE INVENTION

[0001] Diabetes Mellitus is an incurable chronic disease in which the body does not produce or properly utilize insulin. Insulin is a hormone produced by the pancreas that regulates blood sugar (glucose). In particular, when blood sugar levels rise, *e.g.*, after a meal, insulin lowers the blood sugar levels by facilitating blood glucose to move from the blood into the body cells. Thus, when the pancreas does not produce sufficient insulin (a condition known as Type 1 Diabetes) or does not properly utilize insulin (a condition known as Type 2 Diabetes), the blood glucose remains in the blood, resulting in hyperglycemia or abnormally high blood sugar levels.

[0002] The fluctuations in blood glucose levels in people suffering from diabetes cause long-term, serious complications. Some of these complications include blindness, kidney failure, and nerve damage. Additionally, it is known that diabetes is a factor in accelerating cardiovascular diseases such as atherosclerosis (hardening of the arteries), leading to stroke, coronary heart disease, and other diseases. Accordingly, one important and universal strategy in managing diabetes is to control blood glucose levels.

[0003] One way to manage blood glucose levels is testing and monitoring blood glucose levels by using conventional *in vitro* techniques, such as drawing blood samples, applying the blood to a test strip, and determining the blood glucose level using colorimetric, electrochemical, or photometric test meters. Another more recent technique for monitoring blood glucose levels is by using an *in vivo* glucose-monitoring system, that continuously and/or automatically tests glucose, such as, for example, the FreeStyle Navigator® Continuous Glucose Monitoring

System, manufactured by Abbott Diabetes Care, Inc. Unlike conventional blood glucose meters, continuous analyte-monitoring systems employ a sensor at least a portion of which is positioned in a subject, which detects and monitors blood glucose levels. Prior to each use of a new sensor, the user self-inserts at least a portion of the sensor under his/her skin. An inserter assembly may be employed to insert the sensor in the body of the user. In this manner, an introducer sharp, while engaged to the sensor, pierces an opening into the skin of the user, releases the sensor, and is removed from the body of the user. Accordingly, there exists a need for an easy-to-use, simple, insertion assembly that is reliable, minimizes pain, and is easy to use.

SUMMARY

[0004] Sensors for detecting a physical parameter of a subject are disclosed herein. In some embodiments, a sensor is used to determine a level of analyte, such as, *e.g.*, glucose. Devices are disclosed for inserting a sensor into a subject, *e.g.*, at least partially beneath the skin of a subject. Sensor assemblies that include a medical device, such as a sensor and/or an infusion device, and a device to position at least a portion of the medical device are provided, as well as methods of positioning at least a portion of a medical device such as a sensor (*e.g.*, a glucose sensor) and/or an infusion device, and methods of using a positioned medical device, *e.g.*, methods for analyte testing are disclosed herein.

[0005] Sensor assembly embodiments include a housing adapted to adhere to the skin of a subject; an analyte sensor coupled or coupleable to the housing; and an insertion sharp having a longitudinal body including a longitudinal opening to receive at least a portion of the sensor. In some embodiments, the insertion sharp and analyte sensor may be retained in the sensor housing

using a resilient member, such as a spherical or ball-shaped member, press-fit into the sensor housing.

[0006] In certain embodiments, the sensor includes a body having a proximal section and a distal section, and the distal section may be longitudinally (or otherwise) aligned with the proximal section. Some sensor embodiments may include an intermediate section. An intermediate section, if present, may or may not be laterally displaced from at least the distal member, and a gap may be defined between the laterally displaced intermediate section and a portion of the distal section. A second gap may be defined in the sensor between the proximal section and the laterally displaced intermediate section. The proximal section of the sensor may have a substantially curved profile. A proximal section and a distal section of a given sensor may or may not be in axial alignment with respect to each other.

[0007] In some embodiments, the distal section of the sensor body is received in the longitudinally defined opening of the insertion sharp. A gap may be defined between the distal section and the laterally displaced intermediate section, which allows the distal section, in some embodiments a substantial portion – – including the entirety of the distal section – – to be received in the longitudinal opening of the insertion needle. The intermediate section and the proximal section may be proximate the distal section received in the insertion needle.

[0008] In some embodiments, the proximal section of the sensor may be disposed in a horizontal plane, and the distal section of the sensor body may be disposed in a vertical plane, at least during a sensing operation. In some embodiments, the sensor is configured for insertion in a soft tissue of a user. In some embodiments, the sensor is a glucose sensor.

[0009] Embodiments include sensor assemblies which include a sensor including a portion for operative contact with a fluid of the subject; a housing defining a distal surface adapted for attachment to the skin of a subject and housing a circuit coupled to sensor for performing a function with the sensor. In some embodiments, the sensor is integrated with the circuit within the housing to define an on-body device such as a single-unit on-body device. In some embodiments, a switch is provided at least partially disposed in the housing and having a member defining a first position which protrudes from the distal surface of the mount and a second position which is recessed in the mount, the member configured to activate the circuit when in the second position.

[0010] In some embodiments, the member is biased in the first position. The member may include an elongated member disposed in an opening in the mount. In some embodiments, the member is moved from the first position to the second position when the mount contacts the skin of the subject. In some embodiments, an adhesive layer is disposed on the skin of the subject, and wherein the member is moved from the first position to the second position when the mount contacts the adhesive layer.

[0011] In some embodiments, the switch activates the circuit upon the member reaching the second position. In some embodiments, the switch activates the circuit as long as the member is maintained in the second position. In some embodiments, the sensor is a glucose sensor.

[0012] In some embodiments, the circuit applies a potential to the sensor. In some embodiments, the circuit applies a current to the sensor.

[0013] Embodiments include apparatuses for inserting medical devices at least partially through the skin of a subject. An insertion apparatus may include a sheath defining a distal

surface for placement on the skin of the subject; a device support movable between a proximal and distal position, and adapted to support a medical device; a sharp support movable between a proximal position and a distal position, and adapted to support a sharp extending through a portion of the device support; a handle movable between a proximal position and distal position relative to the sheath and adapted to urge the device support and the sharp support from a proximal to a distal position. In some embodiments, the handle defines guides for slidable engagement with the sharp support and/or the device support. In some embodiments, a driver biases the handle towards the proximal position.

[0014] In some embodiments, the user attaches the inserter to the skin, pressing on the sheath to secure the device adhesively to the skin. The handle is pressed distally urging the device and sharp support into the skin and at the same time energizes the driver element. Once the handle is bottomed out and the medical device placed with respect to the skin, the user releases pressure on the handle. The driver element retracts the device and sharp support, while the device is left coupled to the skin (either mechanically or adhesively). The sharp is retracted from the skin, and the inserter device can be removed.

[0015] In variations of the above embodiment, the driver includes a compression member such as a compression spring. The handle is at least partially disposed within the sheath or is at least partially disposed surrounding the sheath. The sharp support may be permanently fixed to the handle. The device support may be permanently affixed to the handle.

[0016] In some embodiments, a stop portion for retaining the device support in the distal position is included. In some embodiments, the device support is coupled to the sharp support until the device support reaches a distal position.

[0017] In some embodiments, the device support is uncoupled from the sharp support when the device support reaches the distal position. In some embodiments, a retention member is provided to couple the sharp support to the sheath when the sharp support is disposed in the proximal position.

[0018] In some embodiments, the medical device is an analyte sensor. In some embodiments, the medical device is a glucose sensor. In some embodiments, the medical device is an infusion set.

[0019] In certain embodiments, apparatuses for inserting a medical device at least partially through the skin of a subject are provided which include a sheath defining a distal surface for placement on the skin of the subject; a handle movable between a proximal position and distal position; a device support for supporting the medical device and defining an aperture therethrough, the device support coupled to the handle; a sharp support for supporting a sharp extending through said aperture and coupled to the device support; and driver for biasing the sharp support towards the proximal position.

[0020] In some embodiments, the driver includes a compression spring. In some embodiments, the handle is at least partially disposed surrounding the sheath.

[0021] In some embodiments, a stop portion for retaining the device support in the distal position is included. In some embodiments, the device support is coupled to the handle until the device support reaches a distal position. In some embodiments, the device support is uncoupled from the sharp support when the device support reaches the distal position.

[0022] Embodiments of analyte sensors are provided which include a body having a proximal section and a distal section. The distal section may be longitudinally aligned with the proximal section. An intermediate section may be included between the proximal and distal sections, and in some embodiments the intermediate section is laterally displaced from at least the distal member. A gap may be defined between the laterally displaced intermediate section and a portion of the distal section.

[0023] In some embodiments, the proximal end is received within a needle seat to create an anchor region to allow the sensor body to slide into an opening defined in the insertion sharp but prevent the sensor body from inadvertently slipping out of the insertion needle. In some embodiments, a width of the distal section of the sensor body is sized to fit within the opening of the insertion sharp. In certain embodiments, the opening in the sharp has a diameter of about 20 to about 26 gauge, *e.g.*, 21 gauge to about 25 gauge, where in certain embodiments the sharp is 21 gauge or 23 gauge or 25 gauge. Such sharp may be used with a sensor having a width or diameter – – at least the portion that is carried by the sharp – – of about .20 mm to about .80 mm, *e.g.*, about .25 mm to about .60 mm, where in some embodiments the width or diameter of at least a portion of a sensor is .27 mm or .33 mm or .58 mm.

[0024] In some embodiments, the intermediate member includes a plane-altering portion. The plane-altering portion allows the proximal section of the sensor body to be in a plane different than the distal section of the sensor body. In some embodiments, the proximal section and the distal section are in planes substantially perpendicular to each other, *e.g.*, the area may define an angle of about 120° to about 60°, *e.g.*, about 90°.

[0025] In some embodiments, the proximal section has a curved portion.

[0026] In some embodiments, the sensor body includes conductive material disposed in or on a surface thereto to define one or more electrodes. The sensor body may include conductive material defining traces disposed in or on a surface of the sensor body. The traces are in communication with the one or more electrodes. The traces may be disposed in or on at least one surface of the proximal section of the sensor body. The one or more electrodes may be disposed on the distal section of the sensor body. At least one of the traces or electrodes may include a metal or carbon material such as gold, platinum, titanium, and carbon. At least one of the traces or electrodes may be formed by ablation of material. The ablation may include laser ablation. In some embodiments, the sensor is a wire.

[0027] In some embodiments, the sensor includes a sensing layer. The sensing layer may include an enzyme. The sensing layer may include an electron transfer agent. The electron transfer agent may be a redox mediator. In some embodiments, the electron transfer agent includes osmium transition metal complexes and one or more ligands. The electron transfer agent may be configured to transfer electrons directly between the analyte and the working electrode. The electron transfer agent may be configured to transfer electrons indirectly between the analyte and the working electrode.

[0028] In some embodiments, the sensing layer includes a redox polymer. The redox polymer may include osmium. The sensing layer may include a catalyst. The catalyst may include an enzyme. The catalyst may act as an electron transfer agent. In some embodiments, the enzyme includes glucose oxidase. In some embodiments, the enzyme includes glucose dehydrogenase.

[0029] In some embodiments, the sensing layer is configured such that the reaction of glucose in the presence of an enzyme forms hydrogen peroxide, and glucose level may be correlated to the level of hydrogen peroxide. In some embodiments, the sensor is a subcutaneous sensor.

[0030] These and other features, objects, and advantages of the disclosed subject matter will become apparent to those persons skilled in the art upon reading the detailed description as more fully described below.

BRIEF DESCRIPTION OF THE DRAWINGS

[0031] A detailed description of various aspects, features, and embodiments of the subject matter described herein is provided with reference to the accompanying drawings, which are briefly described below. The drawings are illustrative and are not necessarily drawn to scale, with some components and features being exaggerated for clarity. The drawings illustrate various aspects and features of the present subject matter and may illustrate one or more embodiment(s) or example(s) of the present subject matter in whole or in part.

[0032] **FIGURE 1A** is a schematic view of the system in accordance with one embodiment of the disclosed subject matter;

[0033] **FIGURE 1B** illustrates analyte monitoring system for real time analyte (*e.g.*, glucose) measurement, data acquisition and/or processing in certain embodiments

[0034] **FIGURE 2** is a view, in partial cross section, of an electrochemical sensor in accordance with one embodiment of the disclosed subject matter;

[0035] **FIGURE 3** is a view, in partial cross-section, of an electrochemical sensor in accordance with another embodiment of the disclosed subject matter;

[0036] **FIGURE 4** is a view of the electrochemical sensor of FIGURE 3 in a folded configuration in accordance with the disclosed subject matter;

[0037] **FIGURE 5A** is a view of an electrochemical sensor in accordance with a further embodiment of the disclosed subject matter;

[0038] **FIGURE 5B** is a view of the electrochemical sensor of FIGURE 5 in a folded configuration in accordance with the disclosed subject matter;

[0039] **FIGURES 6A-6B** are views of an electrochemical sensor in accordance with a further embodiment of the disclosed subject matter;

[0040] **FIGURE 7** is a perspective view of an on-body unit in accordance with one embodiment of the disclosed subject matter;

[0041] **FIGURE 8** is a perspective view in partial cross-section of an on-body unit of FIGURE 7 in accordance with the disclosed subject matter;

[0042] **FIGURE 9** is a schematic view of the system in accordance with one embodiment of the disclosed subject matter;

[0043] **FIGURE 10** is a sectional, perspective view of another embodiment of an inserter in accordance with the disclosed subject matter;

[0044] **FIGURES 11-12** are perspective views of components of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0045] **FIGURE 13** is a sectional, perspective view of a component of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0046] **FIGURES 14-15** are perspective views of components of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0047] **FIGURE 16** is a sectional view of the component of FIGURE 15 in accordance with the disclosed subject matter;

[0048] **FIGURES 17-18** are schematic views of a needle hub in accordance with one embodiment of the disclosed subject matter;

[0049] **FIGURE 19** is a distal end view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0050] **FIGURE 20** is a side view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0051] **FIGURE 21** is a side view of a sharp in accordance with one embodiment of the disclosed subject matter;

[0052] **FIGURE 21A** is a perspective view with parts separated of an inserter in accordance with one embodiment of the disclosed subject matter;

[0053] **FIGURE 21B** is a schematic view of an alternate embodiment for forming a sharp to be used in an inserter in accordance with one embodiment of the disclosed subject matter;

[0054] **FIGURE 22** is a perspective view of an inserter in accordance with one embodiment of the disclosed subject matter;

[0055] **FIGURE 23** is a perspective view with parts separated of an inserter in accordance with one embodiment of the disclosed subject matter;

[0056] **FIGURE 24** is an enlarged sectional view with parts separated of an inserter in accordance with one embodiment of the disclosed subject matter;

[0057] **FIGURES 24A-24C** depict an alternative method for retaining a sharp and sensor within the sensor housing;

[0058] **FIGURES 25-27** are perspective views of components of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0059] **FIGURES 28-29** are sectional views of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0060] **FIGURES 30-31** are sectional views of components of the inserter of FIGURE 10 in accordance with the disclosed subject matter;

[0061] **FIGURE 31A** is a sectional view of components of the inserter of FIGURE 10 shown separated from the on-body unit in accordance with the disclosed subject matter.

[0062] **FIGURES 32-33** illustrate, by schematic, a power supply switch mechanism including conductive plug of the on-body integrated sensor and sensor electronics assembly in accordance with embodiments of the disclosed subject matter;

[0063] **FIGURE 34** is a perspective view of an embodiment of an inserter in accordance with one embodiment of the disclosed subject matter;

[0064] **FIGURES 35-36** are perspective views of the inserter of FIGURE 34 in accordance with the disclosed subject matter;

[0065] **FIGURES 37-39** are sectional, perspective views of the inserter of FIGURE 34 in accordance with the disclosed subject matter;

[0066] **FIGURES 40-41** are perspective views of the inserter of FIGURE 34 in accordance with the disclosed subject matter;

[0067] **FIGURES 42-43** are perspective views of another embodiment of an inserter in accordance with the disclosed subject matter;

[0068] **FIGURES 44-49** are perspective views of components of the inserter of FIGURE 42 in accordance with the disclosed subject matter;

[0069] **FIGURE 50** is a sectional view of the inserter of FIGURE 42 in accordance with the disclosed subject matter;

[0070] **FIGURE 51** is a sectional, perspective view of the inserter of Figure 42 in accordance with the disclosed subject matter;

[0071] **FIGURE 52** is a perspective view of the inserter of FIGURE 42 in accordance with the disclosed subject matter;

[0072] **FIGURES 53-54** are sectional, perspective views of the inserter of FIGURE 42 in accordance with the disclosed subject matter;

[0073] **FIGURES 55-56** are perspective views of the inserter of FIGURE 42 in accordance with the disclosed subject matter;

[0074] **FIGURES 57-58** are perspective views of another embodiment of an inserter in accordance with the disclosed subject matter;

[0075] **FIGURES 59-63** are perspective views of components of the inserter of FIGURE 57 in accordance with the disclosed subject matter;

[0076] **FIGURE 64** is a sectional views of the inserter of FIGURE 57 in accordance with the disclosed subject matter;

[0077] **FIGURES 65-67** are sectional, perspective views of the inserter of Figure 57 in accordance with the disclosed subject matter;

[0078] **FIGURE 68** is a perspective view of another embodiment of an inserter In accordance with the disclosed subject matter;

[0079] **FIGURE 69** is a side view of the inserter of FIGURE 68 in accordance with the disclosed subject matter;

[0080] **FIGURES 70-71** are cross-sectional views of the inserter of FIGURE 68 in accordance with the disclosed subject matter;

[0081] **FIGURE 72** is a cross-sectional view of another inserter in accordance with the disclosed subject matter;

[0082] **FIGURE 72A** is an exploded perspective view of the inserter of FIGURE 72 in accordance with the disclosed subject matter;

[0083] **FIGURES 72B-I** are perspective views of the inserter of FIGURE 72 showing the assembly of various components in accordance with the disclosed subject matter;

[0084] **FIGURES 72J-N** are cross-sectional views of the inserter of FIGURE 72 in accordance with the disclosed subject matter;

[0085] **FIGURE 72O** illustrates a process for utilizing a sterilized versions of the inserter of FIGURE 72 in accordance with the disclosed subject matter;

[0086] **FIGURE 72P** illustrates an alternate process for utilizing a sterilized versions of the inserter of FIGURE 72 in accordance with the disclosed subject matter;

[0087] **FIGURE 73** is a perspective view of another inserter in accordance with the disclosed subject matter;

[0088] **FIGURE 73A** is a perspective view of a component of the inserter of FIGURE 73 in accordance with the disclosed subject matter;

[0089] **FIGURE 73B** is a cross-sectional view of a component of the inserter of FIGURE 73 in accordance with the disclosed subject matter;

[0090] **FIGURES 73C-G** are perspective views of a components of the inserter of FIGURE 73 in accordance with the disclosed subject matter;

[0091] **FIGURES 73H-N** are cross-sectional views of the inserter of FIGURE 73 in accordance with the disclosed subject matter;

[0092] **FIGURE 73O** illustrates a process for utilizing a sterilized versions of the inserter of FIGURE 72 in accordance with the disclosed subject matter;

[0093] **FIGURE 74** is a perspective view of another inserter in accordance with the disclosed subject matter;

[0094] **FIGURES 75-82** are additional views of the components of the inserter of FIGURE 74 in accordance with the disclosed subject matter;

[0095] **FIGURE 83-88** are cross-sectional views of the inserter of FIGURE 73 in accordance with the disclosed subject matter; and

[0096] **FIGURES 89-90** are views of an alternate embodiment of the inserter of FIGURE 73 in accordance with the disclosed subject matter.

[0097] **Figures 91-103** are views of an alternate embodiment of the inserter of FIGURE 73 in accordance with the disclosed subject matter.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0098] A detailed description of the disclosure is provided herein. It should be understood, in connection with the following description, that the subject matter is not limited to particular embodiments described, as the particular embodiments of the subject matter may, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the disclosed subject matter will be limited only by the appended claims.

[0099] Where a range of values is provided, it is understood that each intervening value between the upper and lower limit of that range, and any other stated or intervening value in that stated range, is encompassed within the disclosed subject matter. Every range stated is also intended to specifically disclose each and every "subrange" of the stated range. That is, each and every range smaller than the outside range specified by the outside upper and outside lower limits given for a range, whose upper and lower limits are within the range from said outside lower limit to said outside upper limit (unless the context clearly dictates otherwise), is also to be understood as encompassed within the disclosed subject matter, subject to any specifically excluded range or limit within the stated range. Where a range is stated by specifying one or both of an upper and lower limit, ranges excluding either or both of those stated limits, or including one or both of them, are also encompassed within the disclosed subject matter, regardless of whether or not words such as "from," "to," "through," or "including" are or are not used in describing the range.

[00100] Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this disclosed

subject matter belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present disclosed subject matter, this disclosure may specifically mention certain exemplary methods and materials.

[00101] All publications mentioned in this disclosure are, unless otherwise specified, incorporated by reference herein for all purposes, including without limitation to disclose and describe the methods and/or materials in connection with which the publications are cited.

[00102] The publications discussed herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present disclosed subject matter is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates, which may need to be independently confirmed.

[00103] As used herein and in the appended claims, the singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

[00104] Nothing contained in the Abstract or the Summary should be understood as limiting the scope of the disclosure. The Abstract and the Summary are provided for bibliographic and convenience purposes and due to their formats and purposes should not be considered comprehensive.

[00105] As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present disclosed subject matter.

Any recited method can be carried out in the order of events recited, or in any other order which is logically possible. Reference to a singular item includes the possibility that there are plural of the same item present. When two or more items (for example, elements or processes) are referenced by an alternative "or," this indicates that either could be present separately or any combination of them could be present together except where the presence of one necessarily excludes the other or others.

System Overview

[00106] Embodiments include analyte monitors that are provided in small, lightweight, battery-powered and electronically-controlled systems. Such systems may be configured to detect physical parameters of subjects, such as signals indicative of *in vivo* analyte levels using an electrochemical sensor, and collect such signals, with or without processing. The electrochemical sensors may employ any suitable measurement technique, *e.g.*, may detect current, may employ potentiometry, etc. Techniques may include, but are not limited to amperometry, coulometry, and voltammetry. In some embodiments, sensing systems may be optical, colorimetric, and the like. In some embodiments, the portion of the system that performs this initial processing may be configured to provide the raw or at least initially processed data to another unit for further collection and/or processing. Such provision of data may be effected, for example, by a wired connection, such as an electrical, or by a wireless connection, such as an IR or RF connection.

[00107] Certain embodiments of analyte-monitoring systems for *in vivo* measurement employ a sensor that measures analyte levels in interstitial fluids at least partially under the surface of the subject's skin. A sensor in such a system may operate as an electrochemical cell. Such a sensor

may use any of a variety of electrode configurations, such as a three-electrode configuration (*e.g.,* with "working," "reference," and "counter" electrodes) driven by a controlled potential (potentiostat) analog circuit; a two-electrode system configuration (*e.g.,* with only working and counter electrodes or a working electrode and a counter/reference electrode), which may be self-biasing and/or self-powered; and/or other configurations (see, *e.g.*, U.S. Patent Application Serial No. 12/393,921, the disclosure of which is incorporated by reference herein for all purposes). In some embodiments, the sensor may be positioned within a blood vessel.

[00108] In certain systems, the analyte sensor is in communication with a sensor control unit. As used in this disclosure, an on-body unit sometimes refers to such a combination of an analyte sensor with such a sensor control unit. The on-body unit may include a housing in which the sensor control unit electronics and at least a portion of the sensor are received.

[00109] Certain embodiments are modular. The on-body unit may be separately provided as a physically distinct assembly from a monitor unit, *e.g.*, which displays or otherwise indicates analyte levels to a user. The on-body unit may be configured to provide the analyte levels detected by the sensor and/or other information (such as temperature, sensor life, etc.) over a communication link to the monitor unit. The monitor unit, in some embodiments, may include, *e.g.,* a mobile telephone device, an in vitro glucose meter, a personal digital assistant, or other consumer electronics such as MP3 device, camera, radio, personal computer, etc., or other communication-enabled data-processing device.

[00110] The monitor unit may perform a variety of functions such as but not limited to data storage and/or processing and/or analysis and/or communication, etc., on the received analyte data to generate information pertaining to the monitored analyte levels and/or process the other

information. The monitor unit may incorporate a display screen, which can be used, for example, to display measured analyte levels, and/or an audio component such as a speaker to audibly provide information to a user, and/or a vibration device to provide tactile feedback to a user. It is also useful for a user of an analyte-monitoring system to be able to see trend indications (including the magnitude and direction of any ongoing trend, *e.g.*, the rate of change of an analyte or other parameter, and the amount of time a subject is above and/or below a threshold, such as a hypoglycemic and/or hyperglycemic threshold, etc.); such data may be displayed either numerically, or by a visual indicator such as an arrow that may vary in visual attributes, like size, shape, color, animation, or direction. The monitor unit may further be adapted to receive information from or about an *in vitro* analyte test strip, which may be manually or automatically entered into the monitor unit. In some embodiments a monitor unit may incorporate an *in vitro* analyte test strip port and related electronics in order to be able to make discrete (*e.g.*, blood glucose) measurements using an *in vitro* test strip (see, *e.g.*, U.S. Patent No. 6,175,752, the disclosure of which is incorporated by reference herein for all purposes).

[00111] The modularity of these systems may vary where one or more components may be constructed to be single use and one or more may be constructed to be re-useable. In some embodiments the sensor is designed to be attachable and detachable from the sensor control unit (and the on-body unit may be reusable), *e.g.*, so that one or more of the components may be reused one or more times, while in other embodiments, the sensor and sensor control unit may be provided as an integrated, undetachable package, which may be designed to be disposable after use, *i.e.*, not re-used.

[00112] FIGURE 1A shows one embodiment of an analyte measurement system 10. In such a system, a data-processing unit or sensor control unit 12 may interact with an analyte sensor 14 to obtain signals representative of analyte levels. Sensor control unit 12 may further include communications circuitry with associated electronics (not shown). In some embodiments, the sensor control unit 12 and at least a portion of a sensor are configured to be maintained "on the body" of the subject, in the substantially same position on the body of the subject, for a period of time that may include hours, days, weeks, or a month or more. Accordingly, the sensor control unit 12 and sensor 14 may be referred to collectively herein as an on-body unit 16. A monitor unit 18 may also be provided. In the embodiment shown, sensor control unit 12 and monitor unit 18 communicate *via* connection 20 (in this embodiment, a wireless radio frequency (RF) connection). Communication may occur, *e.g.*, *via* RF communication, infrared communication, Bluetooth communication, Zigbee communication, 802.1x communication, or WiFi communication, etc. In some embodiments, the communication may include a radio frequency of 433 MHz, 13.56 MHz, or the like. In some embodiments, communication between sensor control unit 12 and monitor unit 18 may include radio frequency identification (RFID) techniques, and may be active RFID or passive RFID, where in some embodiments passive RFID technology and the respective system components include the necessary components therefor. For example, in certain embodiments, the on-body unit 16 and the monitor unit 18 may be configured to communicate using RFID communication protocol, wherein the on-body unit 16 may be configured to communicate or provide analyte-related signals to the monitor unit 18 based on the presence or reception of at least one signal from the monitor unit 18. That is, in certain embodiments, the monitor unit 18 may be configured to provide or radiate RF power signals, and when the on-body unit 16 is positioned within the radiated or provided RF signal

range radiated from the monitor unit 18, the on-body unit 16 in certain embodiments is configured to provide one or more signals associated with the monitored analyte level received from the analyte sensor 14 to the monitor unit 18. For example, in one embodiment, the monitor unit may include a backscatter RFID reader configured to transmit an RF field such that when the on-body unit is within the transmitted RF field, an antenna is tuned and in turn provides a reflected or response signal (for example, a backscatter signal) to the monitor unit. The reflected or response signal may include sampled analyte level data from the analyte sensor. Additional exemplary details for various embodiments can be found in, *e.g.*, U.S. Patent Application Serial No. 12/698,124 filed February 1, 2010, the disclosure of which is incorporated by reference herein for all purposes.

[00113] In some embodiments, a secondary monitor unit 22 may be provided. A data-processing terminal 24 may also be included, *e.g.*, for providing further processing or review of analyte data. In some embodiments, the secondary monitor unit 22 may include similar components and/or functionalities as the monitor unit 18, or alternatively, include more or less functionalities or components compared to the monitor unit 18 to, for example, analyze, process, store, and/or communicate data from the analyte sensor 14 and/or monitor unit 18.

[00114] In some embodiments, system 10 may be a continuous analyte monitor (*e.g.*, a continuous glucose-monitoring system or CGM), and accordingly operate in a mode in which the communications *via* connection 20 has sufficient range to support a flow of data from on-body unit 16 to monitor unit 18. In some embodiments, the data flow in a CGM system is automatically provided by the on-body unit 16 to the monitor unit 18. For example, no user intervention may be required for the on-body unit 16 to send the data to the monitor unit 18, *e.g.*,

it may be continually and/or automatically broadcasted. In some embodiments, the on-body unit 16 provides signal relating to analyte level to the monitor unit 18 automatically and periodically. For example, one or more signals may be provided, *e.g.*, automatically sent, on a schedule, *e.g.*, once every 250ms, once a second, once a minute, etc. That is, in certain embodiments, the on-body unit 16 may be configured and/or programmed to communicate or transmit the data acquired from the analyte sensor 14 based on a predetermined schedule, and continue to broadcast or transmit signals related to the real time monitored analyte levels based on the predetermined schedule. In such embodiments, the monitor unit 18 may be configured to receive and/or anticipate and acquire the transmitted signals from the on-body unit 16 based on the predetermined schedule, for example, for further processing, such as display, storing, analysis, and/or further data communication.

[00115] In some embodiments, one or more signals may be provided to the monitor unit 18 upon the occurrence of, or impending occurrence of, an event, *e.g.*, a hyperglycemic event or a hypoglycemic event, etc. In some embodiments, the one or more signals may be provided to the monitor unit 18 on an adaptive schedule. For example, the schedule for automatically communicating the one or more signals may be adjusted by machine learning techniques (*e.g.*, supervised learning techniques, unsupervised learning techniques, data mining, etc.) according to parameters received by the sensor control unit 12 and/or monitor unit 18, such as, *e.g.*, analyte values and trends, activity levels, meal times, etc.). In some embodiments, sensor control unit 12 may further include local memory in which it may record "logged data" or buffered data collected over a period of time and provide some or all of the accumulated data to monitor unit 18 from time-to-time. Or, a separate data-logging unit may be provided to acquire periodically provided data from sensor control unit 12. Data transmission in a CGM system may be one-way

communication, *e.g.*, the on-body unit 16 provides data to the monitor unit 18 without receiving signals from the monitor unit 18 In some embodiments, two-way communication is provided between the on-body unit 16 and the monitor unit 18, using, for example, one or more transceivers or other bi-directional communication components. Such two-way communication may be achieved in certain embodiments independently. That is, in certain embodiments, certain data communication from the on-body unit 16 may be independent of the data received from the monitor unit 18. In other embodiments, certain data communication from the on-body unit 16 may in response or responsive to the data, signal, request, or one or more commands received from the monitor unit 18.

[00116] In some embodiments, one or more signals may be provided to the monitor unit 18 from the on-body unit on user demand. According to such embodiments, the monitor unit 18 requests data from the on-body unit 16. Accordingly, embodiments include systems in which data is transferred from the on-body unit to the monitor unit only when the monitor unit invokes data from the on-body unit.

[00117] The data transfer request may be provided in several ways. For example, in some embodiments, one or both of the on-body unit 16 and monitor unit 18 may include a mechanical switch activatable by a user or activated upon some other action or event, the activation of which initiates the transfer of signal from the on-body unit 16 to the monitor unit 18. A mechanical switch may be provided which is activatable by the user to cause power to be turned on to the on-body system, *e.g.*, to electronic components that control the sensor.

[00118] In some embodiments, the monitor unit 18 is placed in close proximity (*e.g.*, within a range of about one to about ten inches or less in certain embodiments) with the communications

electronics of the on-body unit to cause initiation of data transfer from the on-body unit to the monitor unit, either over a wired connection, or wirelessly by various means, including, for example, various RF-carried encodings and protocols and IR links.

[00119] In some embodiments, a signal relating to analyte level is instantaneously generated by the analyte sensor 14 upon receipt of the request, and provided to the monitor unit 18 as requested.

[00120] In other embodiments, a signal relating to analyte level is obtained according to a schedule, *e.g.*, once every 250ms, once a second, once a minute, etc., and at least temporarily stored. Upon receipt of the data transfer request at the on-body unit 16 from the monitor unit 18, analyte-related information is provided to the monitor unit 18 from the on-body unit 16. In some cases, analyte-related information provided to the monitor unit 18 is or at least includes the most recent analyte signal(s).

[00121] In further embodiments, additional data is provided to the monitor unit 18 on demand. For example, analyte trend data may be provided. Such trend data may include two or more analyte data points to indicate that analyte levels are rising, falling, or stable. Analyte trend data may include data from longer periods of time, such as, *e.g.*, several minutes, several hours, several days, or several weeks.

[00122] For purpose of illustration, and not limitation, an exemplary analyte monitoring system is depicted in FIGURE 1B. FIGURE 1B shows an exemplary in vivo-based analyte monitoring system 1000 in accordance with embodiments of the present disclosure. As shown, in certain embodiments, analyte monitoring system 1000 includes on body electronics 1100 electrically coupled to in vivo analyte sensor 1010 (a proximal portion of which is shown in FIG.

1) and attached to adhesive layer 1400 for attachment on a skin surface on the body of a user. On body electronics 1100 includes on body housing 1190, that defines an interior compartment. Also shown in FIG. 1 is insertion device 1500 that, when operated, transcutaneously positions a portion of analyte sensor 1010 through a skin surface and in fluid contact with ISF , and positions on body electronics 1100 and adhesive layer 1400 on a skin surface In certain embodiments, on body electronics 1100, analyte sensor 1010 and adhesive layer 1400 are sealed within the housing of insertion device 1500 before use, and in certain embodiments, adhesive layer 1400 is also sealed within the housing or itself provides a terminal seal of the insertion device 1500. Devices, systems and methods that maybe used with embodiments herein are described, e.g., in U.S. Patent Application No. 12/698,129 and U.S. Provisional Application Nos. 61/238,646, 61/246,825, 61/247,516, 61/249,535, 61/317,243, 61/345,562, and 61/361,374, the disclosures of each of which are incorporated herein by reference for all purposes.

[00123] Referring back to the FIG. 1B, analyte monitoring system 1000 includes display device 120 which includes a display 1220 to output information to the user, an input component 1210 such as a button, actuator, a touch sensitive switch, a capacitive switch, pressure sensitive switch, jog wheel or the like, to input data or command to display device 1200 or otherwise control the operation of display device 1200. It is noted that some embodiments may include display-less devices or devices without any user interface components. These devices may be functionalized to store data as a data logger and/or provide a conduit to transfer data from on body electronics and/or a display-less device to another device and/or location. Embodiments will be described herein as display devices for exemplary purposes which are in no way intended to limit the embodiments of the present disclosure. It will be apparent that display-less devices may also be used in certain embodiments.

[00124] In certain embodiments, on body electronics 1100 may be configured to store some or all of the monitored analyte related data received from analyte sensor 1010 in a memory during the monitoring time period, and maintain it in memory until the usage period ends. In such embodiments, stored data is retrieved from on body electronics 1100 at the conclusion of the monitoring time period, for example, after removing analyte sensor 1010 from the user by detaching on body electronics 1100 from the skin surface where it was positioned during the monitoring time period. In such data logging configurations, real time monitored analyte level is not communicated to display device 1200 during the monitoring period or otherwise transmitted from on body electronics 1100, but rather, retrieved from on body electronics 1100 after the monitoring time period.

[00125] In certain embodiments, input component 1210 of display device 1200 may include a microphone and display device 1200 may include software configured to analyze audio input received from the microphone, such that functions and operation of the display device 1200 may be controlled by voice commands. In certain embodiments, an output component of display device 1200 includes a speaker for outputting information as audible signals. Similar voice responsive components such as a speaker, microphone and software routines to generate, process and store voice driven signals may be provided to on body electronics 1100.

[00126] In certain embodiments, display 1220 and input component 1210 may be integrated into a single component, for example a display that can detect the presence and location of a physical contact touch upon the display such as a touch screen user interface. In such embodiments, the user may control the operation of display device 1200 by utilizing a set of pre-programmed motion commands, including, but not limited to, single or double tapping the

display, dragging a finger or instrument across the display, motioning multiple fingers or instruments toward one another, motioning multiple fingers or instruments away from one another, etc. In certain embodiments, a display includes a touch screen having areas of pixels with single or dual function capacitive elements that serve as LCD elements and touch sensors.

[00127] Display device 1200 also includes data communication port 1230 for wired data communication with external devices such as remote terminal (personal computer) 1700, for example. Example embodiments of the data communication port 1230 include USB port, mini USB port, RS-232 port, Ethernet port, Firewire port, or other similar data communication ports configured to connect to the compatible data cables. Display device 1200 may also include an integrated in vitro glucose meter, including in vitro test strip port 1240 to receive an in vitro glucose test strip for performing in vitro blood glucose measurements.

[00128] Referring still to FIG. 1B, display 1220 in certain embodiments is configured to display a variety of information - some or all of which may be displayed at the same or different time on display 1220. In certain embodiments the displayed information is user-selectable so that a user can customize the information shown on a given display screen. Display 1220 may include but is not limited to graphical display 1380, for example, providing a graphical output of glucose values over a monitored time period (which may show important markers such as meals, exercise, sleep, heart rate, blood pressure, etc, numerical display 1320, for example, providing monitored glucose values (acquired or received in response to the request for the information), and trend or directional arrow display 1310 that indicates a rate of analyte change and/or a rate of the rate of analyte change, e.g., by moving locations on display 1220.

[00129] As further shown in FIG. 1, display 2220 may also include date display 1350 providing for example, date information for the user, time of day information display 1390 providing time of day information to the user, battery level indicator display 1330 which graphically shows the condition of the battery (rechargeable or disposable) of the display device 1200, sensor calibration status icon display 1340 for example, in monitoring systems that require periodic, routine or a predetermined number of user calibration events, notifying the user that the analyte sensor calibration is necessary, audio/vibratory settings icon display 1360 for displaying the status of the audio/vibratory output or alarm state, and wireless connectivity status icon display 1370 that provides indication of wireless communication connection with other devices such as on body electronics, data processing module 1600, and/or remote terminal 1700. As additionally shown in FIG. 1, display 122 may further include simulated touch screen button 1250, 1260 for accessing menus, changing display graph output configurations or otherwise for controlling the operation of display device 1200.

[00130] Referring back to FIG. 1, in certain embodiments, display 1220 of display device 1200 may be additionally, or instead of visual display, configured to output alarms notifications such as alarm and/or alert notifications, glucose values etc, which may be audible, tactile, or any combination thereof. In one aspect, the display device 1200 may include other output components such as a speaker, vibratory output component and the like to provide audible and/or vibratory output indication to the user in addition to the visual output indication provided on display 1220. Further details and other display embodiments can be found in, e.g., U.S. Patent Application No. 12/871,901, U.S. provisional application nos. 61/238,672, 61/247,541, 61/297,625, the disclosures of each of which are incorporated herein by reference for all purposes.

[00131] After the positioning of on body electronics 110 on the skin surface and analyte sensor 1010 in vivo to establish fluid contact with ISF (or other appropriate body fluid), on body electronics 1100 in certain embodiments is configured to wirelessly communicate analyte related data (such as, for example, data corresponding to monitored analyte level and/or monitored temperature data, and/or stored historical analyte related data) when on body electronics 1100 receives a command or request signal from display device 1200. In certain embodiments, on body electronics 1100 may be configured to at least periodically broadcast real time data associated with monitored analyte level which is received by display device 1200 when display device 1200 is within communication range of the data broadcast from on body electronics 1100, i.e., it does not need a command or request from a display device to send information.

[00132] For example, display device 1200 may be configured to transmit one or more commands to on body electronics 1100 to initiate data transfer, and in response, on body electronics 1100 may be configured to wirelessly transmit stored analyte related data collected during the monitoring time period to display device 1200. Display device 1200 may in turn be connected to a remote terminal 1700 such as a personal computer and functions as a data conduit to transfer the stored analyte level information from the on body electronics 1100 to remote terminal 1700. In certain embodiments, the received data from the on body electronics 1100 may be stored (permanently or temporarily) in one or more memory of the display device 1200. In certain other embodiments, display device 1200 is configured as a data conduit to pass the data received from on body electronics 1100 to remote terminal 1700 that is connected to display device 1200.

[00133] Referring still to FIG. 1, also shown in analyte monitoring system 1000 are data processing module 1600 and remote terminal 1700. Remote terminal 1700 may include a personal computer, a server terminal a laptop computer or other suitable data processing devices including software for data management and analysis and communication with the components in the analyte monitoring system 1000. For example, remote terminal 1700 may be connected to a local area network (LAN), a wide area network (WAN), or other data network for uni-directional or bi-directional data communication between remote terminal 1700 and display device 1200 and/or data processing module 1600.

[00134] Remote terminal 1700 in certain embodiments may include one or more computer terminals located at a physician's office or a hospital. For example, remote terminal 1700 may be located at a location other than the location of display device 1200. Remote terminal 1700 and display device 1200 could be in different rooms or different buildings. Remote terminal 1700 and display device 1200 could be at least about one mile apart, e.g., at least about 100 miles apart, e.g., at least about 1000 miles apart. For example, remote terminal 1700 could be in the same city as display device 1200, remote terminal 1700 could be in a different city than display device 1200, remote terminal 1700 could be in the same state as display device 1200, remote terminal 1700 could be in a different state than display device 1200, remote terminal 1700 could be in the same country as display device 1200, or remote terminal 1700 could be in a different country than display device 1200, for example.

[00135] In certain embodiments, a separate, optional data communication/processing device such as data processing module 1600 may be provided in analyte monitoring system 1000. Data processing module 1600 may include components to communicate using one or more wireless

communication protocols such as, for example, but not limited to, infrared (IR) protocol, Bluetooth protocol, Zigbee protocol, and 802.11 wireless LAN protocol. Additional description of communication protocols including those based on Bluetooth protocol and/or Zigbee protocol can be found in U.S. Patent Publication No. 2006/0193375 incorporated herein by reference for all purposes. Data processing module 1600 may further include communication ports, drivers or connectors to establish wired communication with one or more of display device 1200, on body electronics 1100, or remote terminal 1700 including, for example, but not limited to USB connector and/or USB port, Ethernet connector and/or port, FireWire connector and/or port, or RS-232 port and/or connector.

[00136] In certain embodiments, data processing module 1600 is programmed to transmit a polling or query signal to on body electronics 1100 at a predetermined time interval (e.g., once every minute, once every five minutes, or the like), and in response, receive the monitored analyte level information from on body electronics 1100. Data processing module 1600 stores in its memory the received analyte level information, and/or relays or retransmits the received information to another device such as display device 1200. More specifically in certain embodiments, data processing module 1600 may be configured as a data relay device to retransmit or pass through the received analyte level data from on body electronics 1100 to display device 1200 or a remote terminal (for example, over a data network such as a cellular or WiFi data network) or both.

[00137] In certain embodiments, on body electronics 1100 and data processing module 1600 may be positioned on the skin surface of the user within a predetermined distance of each other (for example, about 1-12 inches, or about 1-10 inches, or about 1-7 inches, or about 1-5 inches)

such that periodic communication between on body electronics 1100 and data processing module 1600 is maintained. Alternatively, data processing module 1600 may be worn on a belt or clothing item of the user, such that the desired distance for communication between the on body electronics 1100 and data processing module 1600 for data communication is maintained. In a further aspect, the housing of data processing module 1600 may be configured to couple to or engage with on body electronics 1100 such that the two devices are combined or integrated as a single assembly and positioned on the skin surface. In further embodiments, data processing module 1600 is detachably engaged or connected to on body electronics 1100 providing additional modularity such that data processing module 1600 may be optionally removed or reattached as desired.

[00138] Referring again to FIG. 1B, in certain embodiments, data processing module 1600 is programmed to transmit a command or signal to on body electronics 1100 at a predetermined time interval such as once every minute, or once every 5 minutes or once every 30 minutes or any other suitable or desired programmable time interval to request analyte related data from on body electronics 1100. When data processing module 1600 receives the requested analyte related data, it stores the received data. In this manner, analyte monitoring system 1000 may be configured to receive the continuously monitored analyte related information at the programmed or programmable time interval, which is stored and/or displayed to the user. The stored data in data processing module 1600 may be subsequently provided or transmitted to display device 120, remote terminal 1700 or the like for subsequent data analysis such as identifying frequency of periods of glycemic level excursions over the monitored time period, or the frequency of the alarm event occurrence during the monitored time period, for example, to improve therapy

related decisions. Using this information, the doctor, healthcare provider or the user may adjust or recommend modification to the diet, daily habits and routines such as exercise, and the like.

[00139] In another embodiment, data processing module 1600 transmits a command or signal to on body electronics 1100 to receive the analyte related data in response to a user activation of a switch provided on data processing module 1600 or a user initiated command received from display device 1200. In further embodiments, data processing module 1600 is configured to transmit a command or signal to on body electronics 1100 in response to receiving a user initiated command only after a predetermined time interval has elapsed. For example, in certain embodiments, if the user does not initiate communication within a programmed time period, such as, for example about 5 hours from last communication (or 10 hours from the last communication, or 24 hours from the last communication), the data processing module 160 may be programmed to automatically transmit a request command or signal to on body electronics 1100. Alternatively, data processing module 1600 may be programmed to activate an alarm to notify the user that a predetermined time period of time has elapsed since the last communication between the data processing module 1600 and on body electronics 1100. In this manner, users or healthcare providers may program or configure data processing module 1600 to provide certain compliance with analyte monitoring regimen, so that frequent determination of analyte levels is maintained or performed by the user.

[00140] In certain embodiments, when a programmed or programmable alarm condition is detected (for example, a detected glucose level monitored by analyte sensor 1010 that is outside a predetermined acceptable range indicating a physiological condition which requires attention or intervention for medical treatment or analysis (for example, a hypoglycemic condition, a

hyperglycemic condition, an impending hyperglycemic condition or an impending hypoglycemic condition), the one or more output indications may be generated by the control logic or processor of the on body electronics 1100 and output to the user on a user interface of on body electronics 1100 so that corrective action may be timely taken. In addition to or alternatively, if display device 1200 is within communication range, the output indications or alarm data may be communicated to display device 1200 whose processor, upon detection of the alarm data reception, controls the display 1220 to output one or more notification.

[00141] In certain embodiments, control logic or microprocessors of on body electronics 1100 include software programs to determine future or anticipated analyte levels based on information obtained from analyte sensor 1010, *e.g.*, the current analyte level, the rate of change of the analyte level, the acceleration of the analyte level change, and/or analyte trend information determined based on stored monitored analyte data providing a historical trend or direction of analyte level fluctuation as function time during monitored time period. Predictive alarm parameters may be programmed or programmable in display device 1200, or the on body electronics 1100, or both, and output to the user in advance of anticipating the user's analyte level reaching the future level. This provides the user an opportunity to take timely corrective action.

[00142] Information, such as variation or fluctuation of the monitored analyte level as a function of time over the monitored time period providing analyte trend information, for example, may be determined by one or more control logic or microprocessors of display device 1200, data processing module 1600, and/or remote terminal 1700, and/or on body electronics 1100. Such information may be displayed as, for example, a graph (such as a line graph) to

indicate to the user the current and/or historical and/or and predicted future analyte levels as measured and predicted by the analyte monitoring system 1000. Such information may also be displayed as directional arrows (for example, see trend or directional arrow display 1310) or other icon(s), e.g., the position of which on the screen relative to a reference point indicated whether the analyte level is increasing or decreasing as well as the acceleration or deceleration of the increase or decrease in analyte level. This information may be utilized by the user to determine any necessary corrective actions to ensure the analyte level remains within an acceptable and/or clinically safe range. Other visual indicators, including colors, flashing, fading, etc., as well as audio indicators including a change in pitch, volume, or tone of an audio output and/or vibratory or other tactile indicators may also be incorporated into the display of trend data as means of notifying the user of the current level and/or direction and/or rate of change of the monitored analyte level. For example, based on a determined rate of glucose change, programmed clinically significant glucose threshold levels (e.g., hyperglycemic and/or hypoglycemic levels), and current analyte level derived by an in vivo analyte sensor, the system 1000 may include an algorithm stored on computer readable medium to determine the time it will take to reach a clinically significant level and will output notification in advance of reaching the clinically significant level, e.g., 30 minutes before a clinically significant level is anticipated, and/or 20 minutes, and/or 10 minutes, and/or 5 minutes, and/or 3 minutes, and/or 1 minute, and so on, with outputs increasing in intensity or the like.

[00143] Referring again back to FIG. 1B, in certain embodiments, software algorithm(s) for execution by data processing module 1600 may be stored in an external memory device such as an SD card, microSD card, compact flash card, XD card, Memory Stick card, Memory Stick Duo card, or USB memory stick/device including executable programs stored in such devices for

execution upon connection to the respective one or more of the on body electronics 1100, remote terminal 1700 or display device 1200. In a further aspect, software algorithms for execution by data processing module 1600 may be provided to a communication device such as a mobile telephone including, for example, WiFi or Internet enabled smart phones or personal digital assistants (PDAs) as a downloadable application for execution by the downloading communication device.

[00144] Examples of smart phones include Windows®, Android™, iPhone® operating system, Palm® WebOS™, Blackberry® operating system, or Symbian® operating system based mobile telephones with data network connectivity functionality for data communication over an internet connection and/or a local area network (LAN). PDAs as described above include, for example, portable electronic devices including one or more microprocessors and data communication capability with a user interface (e.g., display/output unit and/or input unit, and configured for performing data processing, data upload/download over the internet, for example. In such embodiments, remote terminal 1700 may be configured to provide the executable application software to the one or more of the communication devices described above when communication between the remote terminal 1700 and the devices are established.

[00145] In still further embodiments, executable software applications may be provided over-the-air (OTA) as an OTA download such that wired connection to remote terminal 1700 is not necessary. For example, executable applications may be automatically downloaded as software download to the communication device, and depending upon the configuration of the communication device, installed on the device for use automatically, or based on user confirmation or acknowledgement on the communication device to execute the installation of the

application. The OTA download and installation of software may include software applications and/or routines that are updates or upgrades to the existing functions or features of data processing module 1600 and/or display device 1200.

[00146] Referring back to remote terminal 1700 of FIG. 1B, in certain embodiments, new software and/or software updates such as software patches or fixes, firmware updates or software driver upgrades, among others, for display device 1200 and/or on body electronics 1100 and/or data processing module 1600 may be provided by remote terminal 1700 when communication between the remote terminal 1700 and display device 1200 and/or data processing module 1600 is established. For example, software upgrades, executable programming changes or modification for on body electronics 1100 may be received from remote terminal 1700 by one or more of display device 1200 or data processing module 1600, and thereafter, provided to on body electronics 1100 to update its software or programmable functions. For example, in certain embodiments, software received and installed in on body electronics 1100 may include software bug fixes, modification to the previously stalled software parameters (modification to analyte related data storage time interval, resetting or adjusting time base or information of on body electronics 1100, modification to the transmitted data type, data transmission sequence, or data storage time period, among others). Additional details describing field upgradability of software of portable electronic devices, and data processing are provided in U.S. Application Nos. 12/698,124, 12/794,721, 12/699,653, and 12/699,844, and U.S. Provisional Application Nos. 61,359,265, and 61/325,155 the disclosure of which is incorporated by reference herein for all purposes.

[00147] Further details regarding on-demand systems are disclosed in U.S. Patent Publication Nos. 2009/0018425 A1, published January 15, 2009; 2009/0054749 A1, published February 26, 2009; 2009/0257911 A1, published October 15, 2009, 2009/0281406 A1, published November 12, 2009; 2009/0294277 A1, published December 3, 2009; 2008/0058625 A1, published March 6, 2008; 2008/0064937 A1, published March 13, 2008; 2008/0071157 A1, published March 20, 2008; 2008/0071158 A1, published March 20, 2008; 2008/0179187 A1, published July 31, 2008; 2008/0319295 A1, published December 25, 2008;2008/0319296 A1, published December 25, 2008; 2007/0149873 A1, published June 28, 2007;2007/0149875 A1, published June 28, 2007; 2009/0321277 A1, published December 31, 2009; 2010/0030052 A1, published February 4, 2010; and pending U.S. Patent Application Nos. 12/211,014, filed September 15, 2008; 12/242,780, filed September 30, 2008; 12/393,921, filed February 27, 2009; 12/495,709, filed June 30, 2009; 12/495,712, filed June 30, 2009; 12/495,730, filed June 30, 2009; 12/544,061, filed August 19, 2009; 12/625,185, filed November 24, 2009; 12/625,208, filed November 24, 2009; 12/625,524, filed November 24, 2009; 12/625,525, filed November 24, 2009; 12/625,528, filed November 24, 2009; 12/624,767, filed November 24, 2009; 12/628,177, filed November 30, 2009; 12/628,198, filed November 30, 2009; 12/628,201, filed November 30, 2009; 12/628,203, filed November 30, 2009; 12/628,210, filed November 30, 2009; 12/698,129, filed February 1, 2010; 12/698,124, filed February 1, 2010; 12/714,439, filed February 26, 2010; 61/163,006, filed March 24, 2009; 61/227,967, filed July 23, 2009; 61/238,159, filed August 29, 2009; 61/238,483, filed August 31, 2009; 61/238,494, filed August 31, 2009; 61/238,581, filed August 31, 2009; 12/807,278, filed August 31, 2010; 61/247,508, filed September 30, 2009; 61/247,514, filed September 30, 2009; 61/247,516, filed September 30, 2009; 61/247,519, filed September 30, 2009; 61/249,535, filed October 7, 2009; 61/256,925, filed October 30, 2009;

61/291,326, filed December 31, 2009; 61/299,924, filed January 29, 2010; 61/297,625, filed January 22, 2010; 61/297,615, filed January 22, 2010, each of which is incorporated by reference herein for all purposes.

The Sensor

[00148] The analyte sensor 14 of the analyte measurement system 10 may be used to monitor levels of a wide variety of analytes. Analytes that may be monitored include, for example, acetylcholine, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (*e.g.*, CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid-stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (*e.g.*, gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be monitored. One or more analyte may be monitored by a given sensor.

[00149] In one embodiment of the present disclosure, sensor 14 is physically positioned in or on the body of a user whose analyte level is being monitored. Sensor 14 may be configured to continuously sample the analyte level of the user and convert the sampled analyte level, *e.g.*, glucose concentration into a corresponding data signal, *e.g.*, a current or voltage, for input into sensor control unit electronics. Alternatively, sensor 14 may be configured to sample analyte levels on demand. The sensor control unit electronics may amplify, filter, average, and/or otherwise process signal provided by the sensor.

[00150] The sensor may take on a number of forms. For example, the sensor may include a flexible or rigid substrate. In some embodiments, the sensor may be a wire. In some embodiments, the sensor may include two or three or more electrodes.

[00151] An embodiment of the sensor 14 is illustrated in FIGURE 2. The shape(s) described herein are exemplary only. Other sensor shapes are contemplated. In some embodiments, sensor 14 includes a substrate which is a dielectric, *e.g.*, a polymer or plastic material, such as polyester or polyamide. In this embodiment, the sensor is constructed so that a portion is positionable beneath skin and a portion is above skin. Accordingly, sensor 14 includes an insertion or internal portion 30 and an external or electrical contact portion 32. The contact portion 32 typically includes several conductive contacts 36, 38, and 40 (herein shown as three contacts) for connection to other electronics, *e.g.*, at the sensor control unit 12. The contacts provided in this embodiment are for a working electrode, a reference electrode, and a counter electrode. In some embodiments, two or more working electrodes are provided. The operative portions of these electrodes, that is, working electrode, reference electrode, and counter electrode (not individually shown), are provided at the insertion portion, *e.g.*, at the distal end of insertion portion 30, *e.g.*, portion 34. In some embodiments, one or more electrodes may be external to the body, *e.g.*, an external counter electrode. The contact and operative portions of the electrodes are connected by circuit traces 42, 44, and 46 running on the surface of the substrate. In some embodiments, the traces are provided in channels, or may be embedded within the substrate, or may traverse different sides of the substrate. The conductive contacts, conductive traces, and electrodes are fabricated from conductive material, such as platinum, palladium, gold, carbon, or the like. More than one material may be used for a given sensor. Further details of sensors are described, *e.g.*, in U.S. Patent Nos. 6,175,572 and 6,103,033, which are incorporated by reference herein for all purposes.

[00152] Sensor 14 may include a proximal retention portion 48. In some embodiments, the insertion portion 30 and the proximal retention portion 48 are substantially longitudinally

aligned. The insertion portion 30 and the proximal retention portion 48 are sized and configured to be positioned with a sharp for installation into the skin of a subject, as described herein. In use, the sensor 14 may be configured to bend (*e.g.*, along the line B) and therefore be positioned in two substantially perpendicular, intersecting planes.

[00153] As illustrated in FIGURE 3, sensor 14' is substantially identical to sensor 14, with many of the differences illustrated in FIGURE 3 and noted herein. Sensor 14" further includes additional features useful for connecting to, *e.g.*, mounting to or in or on, a housing associated with the sensor control unit 12. For example, sensor 14' includes a laterally displaced portion (or sensor tab) 50' and a connector portion, shown in this embodiments as a longitudinal displaced portion 52' which provides a path for electrical connections, *e.g.*, the conductive traces, between the proximal and distal portions of the sensor. Sensor 14' is further provided with a notch or cut-out 54' between the proximal retention portion 48' and the longitudinal displaced portion 52'. Such configuration facilitates the sensor 14' to bend (*e.g.*, along the line indicated by line B) and therefore be positioned in two substantially perpendicular, intersecting planes, as illustrated in FIGURE 4. As will be described below, the sensor tab 50' can be encased in the portion of the body of the sensor control unit 12 to aid in securing and positioning the sensor 14'. Proximal retention portion 48' maintains its longitudinal alignment with insertion portion 30 for positioning within an insertion sharp.

[00154] FIGURES 5A and 5B illustrate a further embodiment of a sensor 14" in accordance with the disclosure. Sensor 14" is substantially identical to sensor 14 and 14', with certain exemplary differences illustrated in FIGURE 4 and noted herein. For example, sensor 14" includes a contact portion 32' which defines a fan-like configuration having a curved edge. The

contact portion 32" typically includes several conductive contacts 36", 38", and 40" (herein shown as three contacts) for connection to other electronics, *e.g.*, at the sensor control unit 12. The contacts provided in this embodiment are for a working electrode, a reference electrode, and a counter electrode. In some embodiments, two or more working electrodes are provided. The operative portions of these electrodes, that is, working electrode, reference electrode, and counter electrode (not individually shown), are provided at the insertion portion, *e.g.*, at the distal end of insertion portion 30", *e.g.*, portion 34". The contact and operative portions of the electrodes are connected by circuit traces 42", 44", and 46" running on the surface of substrate, provided in channels, embedded within the substrate, or traversing different sides of the substrate, substantially as described in connection with FIGURES 2 and 3. Sensor 14" defines a sensor flag indentation 56 " which also serves to assist in retaining the sensor 14" in a vertical orientation, as will be described below, and provides a discrete location for mating with a feature of the sensor control unit 12, *e.g.*, the bottom surface of a printed circuit board. Sensor 14" is likewise capable of bending along axis B, as illustrated in FIGURE 5B. In any of the embodiments of the sensor described herein, the distance between insertion portion 30 to retention portion 48 may be, *e.g.*, about 5 mm, or about 10 mm, or about 15 mm, or about 20 mm.

[00155] FIGURE 6A illustrates a further embodiment of a sensor 14"' in accordance with the disclosure. Sensor 14"' is substantially identical to sensor 14, 14' and 14", with certain exemplary differences illustrated in FIGURE 6A and noted herein. For example, sensor 14"' includes a contact portion 32"'. The contact portion 32"' typically includes several conductive contacts 36"', 38"', and 40"' (herein shown as three contacts) for connection to other electronics, *e.g.*, at the sensor control unit 12. The contacts provided in this embodiment are for a working

electrode, a reference electrode, and a counter electrode. In some embodiments, two or more working electrodes are provided. The operative portions of these electrodes, that is, working electrode, reference electrode, and counter electrode (not individually shown), are provided at the insertion portion, *e.g.*, at the distal end of insertion portion 30'", *e.g.*, portion 34'". As shown, contact portion 32'", proximal retention portion 48'"and the distal portion 30'" of sensor 14'" are linearly aligned with respect to one another. The contact and operative portions of the electrodes may be connected by circuit traces running on the surface of the substrate. In some embodiments, the circuit traces may be embedded within the substrate, or traversing different sides of the substrate. Sensor 14'" is likewise capable of bending along axis B, as illustrated in FIGURE 6B. In FIGURE 6B, contacts 36'", 38'", and 40'" are not visible, because they are located on the underside of contact portion 32'" and thus not shown in this view. It is understood that sensor 14'" may be positioned such that when the sensor is placed in contact with surrounding circuitry the contacts are downwardly positioned to engage circuitry below the contact portion 32'" or, in some embodiments, the contacts are upwardly directed to engage circuitry positioned above the contact portion 32'". In any of the embodiments of the sensor described herein, the distance between insertion portion 30 to retention portion 48 may be, *e.g.*, about 5 mm, or about 10 mm, or about 15 mm, or about 20 mm.

[00156] Embodiments of analyte sensors have been described herein to operate electrochemically, through an arrangement of electrodes having chemical sensing layers applied thereto, by generating an electrical current proportional to the volume of a redox reaction of the analyte (and indicative of analyte concentration), catalyzed by an analyte-specific oxidizing enzyme. Embodiments exist in which the number of electrodes provided to bring about and

detect the level of these reactions is two, three, or a greater number. However, other types of sensors may be employed as described herein.

[00157] A portion of sensor 14 (which collectively refers to sensors 14', 14', and 14''' herein) may be situated above the surface of the skin, with a distal portion 30 penetrating through the skin and into the subcutaneous space in contact with the user's biofluid, such as interstitial fluid. Further details regarding the electrochemistry of sensor 14 is provided in U.S. Patent Nos. 5,264,104; 5,356,786; 5,262,035; 5,320,725; and 6,990,366, each of which is incorporated by reference herein for all purposes.

[00158] In some embodiments, the sensor is implantable into a subject's body for a usage period (*e.g.*, a minute or more, at least one day or more, about one to about 30 days or even longer, about three to about ten days, about three to about seven days, or in some embodiments, longer periods of up to several weeks) to contact and monitor an analyte present in a biological fluid. In this regard, the sensor can be disposed in a subject at a variety of sites (*e.g.*, abdomen, upper arm, thigh, etc.), including intramuscularly, transcutaneously, intravascularly, or in a body cavity.

[00159] In some embodiments, sensor 14 is employed by insertion and/or implantation into a user's body for some usage period. In such embodiments, the substrate may be formed from a relatively flexible material.

[00160] While the embodiments illustrated in FIGURES 2-6 have three electrodes, other embodiments can include a fewer or greater number of electrodes. For example, a two-electrode sensor can be utilized. The sensor 14 may be externally-powered and allow a current to pass proportional to the amount of analyte present. Alternatively, the sensor 14 itself may act as a

current source in some embodiments. In some two-electrode embodiments, the sensor may be self-biasing and there may be no need for a reference electrode. An exemplary self-powered, two-electrode sensor is described in U.S. Patent Application Serial No. 12/393,921, filed February 26, 2009, and entitled "Self-Powered Analyte Sensor," which is hereby incorporated by reference herein for all purposes. The level of current provided by a self-powered sensor may be low, for example, on the order of nanoamperes, in certain embodiments.

On Body Unit

[00161] An exemplary configuration for a sensor 14 (and sensors 14' 14", and 14"') and sensor control unit 12 (*e.g.,* collectively, on-body unit 16) is illustrated in FIGURES 7-8. Sensor control unit 12, including its associated electronics 80, are housed in housing 122. Sensor housing 122 may be provided with a substantially circular configuration, or other shape. Sensor housing 122 has a reduced height (*i.e.*, "Z"-dimension) to provide a low profile when sitting on the skin of the subject. In some embodiments, the height is about 3 mm to about 25 mm, *e.g.*, may be about 4 mm, about 5 mm, about 10 mm, or about 15 mm. In certain embodiments, the sensor housing 122 may have a variable height such that it may have at least one portion that has a height that differs from at least one other portion. For example, electronics 80 may include one or more of, *e.g.*, an analog interface for connecting to the sensor 14, a processor, which may include, *e.g.*, an ASIC 91, antenna 94, power supply 82 to power the sensor and/or communications components, and capacitors 93. In some embodiments, power supply 82 provides a current or voltage to the analyte sensor only. In some embodiments, power supply 82 also powers a communications circuit for providing signal to the monitor unit 18. Power supply 82 may be used to charge capacitors 93 for such periodic signal communication. A serial

communication section may be provided. A temperature sensor, such as a thermistor that detects skin temperature, sensor temperature, and/or ambient temperature may be included to provide compensation to the analyte signal. An RF communication circuit is provided to communicate with the monitor unit 18. (See, FIGURES 1 or 9.) A data storage unit may be provided to store analyte data over a period of time, which in some embodiments may be a short term of time, *e.g.,* several hours or minutes, or over a longer term, *e.g.*, several days or weeks. Additional optional electronics include a serial communication section, a leakage detection circuit, or user input, *e.g.,* a switch to activate/deactivate some or all functions of the device. Many of the components may be combined together and/or their function provided by common components. Furthermore, certain components may be eliminated entirely. For example, a power supply may be omitted if power is provided by inductive coupling.

[00162] In some embodiments, a portion of sensor 14 is disposed on or within housing 122, *e.g.*, in a bent configuration, as illustrated in certain embodiments herein, *e.g.*, in FIGURES 4, 6, and 6B. In some embodiments, a portion of the contact portion of the sensor may be located on an outer surface of the sensor housing 122. The contact portion 32 of sensor 14 may be oriented in a substantially horizontal configuration (*e.g.*, substantially parallel to the skin surface to which it is attached), and secured to a printed circuit board of the sensor control unit 12. The insertion portion 30 of the sensor 14 may extend in a substantially downwardly vertical orientation for placement in the skin of the subject. In some embodiments, the insertion portion 30 is provided with a substantially sharpened and/or pointed configuration to facilitate piercing of the skin. See, *e.g.*, U.S. Patent Application Serial No. 61/238,159 filed August 29, 2009, which is incorporated by reference herein for all purposes. It is understood that sensor 14 may be disposed in other configurations, *e.g.*, in an entirely substantially vertical configuration, etc. As a further example,

the insertion portion 30 may be disposed at an oblique angle, *e.g.*, between about 0° and about 90° with respect to the skin surface.

[00163] Adhesive pad 118 is illustrated in FIGURE 8 to attach sensor housing 122 to the skin of the subject. In some embodiments, adhesive pad 118 is used instead of a separate mount. Adhesive pad 118 may include adhesive on both distal (upper) and proximal (lower) surfaces, such that adhesive pad is attached or attachable to both sensor housing 122 and the skin of the subject. In some embodiments, adhesive pad 118 may be first attached to the skin of the subject with the adhesive on the distal surface thereof. Subsequently, the housing 122 is adhered to the proximal surface of the adhesive pad 118. In other embodiments, proximal surface of adhesive pad 118 is first attached to sensor housing 122, and subsequently, the distal surface of adhesive pad 118 is then attached to the skin of the subject.

[00164] As illustrated in FIGURE 9, the on-body unit 16 communicates with the monitor unit 18. Such communication may be one-way communication, *e.g.*, from the on-body unit 16 to the monitor unit 18. In some embodiments, the communication may be two-way, *e.g.*, both from the on-body unit 16 to the monitor unit 18 and from the monitor unit 18 to the on-body unit 16. Communication between the on-body unit 16 and monitor unit 18 may be achieved using one or more radio frequency communication protocols, inductive coupling, magnetic coupling, direct wired connection, infrared data communication protocol, and the like as described herein.

Insertion Assembly

[00165] Insertion assemblies are provided, which are used to install a medical device to the subject. In some embodiments, an insertion assembly includes an inserter and the medical device itself. The inserter can be configured to insert various medical devices into the subject,

such as for example, an analyte sensor, an infusion set, or a cannula. In some embodiments, the inserter can be configured to install a combination of such devices, *e.g.*, a combined sensor/infusion set, etc., at the same or different times or locations. For example, in certain embodiments a given inserter can be configured to install a first device and a second device at different times. In this regard, the inserter can be reusable. For example, an inserter may be modifiable to be used with more than one medical device, to include more than one type of medical device, *e.g.*, by attaching an adapter and/or removing detaching a portion of an inserter. The inserter can install the medical device in, under, or through the skin of the subject, or place the medical device on the surface of the skin. The medical device can include features or structures, *e.g.*, barbs, tabs, adhesive, etc., to maintain the device in position with respect to the skin after insertion. The inserter device may also be used as a lancet, *e.g.*, to pierce the skin without inserting or installing a medical device.

[00166] In some embodiments, an insertion assembly includes an inserter, a medical device, such as an analyte sensor, and a mount for supporting the medical device at least partially in or on the skin of the subject. In some embodiments, the mount is a support structure, plate and/or member which is attached, adhered, or otherwise secured to the skin of the subject. The mount may be inserted simultaneously with the medical device by the inserter. In other embodiments, the mount is installed after or before installation of the medical device. A mount may be applied by the inserter or separately. The mount may include features or structures (*e.g.*, adhesive, guides, barbs, tabs, etc.) to maintain the sensor in position with respect to the skin after insertion and/or maintain the sensor in relative position with respect to the sensor control unit. In some embodiments, an adhesive pad or strip is used to secure the medical device, *e.g.*, the sensor and/or the sensor control unit, and no mount is used.

[00167] In some embodiments, an insertion assembly includes an inserter, an analyte sensor, a mount, and a power supply. The mount and power supply may be inserted simultaneously with the analyte sensor by the inserter. In other embodiments, the mount and battery are installed after or before installation of the analyte sensor. In such case the mount and/or power supply may be applied by the inserter or separately. The power supply may be used to provide a current or a potential to the sensor and/or to provide power for communication of one or more signals to the monitor unit.

[00168] In some embodiments, an insertion assembly includes an inserter, a medical device such as an analyte sensor, a mount, and a sensor control unit. The mount and sensor control unit may be deployed and/or installed simultaneously with the analyte sensor by the inserter. In other embodiments, the mount and sensor control unit are installed after or before installation of the analyte sensor. For example, the mount and the analyte sensor may be installed by the inserter, and the sensor control unit may be subsequently installed. In other embodiments, the mount is installed, followed by insertion of the analyte sensor by the inserter, and further followed by installation of the sensor control unit. In other embodiments, the mount and sensor control unit are installed first, and the analyte sensor is subsequently installed.

[00169] In some embodiments, electronics of the sensor control unit provide a voltage or current to the analyte sensor. In some embodiments, the electronics processes signals provided by the analyte sensor. In further embodiments, the electronics may include communication functionality for providing signal relating to signal provided by the analyte sensor to a further component, such as, *e.g.*, a monitor unit, a computer, or other component. In some embodiments, communications circuitry, such as RFID antenna or communications circuitry, is

provided. The power supply may be used to power some or all of these functions. In some embodiments, power is provided from the monitor unit, *e.g.*, via inductive coupling.

[00170] An inserter can include a plurality of different components. For example, an inserter may include one or more components for advancing a sharp towards the skin of the subject. The sensor and sensor control unit and/or mounting structure may be supported by a support structure, such as a carriage. A driver may be provided for advancing the sharp and/or the analyte sensor/support structure. In some embodiments, the actuator is directly or indirectly coupled to the sharp and/or support structure, such that manual force and speed applied by the user to the actuator is transferred to the sharp and/or support structure. In some embodiments, the applied force drives the sharp and/or support structure between a retracted position and an advanced position. In some embodiments, the sensor and sensor control unit and/or mounting structure is maintained in a retracted position prior to installation by contacting projections extending inwardly from a sheath. In accordance with this embodiment, the sensor and sensor control unit and/or mounting structure are temporarily maintained operatively between the support structure and the projections disposed on the interior wall of the sheath.

[00171] An inserter can also include one or more components for retracting the sharp, while allowing the analyte sensor and optional mount and/or electronics to remain on the subject. The components for retracting the sharp can include a retractor. It is understood that the retractor and the actuator may be the same structure or include some common components. In some embodiments, the retractor is directly or indirectly coupled to the sharp such that the manual force applied by the user is transferred from the retractor to the sharp to retract the sharp from the skin. In other embodiments, a drive assembly may be provided to retract the sharp. For

example, the drive assembly may include a spring, motor, hydraulic piston, etc., to retract the sharp away from the skin of the subject. The drive assembly may also include a linear drive component.

[00172] In some embodiments, the retractor withdraws the sharp upon actuation by the user. In such cases, the user actuates the retractor when it is desired to withdraw the sharp. For example, the retractor may include a release switch. Upon activation of the release switch, the drive assembly, *e.g.*, the spring or other driver, retracts the sharp from the skin. In other embodiments, the retractor and the actuator include common components. After activating the actuator to advance the sharp and the analyte sensor, the user releases the actuator, which allows the drive assembly to withdraw the sharp from the skin.

[00173] In some embodiments, the retractor withdraws the sharp without further user interaction after actuation of insertion. For example, the inserter may include features or components which automatically retract the sharp upon advancement of the sharp and support structure by a predetermined amount. Inserter devices, in which no further action by the user is required to initiate withdrawal of the sharp after insertion, are referred to herein as having "automatic" withdrawal of the sharp.

Inserter Devices

[00174] An inserter 100 in accordance with an exemplary embodiment is illustrated in FIGURE 10. In some embodiments, inserter 100 has a maximum diameter of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 100 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc.

In some embodiments, inserter 100 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc. Inserter 100 includes a handle 102 and a removable distal cap 104. The cap 104 may maintain a sterile, contaminant-free environment for the medical device and sharp housed therein. As illustrated in FIGURES 10-13, distal cap 104 is detachably secured to handle 102, *e.g.*, by use of one or more mating members, *e.g.*, threads 110 and 111, or hooks, tape, magnets, adhesive, friction-fit, snap-fit, and the like. Inserter 100 includes a base 142 which defines a distal surface 112, which may be a substantially planar surface as shown in this embodiment, for placement on the skin S of a subject, and in other embodiments may be a curved or inclined surface, *e.g.*, a concave or convex surface. Inserter 100 may be utilized to advance a medical device into the skin of the subject, *e.g.*, an analyte sensor, and infusion set, etc., as described herein. In some embodiments, handle 102 is advanced relative to base 142 in order to advance the medical device into the skin of the patient, as will be described in greater detail herein.

[00175] The components of inserter 100 are illustrated in FIGURES 11-27. As illustrated in FIGURE 11, handle 102 includes a contact surface 114 for contact by a user to depress to advance the sensor housing 122 (as illustrated in FIGURE 10) and sensor 14 towards the skin of the subject. Threads 110 are provided on handle 102 (as illustrated in FIGURE 11) for attachment to cap 104 *via* threads 111 (as illustrated in FIGURES 12-13). Cap 104 can include a receptacle, such as an upwardly extending sleeve 125 to assist holding sensor housing 122 fixed in position. The distal portion of cap 104 includes a recess 115 for retaining a desiccant 190 therein. In some embodiments, a silica gel or molecular sieves may be used. Such material can be in granular form (pellets) or pressed into tablets, or otherwise. In some embodiments, silica

gel tablets are used. Embodiments may include desiccant and/or packaging as described in U.S. Patent Application Serial No. 12/714,439, which is incorporated by reference herein for all purposes.

[00176] Cap 104 may be provided with one or more apertures 117, which allows for passage of air to the desiccant 190 to remove moisture from the interior of the inserter 100. Cap 104 may include a stop such as an annular ridge 113, which engages the distal edge portion 116 of handle 102. In some embodiments, a stop such as annular ridge 113 prevents distal movement of handle 102 (as well as sensor housing 122) when cap 104 is attached to handle 102.

[00177] Base 142, as illustrated in FIGURES 10 and 14, includes a distal sheath portion 192, which shields sharp 124 and sensor housing 122 prior to deployment and a distal rim 112 having a substantially planar surface configuration to rest on the subject's skin S. Base 142 also includes side walls 191, which along with inner rail 128 defines a recess for retraction spring 146. Base 142 provides a spring retention portion 148, as illustrated in FIGURE 29.

[00178] Support member or shuttle 134, as illustrated in FIGURES 15-16, supports needle hub 136, from which sharp 124 extends longitudinally within the inserter 100. In some embodiments, the sharp is supported at an oblique angle, *e.g.*, between and including about 0° (parallel to the skin) and about 90° (normal to the skin) with respect to the skin surface. Needle hub 136 can be secured to shuttle 134 *via* interlocking snaps or tabs, an O-ring configuration, adhesive, insert-molding, or other techniques known in the art. Alternatively, needle hub 136 may be integrally molded with shuttle 134. In some embodiments, sharp 124 is a solid needle. In some embodiments, sharp 124 is provided with a substantially cylindrical configuration defining an interior bore, *e.g.*, a rigid cylindrical member or a hypodermic-style needle.

[00179] Needle hub 136 is further illustrated in FIGURES 17-18. Needle hub 136 supports sharp 124, having a sharpened distal portion 160. In some embodiments, as discussed herein, a longitudinal wall opening or gap 162 is provided in at least a portion of the wall of the sharp 124. The length N of the gap 162 is selected to be commensurate with the length of the insertion portion 30 through to the proximal retention portion 48 of the sensor, and in certain embodiments may be about 3 mm to about 50 mm, *e.g.*, about 5 mm, or about 10 mm, or about 15 mm, or about 20 mm. The length L of the sharp 124 may be about 3 mm to about 50 mm, *e.g.*, 5mm or more, or about 10 mm, or about 20 mm, or about 30 mm, or about 50 mm, and is selected based upon the length of the insertion portion 30 of a sensor and the desired depth of the insertion portion 30 of the sensor 14. In some embodiments, the distance or spacing between the two edges of the gap is about 0.2mm to about 0.5mm, *e.g.*, about 0.22mm, about 0.25mm, etc.

[00180] The distal portion 160 of sharp 124 is illustrated in greater detail in FIGURES 19-21. As illustrated in FIGURE 19, sharp 124 has a substantially "C"- or "U"-shaped profile in this embodiment, but may have other configurations, *e.g.*, substantially "V"-shaped. A longitudinal gap 162 is provided in the wall of the sharp 124. FIGURE 20 illustrates distal portion 160 is provided with an angled tip. In some embodiments, the angled tip may be provided with a first angled tip portion 164 and a second steep-angled tip portion 166. The exemplary configuration, which includes multiple edges and faces, provides a sharp point to reduce penetration force, trauma, and bleeding for the subject. The distal section of the sensor body has a width sized to fit within the notch 162 of the insertion sharp 124 having a diameter less than about 20 to about 26 gauge, *e.g.*, 21 gauge to about 25 gauge, where in certain embodiments the sharp is 21 gauge or 23 gauge or 25 gauge. Such sharp may be used with a sensor having a width or diameter - - at least the portion that is carried by the sharp - - of about .20 mm to about .80 mm, *e.g.*, about .25

mm to about .60 mm, where in some embodiments the width or diameter of at least a portion of a sensor is .27 mm or .33 mm or .58 mm. In some embodiments, sharp 124 is fabricated from a sheet of metal and folded into a substantially "V" or "U" or "C" configuration in cross-section. Various technologies can be used to manufacture a folded sheet of metal to form sharp 124. For example, etched-sheet metal technology can be used to form the sharp 124. In this manner, the sharp can be formed having a very sharp edge so that penetration through the skin during insertion is less painful. In other embodiments, a progressive die technology may be utilized to form a complex sheet-metal shape that has a sharp edge as depicted in FIGURE 21A. In some embodiments, the sharp 124 can be molded with a plastic cap so that the sharp can be handled during the inserter assembly process. Further, the die cut sharp may be molded with plastic to reinforce the "V," "U," or "C" shaped sheet metal configuration. In other embodiments, a laser-cut sharp can be formed. In this manner, the laser can be used to form the wall opening or gap 162 and first-angled tip portion 164 and a second, steep-angled tip portion 166.

[00181] In another embodiment, sharp 224 may be formed from a standard hypodermic needle utilizing the method depicted in FIGURE 21B. First, the hypodermic needle (having a circular cross-section) is cut to the desired length for sharp 224. Next, the hypodermic needle is compressed so that its cross-section is permanently deformed from a circular shape to an oval shape. The tip of the hypodermic needle is then ground to a bevel to produce a sharp point to reduce the required penetration force, as previously discussed. Finally, the top section of the needle is removed by appropriate techniques (e.g., grinding, electropolish, etc.). The resulting sharp 224 has a "U"-shaped configuration and provides ample space for the insertion of sensor 14. In some embodiments, the tip-grinding step and the compression step may be carried out in reversed order.

[00182] Due to the compression step, a user may initially start with a larger diameter hypodermic needle so that the finished sharp 224 will have similar dimensions to the previously described sharps.

[00183] FIGURES 22-23 illustrate the position of sensor housing 122 with respect to the needle hub 136 and sharp 124. The sensor housing 122 can be configured to hold at least a portion of sensor 14 and sensor control unit 12. As illustrated in FIGURE 22, the sharp 124 extends through an aperture 168 in the sensor housing 122. Thus, in some embodiments, the sharp 124 is uncoupled to sensor housing 122. The distal portion of sensor 14 is positioned with the sharp 124. As further illustrated in FIGURE 23, electronics 80 of the sensor control unit 12 (*e.g.*, a printed circuit board containing electronics components of the on-body unit 16) and sensor hub 123 are positioned within sensor housing 122. Sensor 14 may include a positioning structure, or slit 127 which receives a positioning member, such as tab 129 of sensor hub 123. A power supply 82, such as a battery, *e.g.*, a single use disposable battery, or rechargeable battery, is provided. The power supply 82 is used to provide potential or current to the sensor in some embodiments. In embodiments where a passive communications protocol such as passive RFID is used, no power supply is provided for the communications. Such power is provided by the monitor unit 18. In some embodiments where the sensor control unit is used to transmit one or more signals, one or more power supplies may be used to provide power for such communications circuitry. In some embodiments, the active operational life of the battery may exceed the active operational life of the sensor 14.

[00184] FIGURE 24 illustrates in cross-section the orientation of the sensor housing 122 with respect to the sharp 124 of inserter 100. As discussed herein, sensor 14 is disposed in a

substantially bent configuration in some embodiments, such that a portion of the sensor, *e.g.*, the insertion portion 30 and the proximal retention portion 48, are substantially vertical (*e.g.*, substantially aligned with the longitudinal axis of the inserter 100 and substantially perpendicular to the skin surface) and the contact portion 32 (shown in profile) is oriented in a substantially horizontal configuration, and in electrical contact with the data-processing unit electronics, such as circuit 80. The sensor tab 50 can be encased in the plastic of the sensor housing 122 (*e.g.*, "overmolded") and secured in place. The notch 56 provides further stability to the sensor 14, *e.g.*, by allowing the sensor tab 50 to be encased by the material of the sensor housing 122, and further provides a means for vertically orienting the sensor 14 during mounting, *e.g.*, by allowing vertical positioning of the notch 56 with respect to a vertical landmark of the sensor housing 122.

[00185] The sensor 14, mounted with the sensor housing 122, can be disposed within a recess of the carriage 130 such as a concave recess in the carriage 130. Alternatively, the sensor 14, mounted with the sensor housing 122 can be disposed between the support structure and one or more projections extending from the wall of the sheath. In yet another alternative, the sensor 14 mounted with the sensor housing 122 can be held in position by a releasable friction fit coupling to the sharp 124. In this manner, the carriage need not have a recess within which the sensor mounted with the sensor housing is disposed. In the initial configuration of the inserter 100 (see, *e.g.*, FIGURE 22) the sharp 124 extends through a longitudinal aperture 168 formed in a carriage 130. In some embodiments, the aperture 168 is appropriately sized, such that neither the sharp 124 nor needle hub 136 is in contact with the carriage 130. Accordingly, the needle hub 136 (and sharp 124) on the one hand, and the carriage 130 and the sensor housing 122, on the other hand, move simultaneously but independently from one another. In other embodiments, a friction fit may be provided between the aperture and the sharp.

[00186] The insertion portion 30 and proximal retention portion 48 of the sensor 14 are disposed within a longitudinal bore 162 within the sharp 124 (See, *e.g.*, FIGURE 19). The proximal retention portion 48 is disposed within the longitudinal bore of the sharp 124 and provides additional stability to the mounting of the sensor 14 within the sharp 124. The longitudinal wall gap or opening 162 of sharp 124 is aligned with the sensor 14, such that the tab 50 and the contact portion 32 extend laterally outward from the sharp 124.

[00187] In some embodiments, a resilient member 70 may be included to provide frictional contact with the sharp 124 and/or the sensor 14. Such frictional contact provides additional stability between the sensor housing 122 and sharp 124, as depicted in FIGURES 24A-24C. In some embodiments, resilient member 70 may be formed as a spherical, ovoid, cylindrical, cube-shaped member, etc. Resilient member 70 may be formed from any elastomeric material, e.g., molded plastic components, rubber, nitrile, viton, urethane, etc.

[00188] In some embodiments, resilient member 70 is press-fit into a recess, such as an eccentric bore 72 located in sensor housing 122 (FIGURE 24C). When sharp 124 is inserted within an aperture in the sensor housing 122, the resilient member 70 exerts a pressure on sharp 124 and sensor 14 to hold them firmly in groove 74. In some embodiments, groove 74 is a V-shape. Alternatively, groove 74 may be U-shaped depending on the configuration of sensor 14 and sharp 124. In some embodiments, resilient member 70 is provided with a flattened or recessed surface which abuts sharp 124.

[00189] With continued reference to FIGURES 15 and 16, shuttle 134 includes wings 182 and resilient distally extending fingers 184. Inner rail 128 is illustrated in FIGURE 25. As illustrated in FIGURE 26, shuttle 134 is sized and configured for longitudinal movement within inner rail

128. Wings 182 of shuttle 134 are configured for longitudinal movement within axial notches 188 of inner rail 128. When fingers 184 of shuttle 134 are disposed in their normally biased outward position, fingers 184 engage the lower surface 194 of inner rail 128. In the configuration illustrated in FIGURE 26, shuttle 134 is locked with respect to inner rail 128. As will be discussed herein, fingers 184 may be biased radially inward to allow upward movement of shuttle 134 relative to inner rail 128.

[00190] As illustrated in FIGURE 10, inner rail 128 includes an upper surface 186 for engagement with handle 102. In some embodiments, surface 186 is adhered or otherwise fixed to handle 102.

[00191] The relationship of inner rail 128, shuttle 134 and base 142 is illustrated in FIGURE 27. In an initial configuration, inner rail 128 and shuttle 134 are in a locked relationship by engagement of wings 182 and fingers 184. Inner rail 128 and shuttle 134 are axially movable within base 142. Spring 146, which is secured between spring retention portion 148 of base 142 and wings 182 of shuttle 134 biases the inner rail 128 and shuttle 134 in a proximal (upward) direction.

[00192] Inserter 100 is illustrated in section in FIGURES 28-29 prior to use in a sensor predeployment position. Cap 104 is attached to the distal portion of inserter 100, *e.g.*, *via* inter-engagement of threads 110 and 111.

[00193] As illustrated in FIGURE 28, the inserter 100 includes an initial configuration in which the handle 102 is disposed in a proximal position with respect to the base 142. In such configuration, the sharp 124 is disposed in a configuration spaced apart from an aperture of the adhesive layer 118.

[00194] As illustrated in FIGURE 30, inner rail 128 includes a carriage 130. In a sensor insertion position, the handle 102 is depressed downward (arrow D) against the bias of spring 146, the inner rail 128 moves downwardly with the carriage 130 and the sensor housing 122. Shuttle 134 supports needle hub 136, from which sharp 124 extends longitudinally within the inserter 100. Initially, shuttle 134 is coupled to inner rail 128 *via* inter-engagement of fingers 184 of shuttle 134 with distal surface 194 of inner rail 128, and both shuttle 134 and inner rail 128 move distally together as a unit.

[00195] As the sharp 124 is urged distally towards the subject's skin (FIGURE 30), it carries the sensor insertion portion 30 of sensor 14 into the subcutaneous portion of the subject's skin S and into contact with the interstitial fluid. As carriage 130 reaches a distal position, the distal surface of the sensor housing 122 engages the upper surface of adhesive pad 118, thereby becoming adhered to the skin surface S of the subject.

[00196] In some embodiments, components are provided which allow the shuttle to be disengaged from the handle 102. For example, flanges 170 on base 142 engage fingers 184 of shuttle 134. Fingers 184 are pivoted or bend inwards by contact with flanges 170 (as indicated by arrows F).

[00197] As illustrated in FIGURE 31, such pivoting of fingers 184 causes fingers 184 to become disengaged from distal edge 194 of inner rail 128. Shuttle 134 is thereby disengaged from inner rail 128. Disengagement of the shuttle 134 from the inner rail 128 permits the spring 146 decompress and to expand, thereby advancing the shuttle 134 to a proximal or retracted position, and withdrawing the sharp 124 from the sensor housing 122, withdrawing from its position around sensor 14, and receding from skin S of the subject, while leaving the sensor 14 in

the skin and the on body unit 16 attached to the skin surface by adhesive pad 118. Once the sharp has been withdrawn from the subject, it is no longer accessible from the distal portion of the inserter 100, which prevents accidental needle sticks. When the carriage 130 reaches the distal position in which flanges 170 engage fingers 184 of needle shuttle 134, needle shuttle 134 withdraws sharp 124 automatically without further input from the user.

[00198] As illustrated in FIGURE 31A, the inserter 100 may be removed from the skin S of the subject, leaving the on-body unit 16 installed on the subject, e.g., lower surface of housing 122 adhered to the skin S via adhesive pad 118 and sensor 14 at least partially inserted in the skin and in contact with the interstitial fluid.

[00199] Prior to activation of the on-body unit 16 which includes the integrated sensor 14 and sensor control unit 12 for use, there may be a period of time from the manufacturing that the assembly 16 may be in a "sleep" or "idle" mode. With a power supply such as a battery integrated within the assembly, for reasons including cost optimization and prolonging shelf life, some embodiments of the present disclosure include optional systems that are activated merely by positioning the sensor 14 and on-body unit 16 on a skin surface as described above, *i.e.*, no additional action may be required of the user other than applying a force to sensor housing 122. As such, insertion of the sensor 14 and/or mounting of the sensor housing 122 causes activation of the electronics 80. In certain embodiments, activation switch configurations are included which may be configured to be triggered, for example, by the insertion device activation, thereby turning on the integrated sensor and sensor electronics assembly into an active mode.

[00200] As illustrated in FIGURE 29, inserter 100 may be provided with a switch 185, which provides automatic activation of the electronics 80 of the sensor control unit 12. In some

embodiments, the switch 185 is a longitudinally slidable member or plunger extending distally from or otherwise disposed on the distal surface of the sensor housing 122. When the sensor housing is advanced proximally, it engages the adhesive pad 118, or alternatively the skin surface of the subject. Upon such engagement, the switch 185 is moved axially (proximally) with respect to the housing 122. When the sensor housing 122 is in approximation with the adhesive pad 118 and/or the skin of the subject, the plunger switch 185 is in the proximal position (not shown). Such axial movement may be used to activate the sensor electronics 80. In some embodiments, a switch 185 is spring biased. Accordingly, as long as the sensor housing 122 is maintained in a fixed relationship with the adhesive pad 118 against the bias, electronic activation is maintained in such embodiments. If the sensor housing 122 is removed from the adhesive or the skin, the switch 185 moves with the bias, and the electronics are deactivated. In other embodiments, the switch 185 provides a one-time activation of the electronics. In such cases, once the electronics are activated, the sensor housing 122 is not required to remain in contact with the adhesive or the skin in order to maintain activation.

[00201] As illustrated in FIGURES 32-33, embodiments of a power supply switch mechanism include conductive plugs of the on-body unit 16 in accordance with the present disclosure. FIGURES 32-33 illustrate enlarged sectional views of sensor housing 122. As shown, the sensor electronics assembly circuit board 860 may be provided with a physical gap 858 that breaks the electrical circuit between the power supply (*e.g.*, battery) and the other circuitry of the sensor electronics assembly.

[00202] In one embodiment, when the predetermined force is applied on the insertion device 100 as discussed above, a conductive portion 852 provided within the housing 122 of the sensor

electronics may be moved in a direction as shown by arrow 854 such that electrical contact is established in the physical gap 858 on the circuit board, by for example, the conductive portion 852 coming into physical contact with the conductive portions of the circuit board 860. In this manner, in one embodiment, the electrical path from the power supply and the remaining circuitry on the circuit board of the sensor electronics is completed, thereby powering the sensor electronics.

[00203] By way of another example, referring to FIGURE 33, the conductive portions 860 of the circuit board are provided on the board itself, and the conductive plug 856, for example, when pushed into the cavity 858, establishes electrical contact between the conductive portions 860 of the circuit board.

[00204] In one embodiment, as discussed above, the actuation of the insertion device 100 to position the sensor 14 and sensor electronics assembly triggers the switch mechanism shown in FIGURES 32-33 by also moving the conductive portion 852 or the conductive plug 856 in the direction complimentary to the direction of the introducer movement, and thereby switching on the sensor electronics. Within the scope of the present disclosure, the activation of the sensor electronics by moving the conductive portion 852 or the conductive plug 856 may include a separate procedure, where, after positioning the sensor and the sensor electronics assembly on the skin surface, a predetermined force is applied on the housing of the integrated sensor 14 and sensor electronics assembly such that the desired movement of the conductive portion 852 or the conductive plug 856 may be achieved. Further embodiments of the insertion devices are described in U.S. Patent Application Serial Nos. 61/149,639, filed February 3, 2009, and No. 12/698,129, filed February 1, 2010, which are incorporated by reference herein in their entirety.

[00205] An inserter 200 in accordance with another exemplary embodiment is illustrated in FIGURE 34. In some embodiments, inserter 200 has a maximum diameter, of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 200 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 200 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc.

[00206] With reference to FIGURE 34, inserter 200 includes a housing 202 and a removable distal cap 204 for maintaining a sterile environment for the medical device and sharp housed therein. Housing 202 and distal cap 204 may be fabricated from any suitable materials such as metal, plastic, etc. In some embodiments cap 204 may be fabricated from a polymer or plastic material. Also provided is a removable proximal cover 206, which, among other things, prevents accidental deployment of the inserter 200. In some embodiments, proximal cover 206 is a sheet of material such as a foil sheet or the like secured to the upper surface of housing 202 using an adhesive, and may include a tab 208 to assist removal of the cover 206. Proximal cover 206 may also be a plastic sheet or member that forms a seal with housing 202. In some embodiments, proximal cover 206 may include a pull tab or a perforated section for easy removal.

[00207] As illustrated in FIGURE 35, proximal cover 206 and distal cap 204 are shown removed from inserter 200. Distal cap 204 is secured to housing 202, *e.g.*, by use of threads 210. In some embodiments, distal cap 204 is secured by a friction fit, snap fit, a bayonet mount, an adhesive, etc. Housing 202 includes a distal surface 212 for placement on the skin of a subject.

Inserter 200 includes an actuator 214 to advance a medical device into the skin of the subject. In some embodiments, actuator 214 is disposed within an opening 216 in housing 202 and can be longitudinally moveable within housing 202.

[00208] The distal portion of inserter 200 is illustrated in FIGURE 36. In some embodiments, an adhesive pad 218, having adhesive material 218 on both faces, is provided across the distal portion 212 of the housing 202. A central aperture 220 may be provided in adhesive pad 218. As will be described in greater detail herein, inserter 200 supports a medical device, such an analyte sensor housing 122 (not shown) and a sharp 224. In some embodiments, sensor housing 122, includes an analyte sensor 14 and a sensor control unit 12. During insertion, sharp 224 passes through aperture 220 and into the skin of the subject carrying at least the sensor with it.

[00209] FIGURE 37 illustrates inserter 200 in cross-section, in an initial configuration prior to use, after removal of the distal cap 204. Actuator 214 may be cylindrical in shape (or other shape as appropriate) and, including an upper contact surface 226, capable of being depressed by a user and/or a mechanism, as described herein. Actuator 214 may further include side walls 228 extending downwardly from upper surface 226, and which engage or otherwise contact the upper surface of carriage 230. Carriage 230 provides a support for holding the medical device, such as sensor housing 122 of on-body unit 16, prior to and during installation. In some embodiments, carriage 230 includes a distal portion 232, which may be configured to form a substantially concave recess 232a as shown in this embodiment, for supporting the medical device therein. In some embodiments, the sensor housing 122 is supported within the recess 232a of carriage 230 in a snap-fit or other relationship. In some embodiments, carriage 230 does not include a recess.

In such embodiments, carriage may include one or more projections which contact and/or advance the sensor housing 122.

[00210] In FIGURE 38 the longitudinal axis L of the inserter 200 is illustrated. Extending distally from the upper surface 226 of actuator 214 and substantially parallel to the longitudinal axis is a support member 234, which may have an elongated configuration. Support member 234 supports needle hub 236, from which sharp 224 extends longitudinally within the inserter 200. In some embodiments, the sharp 224 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface. Needle hub 236 can be secured to support member 234 via an interlocking O-ring configuration, adhesive, or other techniques known in the art. Support member 234 can be omitted and needle hub 236 can be secured to the actuator 214 directly in some embodiments.

[00211] In some embodiments, sharp 224 is a solid needle. In some embodiments, sharp 224 is provided with a substantially cylindrical configuration defining an interior bore, *e.g.*, a rigid cylindrical member or a hypodermic-style needle. Sharp 224 may also be provided with an elongated longitudinal opening or gap in the wall of the sharp 224 (see, sharp 224 in FIGURES 22-24). In some embodiments, sharp 224 is fabricated from a sheet of metal, and folded into a substantially "V" or "U" or "C" configuration in cross-section to define the longitudinal recess.

[00212] The sensor 14, mounted with the sensor housing 122, is carried by the carriage, *e.g.*, disposed within the concave recess 232a in the carriage 230, as described hereinabove (see, *e.g.*, FIGURES 22-24). In the initial configuration of the inserter 200 (see, *e.g.*, FIGURE 37), the sharp 224 extends through a longitudinal aperture 268 formed in the carriage 230. In some embodiments, the aperture 268 is appropriately sized, such that neither the sharp 224 nor needle

hub 236 is in contact with the carriage 230. In other words, in some embodiments a clearance may be provided between the surfaces of the carriage and the sharp and needle hub. In some cases, sharp 224 is capable of substantial lateral movement or "play" with respect to aperture 268. Accordingly, the needle hub 236 (and sharp 224) on the one hand, and the carriage 230 and the sensor housing 122, on the other hand, can move simultaneously but independently from one another.

[00213] Referring back to FIGURE 23, the insertion portion 30 and proximal retention portion 48 of the sensor 14 are disposed within a longitudinal bore of the sharp 224. The proximal retention portion 48 is disposed within the longitudinal bore of the sharp 224 and provides additional stability to the disposition of the sensor 14 within longitudinal bore of the sharp 224. The longitudinal wall gap of sharp 224 is aligned with the sensor 14, such that the tab 50 and the contact portion 32 extend laterally outward from the sharp 224.

[00214] With continued reference to FIGURE 37, an optional sheath 242 is positioned within housing 202, having an annular configuration and including a circumferential recess 244 in which a retraction spring 246 is positioned. The distal portion of spring 246 contacts a spring retention portion 248 in sheath 242. The proximal portion of spring 246 contacts one or more tabs 250 extending laterally outwardly from actuator 214. In the initial configuration, the spring 246 may be in a semi-compressed state, *i.e.*, not fully compressed, nor fully extended. It is understood that sheath 242 may be omitted from inserter 200, and a recess, such as recess 244, provided within housing 202. Similarly, recess 244 may be omitted entirely, and spring 246 or other actuator may be disposed between stops in housing 202.

[00215] Depression of the actuator 214 causes distal longitudinal movement of the carriage 230 and sharp 224, from a proximal position to a distal position. During such downward, distal movement, spring 246 is further compressed between spring retention portion 248 and flanges 250.

[00216] As illustrated in FIGURE 38, depression of the actuator 214 advances the inserter 200 from an initial configuration to a deployed configuration. Depression of the contact surface 226 moves the actuator side walls 228 and the tabs 250 downwardly distally against the bias of spring 246. Contact of the side wall 228 of the actuator 214 with the upper surface of the carriage 230 during depression of the actuator 214 imposes a downward force and consequential distal movement of the carriage 230. As the sharp 224 is urged distally, it carries the sensor insertion portion 30 into the subcutaneous portion of the subject's skin S.

[00217] As illustrated in FIGURE 37, flanges 270 are disposed in the inner wall of sheath 242. When carriage 230 reaches a distal position, as shown in FIGURE 38, the flanges 270 engage the proximal (upper) surface of the carriage 230, and thereby inhibit proximal movement of the carriage 230 (see also FIGURE 41). The distal (lower) surface of the sensor housing 122 engages the upper surface of adhesive pad 218, thereby becoming adhered to the skin surface S of the subject. As the flanges 270 engage the carriage 230, the flanges 270 also engage fingers 274 disposed on the proximal face of the carriage 230. Fingers 274 are pivoted inwards by flanges 270. Such pivoting of fingers 274 causes fingers 274 to become disengaged from retention tab 250 on actuator 214. Spring 246 is thereby permitted to decompress and expand, and thereby provide an upward force on actuator 214. If the user or some apparatus provides no downward force, or minimal downward force to overcome the bias of spring 246, the actuator

214, along with needle hub 236 and sharp 224 move proximally, withdrawing the sharp 224 from the skin S of the subject.

[00218] As shown in FIGURES 39 and 40, the actuator 214 and coupled sharp 224 is permitted to advance to a more proximal position than at the initial configuration illustrated in FIGURES 35 and 37. Thus the sharp 224 retracts from a distal position to a proximal position after installation of the on-body unit and insertion of at least a portion of the sensor. As illustrated in FIGURE 41, the carriage 230 is maintained in a distal position, but the sharp 224 has been withdrawn from the subject and is no longer accessible from the distal portion of the inserter 200, which prevents accidental needle sticks.

[00219] A further embodiment of an inserter is illustrated in FIGURES 42-56 and designated inserter 300. In some embodiments, inserter 300 has a maximum diameter of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 300 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 300 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc.

[00220] As illustrated in FIGURE 42-43, inserter 300 includes, *e.g.*, a handle 302, a sheath 342, and a removable distal cap 304 for maintaining a sterile environment for the medical device and sharp housed therein. FIGURE 43 illustrates that distal cap 304 is removed from handle 302. Distal cap 304 is secured to handle 302 by one of a number of securement means, *e.g.*, by use of threads 310. Sheath 342 defines a distal surface 312 for placement on the skin of a

subject. Inserter 300 may be utilized to advance a medical device into the skin of the subject. In some embodiments, handle 302 is advanced relative to sheath 342 in order to advance the medical device into the skin of the patient.

[00221] The components of inserter 300 are illustrated in FIGURES 44-49. As illustrated in FIGURE 44, handle 302 may include threads 310 for attachment of cap 304 via threads 311 (as illustrated in FIGURE 46). It is understood that other securement techniques, such as a snap-fit or friction-fit may be used to secure cap 304. Cap 304 may include a receptacle 325 for positioning of the sharp 324. Sheath 342, as illustrated in FIGURE 45, includes longitudinal notches 382.

[00222] Projections 386 on carriage 330, as illustrated in FIGURE 47, are configured to engage sheath to secure carriage 330 within the inserter 300, thereby preventing release of the carriage from the inserter. Notches 384 allow for the free travel of projections 386. The bottom of the notches acts as the retention portion that prevents the carriage 330 from falling out of the inserter 300. Projections 375 engage with the triangular latch features 370 of the sheath 342 as illustrated in FIGURES 51 and 53.

[00223] Carriage 330 also is provided with fingers 374 which engage a shoulder wall 376 of handle 302 (as illustrated in FIGURE 51), as will be described in greater detail herein.

[00224] Inserter 300 also includes a spring retention component 348, as illustrated in FIGURE 48. Spring retention component 348 defines an upper surface 349, which engages spring 346 (as illustrated in FIGURE 51). Spring retention component 348 also includes locking towers 351, which engage flanges 328 of needle carrier 334 to prevent accidental deployment of the sharp 324 after use of the inserter 300 is completed.

[00225] Inserter 300 is illustrated in cross-section in FIGURE 50 prior to use. Cap 304 is attached to the distal portion of inserter 300, via securement means, such as inter-engagement of threads 310 and 311. Cap 304 includes a desiccant tablet 390; a seal, such as a foil seal 392; and a Tyvek® layer 394, which allows breathability between the desiccant tablet 390 and the interior of the inserter 300.

[00226] As illustrated in FIGURE 51, the inserter 300 includes an initial configuration in which the handle 302 is disposed in a proximal position with respect to the sheath 342. In such configuration, the sharp 324 is disposed in a configuration spaced apart from the aperture 320 of the adhesive layer 318. The distal portion of inserter 300 is illustrated in FIGURE 52.

[00227] With continued reference to FIGURE 51, the longitudinal axis L of the inserter 300 is illustrated. Extending distally from the upper surface of handle 302 is an inner wall portion 326 and intermediate wall portion 374. Support member 334 extends from wall portion 326 and supports needle hub 336, from which sharp 324 extends longitudinally within the inserter 300. In some embodiments, the sharp is supported at an oblique angle, *e.g.*, between 0° and 90° with respect to the skin surface.

[00228] Sheath 342 is positioned within handle 302, having an annular configuration in which a retraction spring 346 is positioned. The distal portion of spring 346 contacts a surface 349 of spring retention component 348. The proximal portion of spring 346 contacts the inner surface 350 of handle 302. In the initial configuration, the spring 346 is in an extended or semi-extended configuration.

[00229] FIGURE 53 illustrates inserter 300 in cross-section, during insertion. Depression of handle 302 with respect to sheath 342 against the bias of spring 346 causes distal longitudinal

movement of the carriage 330 and sharp 324, from a proximal position towards a distal position. During such downward, distal movement, spring 346 is compressed between surface 349 of spring retention component 348 and surface 350 of handle 302. As the sharp 324 is urged distally, it carries the sensor insertion portion 30 of sensor 14 into the subcutaneous portion of the subject's skin S.

[00230] As carriage 330 reaches a distal position, the distal surface of the sensor housing 122 engages the upper surface of adhesive pad 318, thereby becoming adhered to the skin surface S of the subject. Also, flange 370 engages fingers 374 disposed on the carriage 330. Fingers 374 are pivoted outwards by flanges 370 in direction T. Such pivoting of fingers 374 causes fingers 374 to become disengaged from slots 376 in intermediate housing walls 374. Carriage 330 is thereby disengaged from handle 302 and needle carrier 334.

[00231] As illustrated in FIGURE 54, handle 302, along with needle hub 336 and sharp 324 are permitted to move proximally, while the sheath 342 and sensor housing 122 remain adjacent to the skin of the subject. If the user or some apparatus provides no downward force, or minimal downward force to the handle 302 to overcome the bias of spring 346, spring 346 is permitted to expand, thereby withdrawing the sharp 324 from the skin S of the subject.

[00232] Upon reaching the proximal position, flanges 328 on needle carrier 334 engage locking towers 351 of needle floor component 348. The inter-engagement of flanges 328 and locking towers 351 prevents inadvertent deployment of sharp 324 after installation of the medical device.

[00233] As shown in FIGURES 55 and 56, the carriage 330 is maintained in a distal position, but the sharp 324 has been withdrawn from the subject and is no longer accessible from the distal portion of the inserter 300, which prevents accidental needle sticks.

[00234] A further embodiment of an inserter is illustrated in FIGURES 57-67, and designated inserter 400. In some embodiments, inserter 400 has a maximum diameter of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 400 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 400 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc.

[00235] Inserter 400 generally includes, *e.g.*, a handle 402, sheath 442, and a removable distal cap 404 for maintaining a sterile environment for the medical device and sharp housed therein. As illustrated in FIGURE 58, distal cap 404 is shown removed from handle 402. Distal cap 404 is detachably secured to handle 402, *e.g.*, by use of threads 410. Sheath 442 includes a distal surface 412 for placement on the skin of a subject. Inserter 400 may be utilized to advance a medical device into the skin of the subject. In some embodiments, handle 402 is advanced relative to sheath 442 in order to advance the medical device distally and into the skin of the patient.

[00236] The components of inserter 400 are illustrated in FIGURES 59-63. As illustrated in FIGURE 59, handle 402 includes threads 410 for attachment of cap 404 via threads 411 (as illustrated in FIGURE 61). Cap 404 may include a receptacle 425 for positioning of the sharp

424. Sheath 442, as illustrated in FIGURE 60, includes longitudinal notches 482. Projections 486 on carriage 430, as illustrated in FIGURE 62, are configured to engage sheath 442 to secure carriage 430 within inserter 400, thereby preventing release of the carriage from the inserter. Sheath 442 also includes notches 484 which receive projection 475 of carriage 430. Notches 484 allow for the free travel of projections 486. The bottom of the notches acts as the retention portion that prevents the carriage 430 from falling out of the inserter 400. Projections 475 engage with the latch features 470 of the sheath 442 as illustrated in FIGURES 66 and 67. Carriage 430 also is provided with fingers 474 which engages a shoulder wall 476 of needle carrier 436, as illustrated in FIGURES 65-66, and as will be described in greater detail herein.

[00237] Sheath 442 also includes a spring retention portion 448, provided at the distal end of circumferential notch 496, as illustrated in FIGURES 60, 64 and 65. Needle carrier 434, as illustrated in FIGURE 63, includes wings 450, which provide an upper engagement surface for spring 446. Wings 450 also include recesses 451 including a shoulder 476 for engagement with fingers 474 of carriage 430.

[00238] Inserter 400 is illustrated in cross-section in FIGURE 64 in a state prior to use and prior to removal of cap 404, which is shown attached to the distal portion of handle 402, via inter-engagement of threads 410 and 411. Cap 404 includes a desiccant tablet 490, a seal such as a foil seal 492, and a Tyvek® layer 494, which allows breathability between the desiccant tablet 490 and the interior of the inserter 400.

[00239] As illustrated in FIGURE 65, the inserter 400 is shown in an initial configuration in which handle 402 is disposed in a proximal position with respect to the sheath 442. In such configuration, the sharp 424 is disposed in a configuration spaced apart from the aperture 420 of

the adhesive layer 418. The longitudinal axis L of the inserter 400 is illustrated. Extending distally from the upper surface of handle 402 is inner wall 475. The distal end portions of wall 475 provide a downward force on the carriage 430 upon depression of the handle 402 by a user. Alternatively, instead of handle having a distally extending inner wall, the carriage can include one or more upwardly extending walls or projections (not shown). The one or more upwardly extending inner walls or projections can have a length sufficient to either contact the upper surface of 402 or, alternatively, contact corresponding downwardly extending inner walls of the handle 402. In this manner, depression of handle 402 by a user provides a downward force on the one or more upwardly extending walls or projections of the carriage to advance the carriage (and on-body unit) distally to an installation and insertion position. In one embodiment a downwardly extending wall of the handle 402 and a corresponding upwardly extending wall of the carriage are aligned such that depression of the handle 402 by a user allows the upwardly extending wall and the downwardly extending wall to make direct contact, thereby permitting the carriage 430 and on-body unit to advance distally. In such embodiment, the downwardly extending inner wall of the handle has a distal end that is disposed proximally of the proximal most end of sheath 442.

[00240] Needle carrier 434 can be axially moveable within handle 402. Needle carrier 434 supports needle hub 436, from which sharp 424 extends longitudinally within inserter 400. In some embodiments, sharp 424 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface. Initially, needle carrier 434 is coupled to carriage 430 via inter-engagement of fingers 474 of carriage 430 with shoulder 476 of needle carrier 434. Spring 446 is disposed between spring retention portion 448 of sheath 442 and wings 450 (FIGURE 63) of needle carrier 434. Initially, spring 446 is in an expanded or semi-

expanded state while handle 402 is disposed proximally from sheath 442. In another exemplary embodiment, needle carrier 434 can be secured to handle 402, for example, secured to downwardly extending inner wall 475. In this manner, needle carrier and carriage 430 are longitudinally moveable with respect to sheath 442. In this regard, needle carrier 434 includes one or more apertures to receive one or more downwardly extending inner walls 475 of handle 402. In some embodiments, neither the needle carrier 434 nor the carriage 430 are in slidable contact with sheath 442, *e.g.*, spaced apart from sheath 442, during longitudinal movement of the needle carrier 434 and/or carriage 430.

[00241] FIGURE 66 illustrates inserter 400 in cross-section, during insertion. Depression of handle 402 with respect to sheath 442, against the bias of spring 446, causes distal longitudinal movement of the carriage 430 and needle carrier 434, from a proximal position towards a distal position. During such downward proximal movement, spring 446 is compressed between spring retention portion 448 and wings 450 (FIGURE 63) of needle carrier 434. As the sharp 424 is urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIGURE 23) into the subcutaneous portion of the subject's skin S.

[00242] As carriage 430 reaches a distal position, the distal surface of the sensor housing 122 engages the upper surface of adhesive pad 418, thereby becoming adhered to the skin surface S of the subject. Flange 470 engages fingers 474 disposed on the carriage 430. Fingers 474 are pivoted outwards by flanges 470 in direction T. Such pivoting of fingers 474 causes fingers 474 to become disengaged from shoulder 476 of needle carrier 434. Needle carrier 434 is thereby disengaged from carriage 430.

[00243] As illustrated in FIGURE 67, disengagement of the needle carrier 434 from the carriage 430 permits the spring 446 to expand, thereby advancing the needle carrier 434 to a proximal position and withdrawing the sharp 424 from the skin S of the subject while leaving the sensor 14 in the skin. Once the sharp 424 has been withdrawn from the subject, it is no longer accessible from the distal portion of the inserter 400 and unable to make contact by accident with the subject's skin because it is positioned at a proximal position within the carrier handle 402.

[00244] A further embodiment of an inserter is illustrated in FIGURES 68-71 and designated inserter 500. In some embodiments, inserter 500 has a maximum diameter of about 30 mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 500 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 500 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc.

[00245] Inserter 500 includes, *e.g.*, a bellows portion 502, a sheath 542, and a removable distal cap 504 for maintaining a sterile environment for the medical device and sharp housed therein. As illustrated in FIGURE 69, distal cap 504 is shown removed from sheath 542. Sheath 542 defines a distal surface 512 for placement on the skin of a subject. Inserter 500 may be utilized to advance a medical device into the skin of the subject. In some embodiments, bellows portion 502 is compressed in order to advance the medical device into the skin of the subject. Bellows portion 502 includes a series of concentric folds, including raised portions 516 and folded portions 518.

[00246] Inserter 500 is illustrated in cross-section in FIGURE 70 prior to use and prior to removal of cap 504, which is attached to sheath 542 via inter-engagement of threads 510 on sheath and threads 511 on cap 504. Cap 504 includes a desiccant tablet 590. Cap 504 may further include a receptacle for maintaining the position of the sharp 524 within the sheath 542 prior to use.

[00247] As illustrated in FIGURE 70, the inserter 500 includes an initial configuration in which the bellows portion 502 is disposed in a relaxed, extended position. In such configuration, the sharp 524 is disposed in a position spaced apart from the aperture 520 of the adhesive layer 518. The proximal end portion of the housing includes a button or actuator portion 514. Extending distally from the actuator portion 514 are side walls 528 and needle hub 536. Downward force on the actuator portion 514 causes a downward force on the needle hub 536 and on the carriage 530 (through coupling to side walls 528). Carriage 530 includes a recess 532 for reception of the sensor housing 122 therein. Sharp 524 extends longitudinally from needle hub 536 within the inserter 500. In some embodiments, the sharp is supported at an oblique angle, *e.g.*, between including about 0° and 90° with respect to the skin surface.

[00248] FIGURE 71 illustrates inserter 500 in cross-section, during insertion. Depression of bellows portion 502 with respect to sheath 542 against the bias of spring 546 causes distal longitudinal movement of the carriage 530 and sharp 524 from a proximal position toward a distal position. During such downward, proximal movement, spring 546 is compressed between an upper (proximal) portion adjacent to actuator 514 and a lower (distal) portion adjacent to sheath 542. As the sharp 524 is urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIGURE 23) into the subcutaneous portion of the subject's skin S.

[00249] By removing downward force on the actuator portion 514, the bias of spring 546 provides an upward (proximal) force, which permits sharp 524 to withdraw from the skin S of the subject. Once the sharp 524 has been withdrawn from the subject, it is no longer accessible from the distal portion of the inserter 500, and unable to make contact by accident with the subject's skin.

[00250] An inserter 2400 in accordance with another exemplary embodiment is illustrated in FIGURE 72. In some embodiments, inserter 2400 has a maximum diameter, of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.5 mm, about 54.5 mm, etc. In some embodiments, inserter 2400 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 2400 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc.

[00251] With reference to FIGURE 72, inserter 2400 includes a housing 2402 and a removable distal cap 2412 for maintaining a sterile environment for the medical device and sharp housed therein. Housing 2402 and distal cap 2412 may be fabricated from any suitable materials such as metal, plastic, etc. In some embodiments, cap 2412 may be fabricated from a polymer or plastic material.

[00252] An exploded view of the components of inserter 2400 is illustrated in FIGURE 72A. As shown, inserter 2400 generally comprises plunger 2405, spring 2406, housing 2402, sharp 2404, sensor housing 122, sharp holder 2408, adhesive patch 218, and cap 2412 when fully assembled.

[00253] A more detailed view of sharp holder 2408 is shown in FIGURE 72B. Needle holder 2408 retains sharp 2404 in a fixed position with respect to itself within inserter 2400, thereby allowing it to safely penetrate a subject's skin during later use.

[00254] To assemble inserter 2400, sharp 2404 is inserted through an opening in sensor housing 122 as shown in FIGURE 72C. Needle holder 2408 prevents sharp 2404 from being fully inserted through sensor housing 122. In some embodiments, sensor housing 122 includes an analyte sensor 14 and a sensor control unit 12.

[00255] Next, plunger 2405, spring 2406, and housing 2402 are assembled as shown in FIGURES 72D-72F. Plunger 2405 contains a spring retention member which is inserted through the center of spring 2406. Lip 2414 of plunger 2405 engages inner wall 2416 of housing 2402 when assembled (FIGURE 72). This causes spring 2406 to be contained between lip 2418 of housing member 2402 and the bottom surface 2424 of plunger 2405. The resulting sub-assembly of inserter 2400 shown in allows plunger 2405 to move between a proximal position, with spring 2406 fully extended, and a distal position, wherein bottom surface 2424 engages wall 2426 of housing 2402.

[00256] The sensor housing assembly shown in FIGURE 72C is then inserted into the inserter sub-assembly shown in FIGURES 72D-72F. As shown in FIGURE 72F, sensor housing 122 is inserted into housing 2402 with the tip of sharp 2404 pointing away from plunger 2405. The resulting assembly is depicted in FIGURE 72G. As shown in FIGURE 72, grooves on sharp holder 2408 engage tabs 2422 on plunger 2405.

[00257] Finally, adhesive patch 218 is placed over the opening of housing 2402 and cap 2412 is friction fit over housing 2402 as shown in FIGURE 72H. The fully assembled inserter 2400 is

depicted in FIGURE 72I. In some embodiments, adhesive pad 218 has an adhesive material on both faces. A central aperture 220 may be provided in adhesive pad 218 to allow sharp 2404 to be deployed into the skin of a subject. During insertion, sharp 2404 passes through aperture 220 and into the skin of the subject carrying at least the sensor with it.

[00258] FIGURE 72J illustrates inserter 2400 in cross-section, in an initial configuration prior to use, after removal of the distal cap 2412. As shown, sharp 2404 extends longitudinally within the inserter 2400. In some embodiments, sharp 2404 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface.

[00259] In some embodiments, sharp 2404 is a solid needle. In some embodiments, sharp 2404 is provided with a substantially cylindrical configuration defining an interior bore, *e.g.*, a rigid cylindrical member or a hypodermic-style needle. Sharp 2404 may also be provided with an elongated longitudinal opening or gap in the wall of the sharp 2404. In some embodiments, sharp 2404 is a fabricated from a sheet of metal, and folded into a substantially "V" or "U" or "C" configuration in cross-section to define the longitudinal recess.

[00260] Depression of plunger 2405 causes distal longitudinal movement of sensor housing 122 and sharp 2404, from a proximal position to a distal position. During such downward, distal movement, spring 246 is further compressed between lip 2418 and bottom surface 2424. Lip 2414 is pushed outward by sensor housing 122 and the friction between sensor housing 122 and lip 2414 of the housing hold the sensor housing 122 up against plunger 2405.

[00261] As illustrated in FIGURE 72K, depression of plunger 2405 advances the inserter 2400 from an initial configuration to a deployed configuration. Contact of plunger 2405 and sharp holder 2408 during depression of plunger 2405 imposes a downward force and

consequential distal movement of sharp 2405.the carriage 230. As the sharp 2404 is urged distally, it carries the sensor insertion portion 30 into the subcutaneous portion of the subject's skin S.

[00262] When plunger 2505 reaches a distal position, as shown in FIGURE 72L, bottom surface 2424 engages wall 2426 and prevents further downward movement. The distal (lower) surface of sensor housing 122 engages the upper surface of adhesive pad 218, thereby becoming adhered to the skin surface S of the subject.

[00263] As the subject or some apparatus removes force from pusher 2405, spring 2406 urges pusher 2405 toward its proximal position as shown in FIGURE 72M, leaving sensor housing 122 adhered to the skin surface S of the subject. Tabs 2424 provide additional force on sensor housing 122 to assist holding it to adhesive patch 218 while the sharp 2404 is withdrawn through sensor housing 122. Eventually, the upward force exerted by spring 2406 returns inserter 2400 to its initial configuration as illustrated in FIGURE 72N.

[00264] In some embodiments, inserter 2400 may be distributed in a sterilized package 2480 as depicted in FIGURE 72O. To use inserter 2400 in this configuration, a user would first clean the insertion site on the skin with alcohol. The subject would then remove inserter 2400 from sterilized package 2480 as shown in step 1. Next a subject would place the inserter on the insertion site and push down on inserter 2400 until sensor housing 122 is adhered to the subject's skin as shown in steps 2-3. Finally, the subject would remove inserter 2400 from the insertion site and dispose of the inserter.

[00265] In another embodiment, the sterilized inserter 2500 shown in FIGURE 72O may be utilized with driver apparatus 3900 (FIGURES 93-93H) as shown in FIGURE 72P. In this

manner, insertion of sensor housing unit is semi-automated which may deliver a more consistent user experience and reduce the risk of user error. Additionally, because inserter 2500 is already sterilized, utilizing the method depicted in FIGURE 72P also reduces the risk of possible infection.

[00266] A further embodiment of an inserter is illustrated in FIGURES 73-73N, and designated inserter 2500. In some embodiments, inserter 2500 has a maximum diameter of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 50.25 mm, about 52 mm, etc. In some embodiments, inserter 2500 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 50.25 mm, about 53 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 2500 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc.

[00267] Inserter 2500 generally includes, *e.g.*, a handle 2502, sheath 2512, and a removable distal cap 2504 for maintaining a sterile environment for the medical device and sharp housed therein (FIGURE 73). As illustrated in FIGURES 73A-73B, handle 2502 is shown removed from distal cap 2504. Distal cap 2504 is detachably secured to handle 2502, *e.g.*, by use of threads 2506. It is understood that cap may be secured using snap-fit or press-fit configuration. Inserter 2500 may be utilized to advance a medical device into the skin of the subject. In some embodiments, handle 2502 is advanced relative to sheath 2512 in order to advance the medical device distally and into the skin of the patient.

[00268] Handle 2502 further includes needle carrier guides 2508 which allow the needle carrier 2514 to slidingly move relative to distal cap 2504. Detent 2507 prevents sheath 2512

from moving towards a "firing position" until a minimum force is applied. Location feature 2510 allows for the proper positioning of distal cap 2508 and carriage 2516 when engaged.

[00269] Further components of inserter 2500 are illustrated in FIGURES 73C-73G. Sheath 2512, as illustrated in FIGURES 73C, may include longitudinal notches 2518 which snap into detents 2507. Retention members, such as ribs 2520, pinch spring arms 2522 located on carriage 2516 to prevent sensor housing 122 from falling out of inserter 2500 when sheath 2512 is in the extended position. Ribs 2520 do not extend to the bottom of sheath 2512, thus allowing carriage 2516 to release sensor housing 122 when it has traveled to the bottom of sheath 2512 during insertion. Interfering structure, such as locking beam 2524, prevents inserter 2500 from being used again once needle carrier 2514 passes the locking beam (FIGURE 73N). Specifically, locking feature 2526 of needle carrier 2514 engages with locking beam 2524 to prevent further use of inserter 2500.

[00270] Needle carrier 2514 is illustrated in greater detail in FIGURES 73D-73E. In some embodiments, needle carrier 2514 includes guides, such as rail guides 2528, which interface with rail guides 2508, thereby allowing needle carrier 2514 to slidingly move relative to handle 2502. Notches 2527 are provided in sheath 2512 which has a larger dimension than the wings 2550 of needle carrier 2514, such that the needle carrier 2514 does not contact sheath 2512 during longitudinal movement of needle carrier 2514. Needle carrier 2514 also comprises detents/notches 2530 which interface with the upper edge of the spring when inserter 2500 is fully assembled (see FIGURES 73H-73N). In some embodiments, needle carrier 2514 comprises an attachment feature 2532 capable of accommodating a custom needle hub or

attachment. Rails 2524, located on the inner perimeter of needle carrier 2514, slidingly engage with slots 2536 located on carriage 2516.

[00271] Carriage 2516 is illustrated in greater detail in FIGURES 73F-73G. As shown, carriage 2516 may comprise latches 2538 which connect it to needle carrier 2514 by locking with latches 2540. Spring hook 2542 allows for support for retaining sensor housing 122 when the inserter has not been fired and allows for release of sensor housing 122 when it has been attached to the skin of the user.

[00272] Inserter 2500 is illustrated in cross-section in FIGURE 73H in a state prior to use in which handle 2502 is disposed in a proximal position with respect to the sheath 2512. In such configuration, the sharp 2550 is disposed in a configuration spaced apart from the aperture 420 of the adhesive layer (not shown). The longitudinal axis L of the inserter 2500 is illustrated. The upper surface of spring 2544 is retained in inserter 2500 by detents/notches 2530 located on needle carrier 2514. The bottom surface of spring 2544 is retained by spring floor 2545 located on sheath 2512. Initially, spring 2544 is in an expanded or semi-expanded state while handle 2502 is disposed proximally from sheath 2512.

[00273] Extending distally from the upper surface of handle 2502 is inner wall 2552. In some embodiments, the distal end portions of wall 2508 provide a downward force on carriage 2516 upon depression of handle 2502 by a user. Alternatively, instead of handle 2502 having a distally extending inner wall 2508carriage 2516 can include one or more upwardly extending walls or projections (not shown). The one or more upwardly extending inner walls or projections can have a length sufficient to either contact the upper surface of handle 2502 or, alternatively, contact corresponding downwardly extending inner walls of handle 2502. In this manner,

depression of handle 2502 by a user provides a downward force on the one or more upwardly extending walls or projections of carriage 2516 to advance carriage 2516 (and sensor housing 122) distally to an installation and insertion position. In such embodiment, the downwardly extending inner wall of the handle has a distal end that is disposed proximally of the proximal most end of sheath 2512.

[00274] Sharp 2550 extends longitudinally from needle carrier 2514 within inserter 2500. In some embodiments, sharp 2550 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface.

[00275] FIGURE 73I illustrates inserter 2500 in cross-section after a user applies an initial downward force to button 2502. In some embodiments, a predetermined minimum force must be used so that longitudinal notches 2518 advance past detent 2507.

[00276] After detent 2507 has been overcome, further depression of handle 2502 with respect to sheath 2512, against the bias of spring 2544, causes distal longitudinal movement of the carriage 2516 and needle carrier 2514, from a proximal position towards a distal position as shown in FIGURE 73J. During such downward proximal movement, spring 2544 is compressed between detents/notches 2530 and retention tab 2546. As sharp 2550 is further urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIGURE 23) into the subcutaneous portion of the subject's skin S.

[00277] As carriage 2516 reaches a distal position as shown in FIGURE 73J, the distal surface of the sensor housing 122 engages the upper surface of adhesive pad (not shown), thereby becoming adhered to the skin surface S of the subject. Latch 2538 engages the upper surface of retention tab 2546 as shown in FIGURES 73K. As a result, the top portion of latch 2538 is

pivoted outward in direction T. Such pivoting of latch 2538 causes needle carrier to become disengaged from carriage 2516.

[00278] As illustrated in FIGURE 73L, disengagement of the needle carrier 2514 from the carriage 2516 permits spring 2544 to expand, thereby advancing the needle carrier 2514 to a proximal position and withdrawing the sharp 2550 from the skin S of the subject while leaving the sensor housing 122 attached to the skin. As the sharp is withdrawn (FIGURE 73M), locking feature 2526 advances past locking beam 2524 because of the upward force exerted on needle carrier 2514 by spring 2544.

[00279] Referring now to FIGURE 73N, once the sharp 2550 has been withdrawn from the subject, button 2500 cannot be pressed again because any downward movement will be blocked by the interaction of locking beam 2524 and locking feature 2526.

[00280] In some embodiments, inserter 2500 may come in a sterilized package which is capable of a one-time use as shown in FIGURE 73O. To use inserter 2500 in this manner, a user would first sterilize the insertion site on the skin with alcohol. The subject would then twist off cap 2504 as shown in step 1. Next a subject would place the inserter on the sterilized insertion site and push down on inserter 2500 until sensor housing 122 is adhered to the subject's skin as shown in steps 2-3. Finally, the subject would remove inserter 2500 from the insertion site and dispose of the inserter. In this manner, the inserter 2500 itself serves as its own sterilized packaging.

[00281] A further embodiment of an inserter is illustrated in FIGURES 74-90, and designated inserter. In some embodiments, inserter 2700 has a maximum diameter of about 30mm to about 60 mm, *e.g.*, about 40 mm, about 43 mm, about 43.5 mm, about 46 mm, about 50 mm, etc. In

some embodiments, inserter 2700 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 49.5 mm, about 55 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 2700 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc.

[00282] Inserter 2700 generally includes, *e.g.*, a housing 2702 (FIGURES 75-76), sheath 2708 (FIGURES 77-78), and a removable distal cap 2704 for maintaining a sterile environment for the medical device and sharp housed therein (FIGURE 74). As illustrated in FIGURES 75-76, housing 2702 is shown removed from distal cap 2704. Distal cap 2704 is detachably secured to housing 2702, *e.g.*, by use of threads 2706. It is understood that cap may be secured using snap-fit or press-fit configuration. Inserter 2700 may be utilized to advance a medical device into the skin of the subject. Sheath 2708 generally a cavity or open space, within which sharp carrier 2716 and medical device carrier 2730 are moveable. In some embodiments, housing 2702 is advanced relative to sheath 2708 in order to advance the medical device distally and into the skin of the patient.

[00283] Housing 2702 includes sheath guide rail 2710 which interfaces with rail guides 2712 located on sheath 2708 (FIGURE 77), thereby allowing housing 2702 to slidingly move relative to sheath 2708. Housing 2702 may further includes sharp carrier guide rail 2714 which interfaces with rail guides 2718 located on sharp carrier 2716 (FIGURE 70). Sheath 2708, sharp carrier 2716, and housing 2702 may alternatively move relative to one another without the use of guide rails.

[00284] Ledge 2720 and/or ledge 2722 are provided on an interior portion of housing 2702. Ledge 2720 engages sheath 2708 to hold sheath 2708 in a pre-use position prior to insertion of the medical device. Ledge 2722 engages sheath 2708 to secure sheath 2708 in a post-use position after insertion of the medical device. Housing 2702 further includes detent 2724 which prevents housing 2702 from moving relative to sheath 2708 until a minimum force has been applied, e.g., distally by user to housing 2702. In some embodiments, housing 2702 includes insertion hard stop 2724. The sheath 2708 is secured to the housing 2702 via snap 2726. Snap 2726 snaps into the housing detent 2724 (In some embodiments, it is pinched between ledge 2720 and detent 2724, thus controlling its height relative to the housing 2702). The needle carrier 2716 is located and secured to the medical device carrier 2730 (located via interaction of locating features 2748 and 2750 and secured via interaction of carrier arms 2732 and angled top surface of 2716). The insertion hard stop 2724 is a controlled surface onto which the top of sheath surface 2728 will engage at the end of the insertion stroke to prevent further relative movement in some embodiments.

[00285] Further components of inserter 2700 are illustrated in FIGURES 77-82. Sheath 2708 is a generally cylindrical component. As illustrated in FIGURES 77-78, sheath 2708 may include attachment snaps 2726 which are biased into detent 2724 of housing 2702 to create a minimum force that must be overcome in order to advance sharp 224 into the subject's skin and install the sensor housing 122. In some embodiments, the force to be overcome can be about 0.5 lbf to about 5 lbf., e.g., about 1lbf, about 2 lbf, about 3 lbf, about 4 lbf, etc. Support wall 2728 prevents carrier arms 2732 on carrier 2730 from bending outwardly, clear of sharp carrier 2716. Ribs 2734 pinch carrier arms 2732 on carrier 2730, thus preventing sensor housing 122 from falling out of inserter 2700 when sheath 2708 is in the extended position. Ribs 2734 are not

present at the bottom of sheath 2708, thus allowing room for spring arms 2736 on carrier 2730 to release sensor housing 122 when carrier 2730 has traveled to the bottom of sheath 2708. Slot 2738, located on sheath 2708, interfaces with locating feature 2740 on carrier 2730, thus orienting carrier 2730 to sheath 2708 during assembly.

[00286] Referring next to FIGURES 79-80, depicted is sharp carrier 2716 in a perspective and cross-sectional view, respectively. Sharp carrier 2716 contains notches 2724 which allow clearance for the passage of carrier arms 2732 located on medical device carrier 2730. Guidance walls 2744 securely hold spring 2746 in place (FIGURE 83). Locating features 2748, e.g., bosses or tabs, align with locating features 2750, e.g., recesses or apertures, on carrier 2730. Snap features 2752 secure sharp 224 securely within inserter 2700. It is contemplated that sharp 224 may be secured to sharp carrier 2716 by other techniques, e.g., friction fit, adhesive, welding, etc.

[00287] Medical device carrier 2730 is depicted in more detail in FIGURES 81-82. As shown, carrier 2730 contains spring locating ring 2754 which receives one end of spring 2746. In some embodiments, spring 2746 surrounds spring locating ring 2754. In some embodiments, the inner area remains clear to leave room for the deflection of sharp carrier feature snaps 2752 that deflect out when the sharp is inserted. Carrier 2730 further comprises locating features 2756 which interface with locating features on housing 2702.

[00288] Inserter 2700 is illustrated in cross-section in FIGURE 83 in a state prior to use in which housing 2702 is disposed in a proximal position with respect to the sheath 2708. In such orientation, sharp 224 is disposed in a configuration spaced apart from the aperture 420 of the adhesive layer 118. The upper surface of spring 2746 is retained in inserter 2700 by sharp carrier

2716. The bottom surface of spring 2746 is retained by spring location ring 2754. Initially, spring 2746 is in a compressed or semi-compressed state while housing 2702 is disposed proximally from sheath 2708.

[00289] Sharp 224 extends longitudinally from sharp carrier 2716 within inserter 2700. In some embodiments, sharp 224 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface.

[00290] FIGURE 84 illustrates inserter 2700 in cross-section after a user applies an initial downward force to housing 2702. In some embodiments, a predetermined minimum force must be used so that attachment snaps 2726 advance past detent 2724.

[00291] After detent 2724 has been overcome, e.g., snap 2726 is radially displaced, further depression of housing 2702 with respect to sheath 2708 causes distal longitudinal movement of the carrier 2730 and sharp carrier 2716, from a proximal position towards a distal position as shown in FIGURE 85. As sharp 224 is further urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIGURE 23) into the subcutaneous portion of the subject's skin S.

[00292] As carrier 2716 reaches a distal position, the distal surface of the sensor housing 122 engages the upper surface of adhesive pad 118, thereby becoming adhered to the skin surface S of the subject. Concurrently, carrier arms 2732 are advanced distally and clear the support wall 2728. This allows carrier arms 2732 to deflect radially outwardly. When carrier arms 2732 deflect outwardly, shoulder portions of carrier arms 2732 are no longer in an interference relationship with the sharp carrier 2716. Thus spring 2746 is permitted to expand as shown in FIGURE 87, thereby advancing the sharp carrier 2716 to a proximal position and withdrawing the sharp 224 from the skin S of the subject while leaving the sensor housing 122 attached to the

skin. Handle 2702 is maintained in the distal position. Sheath snap 2726 of the sheath 2708 have now moved up to lock over feature 2722 of the housing 2702. Now the housing 2702 and the sheath 2708 can no longer move longitudinally with respect to each other.

[00293] In some embodiments, the changing interaction of sheath snap 2726 with the housing detent/ledges 2720, 2724, and 2722 determine whether the sheath 2708 is locked. When snap 2726 is in the pre-fire position, ledge 2720 prevents sheath 2708 from being pulled out of the housing 2702. In this position, detent 2724 may also impede the movement of pushing the sheath 2708 into the housing 2702. When the detent is overcome by a at least at minimum force, the sheath 2704 moves longitudinally with respect to the housing 2702 until the snap 2726 snaps over housing ledge 2722. At this point, ledge 2722 prevents the sheath 2708 from being pulled out of the housing again, but from a new position (this position may be referred to as the used/post-fire position). Sharp carrier snap 2752 function is to hold onto the sharp/needle. in some embodiments, the sharp/needle carrier 2716 is held in the post-fire position relative to the housing 2702 by, e.g., an interference between the rails of the housing 2714 and the guide rails of the sharp carrier 2718 (this interference is only present once the sharp carrier is fully retracted) and/or by medical device carrier projections 2732 interfering with the bottom/floor of the sharp carrier (See, e.g., FIG. 88).In another embodiment of inserter 2700, adhesive pad 118 may be attached directly to sensor housing 122. This necessitates a different shape of inserter 2700 as depicted in FIGURE 89. Additionally, carrier 2630 is slightly wider to accommodate adhesive pad 118 attached to sensor housing 122 (FIGURE 90).

[00294] A further embodiment of an inserter is illustrated in FIGURES 91-103. In some embodiments, inserter 3700 has a maximum diameter of about 30mm to about 60 mm, *e.g.*,

about 40 mm, about 43 mm, about 43.5 mm, about 46 mm, about 50 mm, etc. In some embodiments, inserter 3700 has a maximum height of about 40 mm to about 80 mm, *e.g.*, about 44 mm, about 46 mm, about 49.5 mm, about 55 mm, about 67 mm, about 71 mm, etc. In some embodiments, inserter 3700 has a volume of about 35 cm^3 to about 110 cm^3, *e.g.*, about 40 cm^3, about 41 cm^3, about 50 cm^3, about 60 cm^3, about 61 cm^3, about 62 cm^3, about 69 cm^3, about 70 cm^3, about 79 cm^3, about 90 cm^3, about 106 cm^3, etc.

[00295] Figures 91A-D depict the various stages of insertion from an initial stage in which the cap is attached (FIGURE 91A), to removal of the cap (FIGURE 91B), deployment of the sharp and sensor housing unit (FIGURE 91C) and removal of the inserter from the subject's skin (FIGURE 91D). Inserter 3700 generally includes, *e.g.*, a housing 3702 (FIGURES 91-92B), sheath 3708 (FIGURE 93A-B), and a removable distal cap 3704 (FIGURE 94A-C) for maintaining a sterile environment for the medical device and sharp housed therein. As illustrated in FIGURES 91 and 94A-B, housing 3702 is shown removed from distal cap 3704. Distal cap 3704 is detachably secured to housing 3702, *e.g.*, by use of threads 3706. It is understood that in some embodiments, the cap may be secured using snap-fit or press-fit configuration. Inserter 3700 may be utilized to advance a medical device into the skin of the subject. Sheath 3708 generally encloses or defines a cavity, within which sharp carrier 3716 (FIGURES 95A-B) and medical device carrier 3730 (FIGURE 96) are moveable. In some embodiments, housing 3702 is advanced relative to sheath 3708 in order to advance the medical device distally and into the skin of the patient.

[00296] Housing 3702 includes sheath guide rail 3710 which interfaces with rail guides 3712 located on sheath 3708, thereby allowing housing 3702 to slidingly move relative to sheath 3708.

Sheath 3708, sharp carrier 3716, and housing 3702 may alternatively move relative to one another without the use of guide rails. The housing can include a distally extending sidewall having a non-linear or arcuate shape. In the embodiment illustrated in FIGURES 91-103 the housing is configured with a undulating sidewall which transitions from a concave portion to a convex portion. This contour enhances the users tactile recognition and provides a more ergonomic gripping surface which reduces accidental slippage by the user's hand. Further, the housing is configured with a cavity sized to receive the sheath 3708, as described in further detail below.

[00297] Housing ledge 3720 and/or ledge 3722 are provided on an interior portion of housing 3702. Ledge 3720 engages sheath 3708 to hold sheath 3708 in a pre-use position prior to insertion of the medical device. Ledge 3722 engages sheath 3708 to secure sheath 3708 in a post-use position after insertion of the medical device. Housing 3702 further includes detent 3724 which prevents housing 3702 from moving relative to sheath 3708 until a minimum force has been applied, e.g., distally by user to housing 3702. The sheath 3708 is secured to the housing 3702 via retention features 3726, which can be configured, e.g., as a snap. Retention feature 3726 snaps into the housing detent 3724 (In some embodiments, it is pinched between ledge 3720 and detent 3724, thus controlling its height relative to the housing 3702). The surfaces of the housing ledges 3720, 3722, 3724 and retention features 3726 are preferably configured to engage in a single point of contact or a plurality of discrete points of contact ,e.g., line. Such discrete points of contact are advantageous over conformal surface-to-surface contact in that a more thorough sterilization process can be performed. A variety of sterilization mediums can be employed, e.g., Ethylene Oxide (EtO), wherein the gaseous medium is delivered over the various inserter components. Accordingly, the discrete points of contact allow for a

greater surface area of each inserter component to be exposed to the gaseous medium, thereby providing for a more thorough and rapid sterilization process. The housing includes distally extending protrusions 3727 which are received in apertures 3756 of the medical device carrier 3730 to couple the housing and medical device carrier. Consequently, there is no relative movement between the housing 3702 and the medical device carrier 3730.

[00298] Sheath 3708 is a generally formed as a unitary tubular member having proximal 3708a and distal 3708c cylindrical portions. In some embodiments, the portions 3708a and 3708c have an elliptical, square, hexagonal, or other cross-section. As illustrated in FIGURES 93A-B, the distal cylindrical portion can be formed with a greater diameter than the proximal portion, with the proximal and distal portions integrally connected via a shelf 3708b. Accordingly, the sheath can be formed as a single-piece and generally cylindrical member with the proximal portion having sufficient rigidity to prevent displacement of the carrier arms 3732, as described in further detail below. Sheath 3708 can include retention members 3726, e.g. detent snaps, which are biased into detent 3724 of housing 3702 to create a minimum force that must be overcome in order to advance sharp 324 into the subject's skin and install the sensor housing 322. The retention members 3726 can extend proximally from the shelf 3708b of the sheath and be formed as a separate member such that the retention members are spaced or offset from the cylindrical wall of the sheath. The actuation force of the inserter is determined by the stiffness of retention members 3726 (which is a function of length, thickness, and cross section) as well as the steepness of the angle of detent 3724 of the housing. In some embodiments, the force to be overcome can be about 0.5 lbf to about 5 lbf., e.g., about 1lbf, about 2 lbf, about 3 lbf, about 4 lbf, etc.

[00299] As described above, the proximal portion 3708a of the sheath is sized such that an interior support wall surface 3728 prevents carrier arms 3732 on medical device carrier 3730 from displacement or bending outwardly, clear of sharp carrier 3716. Maintaining the carrier arms 3732 in a fixed or constrained position within the sheath allows a user to accurately know the relative positioning of the needle within the inserter. Conversely, the distal portion 3708c of the sheath is sized such that the diameter of the interior wall surface is greater than the carrier arms 3732, thus allowing room for spring arms 3732 on carrier 3730 to expand or displace radially outward thereby releasing the sharp carrier 3716 to retract to the proximal position. Guide rails 3712 are included on the exterior surface of the proximal portion of the sheath 3708a. The guide rails 3712 remain engaged with the housing guide rail 3710 of the housing throughout the insertion operation, i.e., from advancement of the housing from the proximal position to the distal position. Thus even prior to insertion, rotational position of the housing and sheath is controlled and "rocking" is minimized. In general, rocking is minimized by increasing the length of engagement with respect to the diameter of engagement. In the embodiment disclosed herein, the length of engagement between the sheath and housing, i.e. along the longitudinal axis, is relatively large while the diameter at which the engagement occurs is relatively small, i.e. at proximal portion of sheath 3708a. Additionally, sheath 3708 includes a slot 3738 extending distally from the shelf 3708b and configured to receive the guide rail 3710 of the housing upon delivery of the medical device and insertion of the sharp into the subject.

[00300] Referring next to FIGURES 95A-B, depicted is sharp carrier 3716 in a perspective and cross-sectional view, respectively. Sharp carrier 3716 contains notches 3724 which allow clearance for the passage of carrier arms 3732 located on medical device carrier 3730. Guidance walls 3744 securely hold spring 3746 in place (FIGURES 99A-B). The top or proximal edge of

the sharp carrier includes a chamfered or sloped edge 3725. Locating features 3748, e.g., standoffs or distally extending protrusions, align with locating features 3750, e.g., recesses or apertures, on carrier 3730. Accordingly, the sharp carrier 3716 is located and secured to the medical device carrier 3730 (located via interaction of locating features 3748 and 3750 and secured via interaction of carrier arms 3732 and angled edge surface of 3725. These locating features can extend through the puck carrier 3730 and directly engage the sensor housing 322. Accordingly, when a user actuates the inserter, the sharp carrier drives the sensor housing 322 and sharp 324 towards the subject via the protrusions 3748. The direct coupling of the sharp carrier enhances the control of the positioning of sensor housing 322, and prevents skewing of the sensor housing 322 or sharp 324. Additionally, snap features 3752 secure sharp 324 securely within inserter 3700. It is contemplated that sharp 324 may be secured to sharp carrier 3716 by other techniques, e.g., friction fit, adhesive, welding, etc.

[00301] Medical device carrier 3730 is depicted in more detail in FIGURE 96. As shown, carrier 3730 contains spring locating ring 3754 which receives one end of spring 3746. In some embodiments, spring 3746 surrounds spring locating ring 3754. In some embodiments, the inner area remains clear to leave room for the deflection of sharp carrier feature snaps 3752 that deflect out when the sharp is inserted. As described above, carrier 3730 further comprises locating features 3756 which interface with locating features on housing 3702. Furthermore, detents can be formed at the end of carrier arms 3732 of the medical device carrier to abut or otherwise the sloped edge 3725 of the sharp carrier. As described above, the detents on carrier arms 3732 are configured to engage the edge 3725 of the sharp carrier in a discrete point of contact fashion in order to realize the aforementioned sterilization advantages. Additionally, these surfaces can be configured with rounded surfaces which ensure that there is no surface to "snag" during the

release of the sharp carrier. The medical device carrier 3700 further includes snaps 3542 which loosely hold the sensor housing unit 322 in place. Ribs on the interior surface of the distal portion 3708c of the sheath hold these snaps securely in place while the sheath is fully extended. When the medical device carrier 3700 advances along the sheath to reach the proximal position during use, the snaps 2542 are no longer supported by the sheath and the force of the adhesive skin patch 318 overcomes the retention force of the snaps 3542.

[00302] Inserter 3700 is illustrated in cross-section in FIGURES 97A-C in a state prior to use in which housing 3702 is disposed in a proximal position with respect to the sheath 3708 and the cap 3704 secured to the housing. FIGURE 98 illustrates a cross-sectional view of the inserter in a state prior to use after the cap 3704 has been removed. In such orientation, sharp 324 is disposed in a configuration spaced apart from the aperture 320 (not shown) of the adhesive layer 318. The upper surface of spring 3746 is retained in inserter 3700 by sharp carrier 3716. The bottom surface of spring 3746 is retained by spring location ring 3754 of the medical device carrier 3730. Initially, spring 3746 is in a compressed or semi-compressed state while housing 3702 is disposed proximally from sheath 3708.

[00303] Sharp 324 extends longitudinally from sharp carrier 3716 within inserter 3700. In some embodiments, sharp 324 is supported at an oblique angle, *e.g.*, between and including about 0° and 90° with respect to the skin surface.

[00304] FIGURES 99A-B depict the relationship between the medical device carrier 3730 and the sharp carrier 3716 (with the housing 3702 and sheath 3708 omitted for sake of clarity). FIGURE 99A depicts the initial position of the medical device carrier 3730 and the sharp carrier 3716 with the carrier arms 3732 engaged with the sloped edge 3725 of the sharp carrier. In this

position there is no relative movement between the medical device carrier 3730 and the sharp carrier 3716. However the carrier arms 3732 are not of sufficient rigidity or bias to counteract the bias of the spring 3746 in order to maintain the sharp carrier in the position shown in FIGURE 99A without support from the sheath, as shown in FIGURE 100. Accordingly, the spring 3746 urges the sharp carrier 3716 in the proximal direction thereby displacing the carrier arms 3732 radially outward as shown in FIGURE 99B.

[00305] FIGURE 101 illustrates inserter 3700 in cross-section after a user applies an initial downward force to housing 3702. In some embodiments, a predetermined minimum force must be used so that attachment snaps 3726 advance past detent 3724.

[00306] After detent 3724 has been overcome, e.g., snap 3726 of the sheath is displaced radially inward, further depression of housing 3702 with respect to sheath 3708 causes distal longitudinal movement of the medical device carrier 3730 and sharp carrier 3716, from a proximal position towards a distal position as shown in FIGURES 102A-B. During this phase of insertion the interior surface of proximal portion 3708a of the sheath remains engaged with the carrier arms 3732 to prevent radial displacement of the arms 3732, and thus maintains the coupling of the medical device carrier 3730, sensor housing 322, sharp 3724 and sharp carrier 3716. As sharp 324 is further urged distally, it carries the sensor insertion portion 30 of sensor 14 (FIGURE 23) into the subcutaneous portion of the subject's skin S.

[00307] As carrier 3716 reaches a distal position, the distal surface of the sensor housing 322 engages the upper surface of adhesive pad 318, thereby becoming adhered to the skin surface S of the subject. Concurrently, carrier arms 3732 are advanced distally beyond shelf 3708b of the sheath and clear the support wall 3708a (as highlighted by focus point "A" in FIGURE 102B).

This allows carrier arms 3732 to deflect radially outwardly into the larger diameter distal portion 3708c of the sheath as shown in FIGURE 102C. When carrier arms 3732 deflect outwardly, shoulder portions of carrier arms 3732 are no longer in an interference relationship with the sharp carrier 3716. Thus spring 3746 is permitted to expand as shown in FIGURE 102C, thereby retracting the sharp carrier 3716 to a proximal position and withdrawing the sharp 324 from the skin S of the subject while leaving the sensor housing 322 attached to the skin. Housing (or handle) 3702 is maintained in the distal position and extends over the sheath in a telescoping manner. Sheath detent or snap 3726 of the sheath 3708 can then lock over feature 3722 of the housing 3702. Accordingly, the housing 3702 and the sheath 3708 can no longer move longitudinally with respect to each other.

[00308] In some embodiments, the changing interaction of sheath detent or snap 3726 with the housing detent/ledges 3720, 3724, and 3722 determine whether the sheath 3708 is locked. When snap 3726 is in the pre-fire position, ledge 3720 prevents sheath 3708 from being pulled out of the housing 3702. In this position, detent 3724 may also impede the movement of pushing the sheath 3708 into the housing 3702. When the detent is overcome by a at least at minimum force, the sheath 3704 moves longitudinally with respect to the housing 3702 until the snap 3726 snaps over housing ledge 3722. At this point, ledge 3722 prevents the sheath 3708 from being pulled out of the housing again, but from a new position (this position may be referred to as the used/post-fire position). Sharp carrier snap 3752 function is to hold onto the sharp/needle. in some embodiments, the sharp/needle carrier 3716 is held in the post-fire position relative to the housing 3702 by, e.g., an interference between the rails of the housing 3714 and the guide rails of the sharp carrier 3718 (this interference is only present once the sharp carrier is fully retracted) and/or by medical device carrier projections 3732 interfering with the bottom/floor of the sharp

carrier (See, e.g., FIG. 103). In another embodiment of inserter 3700, adhesive pad 318 may be attached directly to sensor housing 322.

[00309] It is understood that the subject matter described herein is not limited to particular embodiments described, as such may, of course, vary. It is also understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present subject matter is limited only by the appended claims.

[00310] Additional detailed description of embodiments of the disclosed subject matter is provided in but not limited to: U.S. Patent No. 7,381,184; U.S. Patent No. 7,299,082; U.S. Patent No. 7,167,818; U.S. Patent No. 7,041,468; U.S. Patent No. 6,942,518; U.S. Patent No. 6,893,545; U.S. Patent No. 6,881,551; U.S. Patent No. 6,773,671; U.S. Patent No. 6,764,581; U.S. Patent No. 6,749,740; U.S. Patent No. 6,746,582; U.S. Patent No. 6,736,957; U.S. Patent No. 6,730,200; U.S. Patent No. 6,676,816; U.S. Patent No. 6,618,934; U.S. Patent No. 6,616,819; U.S. Patent No. 6,600,997; U.S. Patent No. 6,592,745; U.S. Patent No. 6,591,125; U.S. Patent No. 6,560,471; U.S. Patent No. 6,540,891; U.S. Patent No. 6,514,718; U.S. Patent No. 6,514,460; U.S. Patent No. 6,503,381; U.S. Patent No. 6,461,496; U.S. Patent No. 6,377,894; U.S. Patent No. 6,338,790; U.S. Patent No. 6,299,757; U.S. Patent No. 6,284,478; U.S. Patent No. 6,270,455; U.S. Patent No. 6,175,752; U.S. Patent No. 6,161,095; U.S. Patent No. 6,144,837; U.S. Patent No. 6,143,164; U.S. Patent No. 6,134,461;U.S. Patent No. 6,121,009; U.S. Patent No. 6,120,676; U.S. Patent No. 6,071,391; U.S. Patent No. 5,918,603; U.S. Patent No. 5,899,855; U.S. Patent No. 5,822,715; U.S. Patent No. 5,820,551; U.S. Patent No. 5,628,890; U.S. Patent No. 5,601,435; U.S. Patent No. 5,593,852; U.S. Patent No. 5,509,410; U.S. Patent No. 5,320,715; U.S. Patent No. 5,264,014; U.S. Patent No. 5,262,305; U.S. Patent

No. 5,262,035; U.S. Patent No. 4,711,245; U.S. Patent No. 4,545,382; U.S. Patent Publication No. 2004/0186365, published September 23, 2004; U.S. Patent Application No. 61/238,646, filed August 31, 2009; U.S. Patent Application No. 12/698,129, filed February 1, 2010; U.S. Patent Application No. 61/317,243, filed March 24, 2010; U.S. Patent Application No. 61/345,562, filed May 17, 2010; International Application No. PCT/US10/22860, filed February 22, 2010; and U.S. Patent Application No. 12/807,278, filed August 31, 2010, the disclosures of each of which is incorporated by reference herein for all purposes.

CLAIMS

WHAT IS CLAIMED IS:

1. An apparatus for inserting a medical device into the skin of a subject, which comprises:

a sheath defining a distal surface for placement on the skin of the subject;

a device support movable between a proximal and distal position, and adapted to support the medical device;

a sharp support movable between a proximal and a distal position and adapted to support a sharp extending through a portion of said device support, the sharp support including at least one surface feature adapted to operatively engage the device support and the medical device;

a handle movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from a proximal to a distal position to insert the sharp into the skin of the subject; and

a driver for advancing the sharp support towards the proximal position when the sharp support reaches the distal position.

2. The apparatus of claim 1, wherein the at least one surface feature of the sharp support is a distally extending protrusion.

3. The apparatus of claim 2, wherein the device support includes at least one aperture to operatively receive the protrusion.

4. The apparatus of claim 1, wherein the handle includes at least one distally extending sidewall, the sidewall having a non-planar shape.

5. The apparatus of claim 4, wherein the handle sidewall includes a convex portion and a concave portion.

6. The apparatus of claim 1, wherein the sheath includes a first portion and a second portion, the second portion having a greater diameter than the first portion to define a shelf between the first and second portions.

7. The apparatus of claim 6, wherein the sheath includes at least one guide member extending between the first portion and the shelf.

8. The apparatus of claim 6, wherein the sheath includes at least one detent member extending between the first portion and the shelf.

9. The apparatus of claim 1, wherein the handle is at least partially disposed surrounding the sheath.

10. The apparatus of claim 1, wherein the medical device is an analyte sensor or an infusion set.

11. A method for using a medical device comprising:

providing an apparatus comprising a sheath defining a distal surface, a device support adapted to support the medical device, a sharp support adapted to support a sharp extending through a portion of said device support, a handle movable relative to the sheath, and a driver for displacing the sharp support;

disposing the distal surface of the sheath on the skin of the subject; and

displacing at least a portion of the sheath in a first radial direction;

displacing the handle in a first longitudinal direction;

displacing the sharp support in the first longitudinal direction, the sharp support displacing the sharp and the medical device;

inserting the sharp into the skin of the subject;

delivering the medical device to the subject;

displacing at least a portion of the device support in a second radial direction;

releasing the driver;

displacing the sharp in the second longitudinal direction;

locking at least a portion of the sheath to the handle.

12. The method of claim 11, wherein the first longitudinal direction is from a proximal to distal position, and the second longitudinal direction is from a distal to proximal position.

13. The method of claim 11, wherein the first radial direction radially inward, and the second radial direction is radially outward.

14. The method of claim 12, wherein the sharp is displaced towards the proximal direction when the sharp support reaches the distal position.

15. The method of claim 12, wherein the handle is maintained in a distal position when the sharp support is displaced to the proximal position.

16. A medical device insertion system comprising:

a sheath defining a distal surface for placement on the skin of the subject, the sheath having at least one biased retention feature;

a device support movable between a proximal and distal position, and adapted to support the medical device;

a sharp support movable between a proximal and a distal position and adapted to support a sharp extending through a portion of said device support, the sharp support including at least one surface feature adapted to operatively engage the device support and the medical device;

a handle movable between a proximal position and a distal position relative to the sheath and adapted to urge the device support and the sharp support from a proximal to a distal position to insert the sharp into the skin of the subject,

wherein advancing the handle distally comprises applying a minimum force to overcome the at least one biased retention feature to allow distal movement of the handle relative to the detent;

a driver for advancing the sharp support towards the proximal position when the sharp support reaches the distal position.

17. The system of claim 16, wherein the device support includes at least one retention feature.

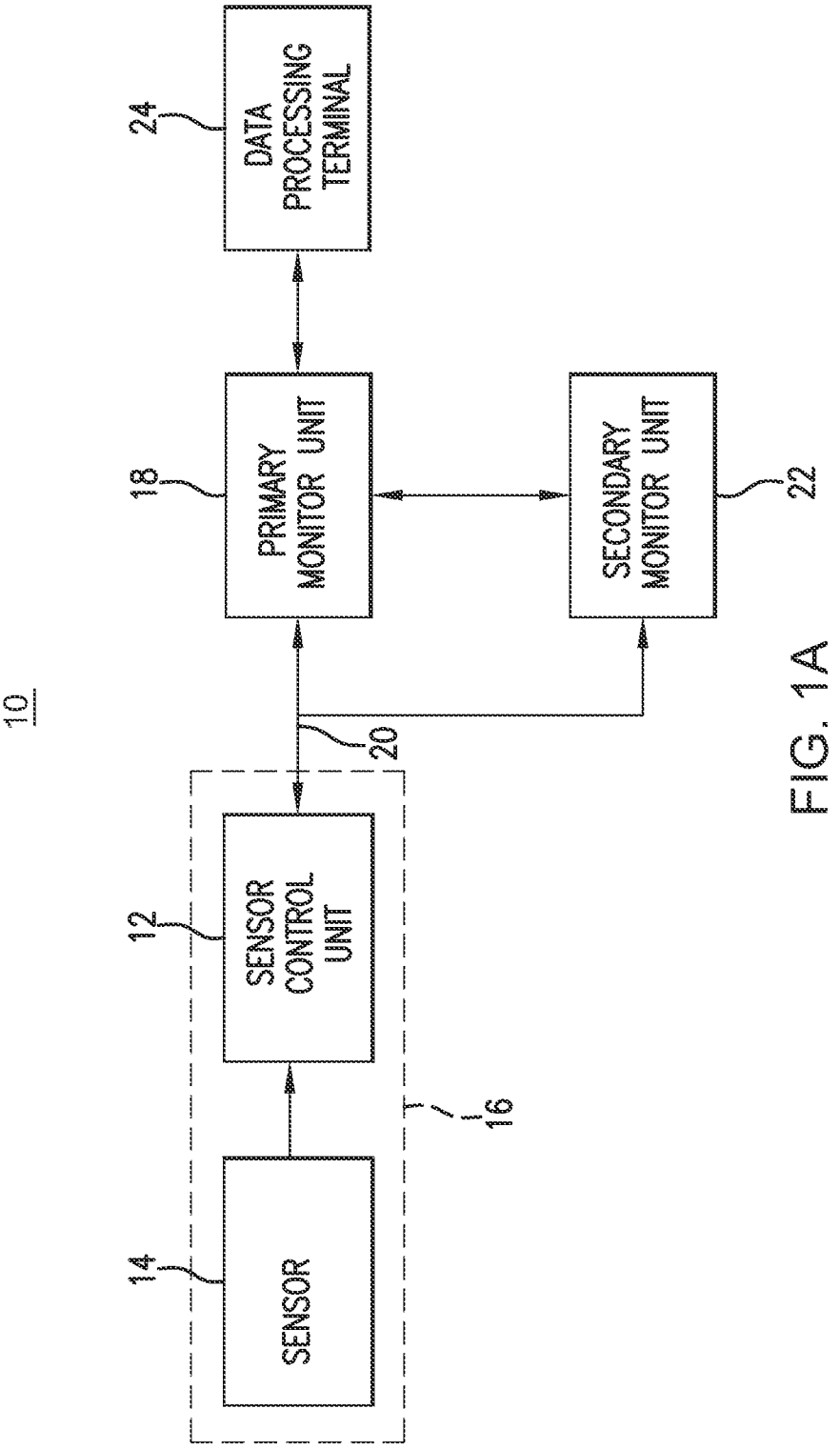
18. The system of claim 17, wherein the sheath maintains the retention feature of the device support operatively engaged with the sharp support until advancement of the handle to the distal position.

19. The system of claim 17, wherein advancement of the handle to the distal position releases the retention feature of the device support to allow proximal movement of sharp support and sharp relative to the device support.

20. The system of claim 16, wherein the handle is maintained in a distal position when the sharp support is advanced to the proximal position.

ABSTRACT

An apparatus for insertion of a medical device in the skin of a subject is provided, as well as methods of inserting medical devices.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SENSOR CONTROL UNIT
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PRIMARY MONITOR UNIT
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SECONDARY MONITOR UNIT
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DATA PROCESSING TERMINAL

FIG. 1A

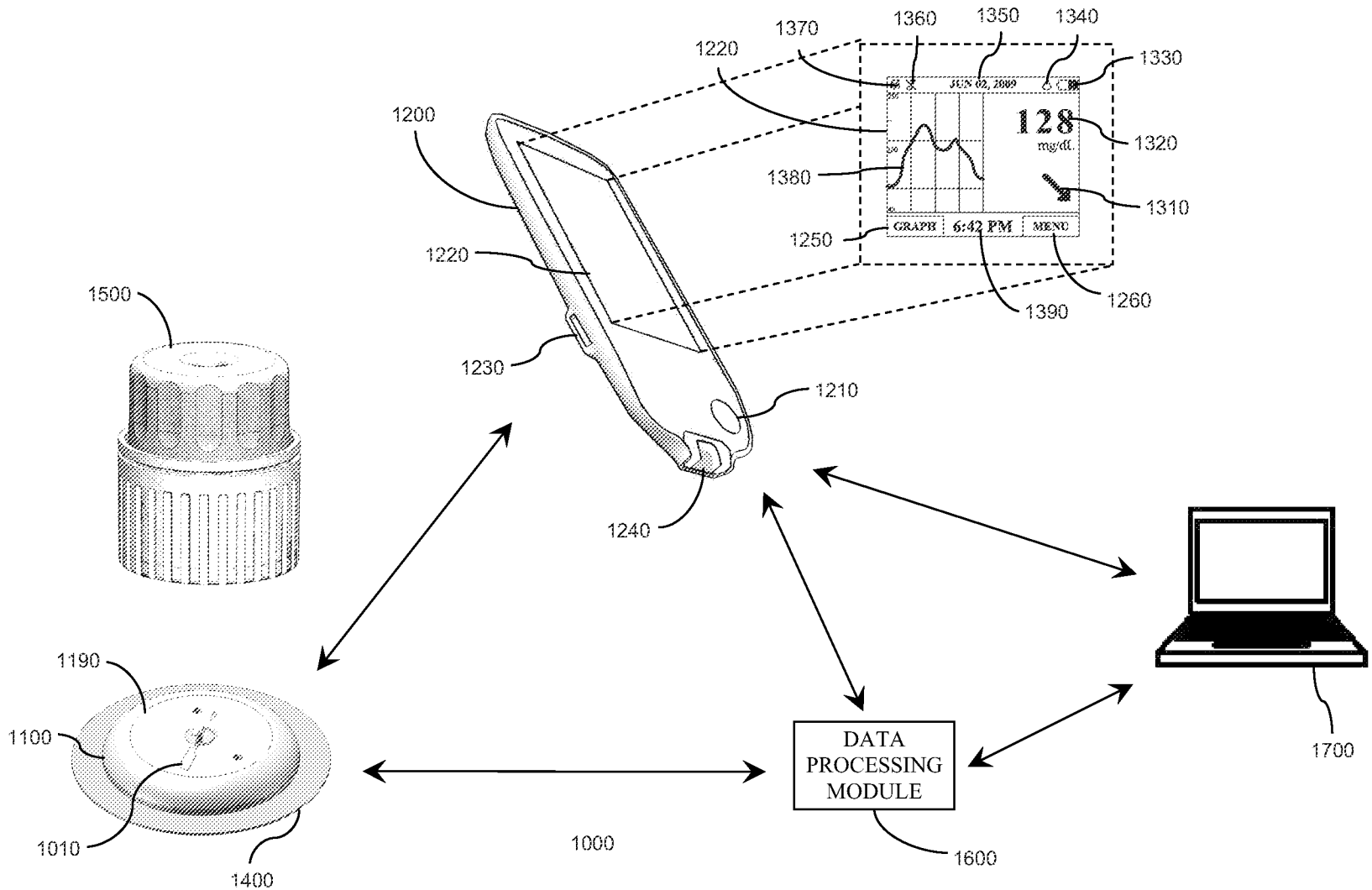
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FIG. 1B

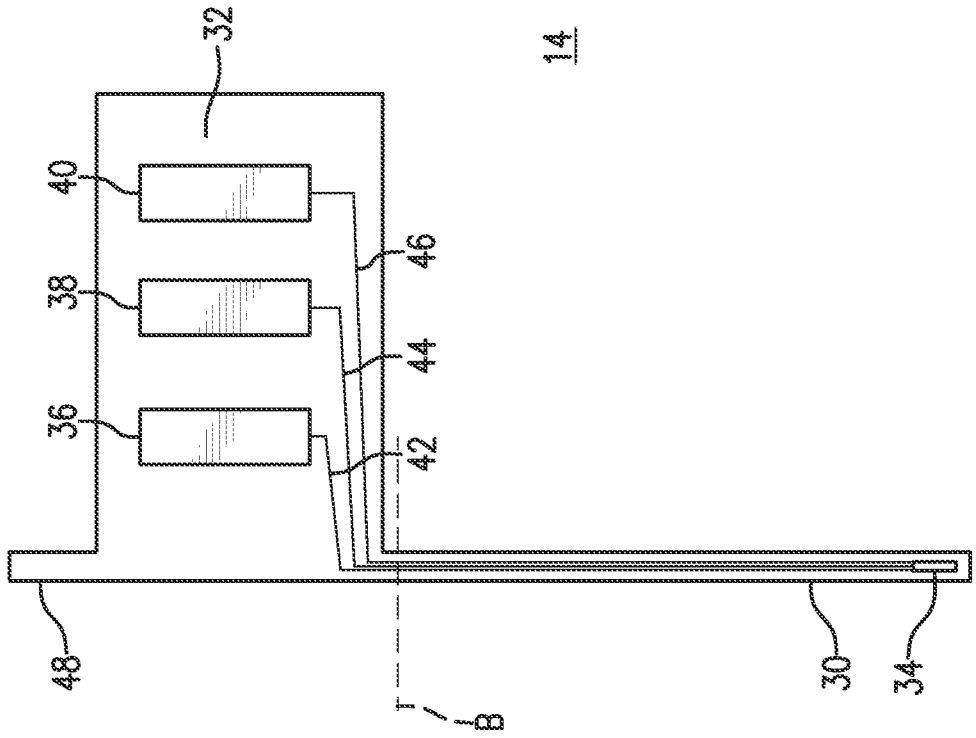

FIG. 2

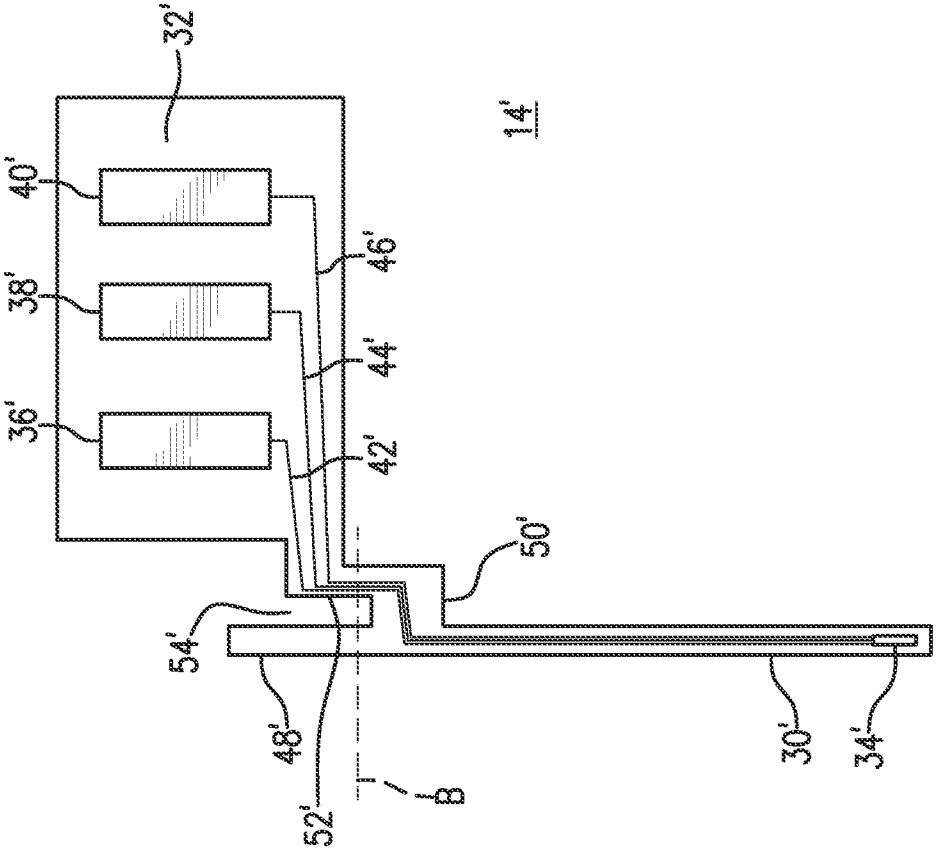

FIG. 3

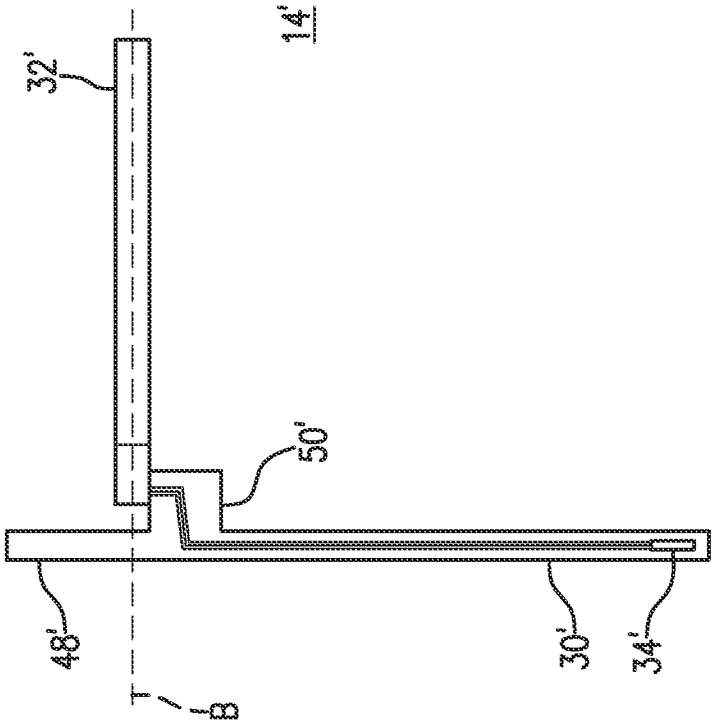

FIG. 4

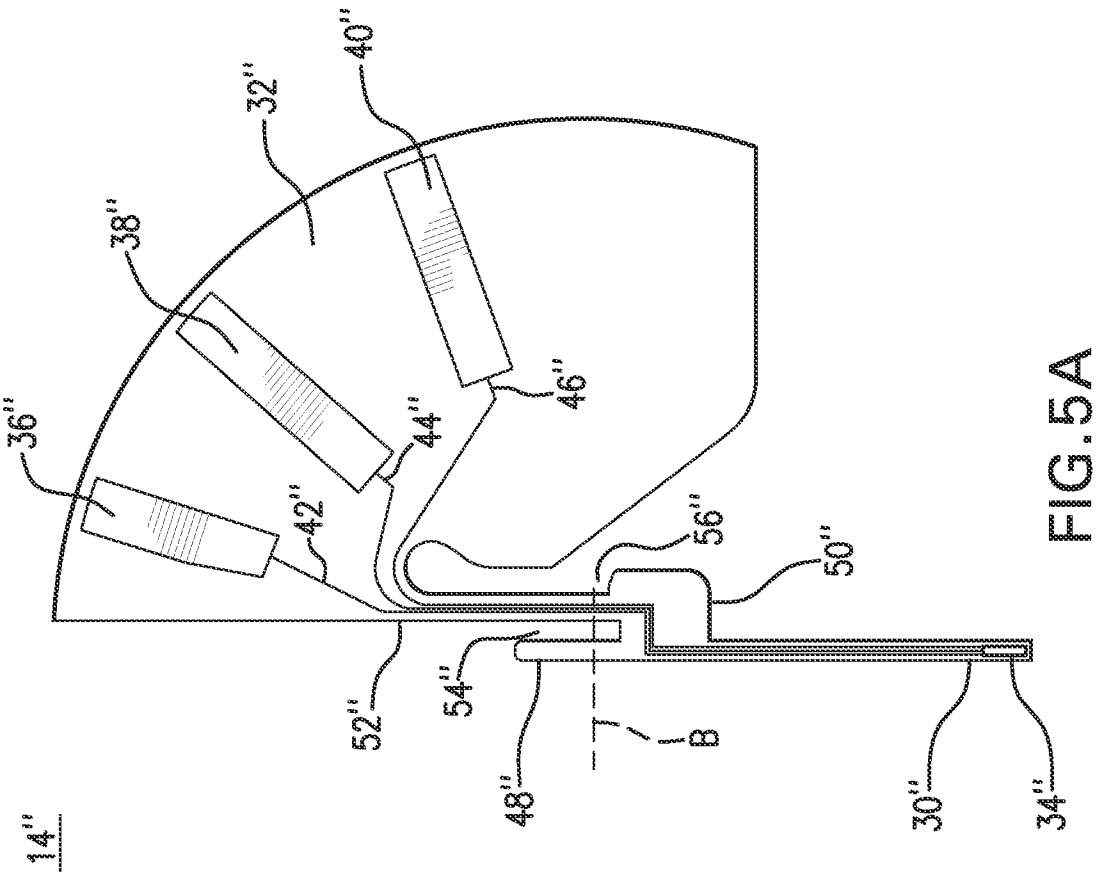

FIG.5A

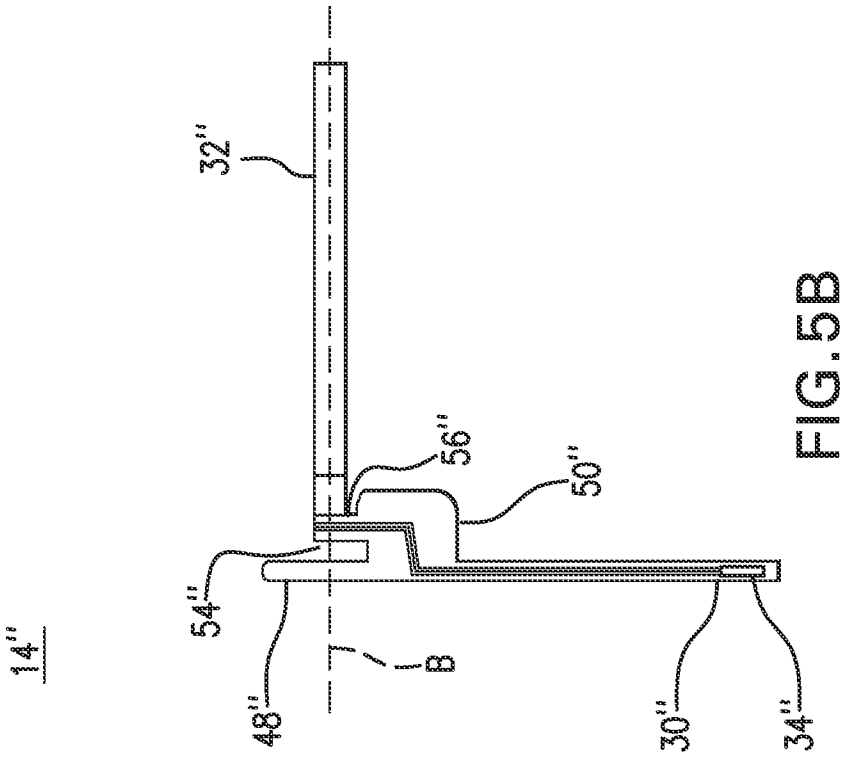

FIG. 5B

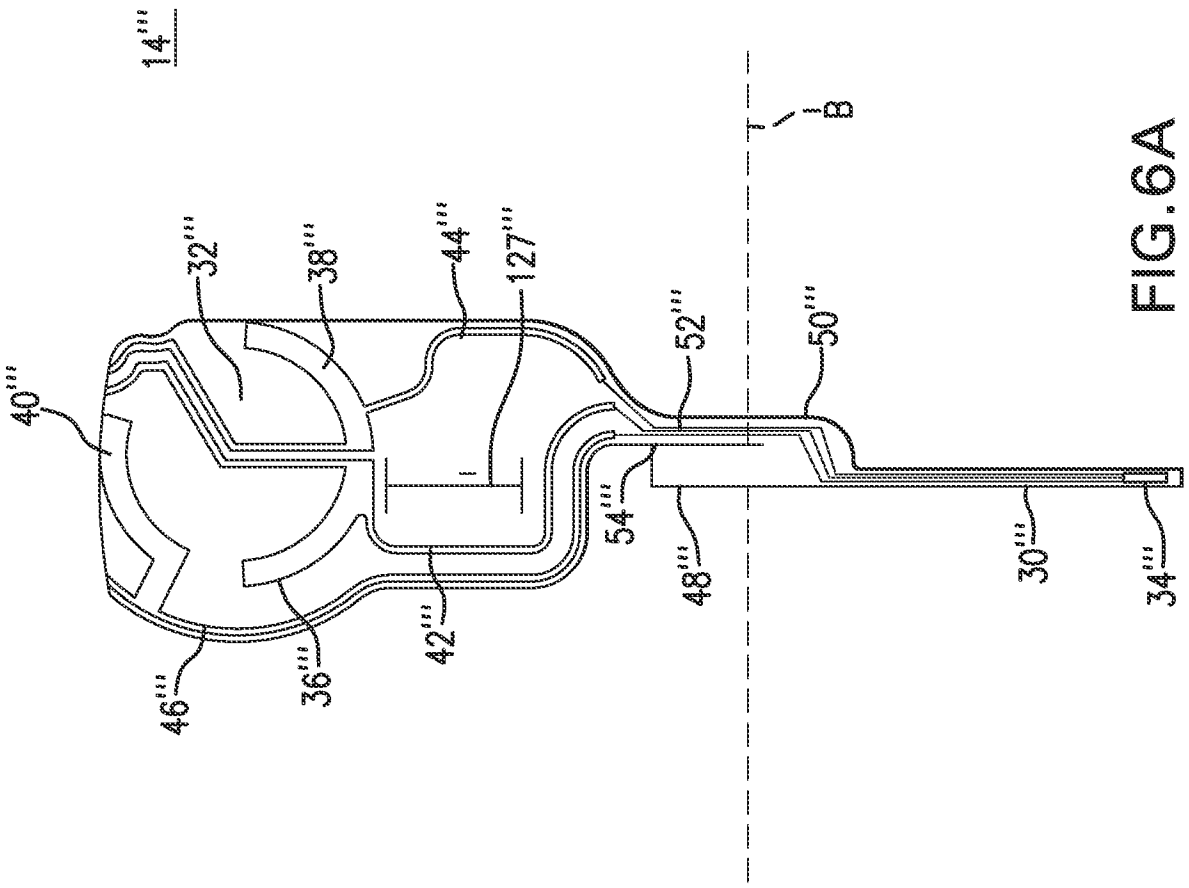

FIG.6A

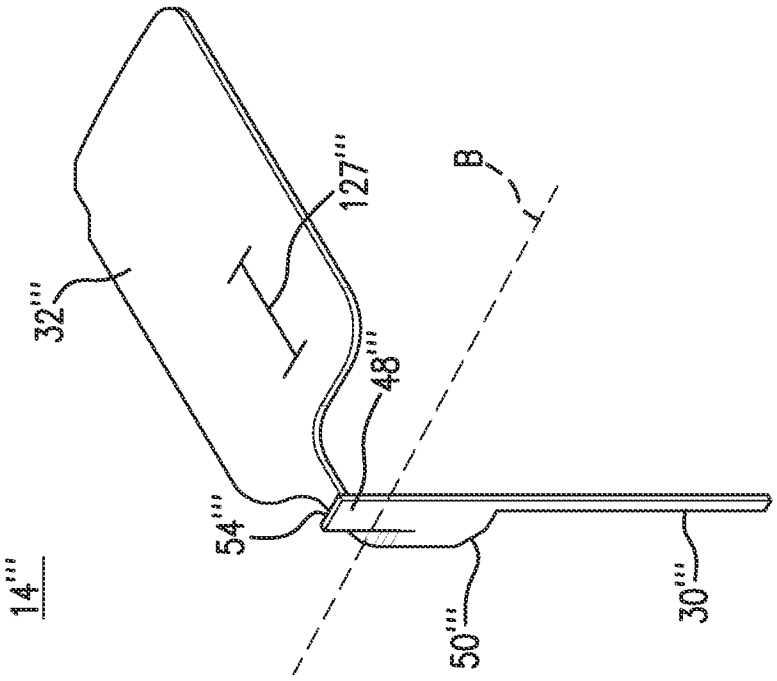

FIG.6B

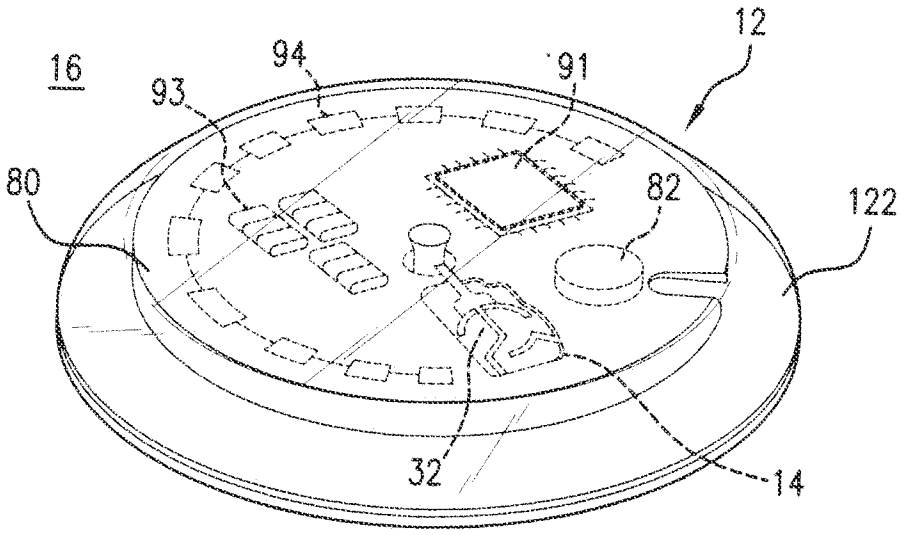

FIG. 7

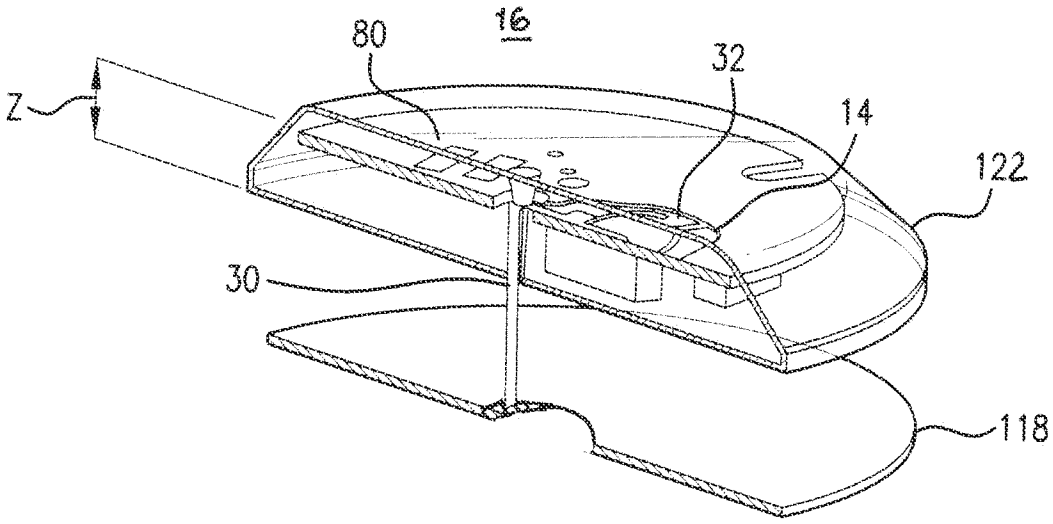

FIG. 8

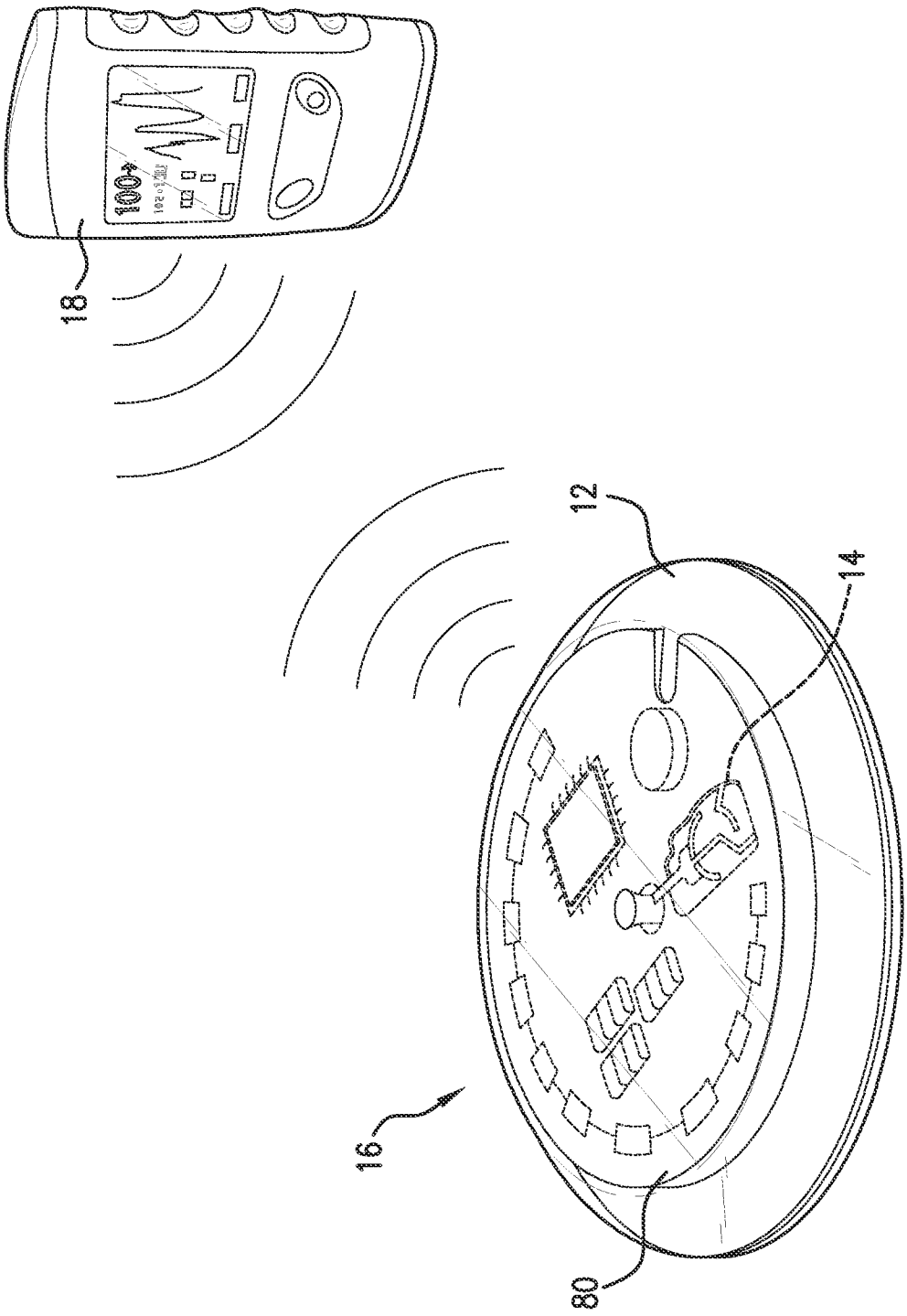

FIG. 9

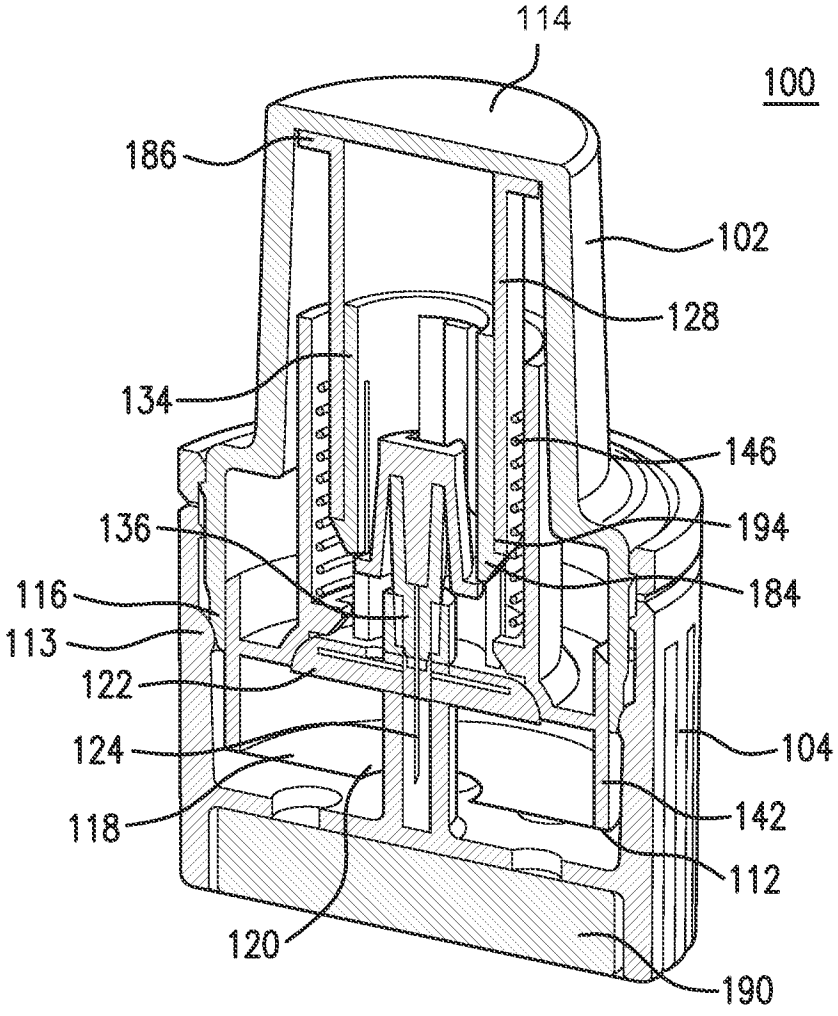
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FIG. 10

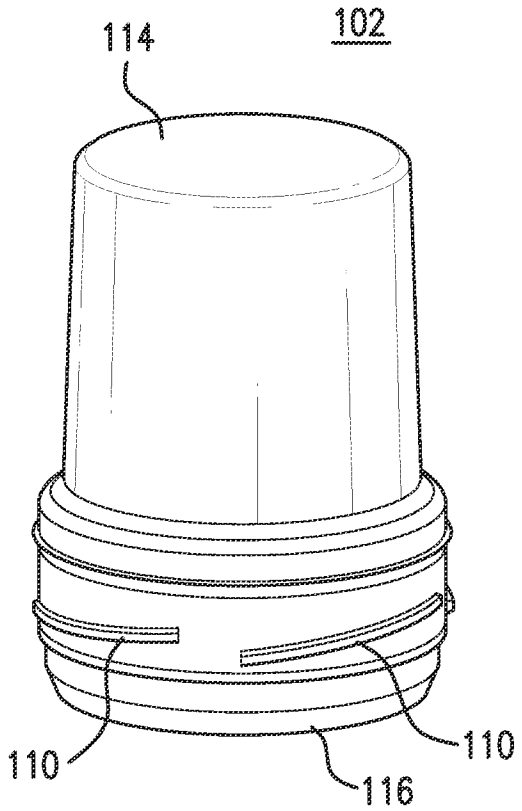


FIG. 11

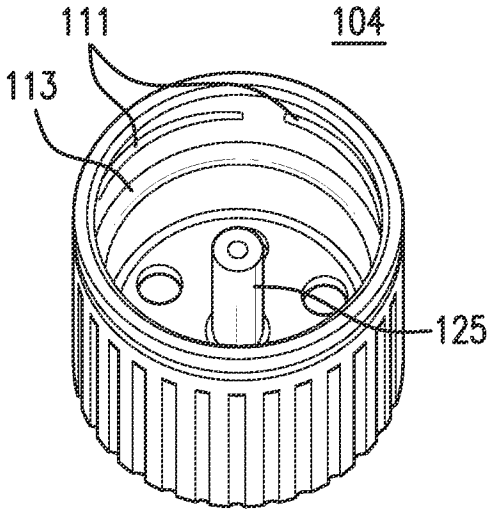


FIG. 12

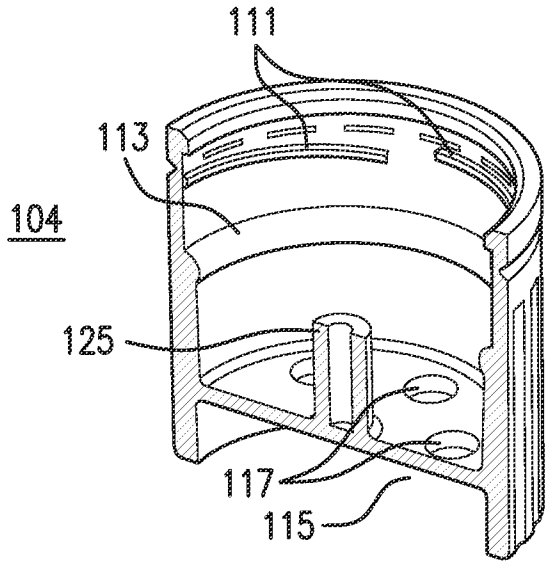


FIG. 13

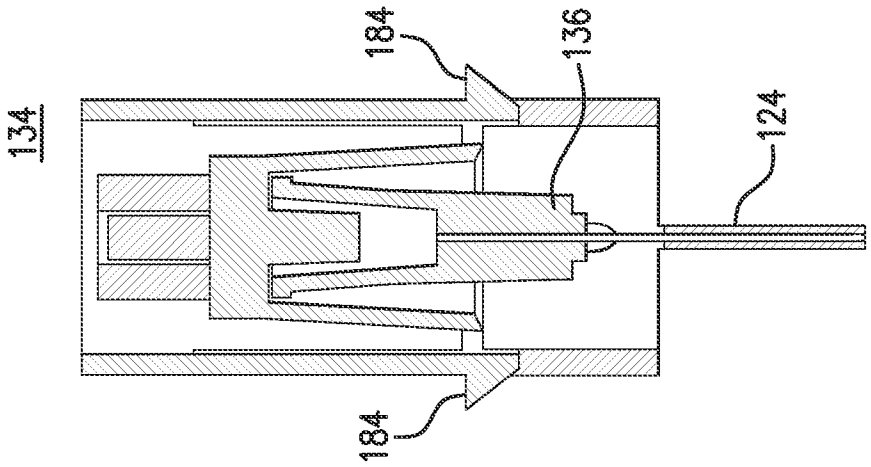


FIG. 16

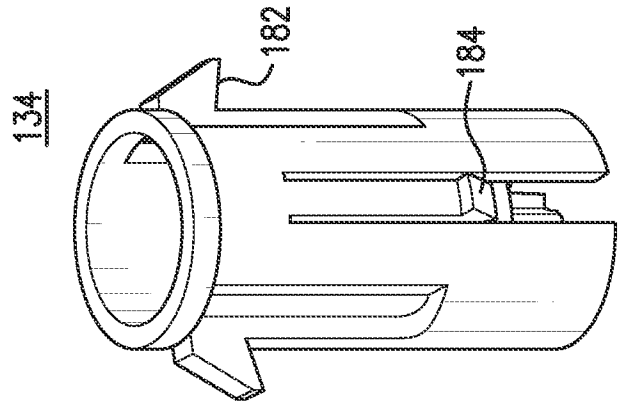


FIG. 15

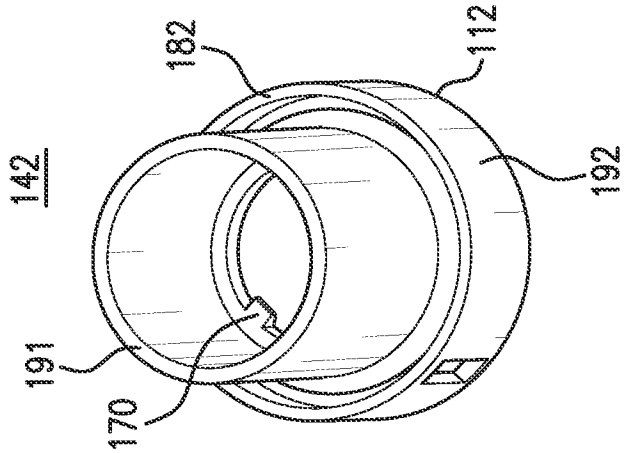


FIG. 14

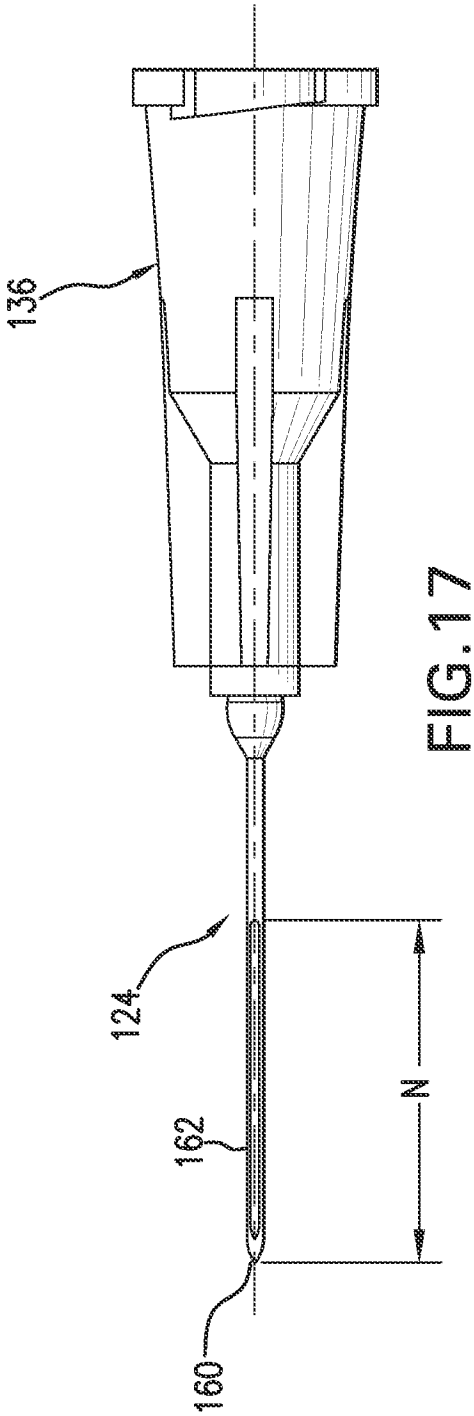


FIG. 17

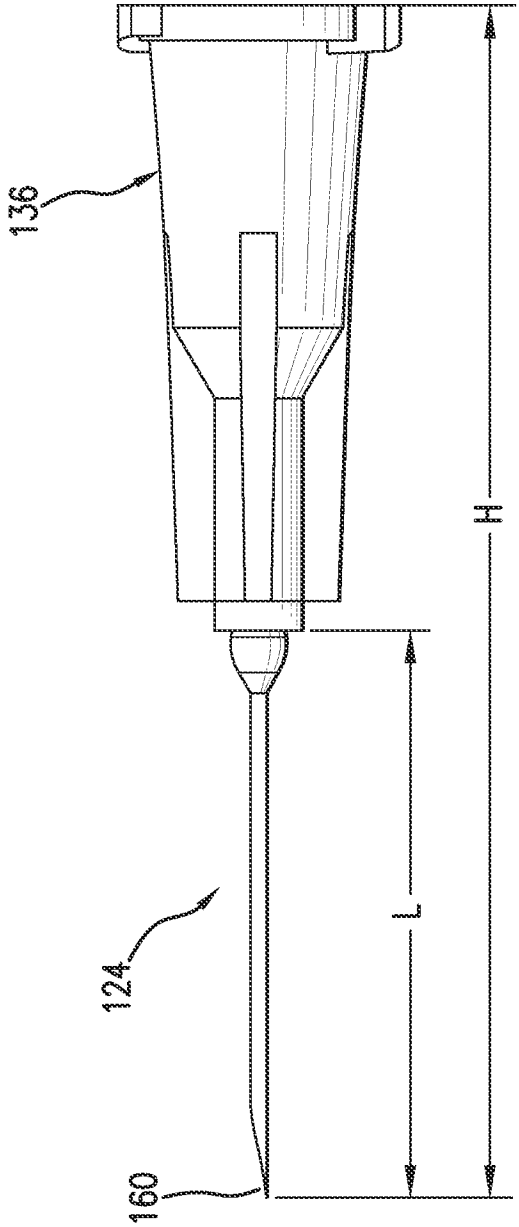


FIG. 18

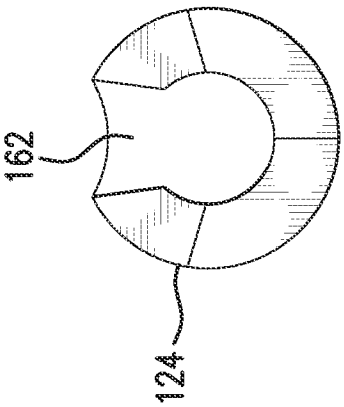


FIG. 19

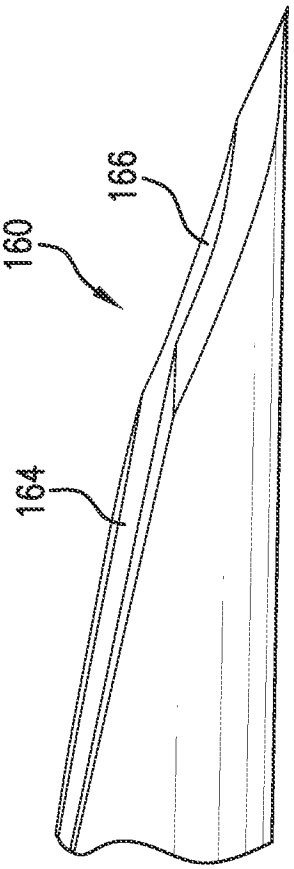


FIG. 20

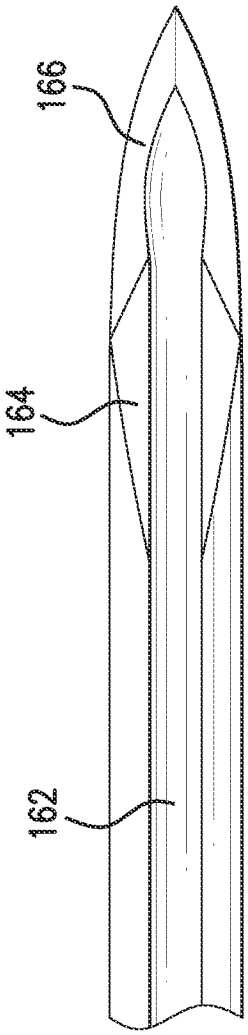


FIG. 21

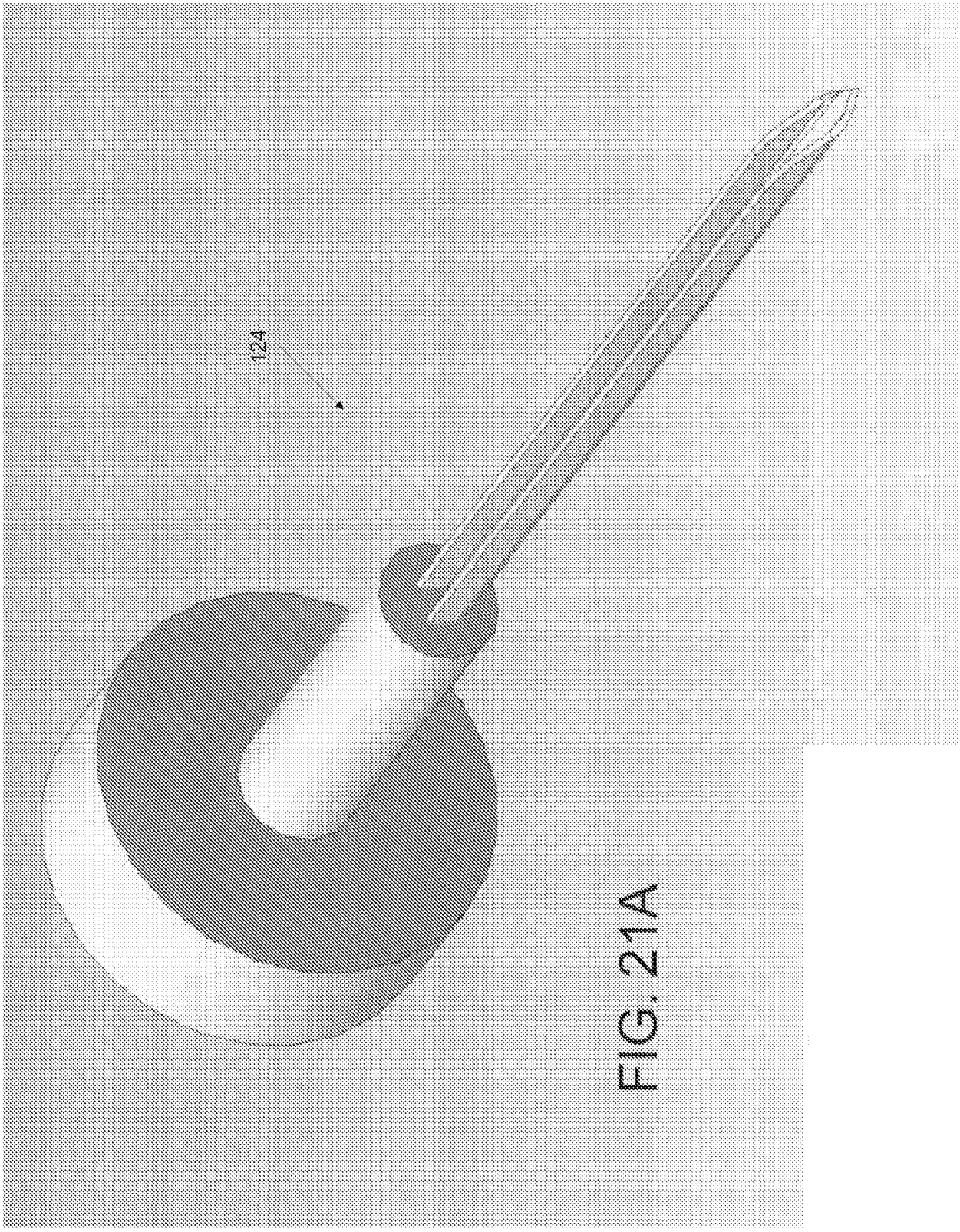


FIG. 21A

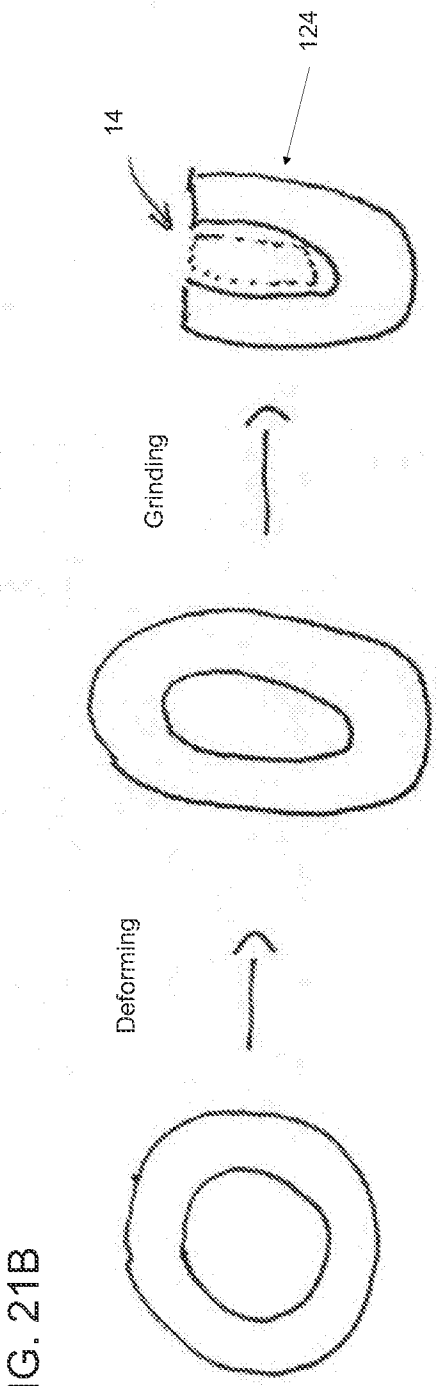


FIG. 21B

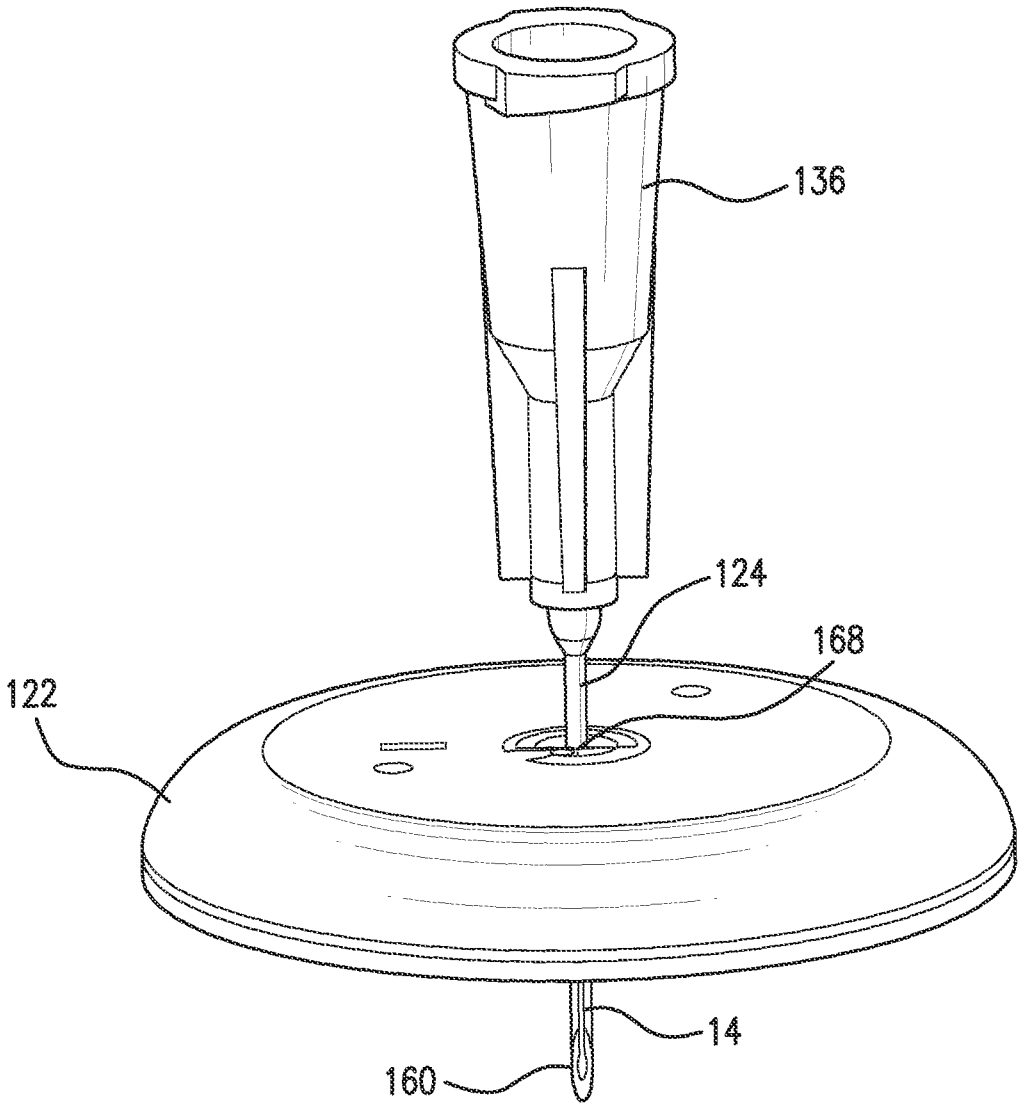


FIG.22

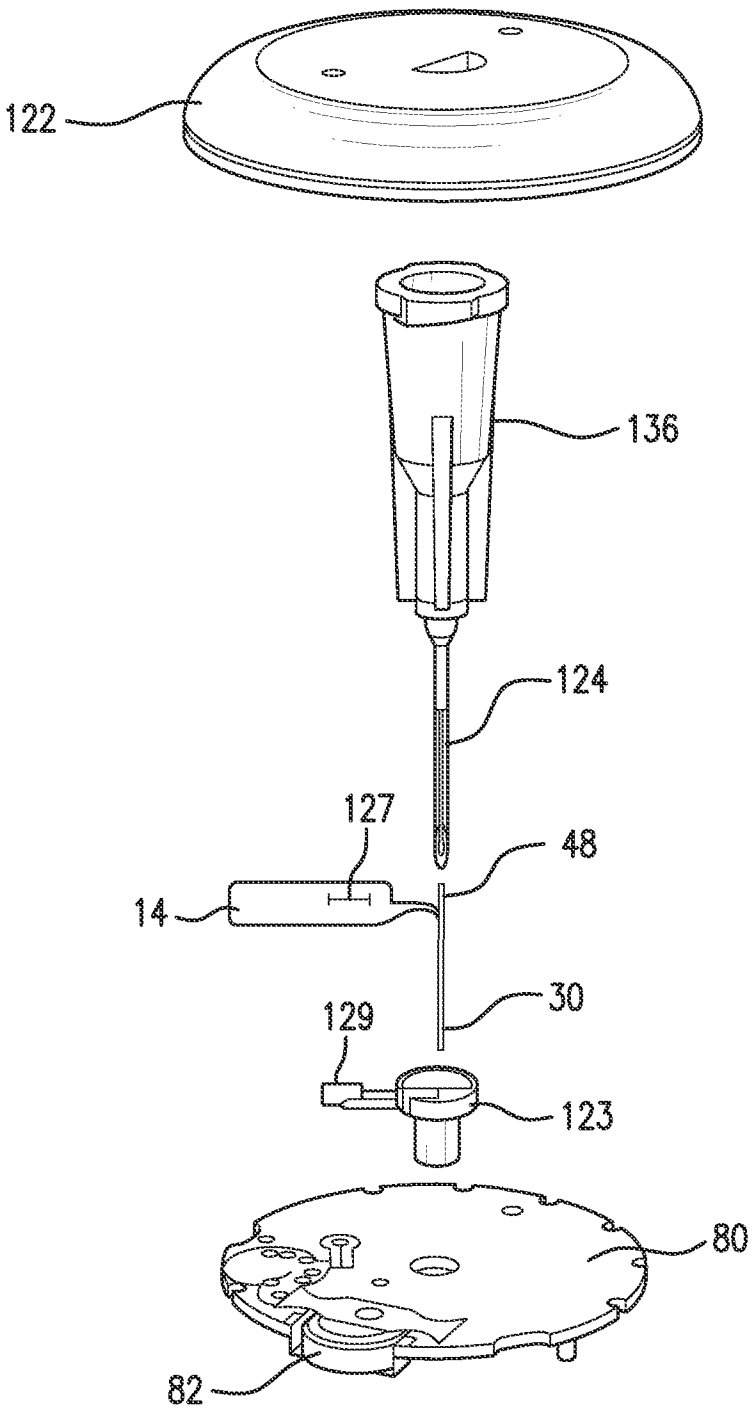


FIG.23

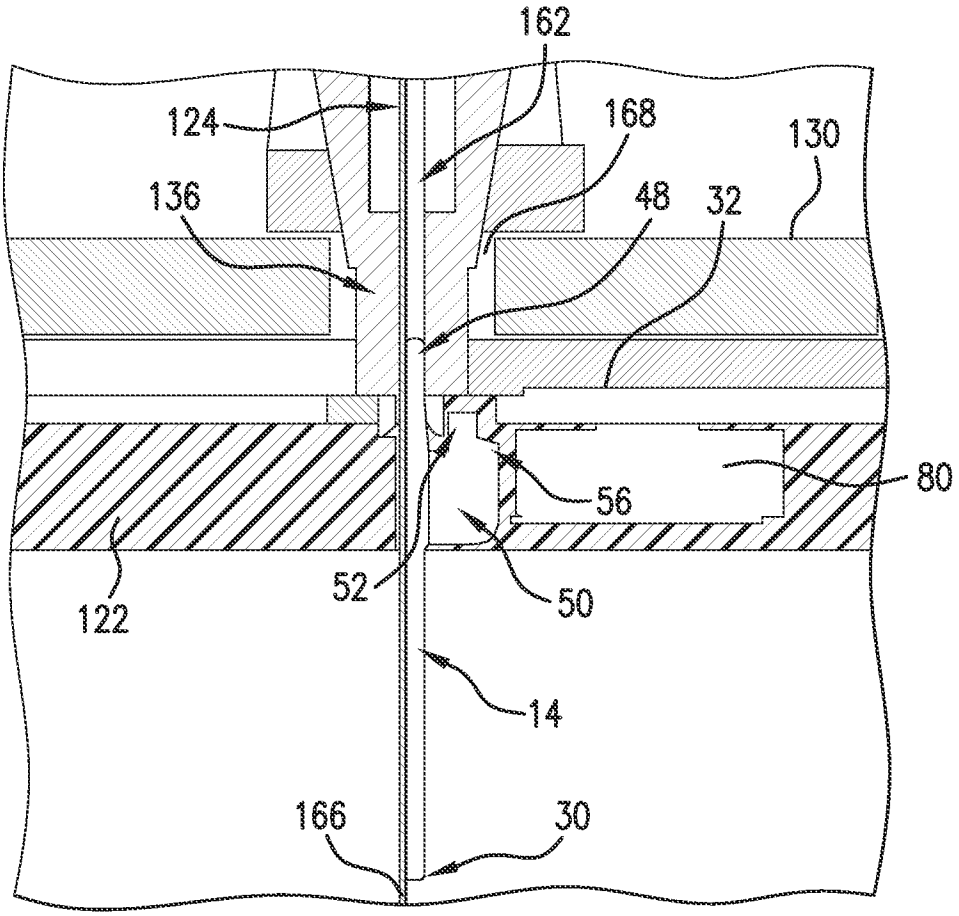


FIG.24

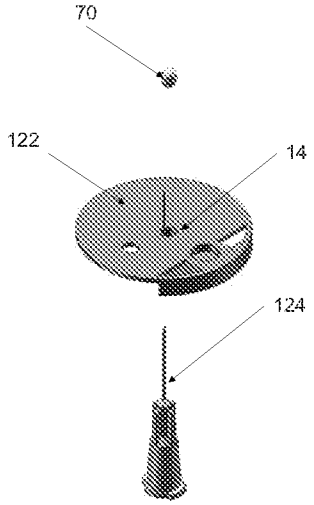


FIGURE 24A

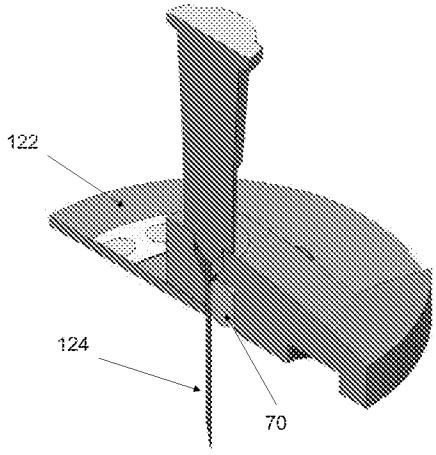


FIGURE 24B

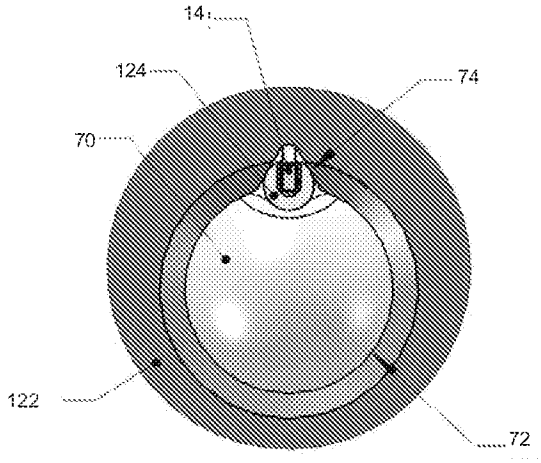


FIGURE 24C

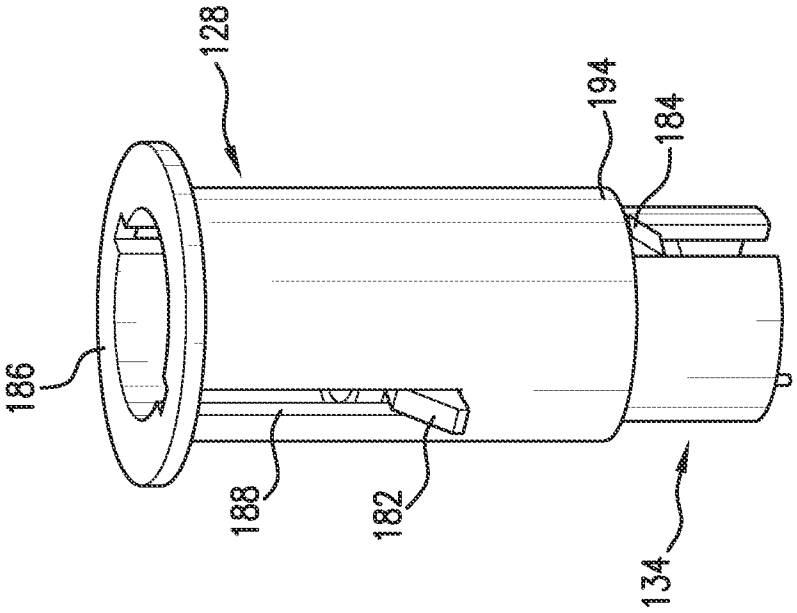


FIG.26

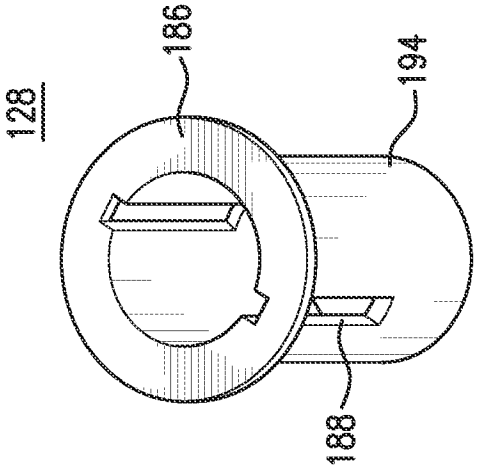
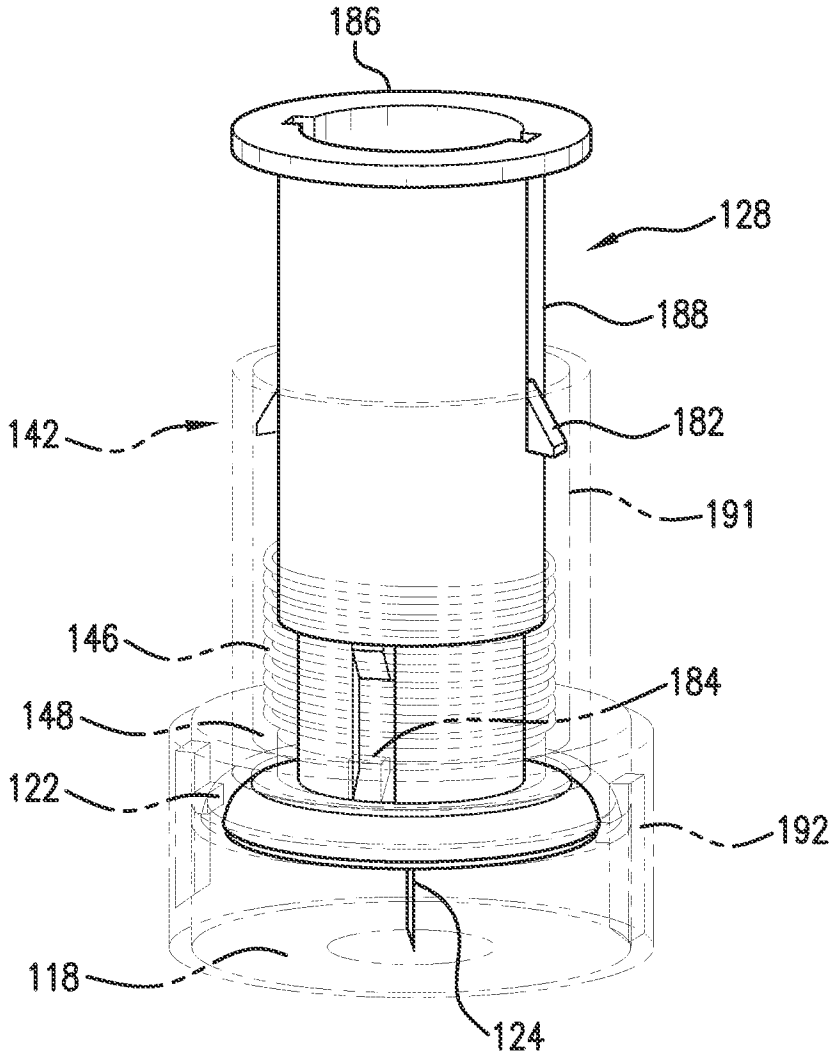


FIG.25



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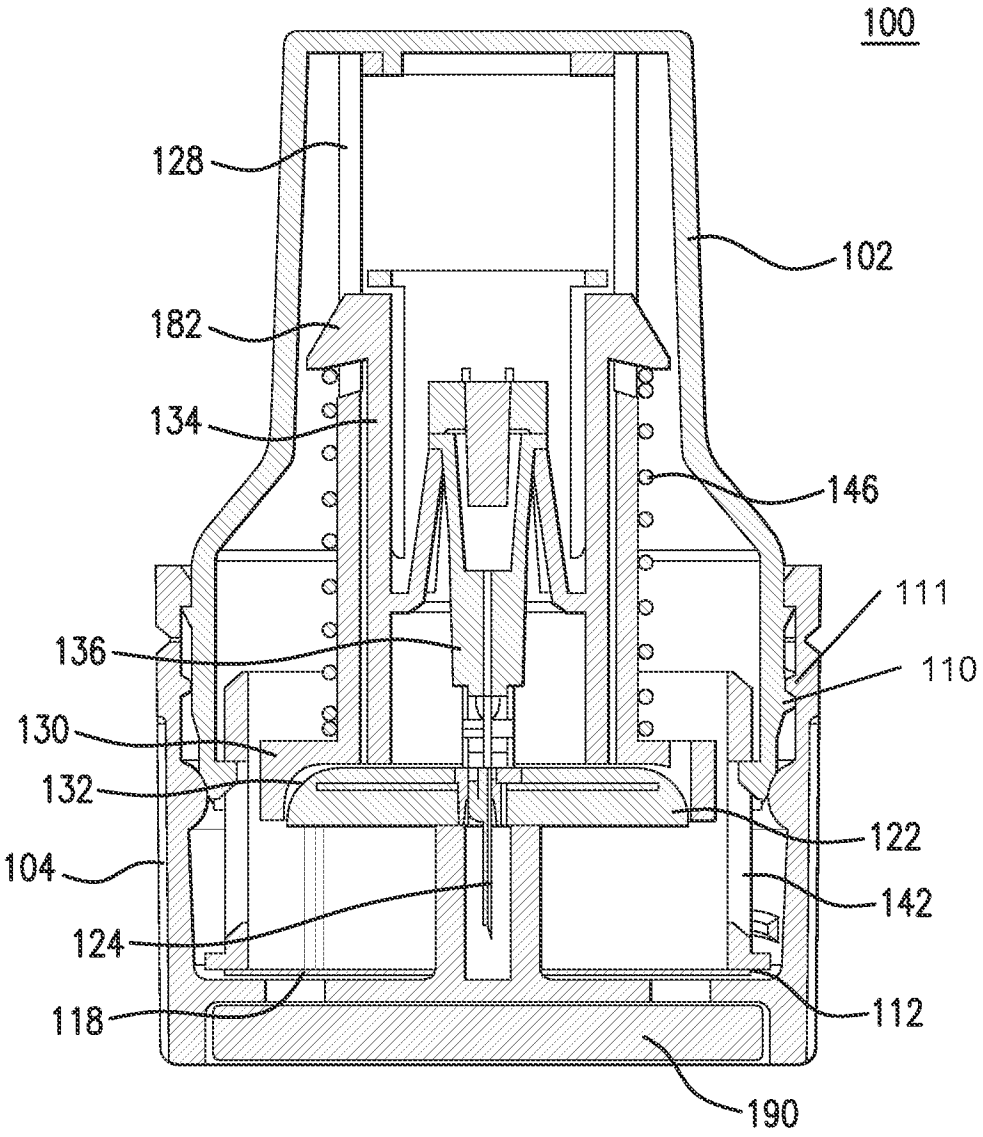
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FIG.28

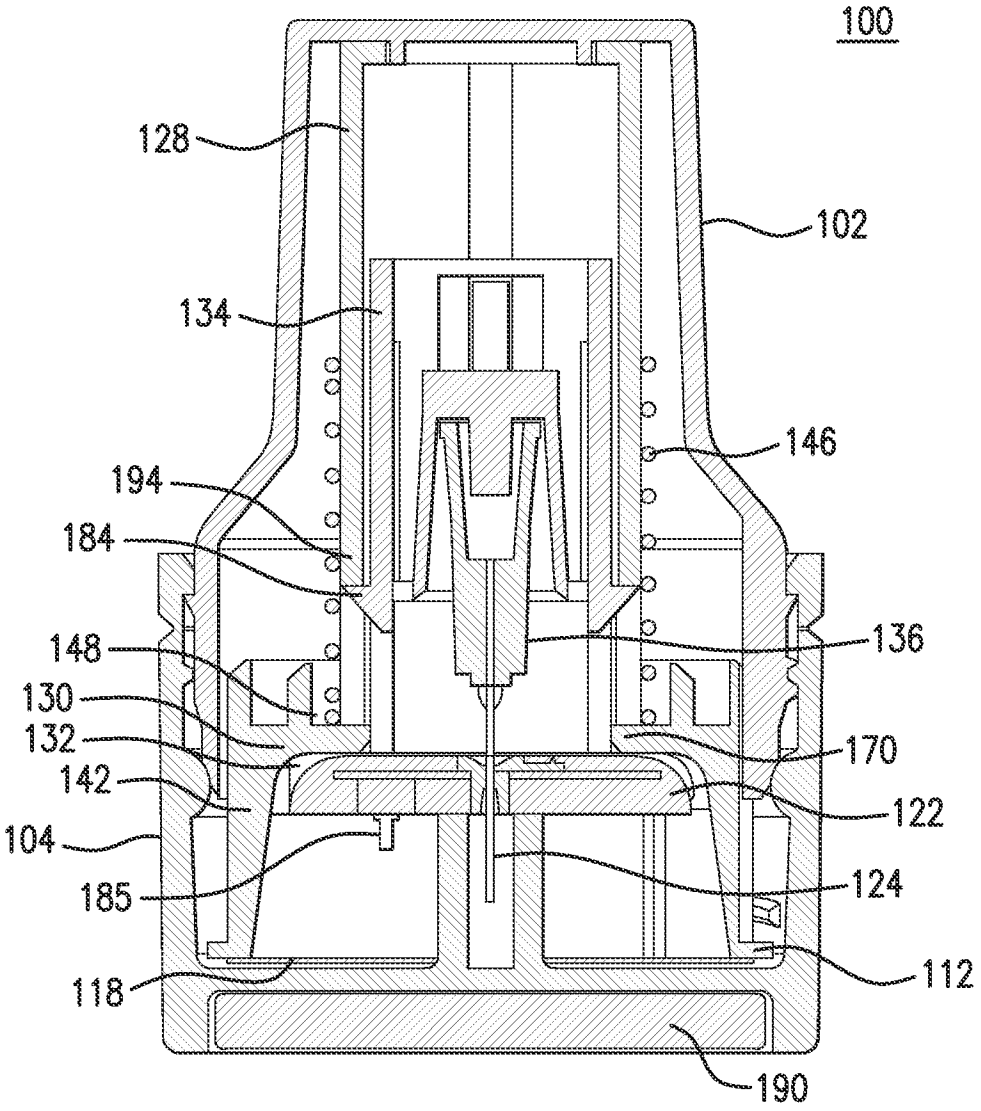
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FIG. 29

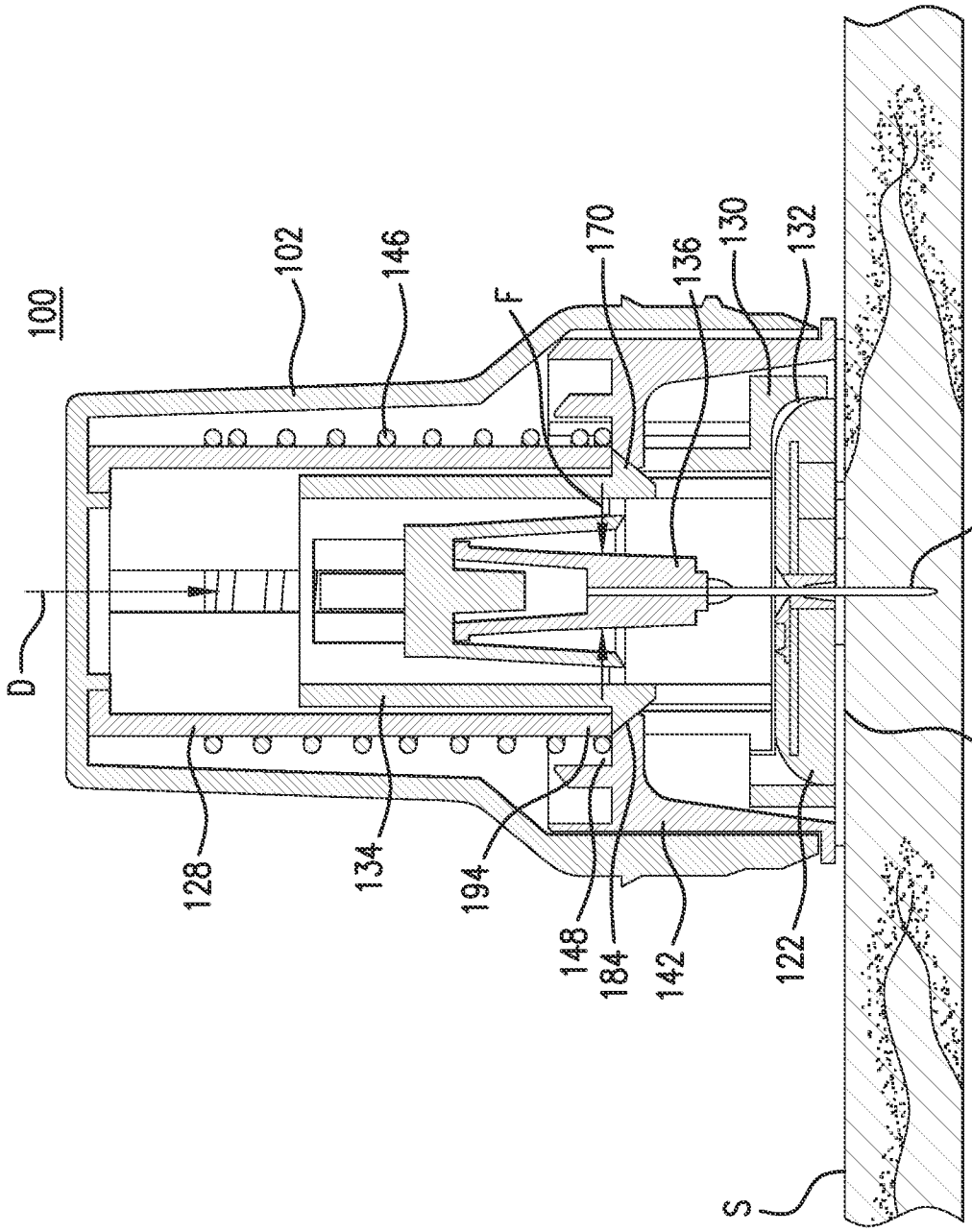
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FIG. 30

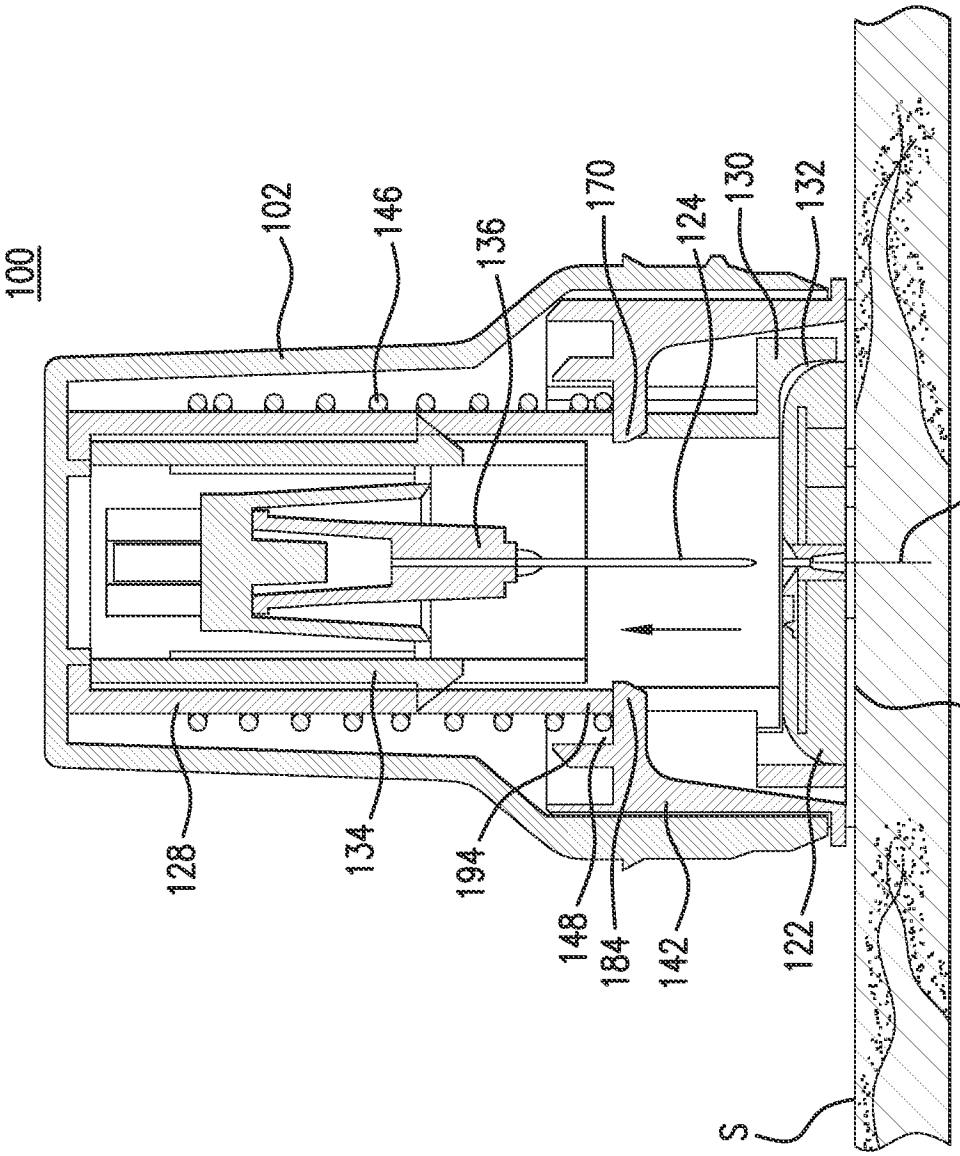
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FIG. 31

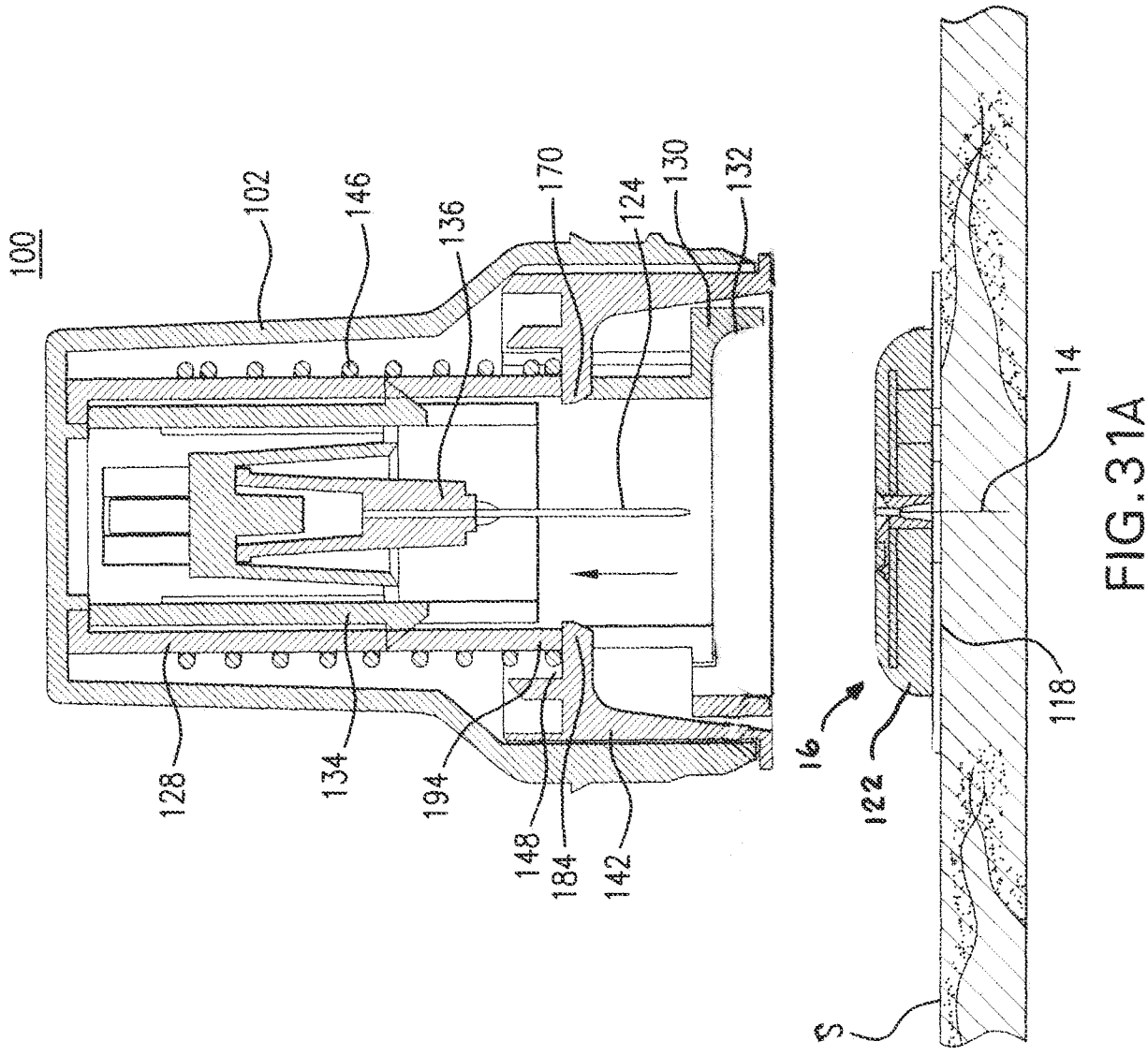
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FIG.31A

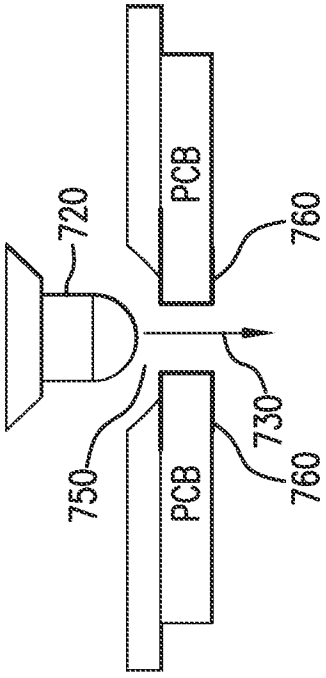

FIG.32

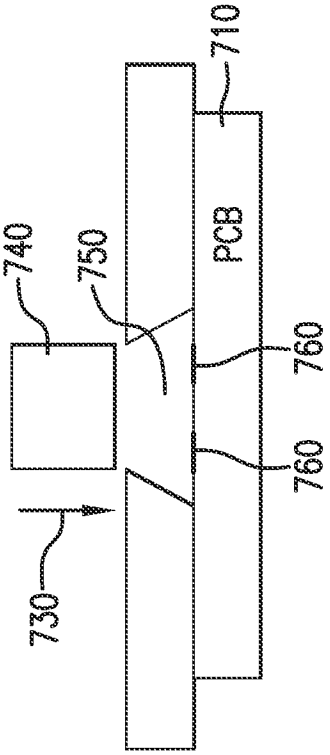

FIG.33

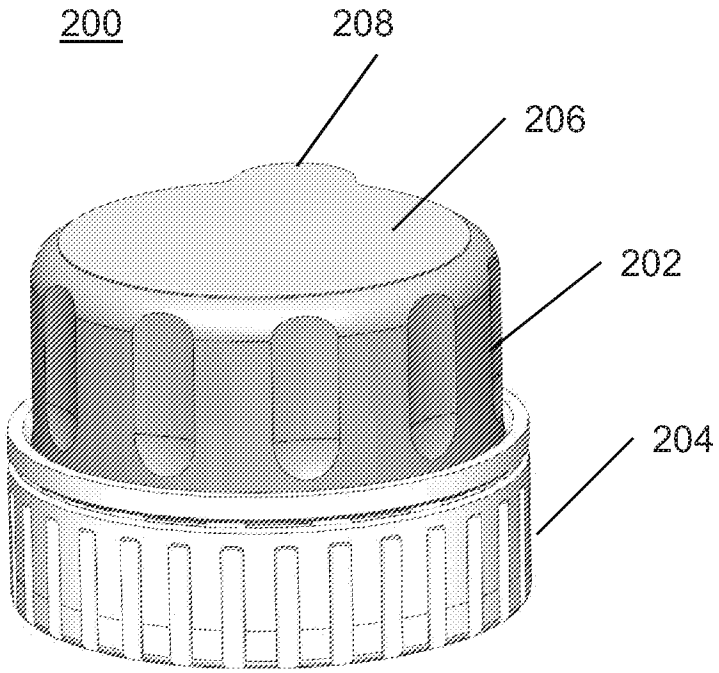

FIGURE 34

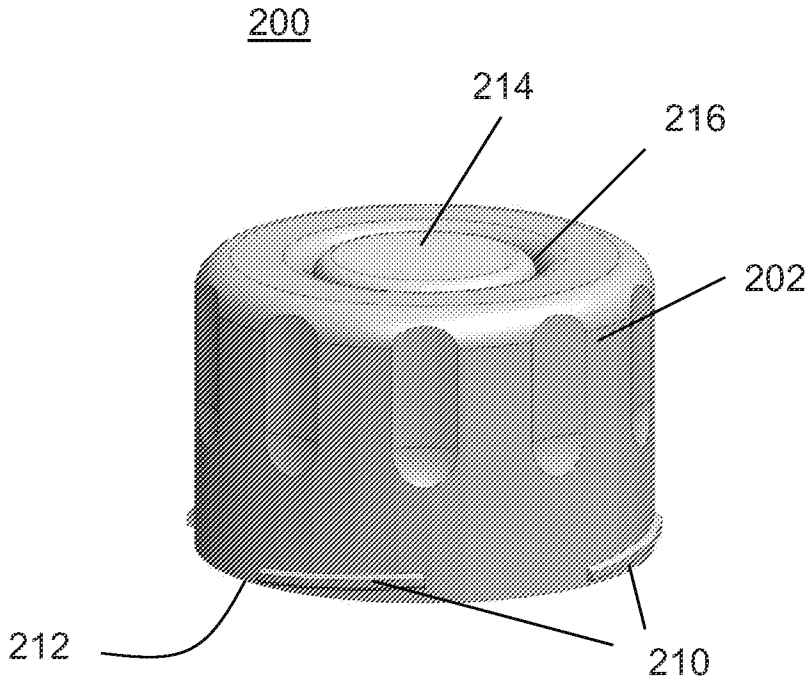

FIGURE 35

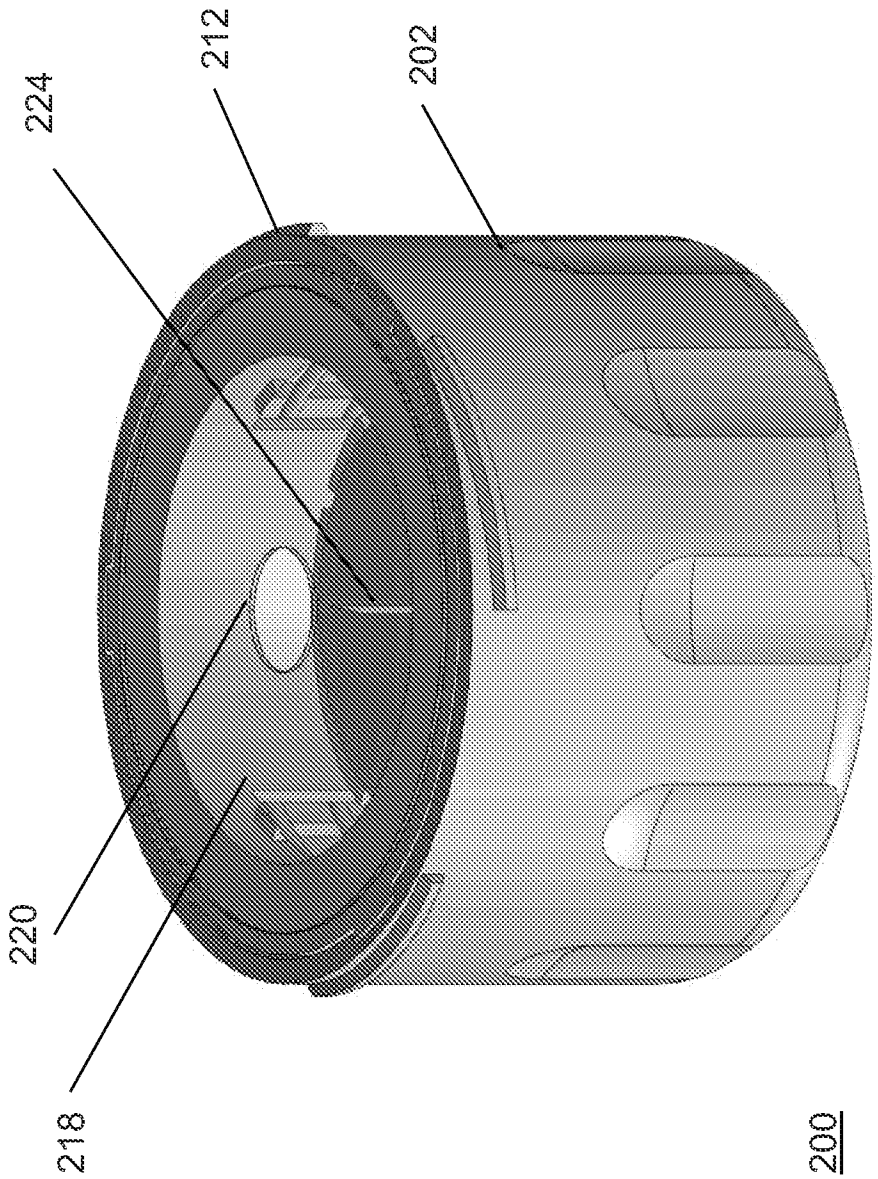

FIGURE 36

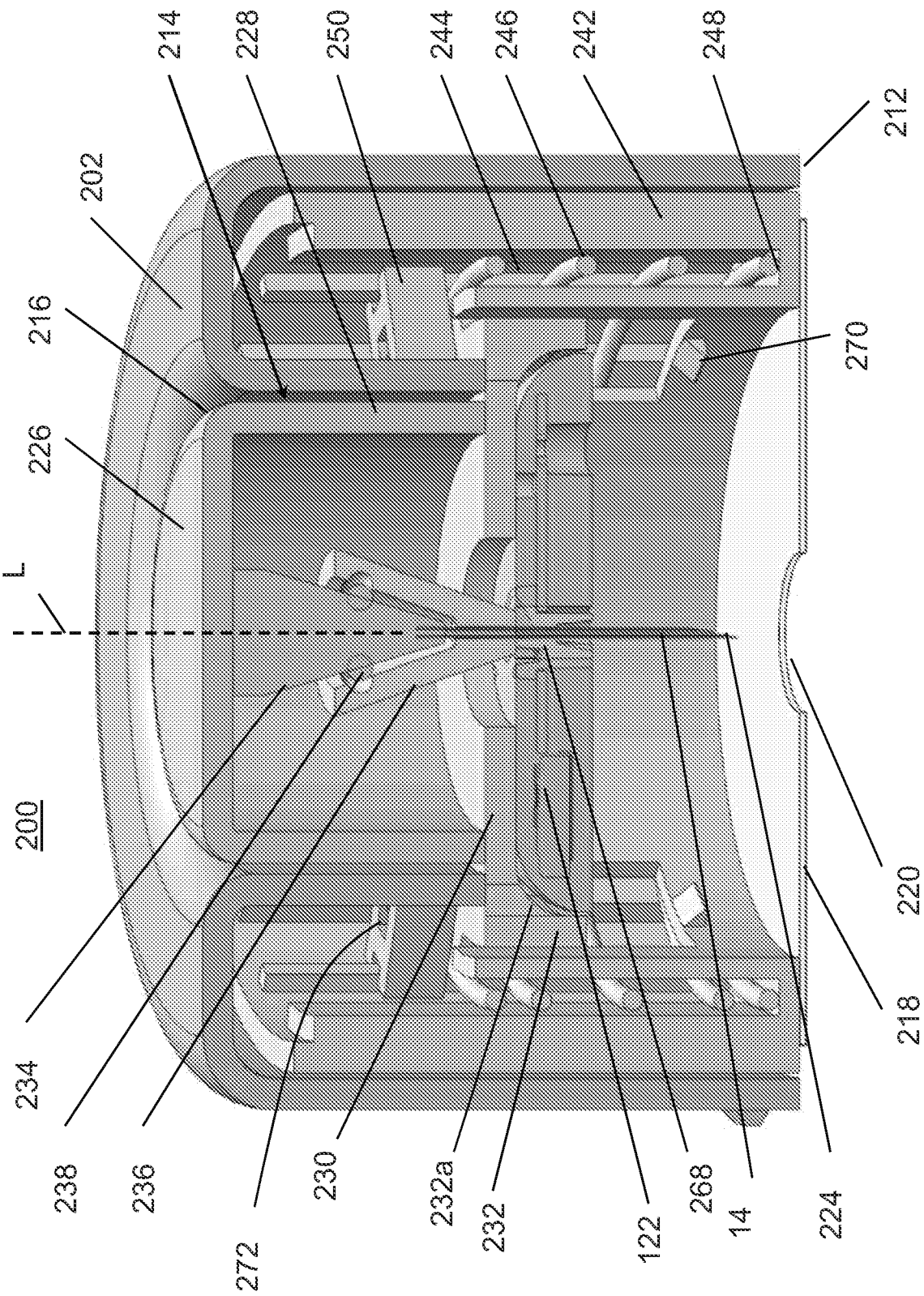
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FIGURE 37

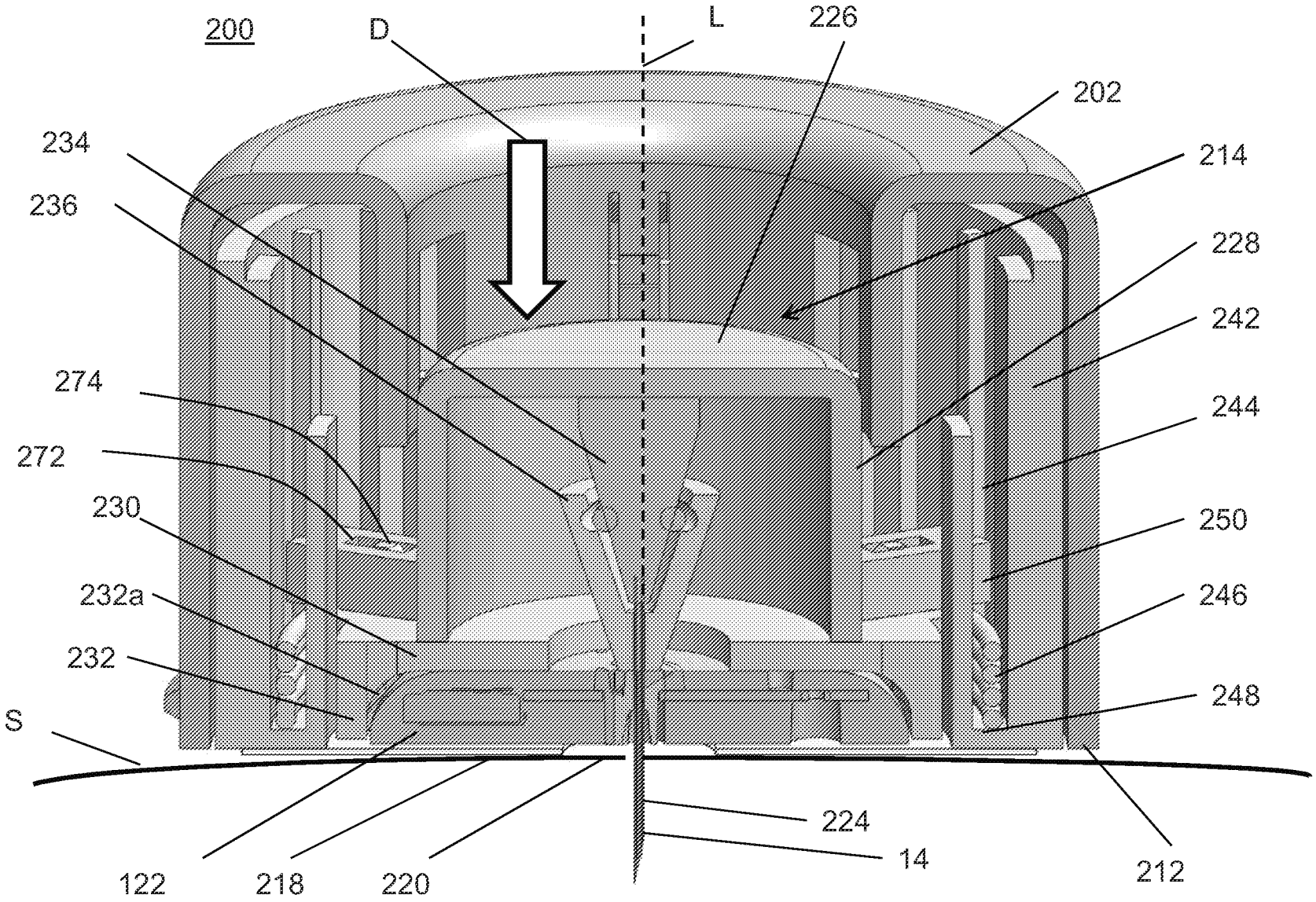
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FIGURE 38

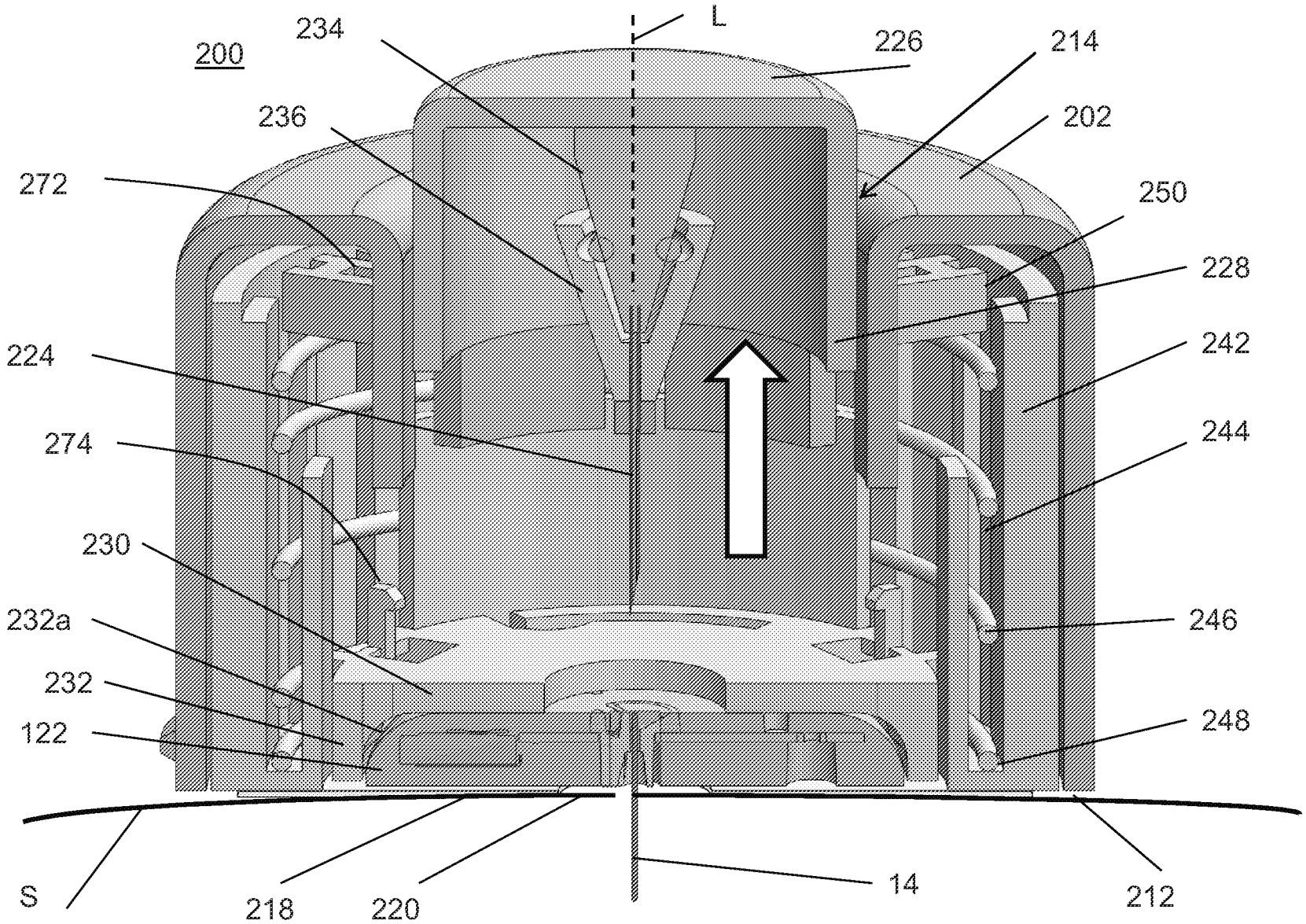
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FIGURE 39

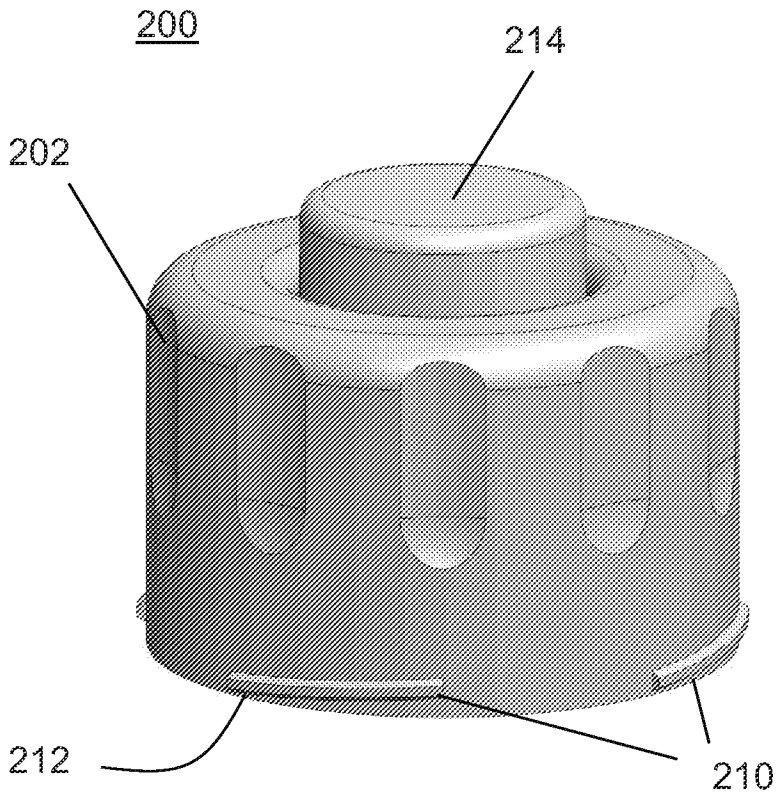

FIGURE 40

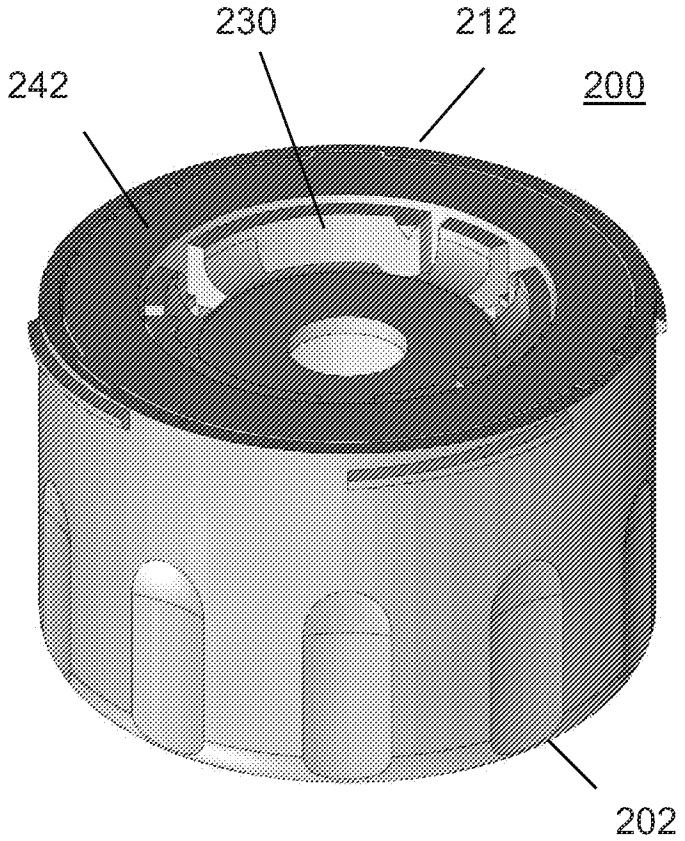

FIGURE 41

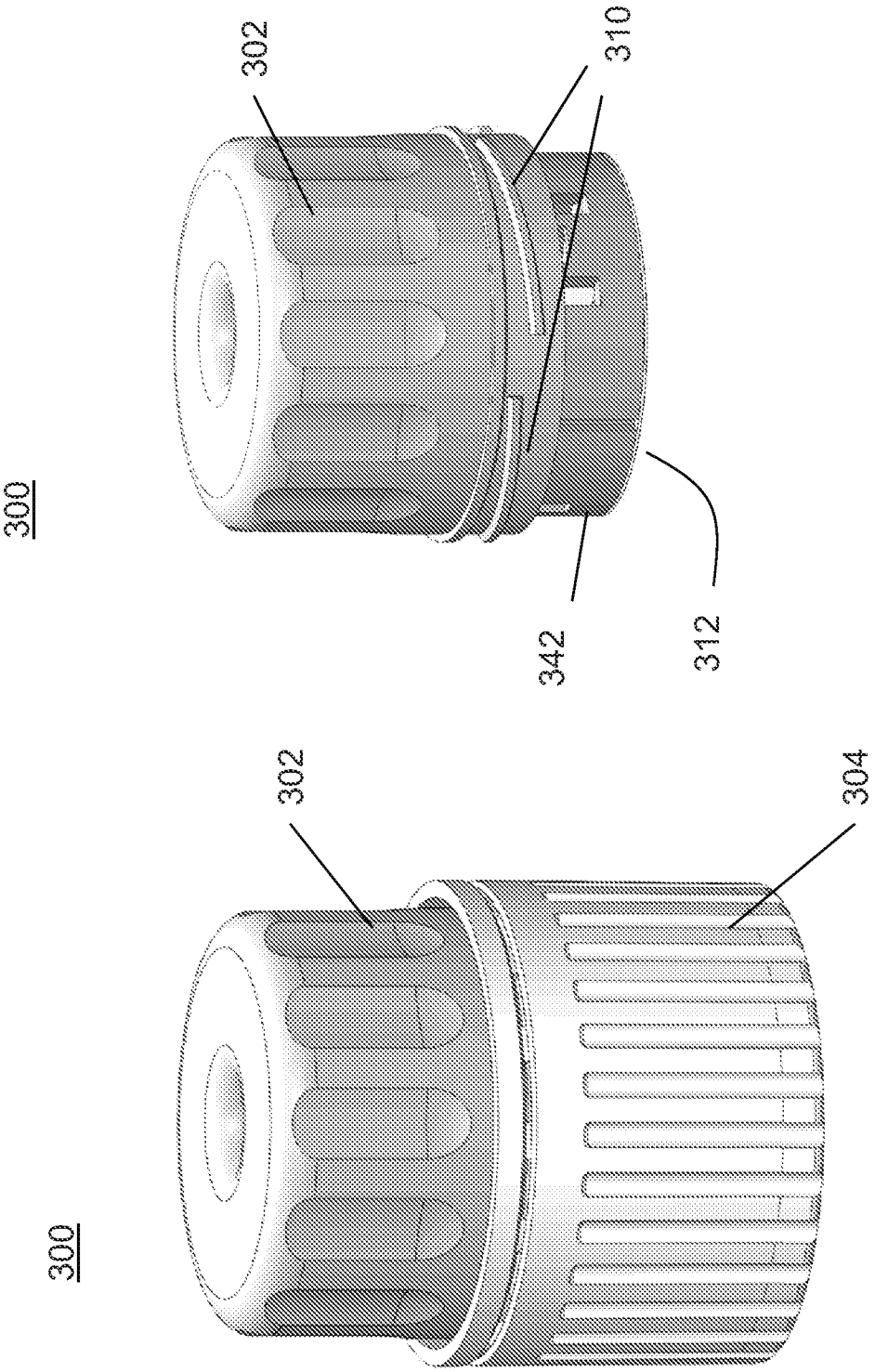

FIGURE 43

FIGURE 42

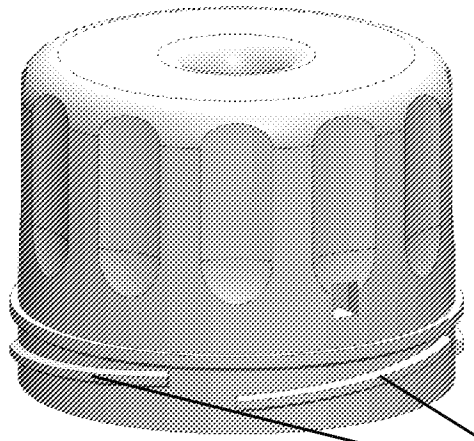

FIGURE 44

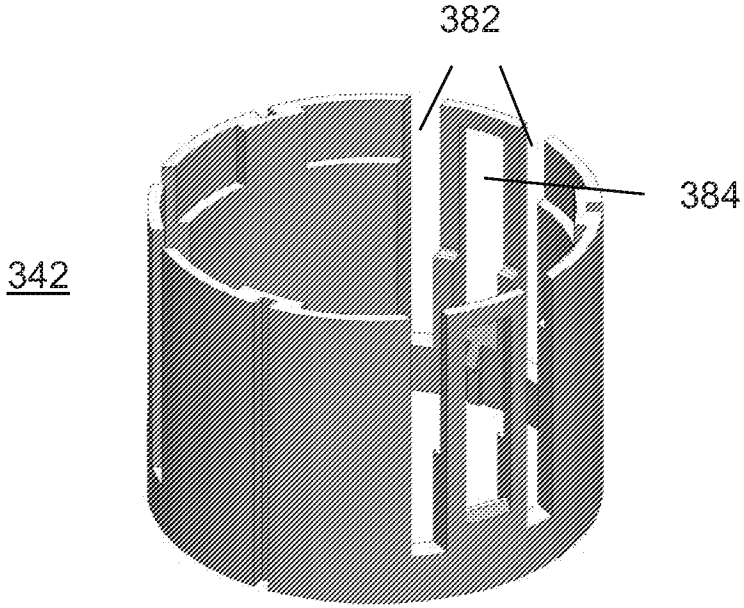

FIGURE 45

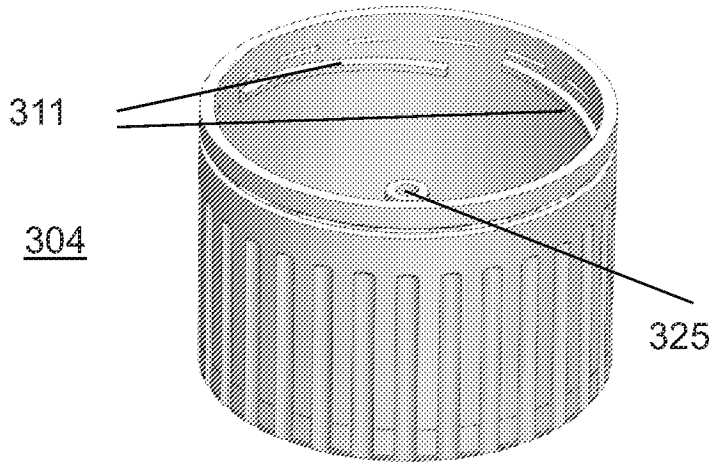

FIGURE 46

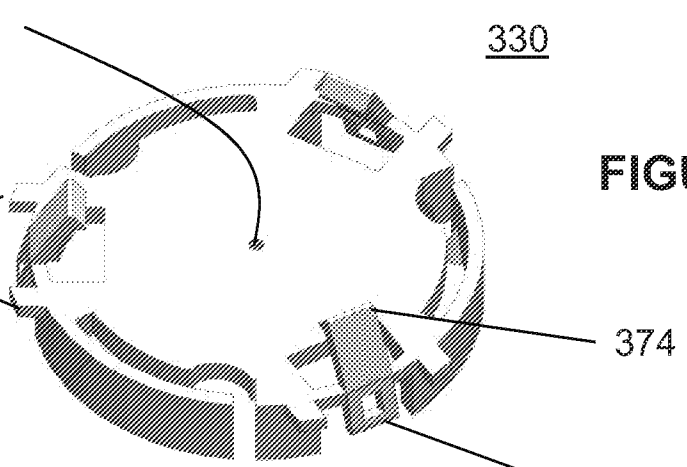

FIGURE 47

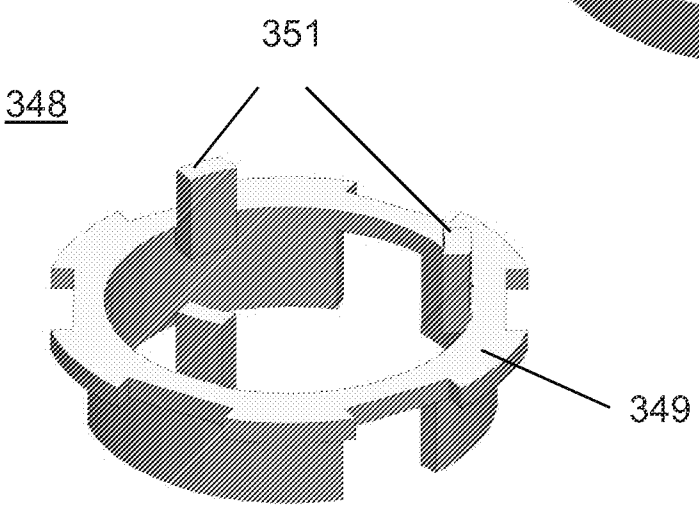

FIGURE 48

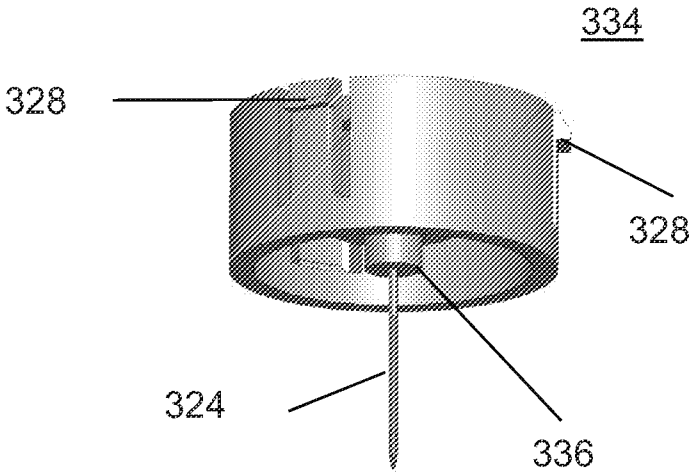

FIGURE 49

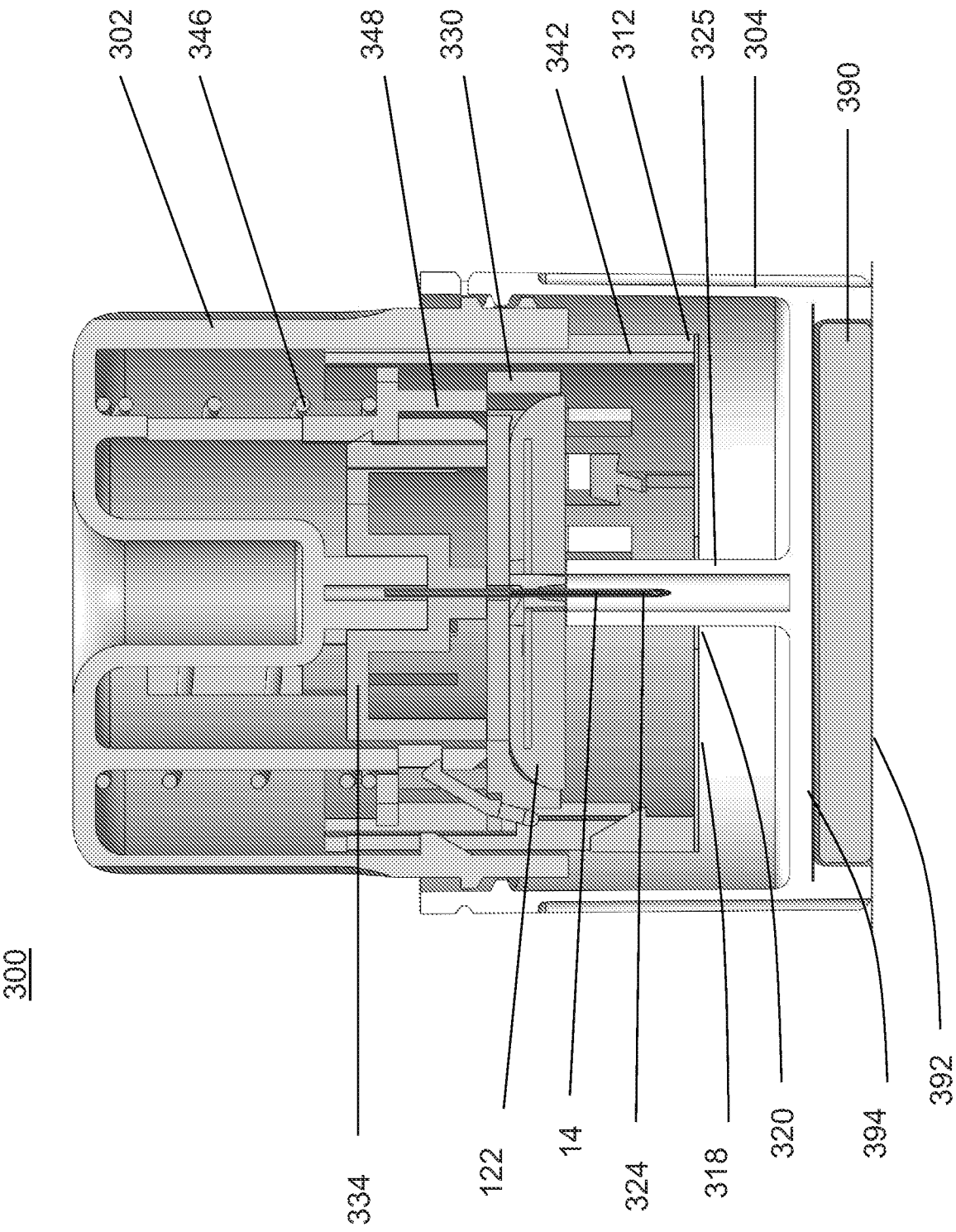
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FIGURE 50

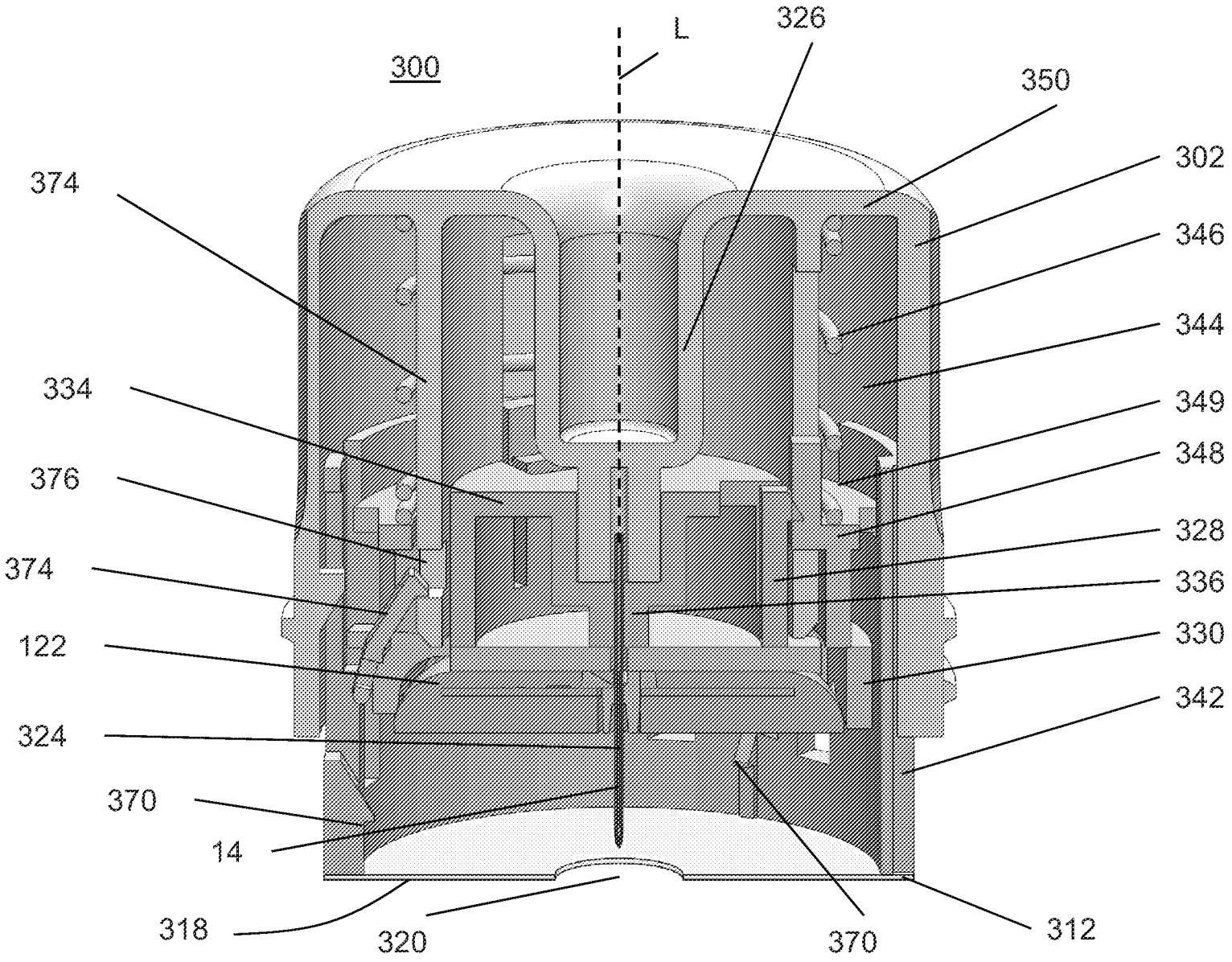
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FIGURE 51

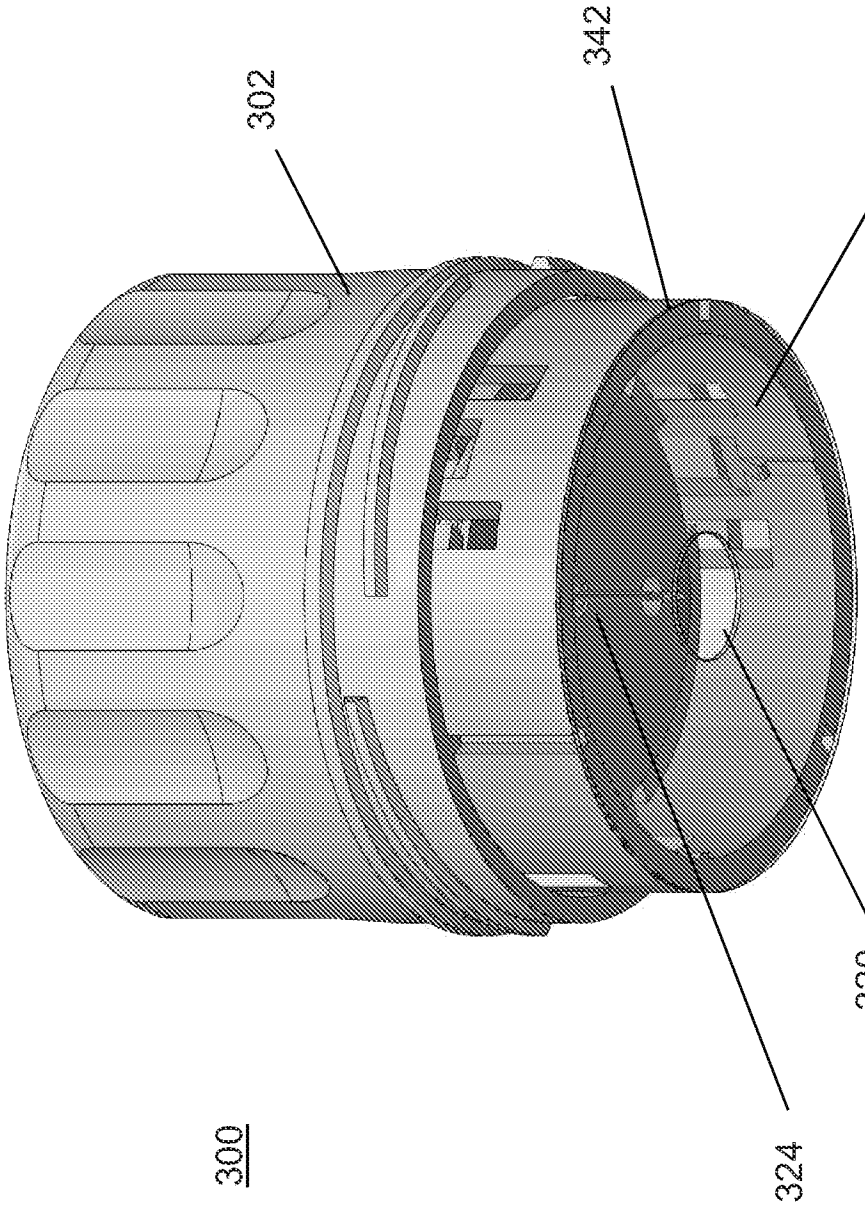

FIGURE 52

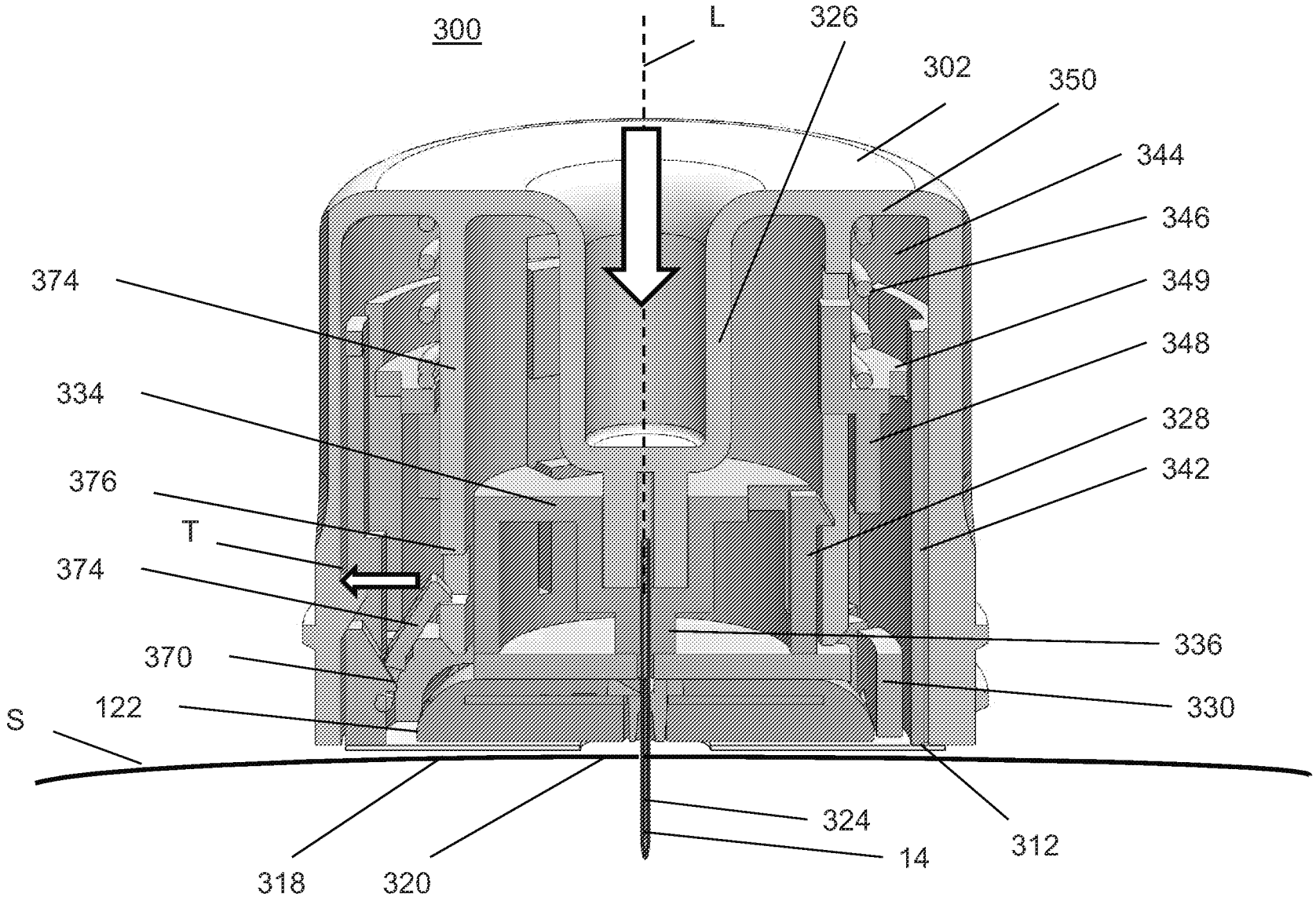
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FIGURE 53

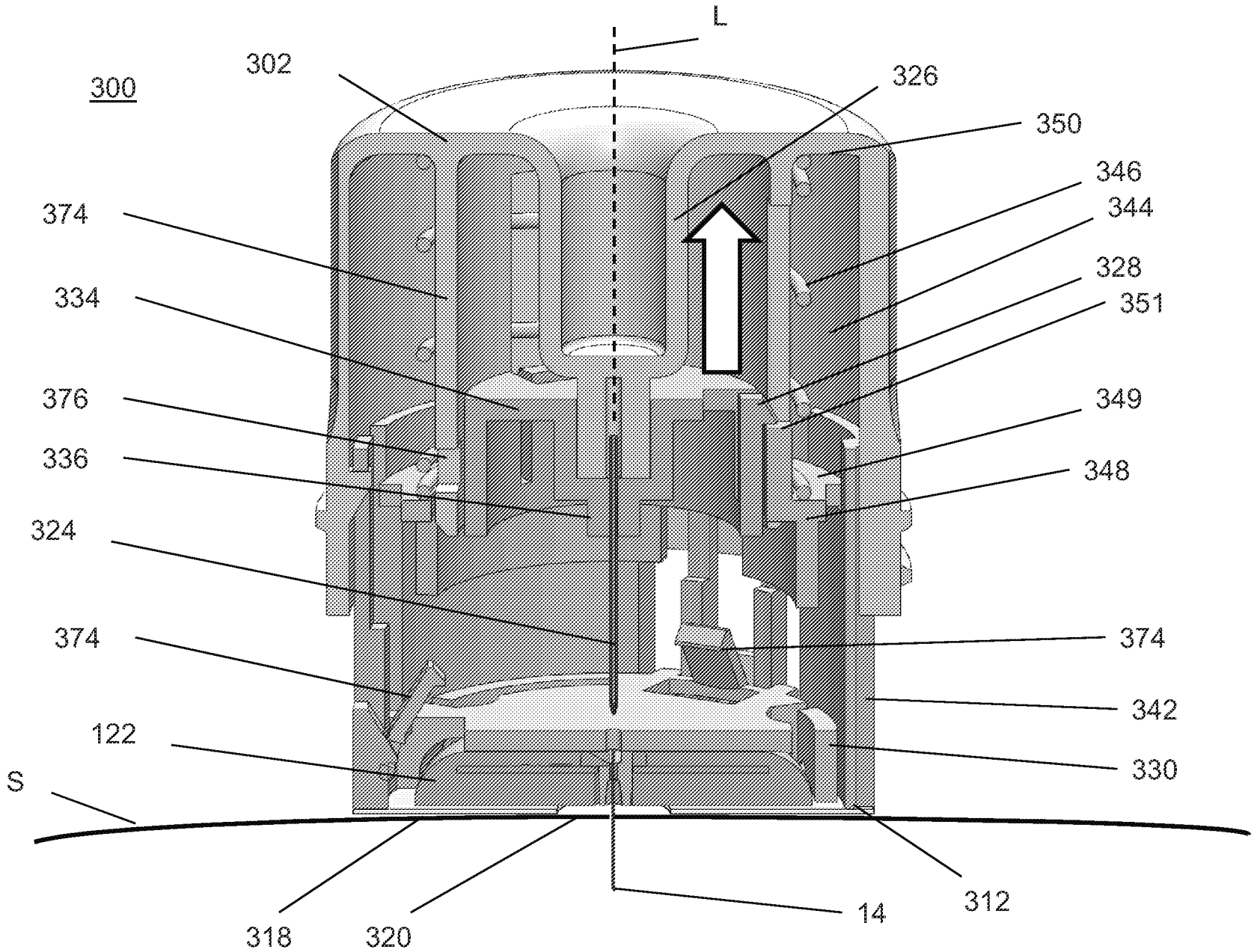
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FIGURE 54

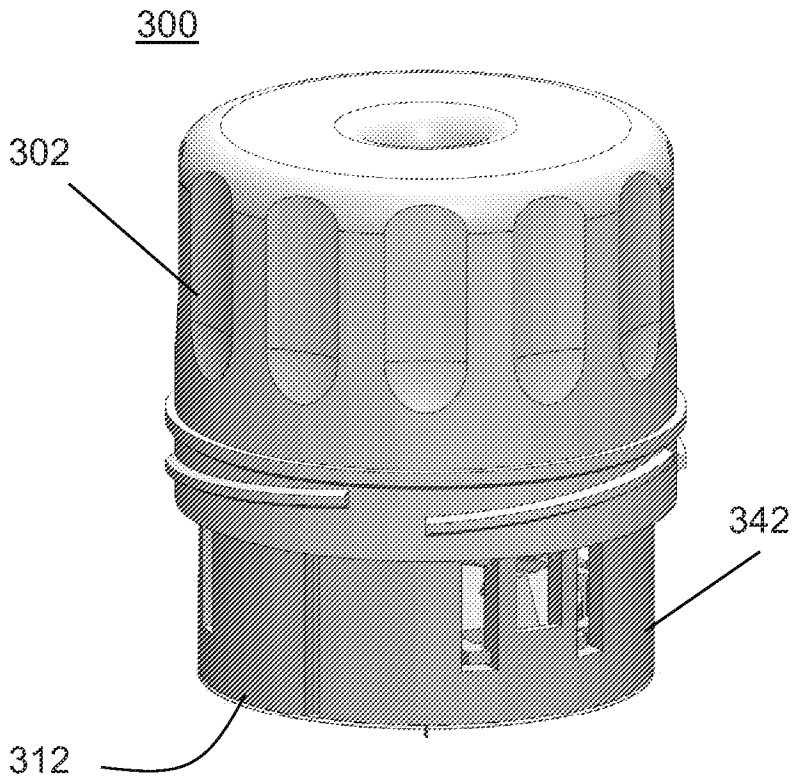

FIGURE 55

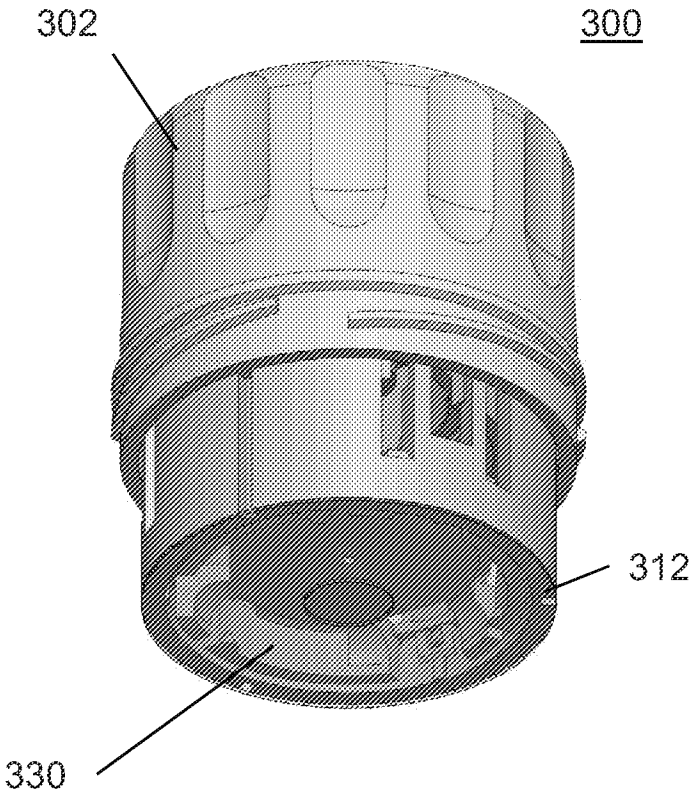

FIGURE 56

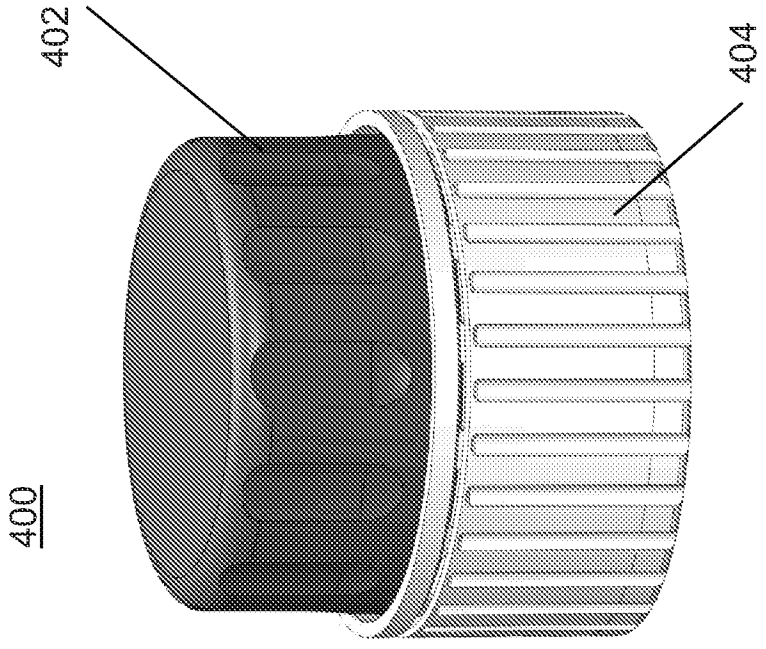

FIGURE 57

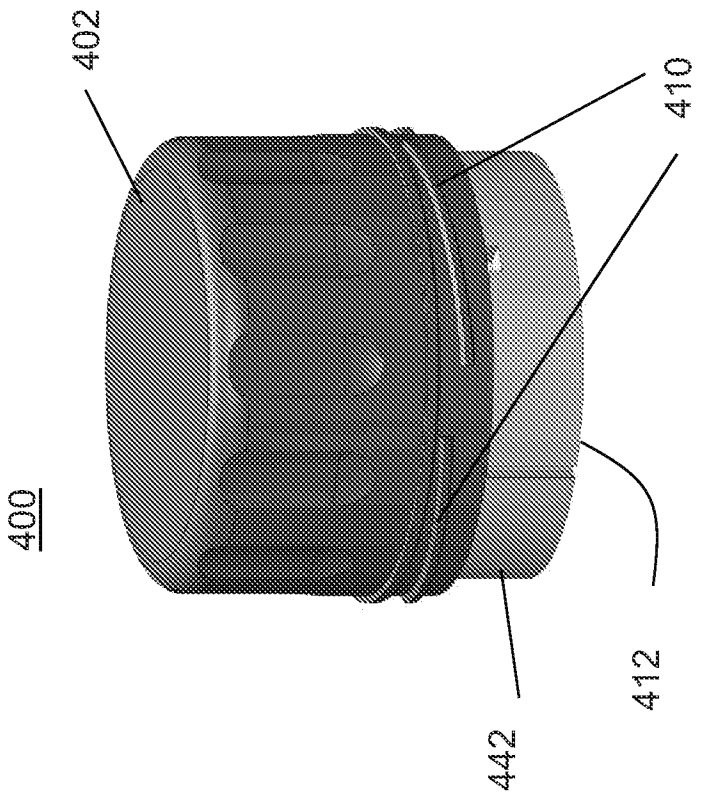

FIGURE 58

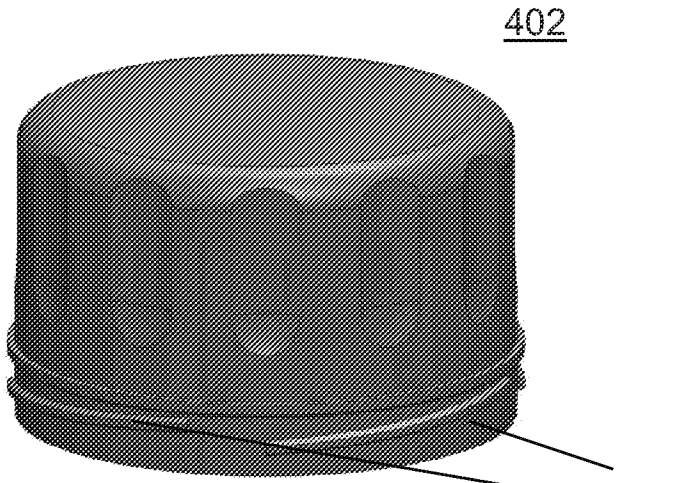

FIGURE 59

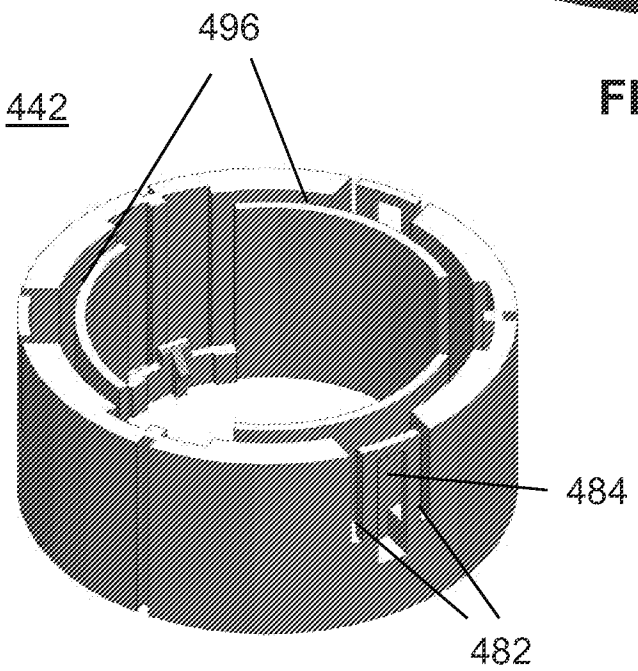

FIGURE 60

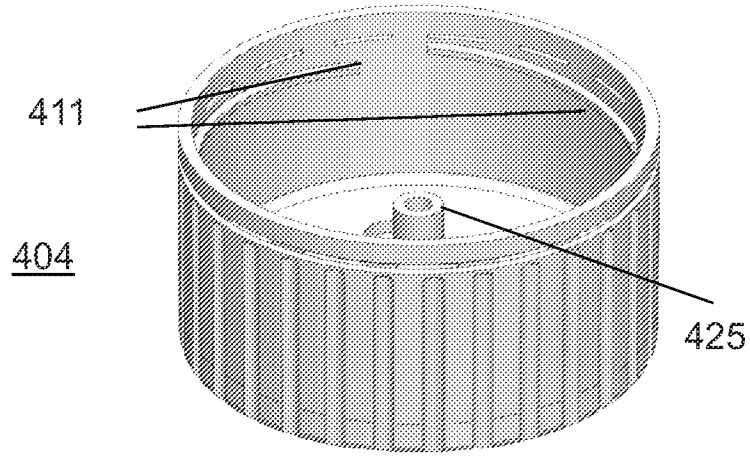

FIGURE 61

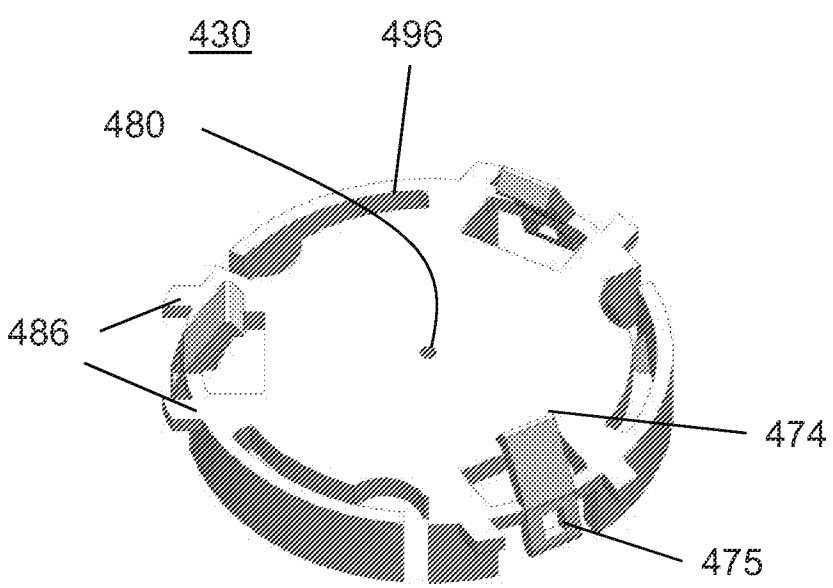

FIGURE 62

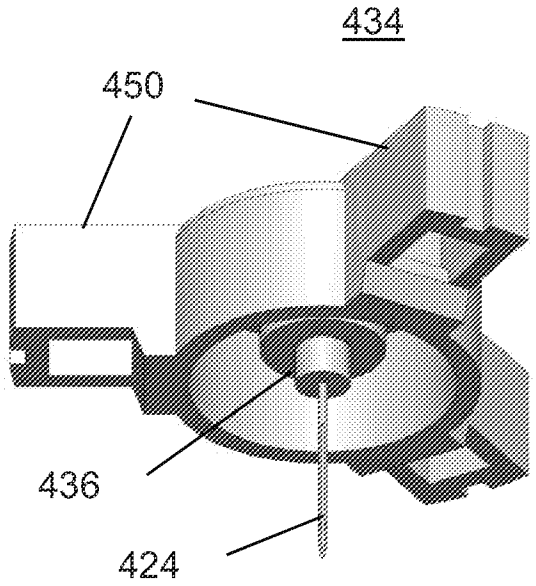

FIGURE 63

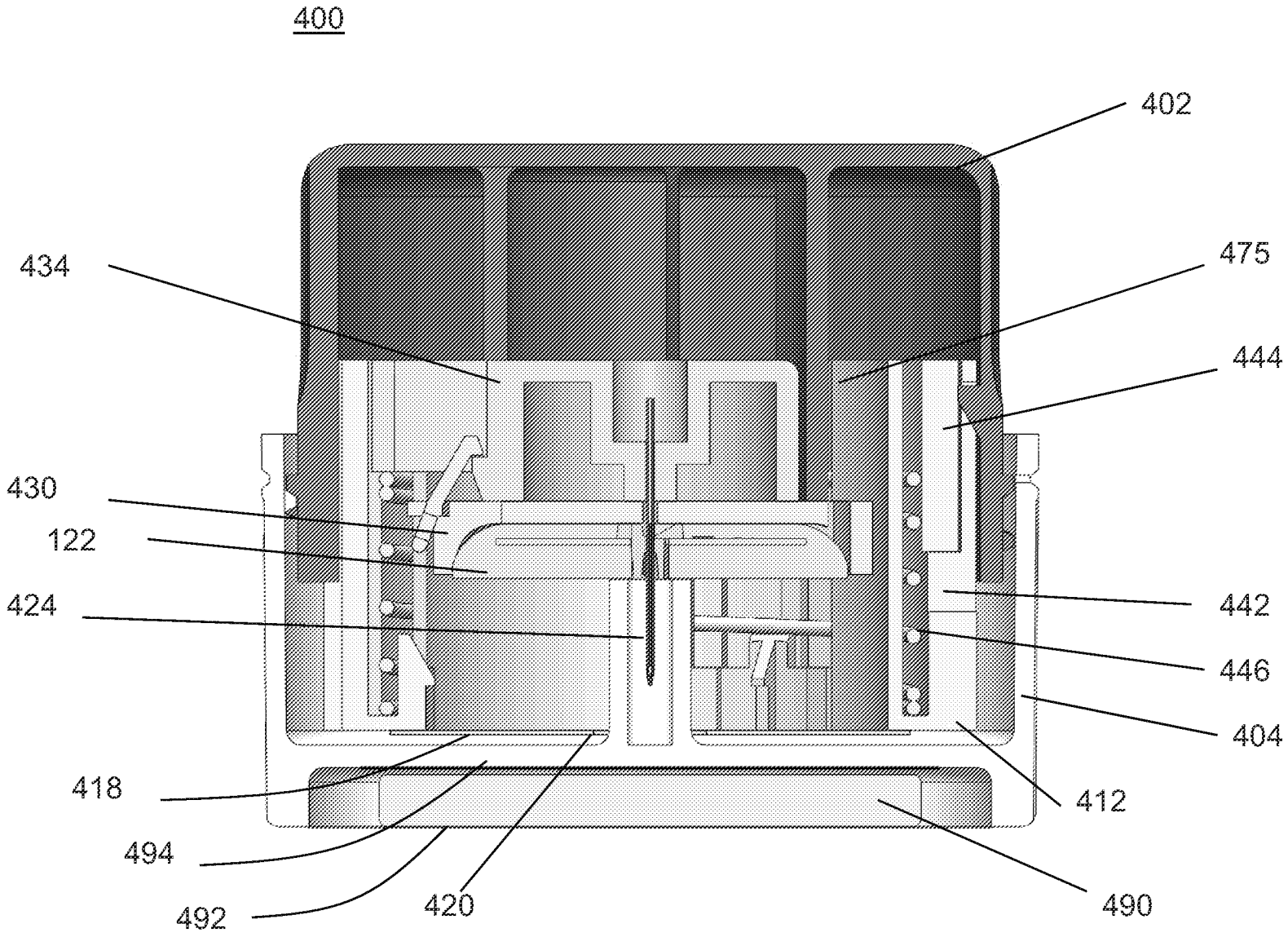
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FIGURE 64

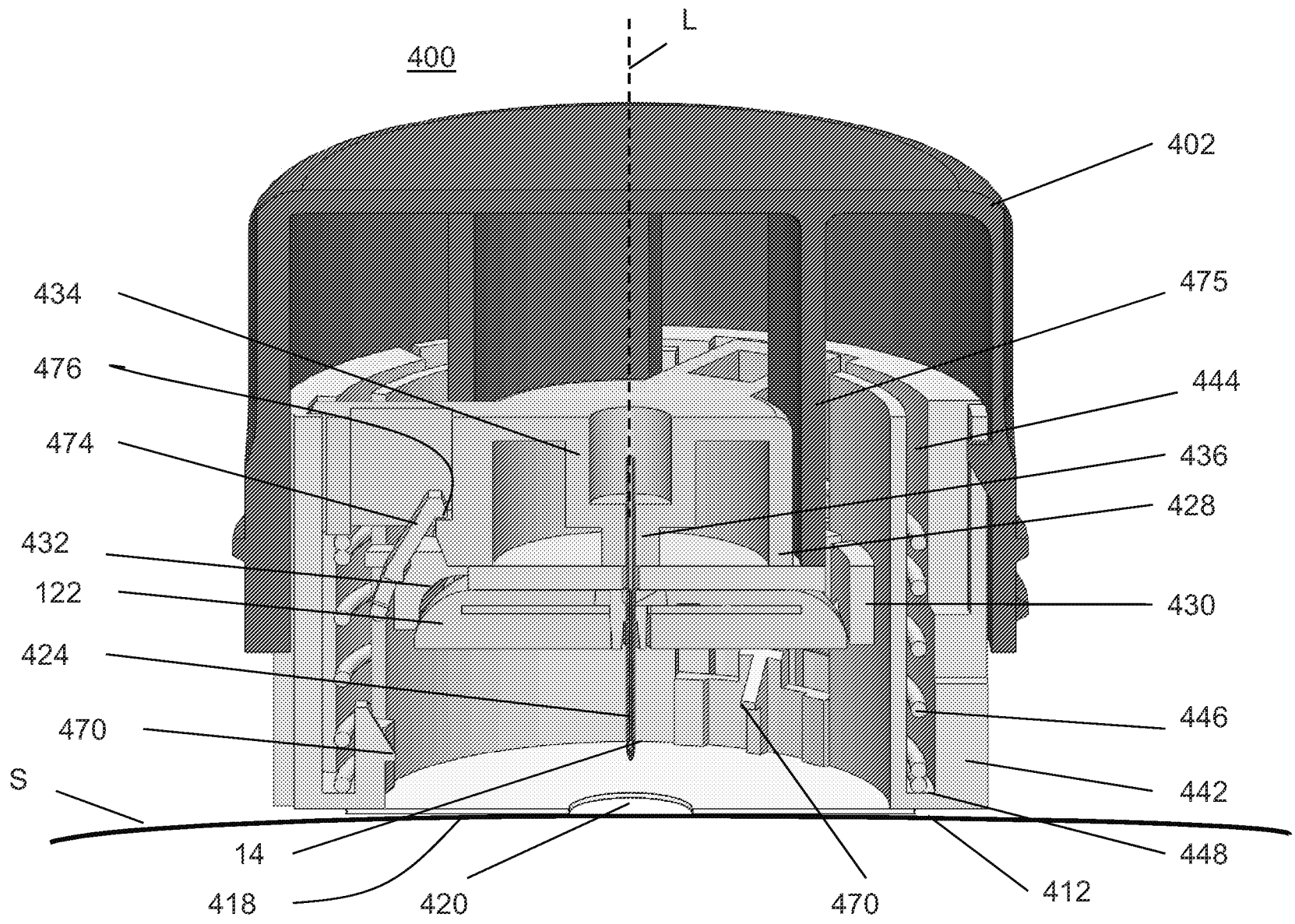
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FIGURE 65

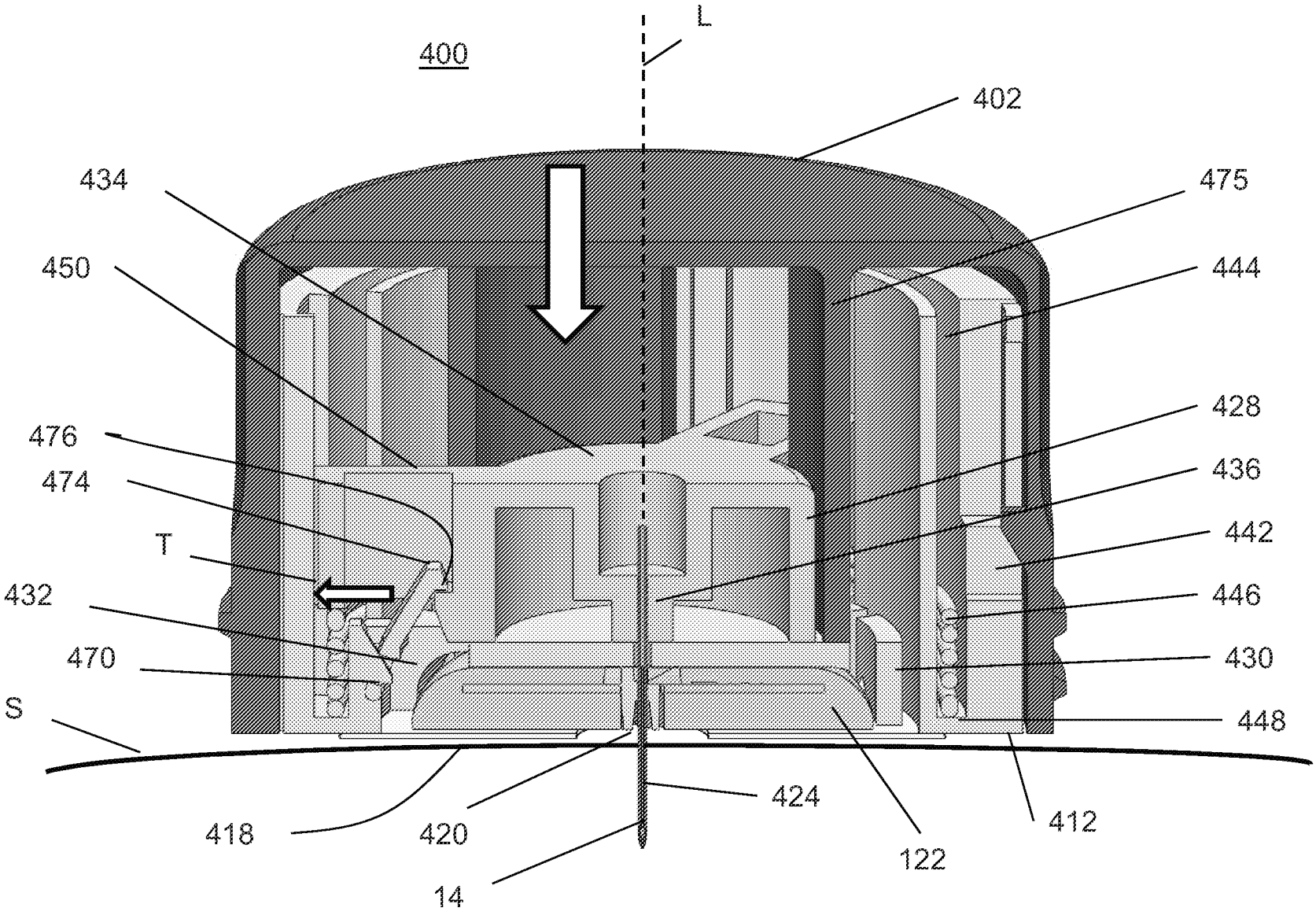
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FIGURE 66

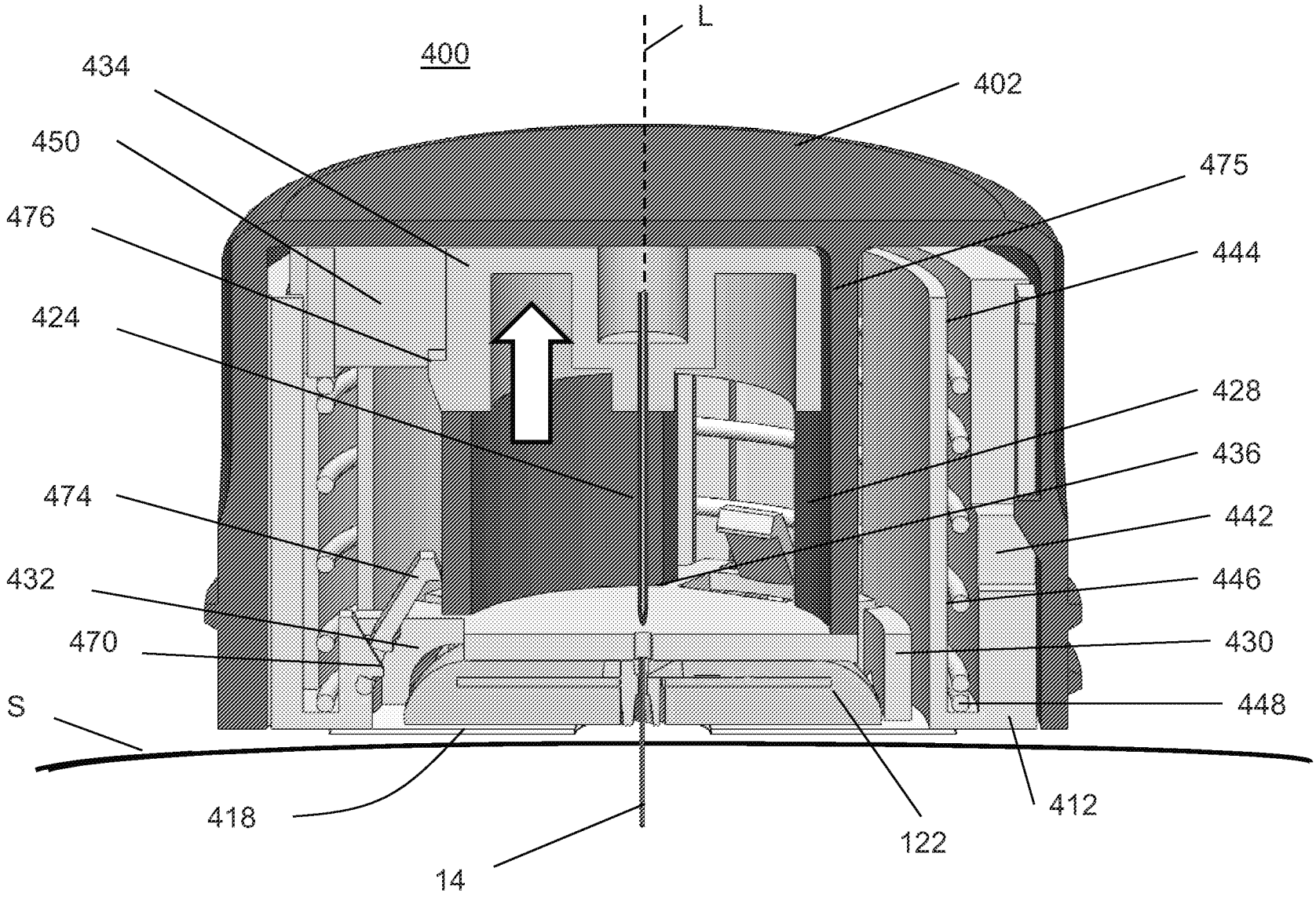
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FIGURE 67

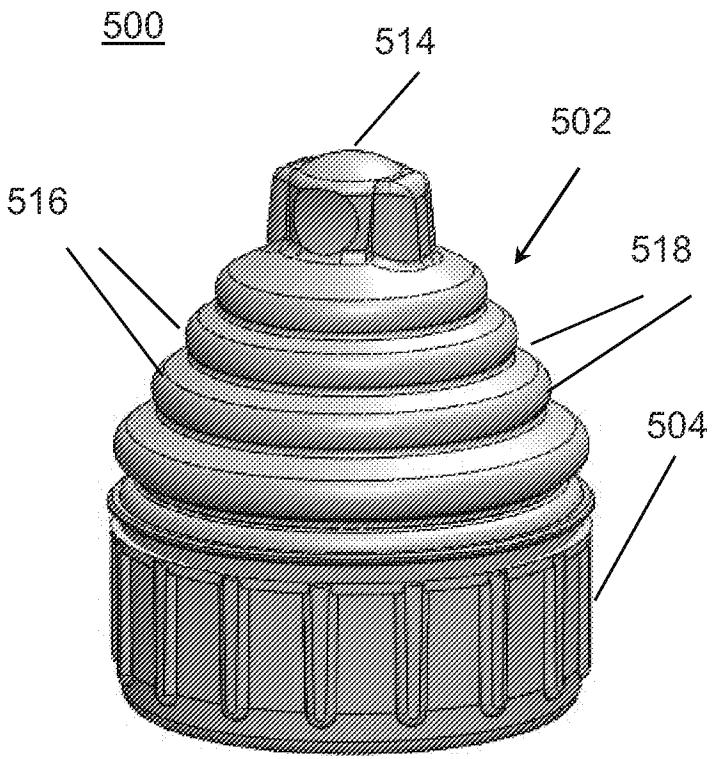

FIGURE 68

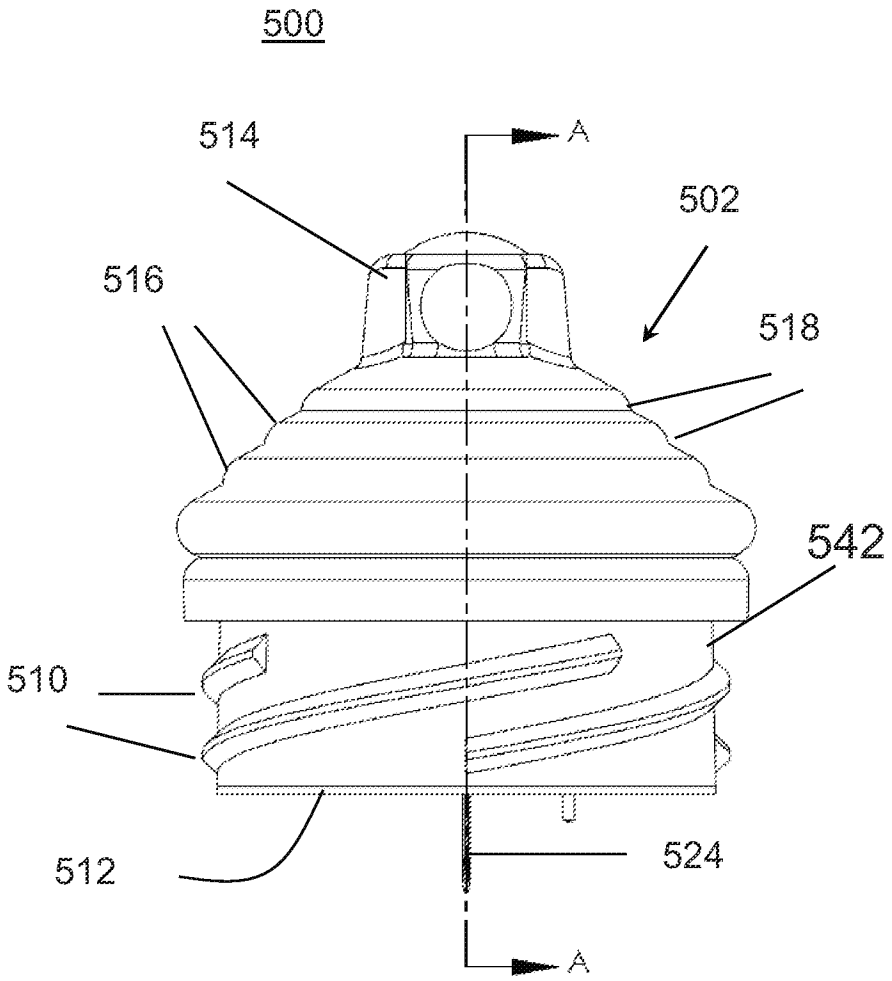

FIGURE 69

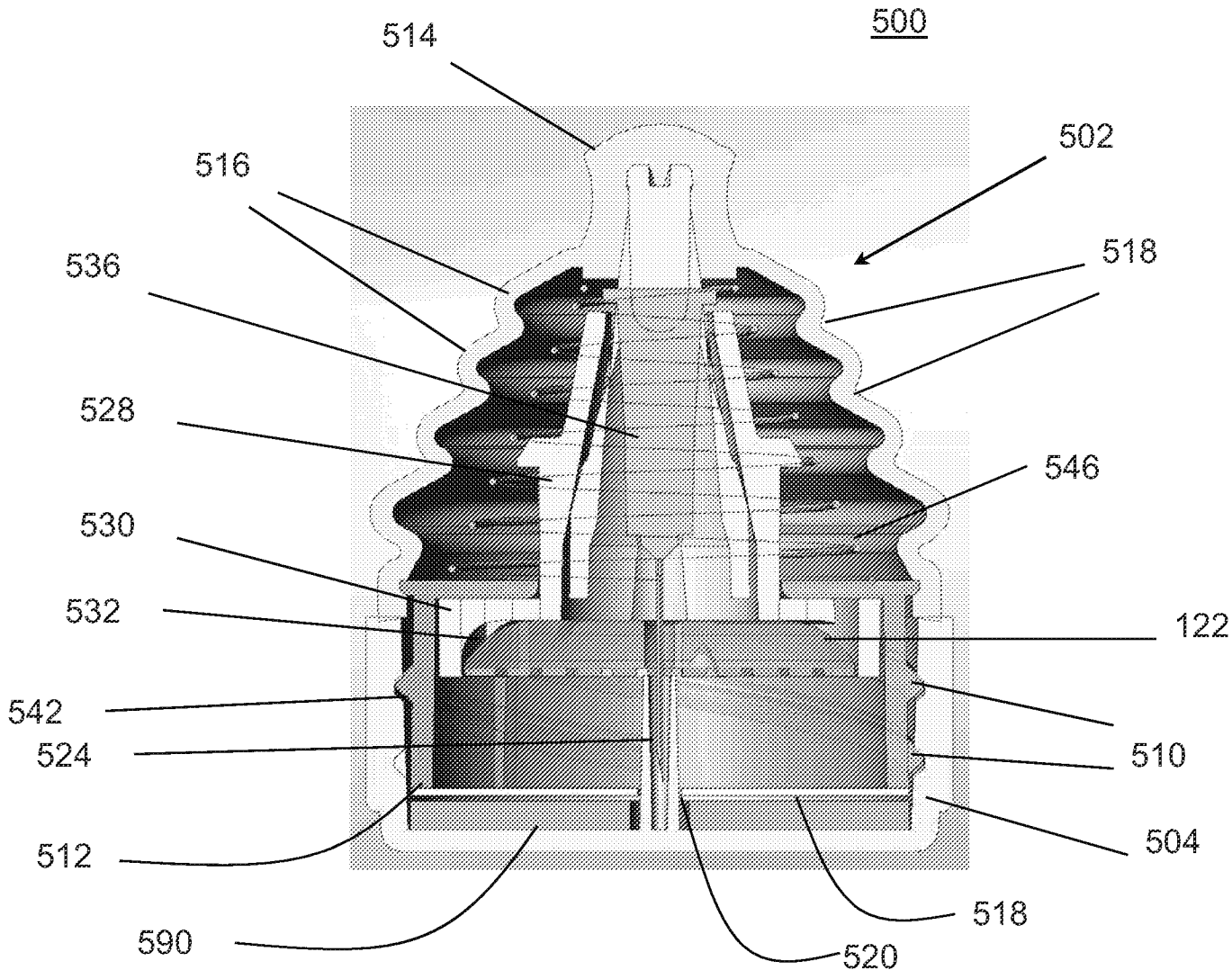
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FIGURE 70

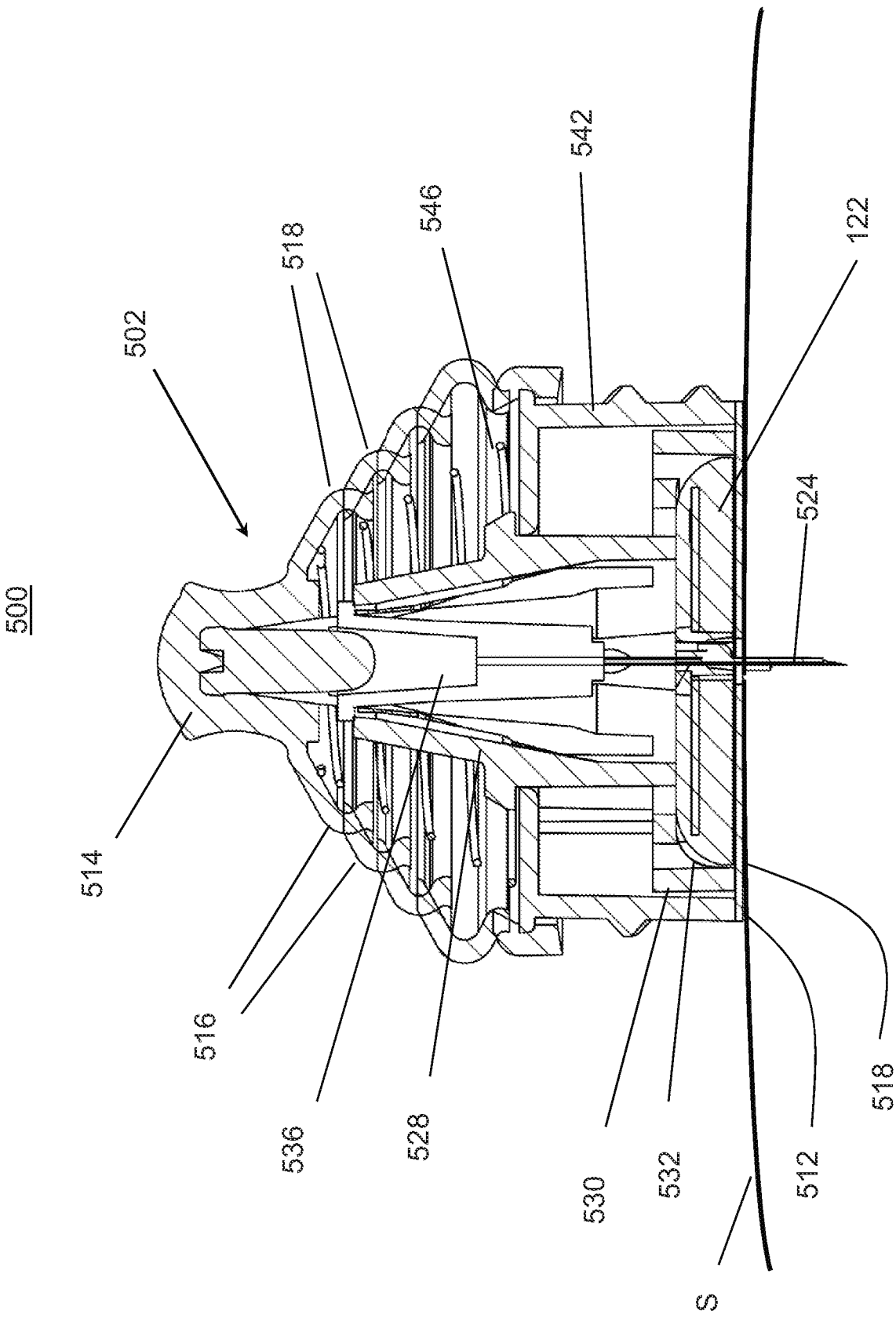

FIGURE 71

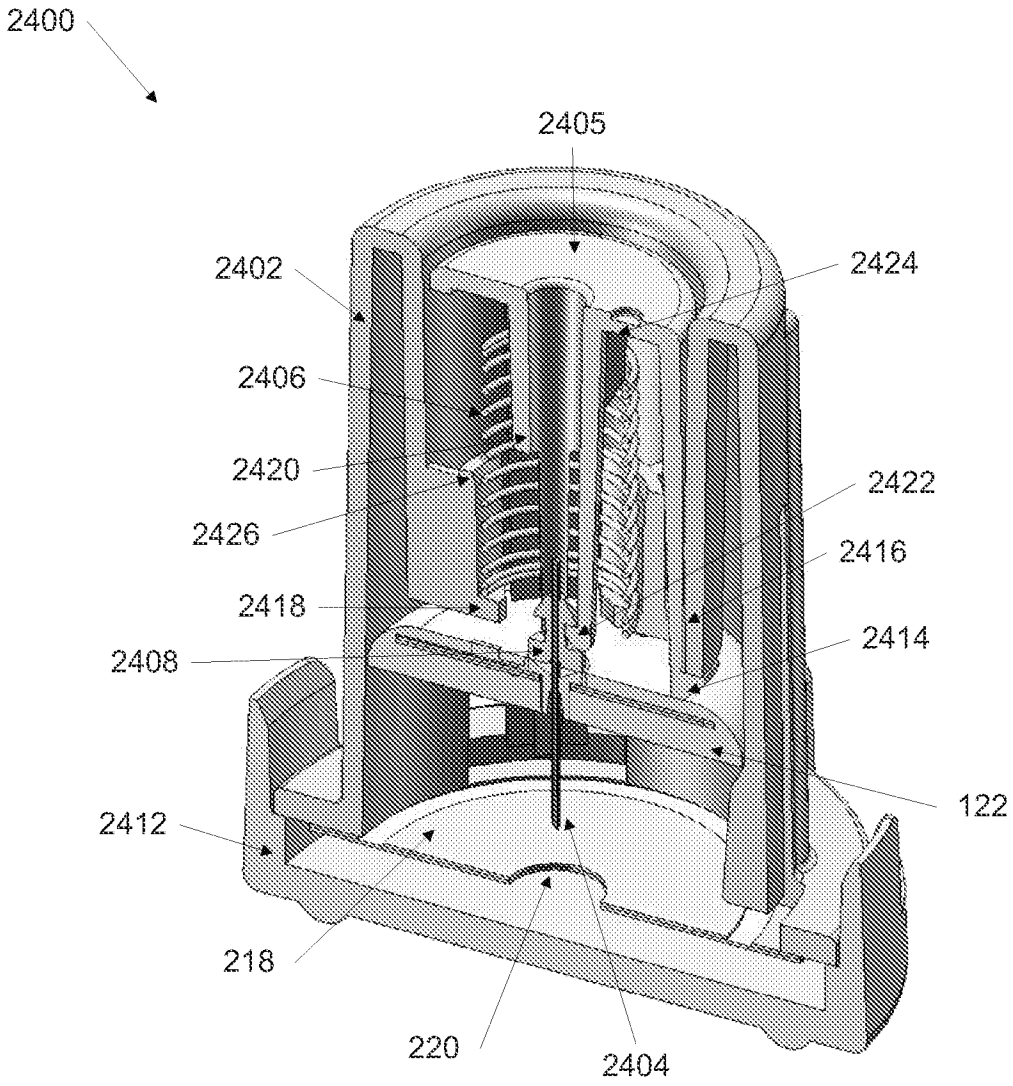
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FIG. 72

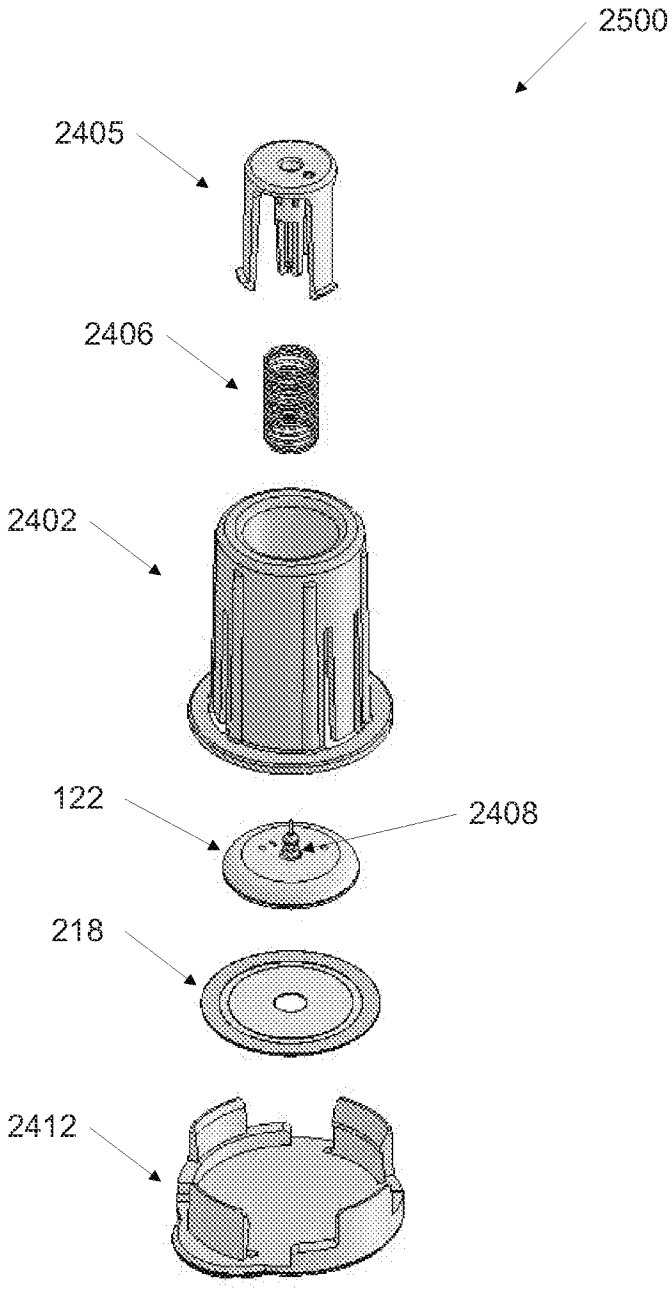

FIG. 72A

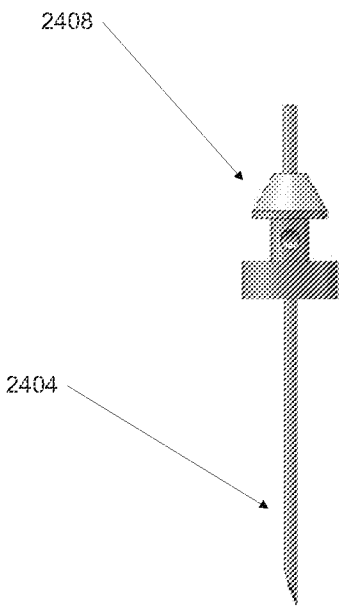

FIG. 72B

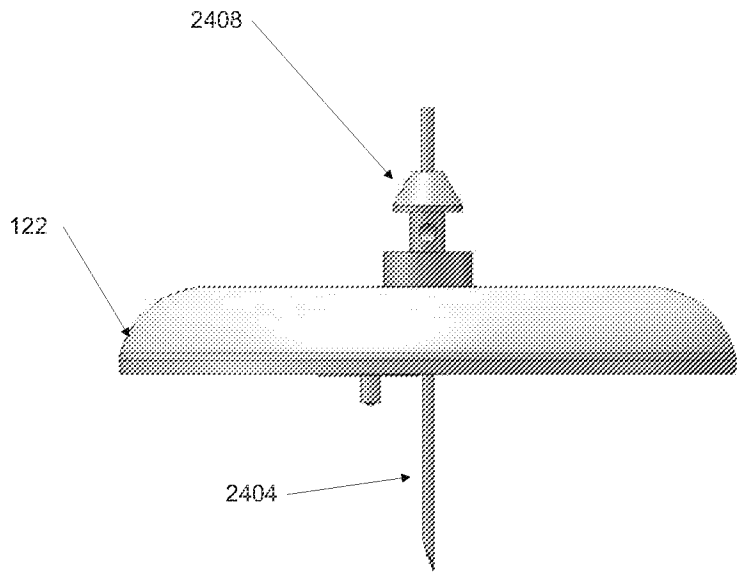

FIG. 72C

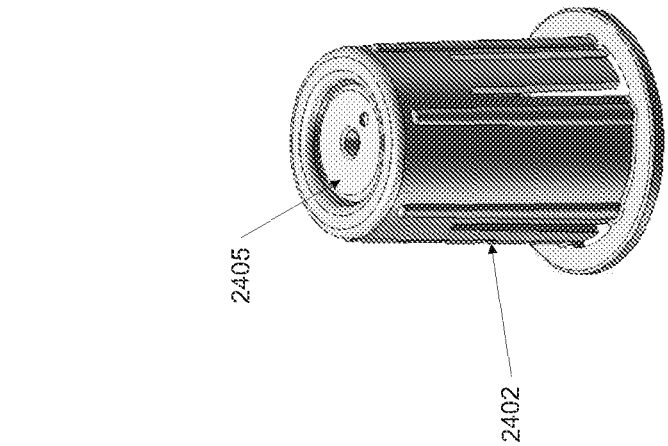

FIG. 72E

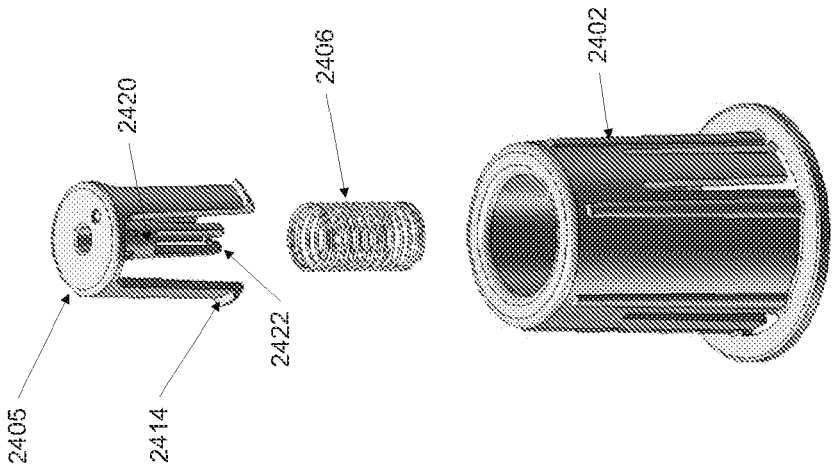

FIG. 72D

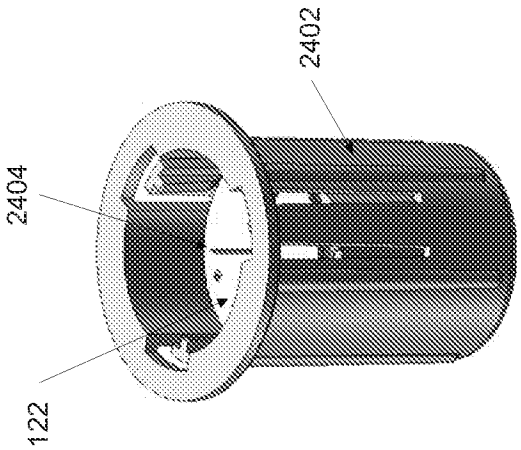

FIG. 72G

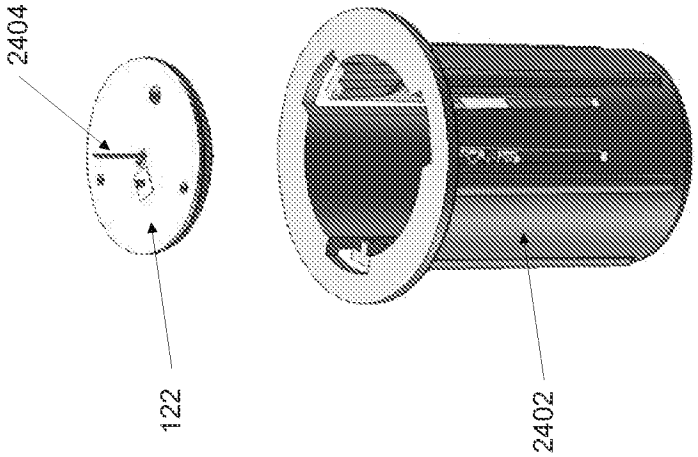

FIG. 72F

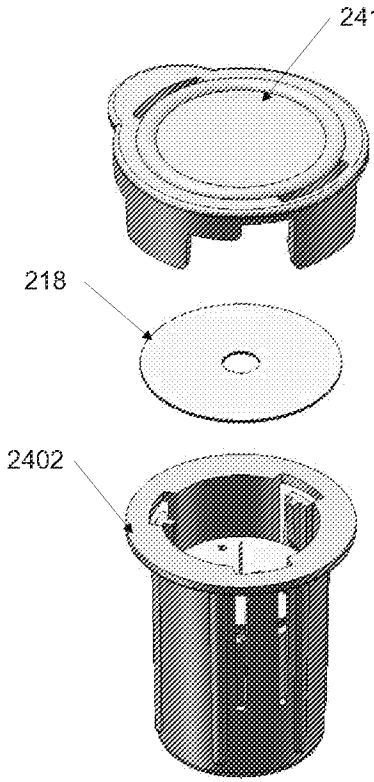

FIG. 72H

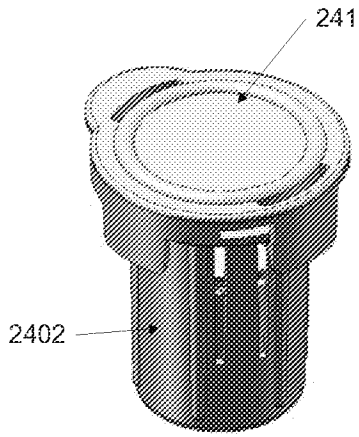

FIG. 72I

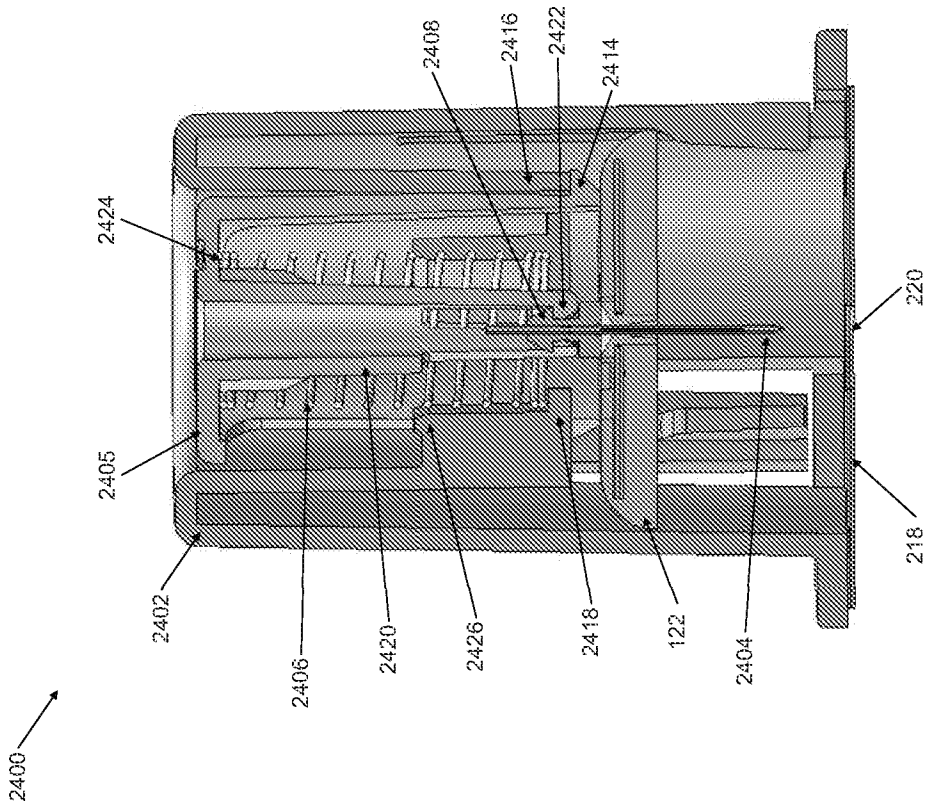
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FIG. 72J

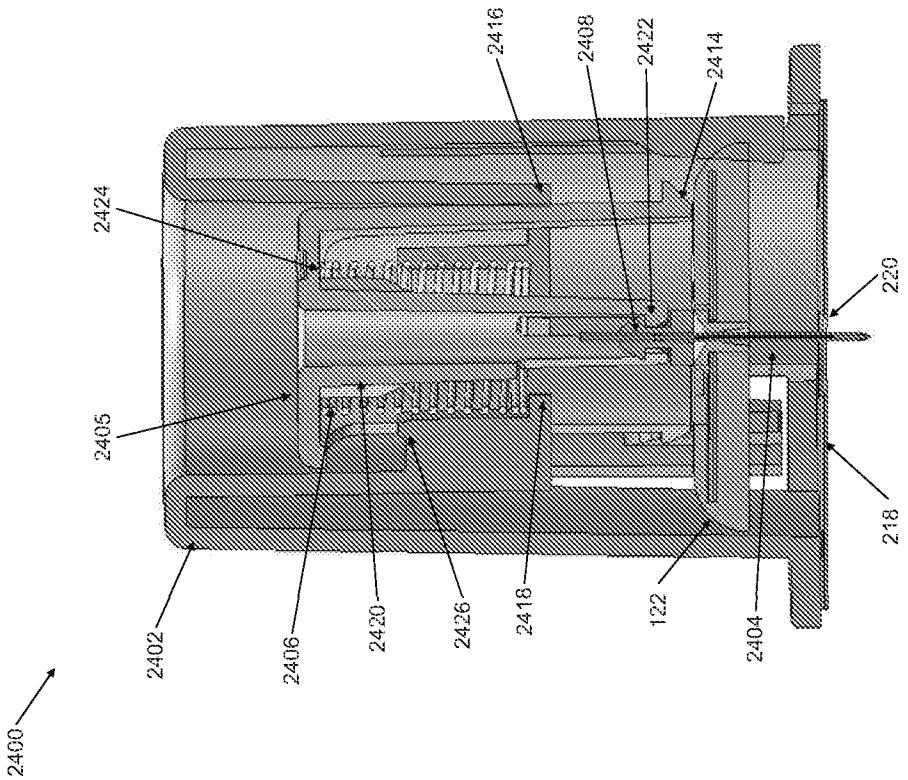
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FIG. 72K

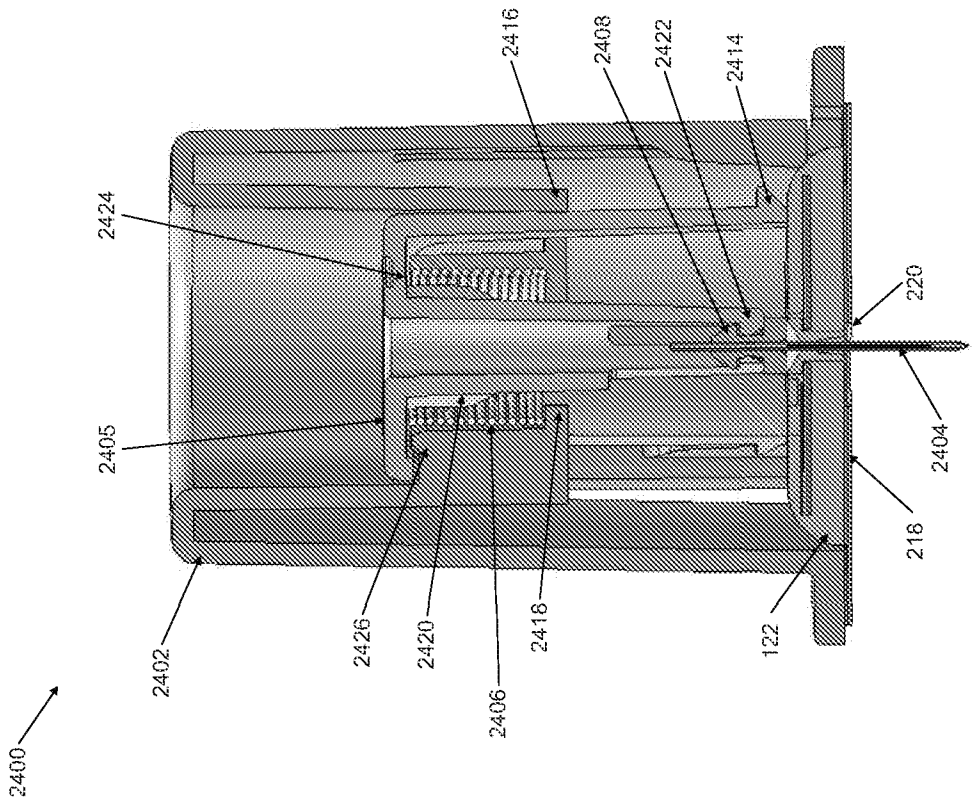
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FIG. 72L

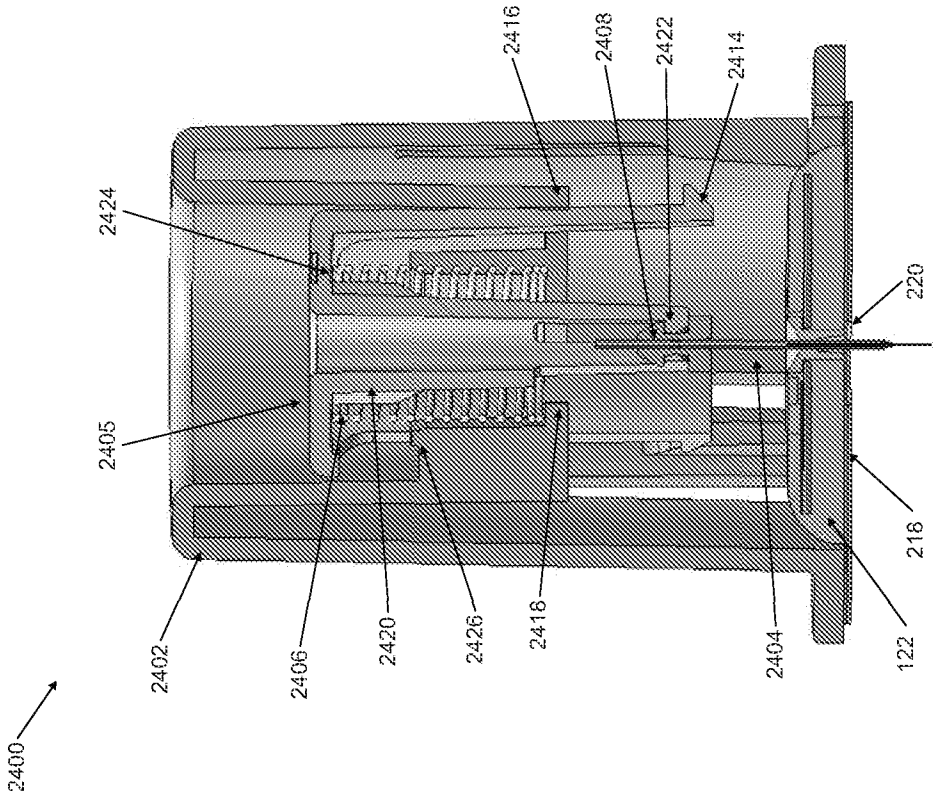
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FIG. 72M

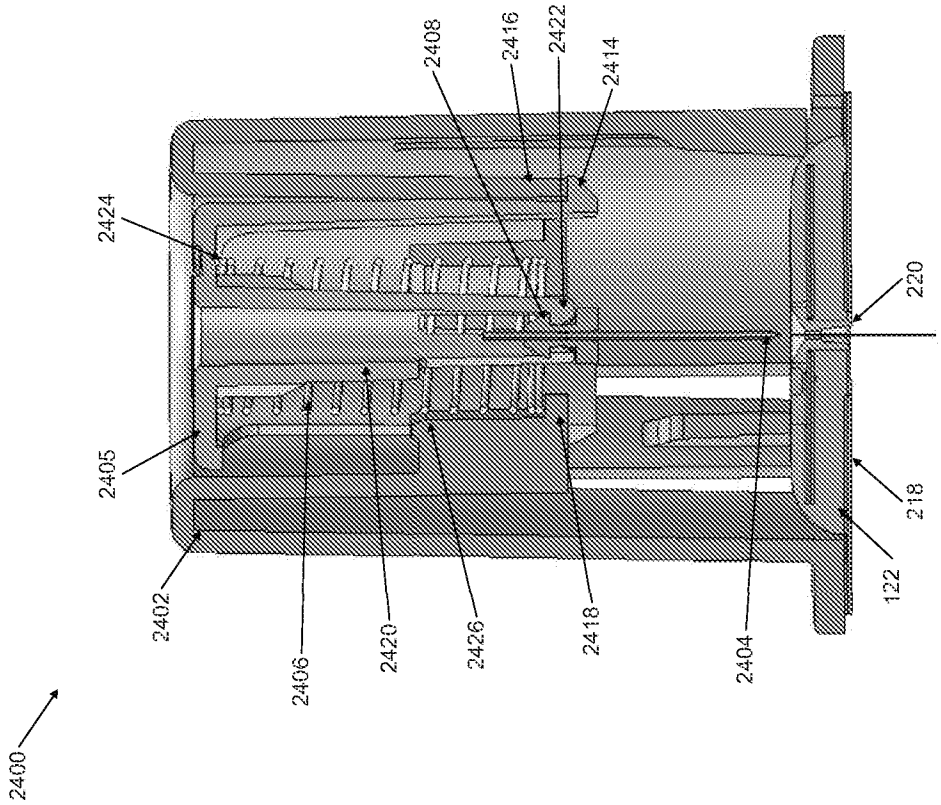
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FIG. 72N

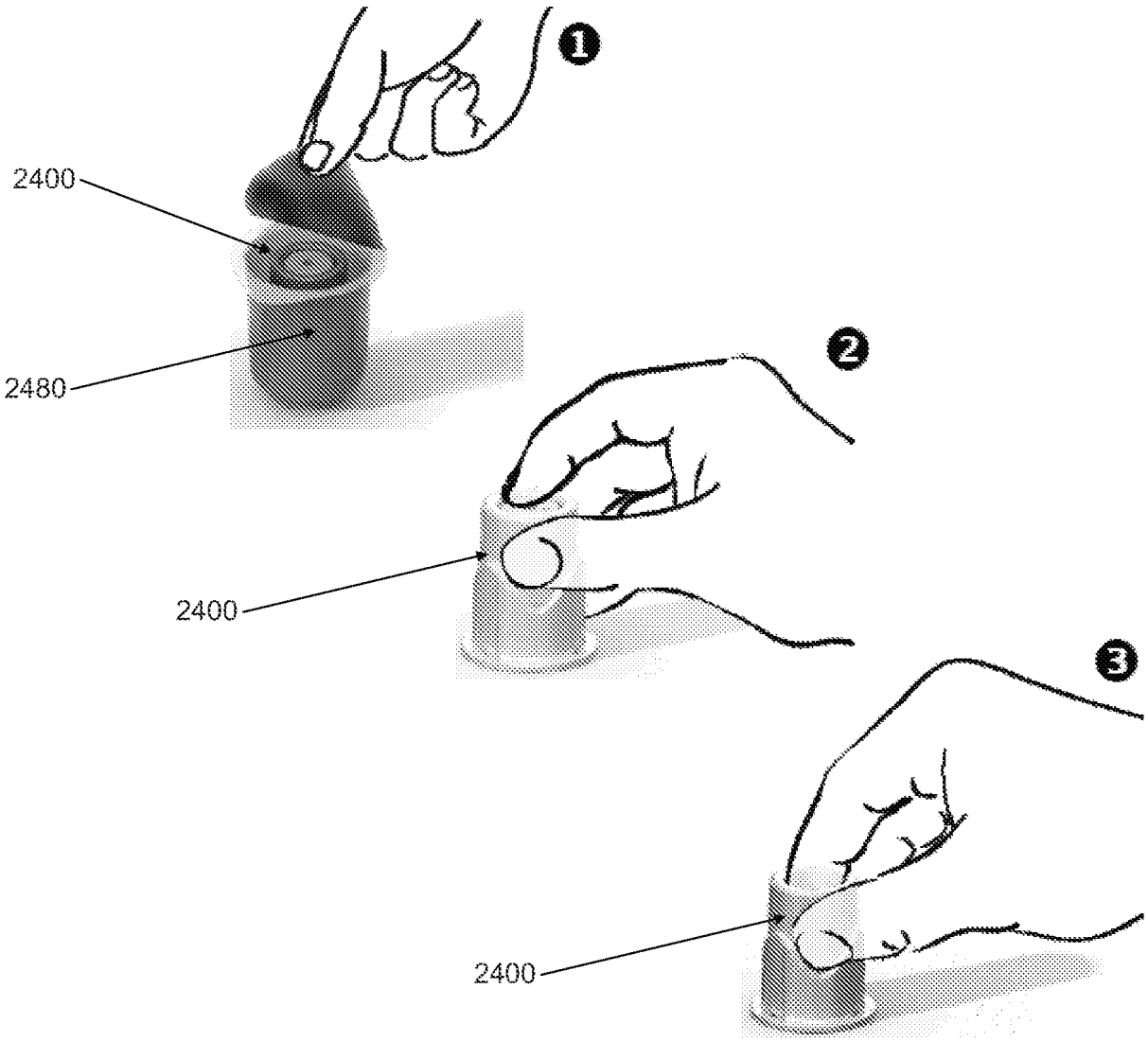

FIG. 72O

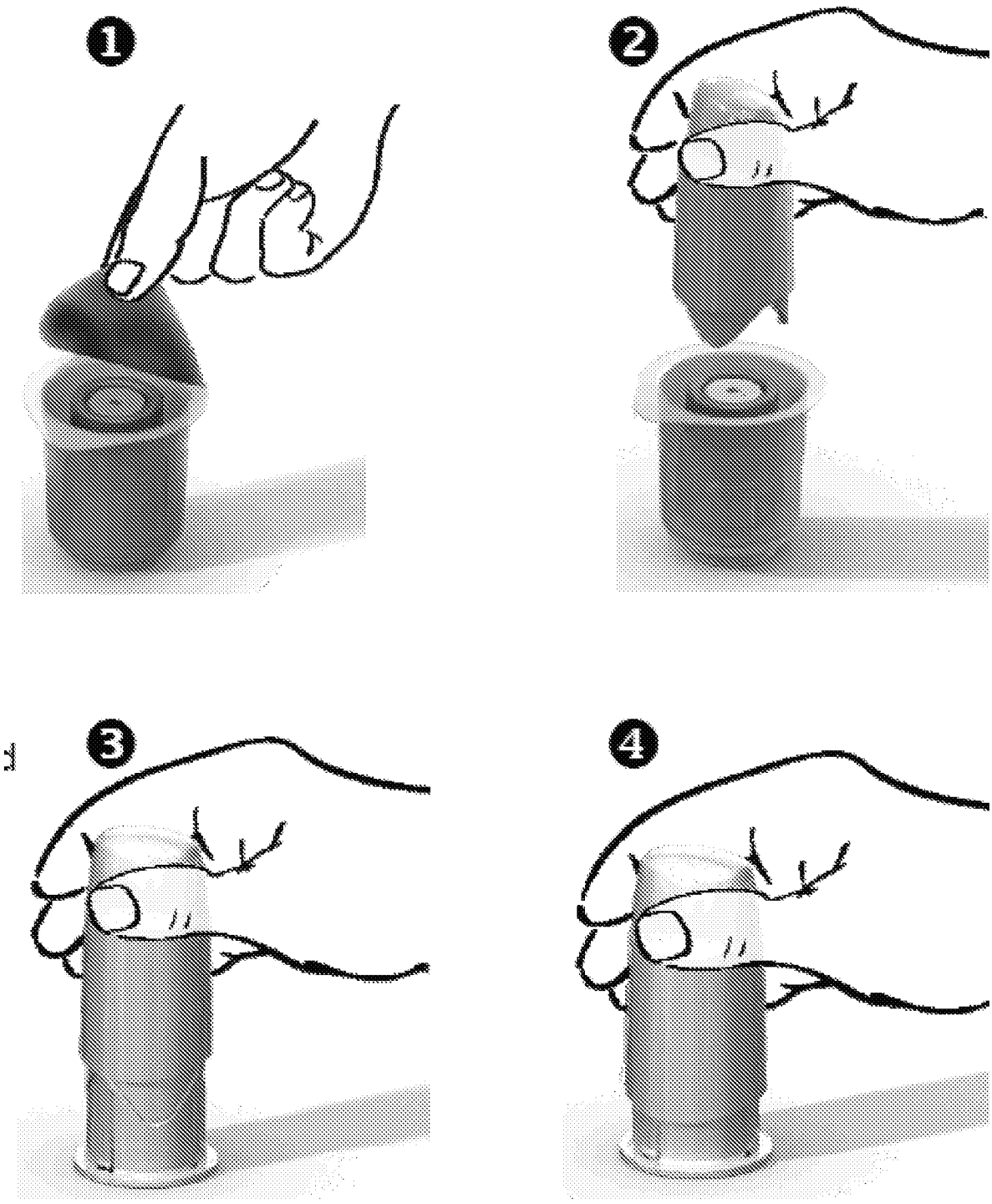

FIG. 72P

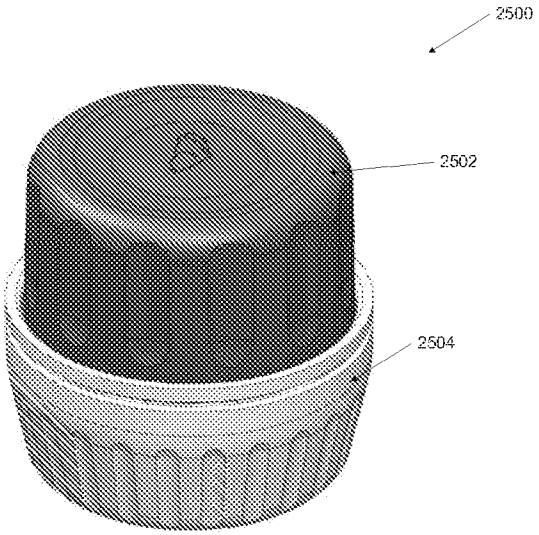

FIG. 73

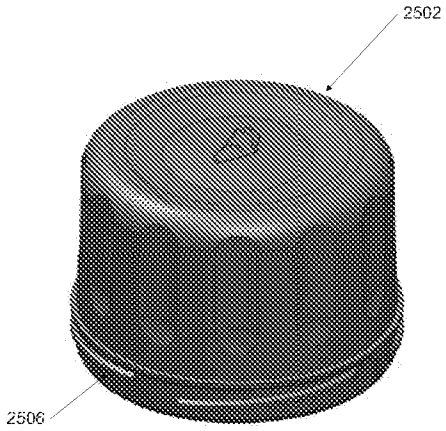

FIG. 73A

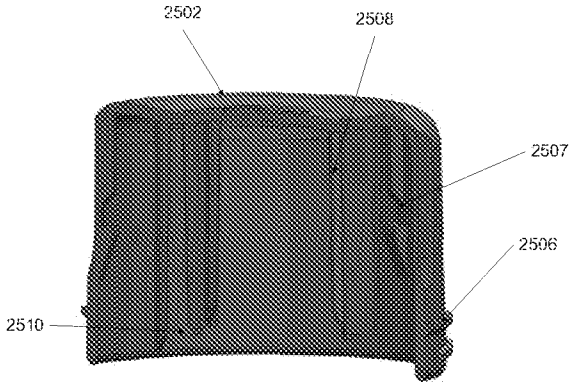

FIG. 73B

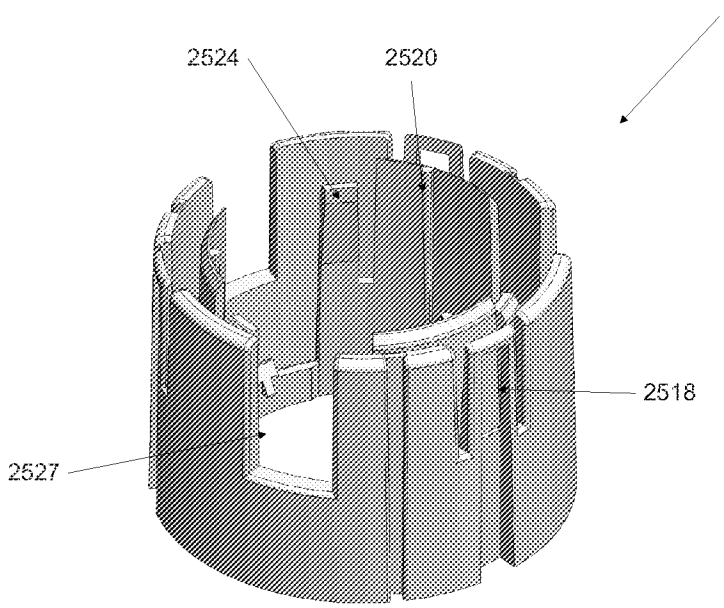

FIG. 73C

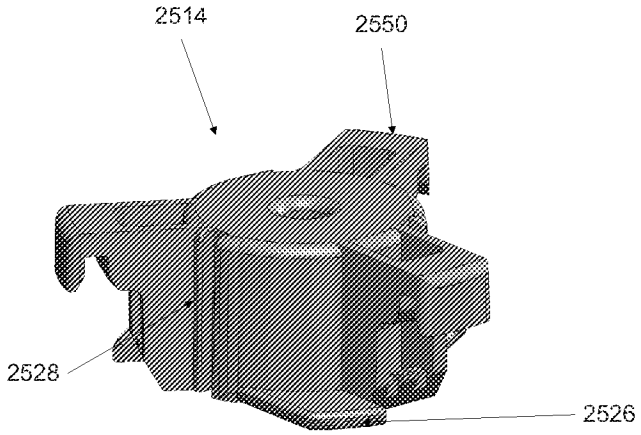

FIG. 73D

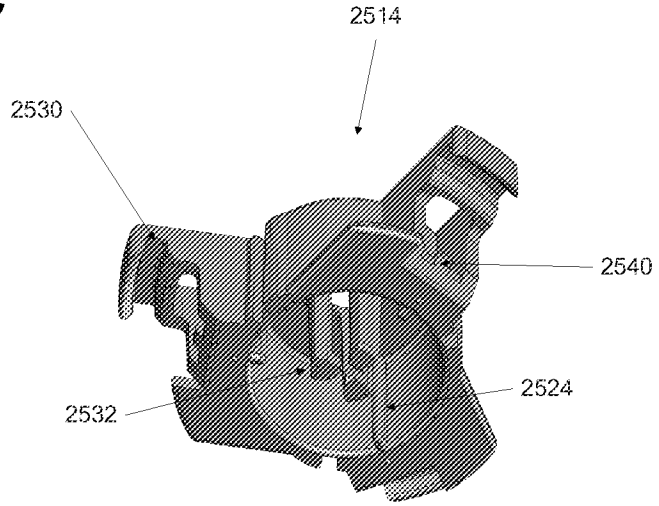

FIG. 73E

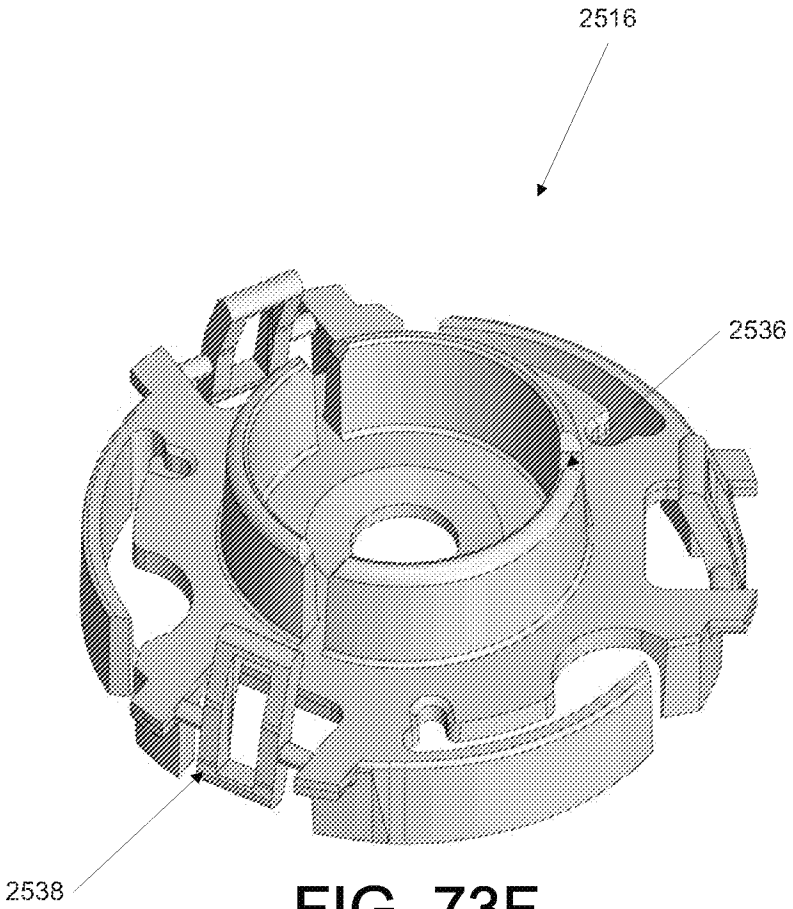

FIG. 73F

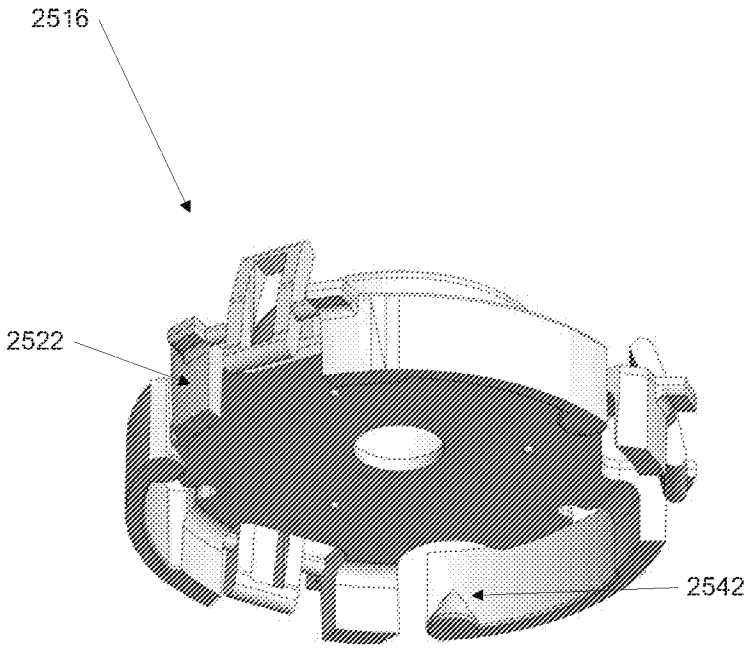

FIG. 73G

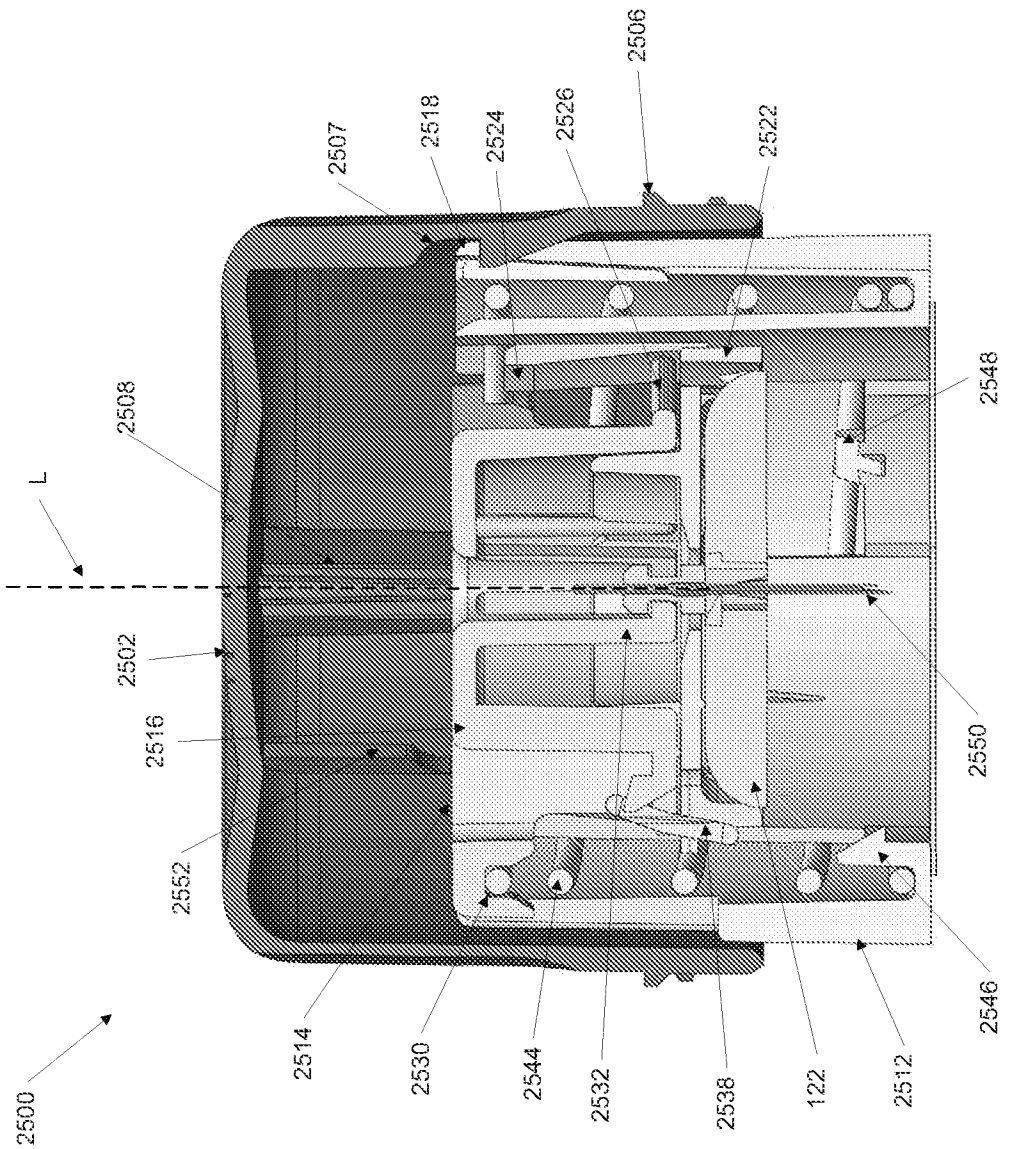
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FIG. 73H

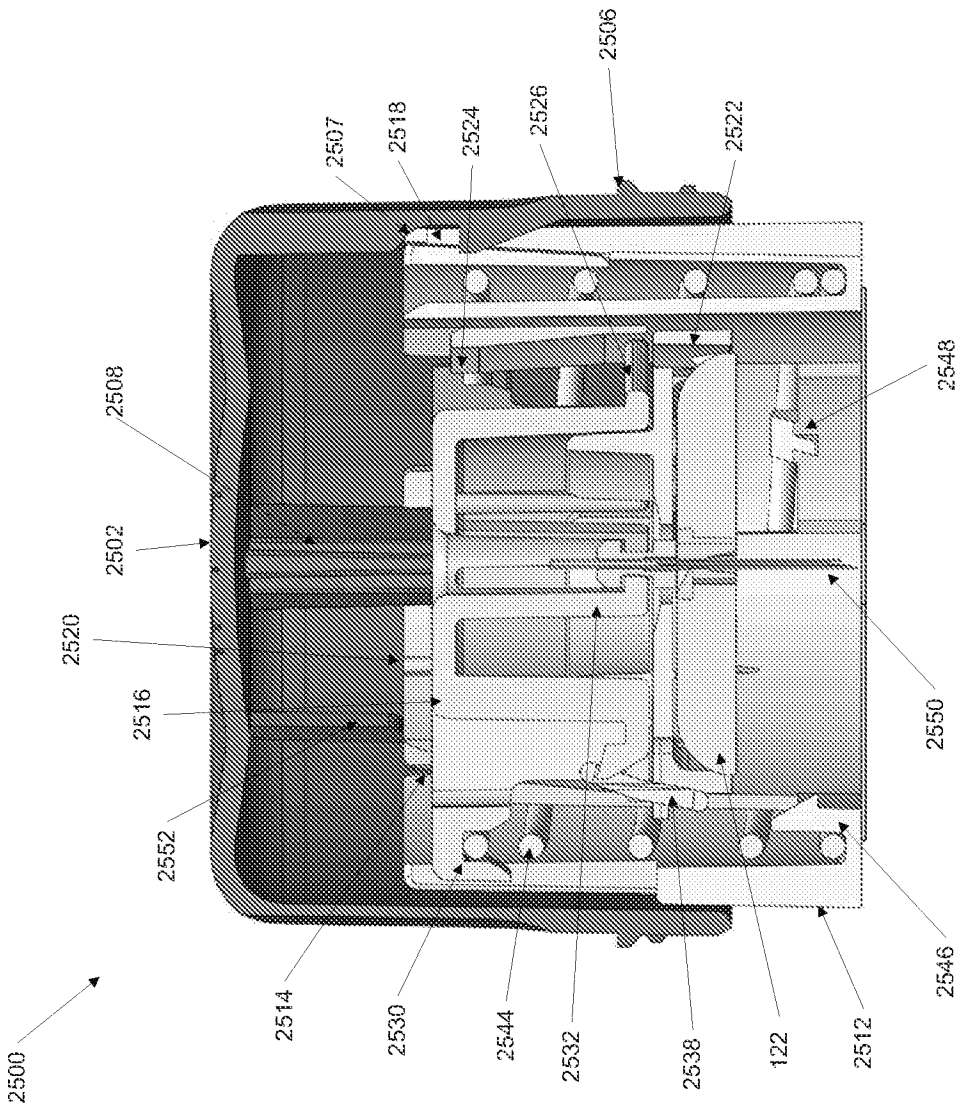
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FIG. 73I

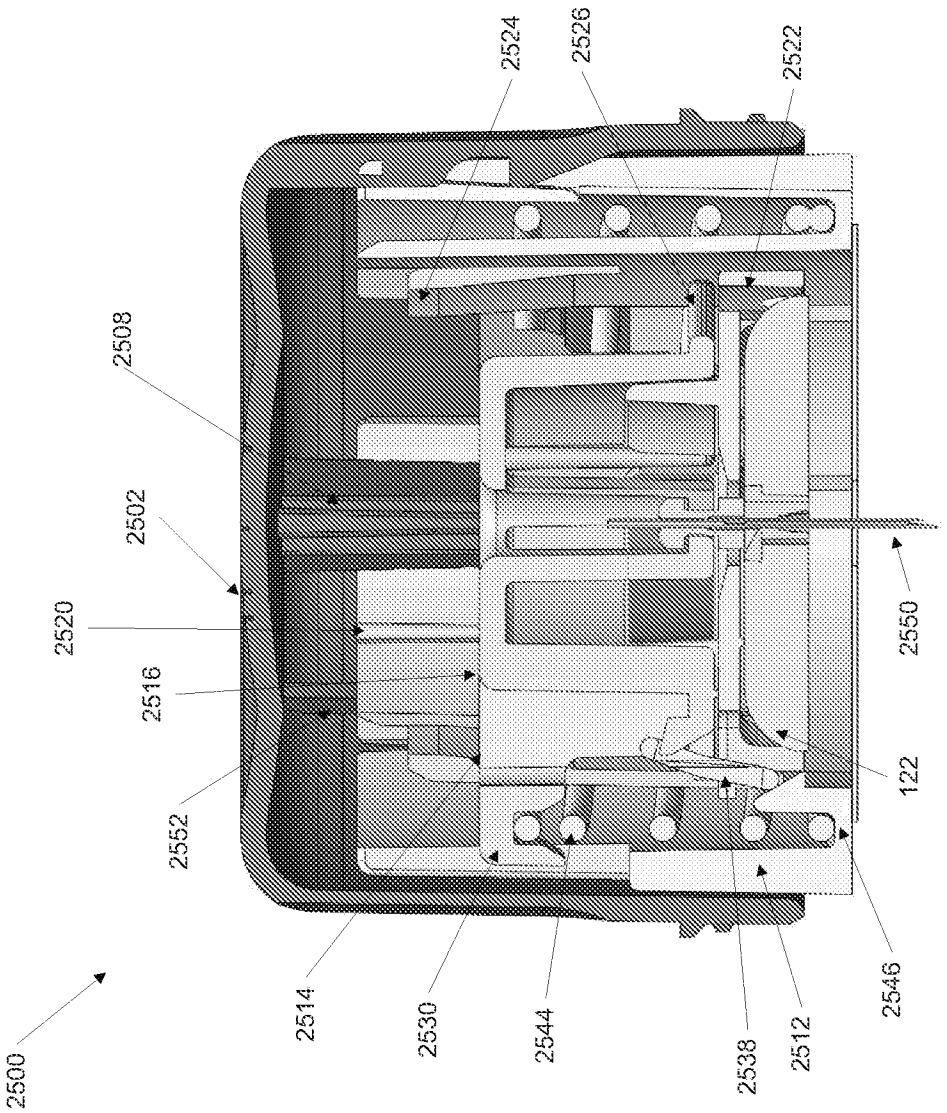
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FIG. 73J

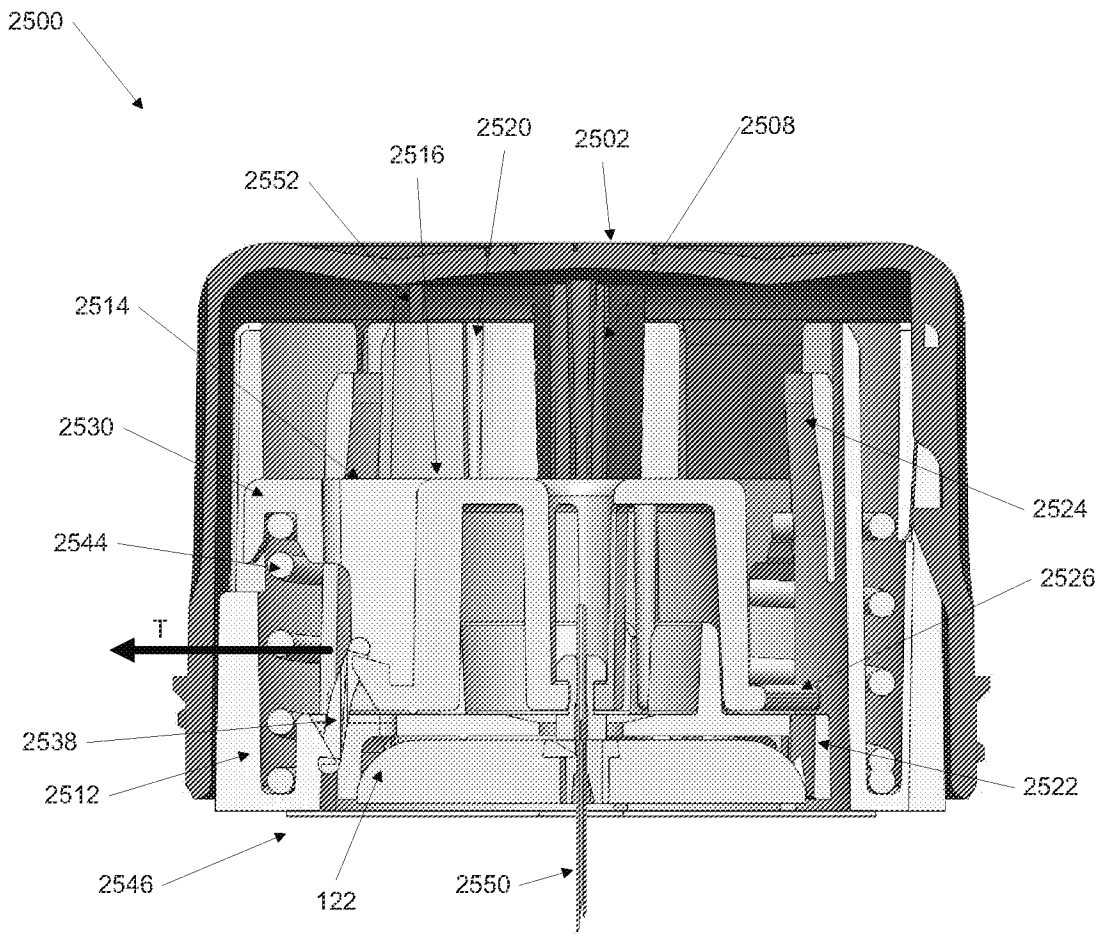
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FIG. 73K

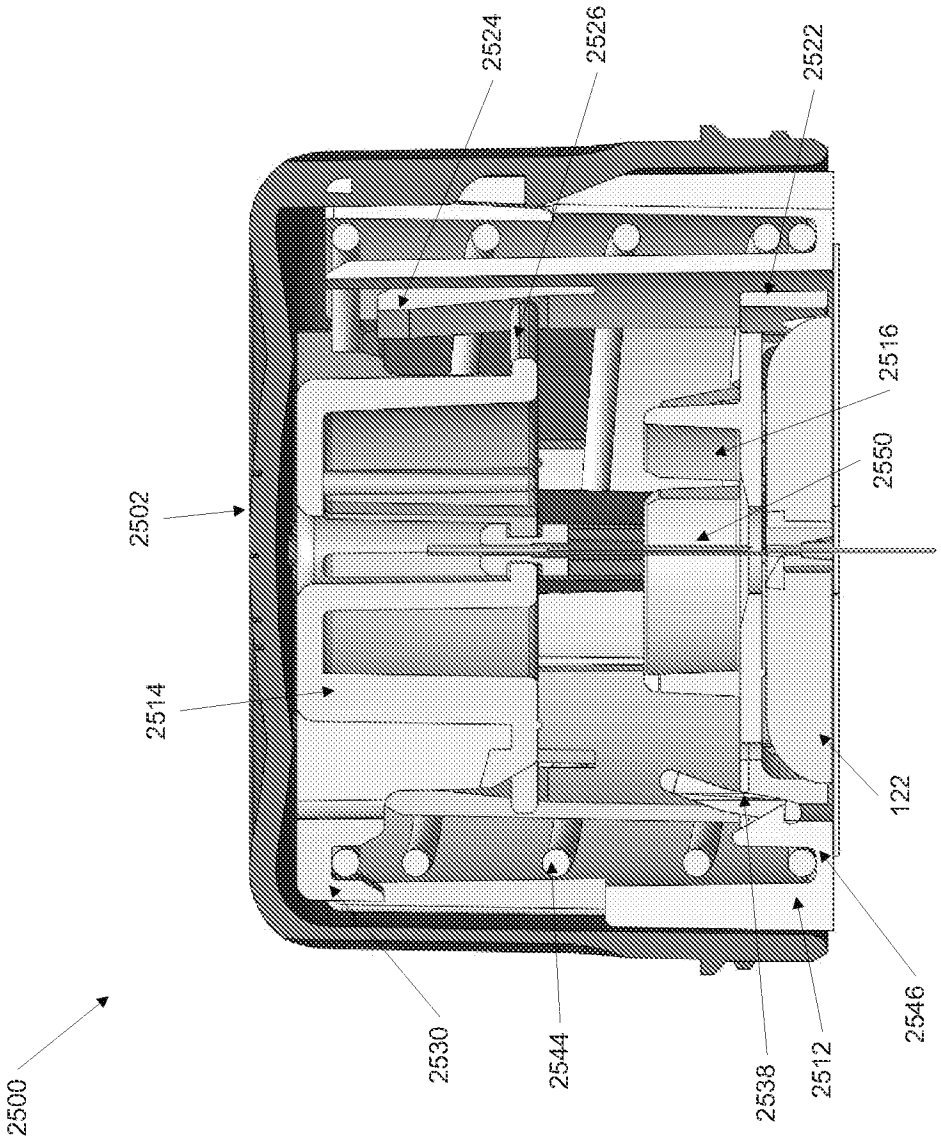
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FIG. 73L