

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01409
U.S. Patent No.: 11,202,591
Issued: December 21, 2021
Application No.: 17/221,154
Filed: April 2, 2021

Title: ANALYTE SENSOR AND
APPARATUS FOR INSERTION OF THE SENSOR

DECLARATION OF GARY D. FLETCHER, Ph.D.

DEXCOM
EXHIBIT 1003

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I, Gary D. Fletcher, Ph.D., do hereby declare as follows:

I. INTRODUCTION AND ENGAGEMENT

1. I have been retained as an independent expert on behalf of Dexcom, Inc. in connection with the above-captioned Petition for Inter Partes Review (“IPR”) to provide my analyses and opinions on certain technical issues related to U.S. Patent No. 11,202,591 (hereinafter “the ’591 patent”).

2. I am being compensated at my usual and customary rate for the time I spent in connection with this IPR. My compensation is not affected by the outcome of this IPR.

3. Specifically, I have been asked to provide my opinions regarding whether claims 1-30 (each a “challenged claim” and collectively the “challenged claims”) of the ’591 patent would have been obvious to a person having ordinary skill in the art (“POSITA”) as of February 2009. It is my opinion that each challenged claim would have been obvious to a POSITA after reviewing the prior art discussed herein.

II. BACKGROUND AND QUALIFICATIONS

4. I am Founder and Principal Consultant at RnDDx Solutions LLC, a consulting firm founded in 2015, focused on industrial mechanical engineering, and research and product development, in medical devices, diagnostics, optical devices, point-of-care blood sample testing, and on expert witness patent litigation, including

subject matter expertise in medical device mechanical engineering, and subject matter expertise in medical devices for blood collection and blood sample processing for diagnostics and therapeutics. I have particular expertise in mechanical engineering design and development of non-invasive and minimally invasive biomedical diagnostics systems, blood collection and stabilization, blood separation, and blood and cell preparation for both diagnostic and therapeutic applications. I have expertise in the development of sample collection devices, including needles and lancets. A complete list of my patents, publications, professional activities, and honors that I have received is set forth in my curriculum vitae, attached hereto as Appendix A.

5. I am also co-Founder of a startup biotech company, Raven Biomaterials, developing novel patented immunomagnetic blood cell separation technology, with both diagnostic and cell therapy manufacturing applications.

6. I received my Bachelor of Arts degree in Physics and Mathematics from DePauw University, Greencastle, Indiana, in 1976, my Master of Philosophy degree in Physics from Yale University in 1978, and my Doctor of Philosophy degree in Physics, also from Yale University, in 1983. My doctoral research was in experimental atomic physics, where I gained experience in mechanical, electrical, and software engineering, optical physics, and vacuum engineering, developing and maintaining the experimental apparatus used in my research. I conducted

postdoctoral research in experimental atomic and laser physics as a Postdoctoral Research Associate in Physics and Assistant Professor of Physics at the University of Virginia. At Lawrence Livermore National Laboratory I expanded my expertise in mechanical and optical engineering by developing x-ray spectroscopic and imaging instruments to measure x-rays emitted from laser-produced high-temperature plasmas. I have 23 years of senior industrial executive experience building new products and new businesses in the healthcare, life sciences, material sciences, medical device, imaging, and diagnostics space. That experience includes leading R&D and product development engineering teams of mechanical, electrical, optical, and software engineers. Among the positions described in my curriculum vitae, my industry experience includes engineering leadership role in 1996 in a company attempting to develop a noninvasive glucose measurement sensor. From 1996 to 2001, I led Engineering and Advanced Technology, including teams of optical, mechanical, electrical, software imaging, and clinical laboratory engineers, developing a noninvasive human complete blood count diagnostic device and diagnostic blood perfusion assessment tool, for a medical diagnostic startup company. As technical manager at Sarnoff Corporation from 2001 – 2004 I led a team developing and licensing a painless minimally invasive blood glucose monitor. While at Becton Dickinson (“BD”), from 2004 to 2014, I developed blood collection devices for point of care diagnostic testing.

7. I am co-inventor on thirteen issued US Patents and ten issued European patents for devices and methods in the area of blood collection and processing including lancing devices and blood separation for diagnostic testing. A complete list of my patents is set forth in my curriculum vitae, attached hereto as Appendix A.

III. MATERIALS CONSIDERED AND INFORMATION RELIED UPON REGARDING '591 PATENT

8. In preparing this declaration, I have reviewed the following materials bearing Exhibit Nos. that I understand are being referenced in the IPR to which my declaration accompanies:

LIST OF EXHIBITS

No.	Description
1001	U.S. Patent No. 11,202,591 (“ '591 patent ”)
1002	File History of U.S. Patent No. 11,202,591
1003	<i>intentionally left blank</i>
1004	U.S. Publication No. 2008/0097246 (“ Stafford ”)
1005	U.S. Publication No. 2005/0101932 (“ Cote ”)
1006	U.S. Publication No. 2007/0073129 (“ Shah ”)
1007	U.S. Publication No. 2007/0135774 (“ Turner ”)
1008	U.S. Patent No. 6,175,752 (“ Say ”)
1009	U.S. Publication No. 2009/0124979 (“ Raymond ”)
1010	U.S. Publication No. 2006/0095014 (“ Ethelfeld ”)
1011	PCT Publication No. WO2008/155377 (“ Hasted ”)

No.	Description
1012	U.S. Publication No. 2009/0076360 (“ Brister-360 ”)
1013	U.S. Publication No. 2006/0155180 (“ Brister-180 ”)
1014	U.S. Publication No. 2004/0133164 (“ Funderburk 164 ”)
1015	U.S. Patent No. 6,560,471 (“ Heller ”)
1016	U.S. Patent No. 6,579,690 (“ Bonnecaze ”)
1017	U.S. Publication No. 2003/0225373 (“ Bobroff-373 ”)
1018	U.S. Publication No. 2009/0240121 (“ Bickoff ”)
1019	PCT Publication No. WO2008/114223 (“ Pesach ”)
1020	U.S. Publication No. 2004/0002682 (“ Kovelman ”)
1021	U.S. Patent No. 7,381,184 (“ Funderburk ”)
1022	<i>intentionally left blank</i>
1023	<i>intentionally left blank</i>
1024	<i>intentionally left blank</i>
1025	U.S. Publication No. 2008/0319414 (“ Yodfat-414 ”)
1026	U.S. Patent No. 7,207,974 (“ Safabash ”)
1027	U.S. Publication No. 2004/0204687 (“ Mogensen-687 ”)
1028	U.S. Publication No. 2002/0022855 (“ Bobroff-855 ”)
1029	U.S. Patent No. 9,566,384 (“ Gyrn ”)
1030	U.S. Patent No. 8,747,363 (“ Nielsen ”)
1031	U.S. Publication No. 2007/0093754 (“ Mogensen-754 ”)
1032	<i>intentionally left blank</i>

No.	Description
1033	<i>intentionally left blank</i>
1034	Steven W. Smith, <i>The Scientist and Engineer's Guide to Digital Signal Processing</i> (2nd ed. 1999)
1035	B.A. Shenoi, <i>Introduction to Digital Signal Processing and Filter Design</i> (2006)
1036	U.S. Publication No. 2009/0099521 (“ Gravesen ”)
1037	U.S. Publication No. 2009/0216215 (“ Thalmann ”)
1038	U.S. Publication No. 2008/0255440 (“ Eilersen ”)
1039	<i>intentionally left blank</i>
1040	PCT Publication No. WO2008/115409 (“ Brenneman ”)
1041	Statement of Defense (Counterclaim), <i>Dexcom Inc. v. Abbott Diabetes Care Inc.</i> , Case No. 21 O 6562/23 (Munich D. Ct. I), Sept. 1, 2023.
1042	U.S. Publication No. 2008/0114280 (“ Stafford-280 ”)

IV. UNDERSTANDING OF PATENT LAW

9. I am not an attorney. For the purposes of this declaration, I have been informed about certain aspects of the law that are relevant to my opinions. My understanding of the law was provided to me by the Petitioner’s attorneys.

10. I understand that when considering the scope of the claims of a patent that the patent claim terms should generally be given the ordinary meaning that the terms would have to a person of ordinary skill in the art in question after reading the patent as of the earliest claimed priority date.

11. I understand that the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the term appears, but in the context of the entire patent, including the specification. I further understand that the principal considerations regarding the scope and meaning of the claims are the plain language of the claim (including the surrounding claim language and context), the patent specification, and the prosecution history. I understand that while a claim is to be read in light of the specification, one must generally avoid importing limitations into the claim from the specification. I am also informed that the prosecution history can often inform the meaning of the claim by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be. I applied these understandings when considering the scope and meaning of the claims of the '591 patent.

12. I understand that a claim is unpatentable if it would have been obvious. I understand that a patent claim is rendered obvious if the claimed subject matter as a whole would have been obvious to a person of ordinary skill in the art as of the date of invention. I understand that this determination is made after weighing the following factors: (1) the scope and content of the prior art; (2) the differences between the prior art as a whole and the claim at issue; (3) the level of ordinary skill

in the pertinent art; and (4) as appropriate, secondary considerations of non-obviousness.

13. I understand that the knowledge of a person of ordinary skill in the art at the time of the alleged invention provides a reference point from which the prior art and claimed invention should be viewed. This reference point safeguards against use of improper hindsight in evaluating whether a claim is obvious. However, if a person of ordinary skill in the art could have implemented the claimed invention as a predictable variation of a known product, then the claim may be rendered obvious. I further understand that a person of ordinary skill in the art is presumed to have knowledge of relevant prior art at the time of the claimed invention, which includes any prior art that was reasonably pertinent to the particular problems the inventor faced.

14. I understand that an obviousness evaluation can be made on a single reference or a combination of multiple prior art references. I understand that a proper obviousness analysis as to two or more references generally requires a reason that would have prompted a person of ordinary skill in the art to combine the elements of multiple prior art references in the way the claimed invention does. I understand that the prior art references themselves may provide a teaching, suggestion, motivation, or reason to combine, but that at other times such combinations can be based on simple common sense. I further understand that an obviousness analysis

recognizes that market demand, rather than scientific literature, often drives innovation, and that a motivation to combine references may be supplied by the direction of the marketplace. I understand that prior art references used in obviousness analyses should be analogous to the claimed invention, which I understand to mean (1) the reference is from the same field of endeavor as the claimed invention (even if it addresses a different problem); or (2) the reference is reasonably pertinent to the problem faced by the inventor (even if it is not in the same field of endeavor as the claimed invention).

15. I understand that a particular combination may be proven obvious merely by showing that it was obvious to try the combination. For example, when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within that person's technical grasp because the result is likely the product not of innovation but of ordinary skill and common sense.

16. I further understand that a proper obviousness analysis focuses on what was known or obvious to a person of ordinary skill in the art, and not just to the patentee. Accordingly, I understand that any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.

17. In sum, my understanding is that prior art teachings are properly combined where a person of ordinary skill in the art, having the knowledge reflected in the prior art and motivated by the general problem addressed by the patent in question, would have been led to make the combination of elements recited in the claims. Under this analysis, the prior art references themselves, or any need or problem known in the field of endeavor at the time of the invention, can provide a reason for combining the elements of multiple prior art references in the claimed manner. I understand that at least the following rationales may support a finding of obviousness:

- a) Combining prior art elements according to known methods to yield predictable results;
- b) Simple substitution of one known element for another to obtain predictable results;
- c) Use of a known technique to improve similar devices (methods, or products) in the same way;
- d) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- e) Choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success (“obvious to try”);

- f) Predictable variation of work in the same or a different field of endeavor if a person of ordinary skill would be able to implement the variation;
- g) Existence of a known problem for which there was an obvious solution encompassed by the patent's claims;
- h) Known work in one field of endeavor that may prompt variations of it for use in either the same or a different field based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; and
- i) Any teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

18. I further understand that an obviousness analysis includes considering whether a POSITA would have a “reasonable expectation of success”—not an “absolute predictability” of success—in achieving the claimed invention by combining prior art references.

19. I have been informed and understand that secondary considerations of nonobviousness may include: (1) whether the invention proceeded in a direction contrary to accepted wisdom in the field; (2) whether there was a long felt but unresolved need in the art that was satisfied by the invention; (3) whether others had tried but failed to make the invention; (4) whether others copied the invention; (5)

whether the invention achieved unexpected results; (6) whether the invention was praised by others; (7) whether others have taken licenses to use the invention; (8) whether experts or those skilled in the art at the making of the invention expressed surprise or disbelief regarding the invention; (9) whether products incorporating the invention have achieved commercial success that is attributable to the invention and (10) whether or not others having ordinary skill in the field independently made the claimed invention at about the same time the inventor made the invention. I understand that for evidence of secondary considerations to be accorded substantial weight, there must be an established nexus between the evidence and the merits of the claimed invention.

20. I am not aware of any allegations by the named inventors of the '591 patent or any assignee of the '591 patent that any secondary considerations tend to rebut the obviousness of any challenged claim of the '591 patent.

21. I understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the descriptions found in the patent being considered.

22. I understand that other challenges to the patentability of a patent, including patent ineligibility, enablement, written description, and definiteness or clarity of claim language, cannot be raised in IPR proceedings before the Board.

23. I understand that Petitioner has the burden of proving unpatentability by a preponderance of evidence, which means that the claims are more likely than not unpatentable.

24. The analysis in this declaration is in accordance with the above-stated legal principles.

V. THE '591 PATENT

25. The '591 patent, titled “Analyte Sensor And Apparatus For Insertion Of The Sensor” issued December 21, 2021, from an application filed April 2, 2021, and claims priority through a series of continuing applications to a provisional application filed February 3, 2009.

A. The '591 Patent's Specification

26. The '591 patent describes an inserter that inserts part of an on-body medical device (*e.g.*, a cannula or an analyte sensor) into a subject using an automatically retractable sharp. *E.g.*, EX1001, 2:13-36, 14:57-59 (“inserter can be configured to insert various medical devices to the subject, such as for example, an analyte sensor, an infusion set, a cannula, or a lancet.”), 16:20-28 (“inserter may include features or components which automatically retract the sharp”), FIGS. 8, 10, 28-31. The '591 patent describes an on-body unit that includes a data processing unit and an analyte sensor “constructed to be maintained ‘on the body’ of the subject for a period of time.” *Id.*, 9:31-41, FIGS. 1-9.

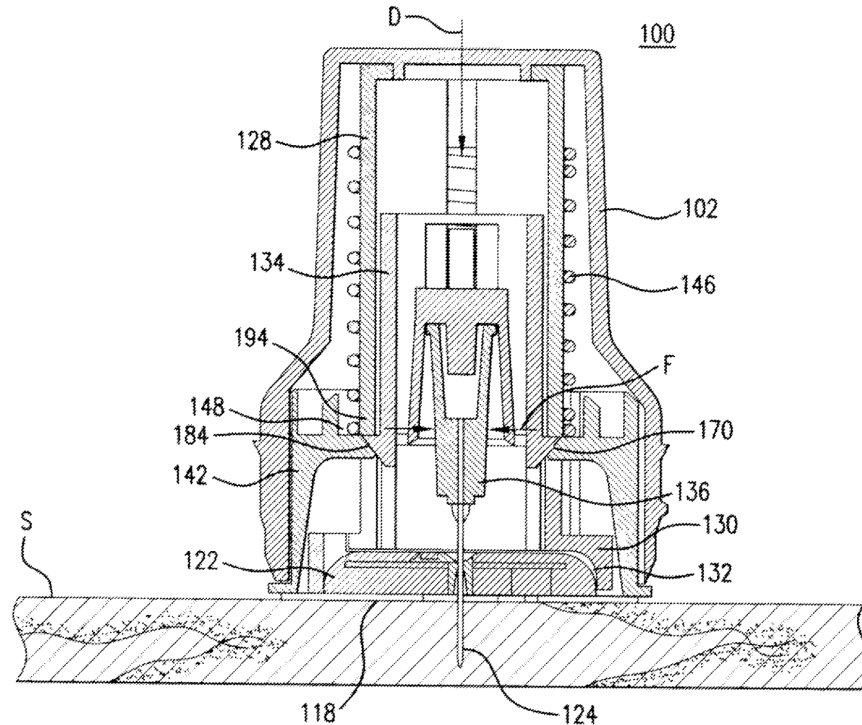


FIG.30

'591 patent, FIG. 30

B. The Prosecution History

27. The application was filed April 2, 2021, along with a preliminary amendment canceling the original claims and adding new claims 21-50. EX1002, 12-19, 124-25. Another preliminary amendment filed August 30, 2021, amended certain dependent claims. *Id.*, 174-184. Following an Examiner-initiated interview on November 2, 2021, the Examiner entered minor amendments and applicant filed terminal disclaimers as to then-co-pending Application No. 17/221,169 and U.S. Patent Nos. 11,006,870 and 11,006,871. *Id.*, 963, 876-885, 976 (indicating Examiner

amendments to claim 21, which issued as claim 1). The Examiner issued a Notice of Allowance on November 12, 2021. *Id.*, 971-978.

VI. LEVEL OF SKILL IN THE ART, AND STATE OF THE ART

A. Person Of Ordinary Skill In The Art

28. A POSITA would have had a bachelor's degree in bioengineering, mechanical engineering, electrical engineering, or a related subject, and one or more years of experience researching, developing, and/or designing insertable medical devices, including, e.g., systems for implanting wearable medical devices such as cannulas, infusion sets, and analyte sensors, or equivalent experience. Less work experience may be compensated by a higher level of education, such as a master's degree, and vice versa.

B. State Of The Art

1. Inserters With Auto-Retracting Needles Were Known

29. Inserters that use automatically retractable sharps to insert part of an on-body unit (e.g., a cannula or glucose sensor) into a subject were well-known before 2009. For example, Cote describes a device comprising an automatically retractable needle for inserting a portion of a cannula into a subject. See, e.g., EX1005, [0207], [0211]. Likewise, Raymond (EX1009) describes an insertion device including a needle with an "automatic retraction feature." See, e.g., EX1009, [0127]; see also EX1014, [0108], [0110].

2. Inserters Were Known To Reduce Subject Pain and Anxiety

30. It was known that manual use of a needle to insert a device through the skin causes a patient pain and anxiety. *See, e.g.*, EX1036, [0004]-[0005] (“When performed manually, the penetration of the catheter-carrying needle into the body, however, may be considered uncomfortable for a patient, or may cause some other anxiety.”); EX1037, [0005] (“[T]he introduction of the infusion cannula or of the puncturing tip into the skin, is associated with a certain amount of pain.”).

31. It was also known that more automatic inserters reduced the amount of pain and anxiety felt by subjects, *e.g.*, by providing for faster needle puncturing and/or retraction. *See, e.g.*, EX1036, [0007] (“[O]ne advantage of the invention is to increase the comfort of a patient during the insertion [by using an inserter in which] the needle, after reaching its extended state, can be withdrawn quickly and automatically by a retraction apparatus.”); EX1037, [0005] (“It is therefore important that such infusion sets, ports or sensor arrangements can be applied easily and safely, which is why many manufacturers have started designing their products as insertion heads for special insertion devices with the aid of which the insertion heads can be applied to the patient's body. Application is made easier in this way, and the pain occasioned by the application is reduced to a minimum, thanks to the quick and targeted puncturing procedure.”).

32. Indeed, by 2007, other patents had recognized that “many manufacturers” had designed inserters to reduce the amount of pain felt by subjects during transcutaneous medical device insertion procedures. EX1037, [0005]; EX1036, [0007].

3. Inserter Designs Were Interchangeably Used For Insertion Of Different Types Of Subcutaneous Devices

33. It was well-known in the art that various inserter designs were interchangeably used for inserting both an analyte (e.g., glucose) sensor or a cannula or other transcutaneous device. *See, e.g.*, EX1010 (Ethelfeld), [0015] – [0016], [0020]–[0023] (teaching an inserter for either a cannula or a glucose sensor) and EX1011 (Hasted), 4:20-5:2 (teaching an inserter used to deliver either an infusion device or a sensor device: “a sensor device provided with a subcutaneously placed sensor which is in contact with the patient’s blood and able to register desired elements in the blood e.g. the sugar level.”).

34. Numerous other background references confirm this interchangeability. *See, e.g.*, EX1025, US2008/0319414 (“Yodfat-414”), [0070]; EX1026, US 7,207,974 (“Safabash”), 1:33-40; EX1027, US 2004/0204687 (“Mogensen-687”), [0079]; EX1028 US 2002/0022855 (“Bobroff-855”), [0019]; EX1029, US 9,566,384 (“Gyrn”), 2:23-26; EX1030, US 8,747,363 (“Nielsen”), 13:12-16. Indeed, the ’591 patent states that its “inserter can be configured to insert various medical devices to the subject, such as for example, an analyte sensor, an infusion set, a

cannula, or a lancet” (EX1001, 14:54-59), yet provides no meaningful guidance on how to configure or adapt the inserter for the various types of devices. *See also id.*, 1:21-31 (“an inserter device, for example, to insert an analyte sensor and/or an infusion set”), 2:13-20. This reflects the known interchangeability of inserter devices between infusion sets and analyte sensors and similar devices.

4. Low-Profile On-Body Devices Were Known

35. The desirability of “low profile,” “unobtrusive” on-body units was well known. *E.g.*, EX1005, [0228]; *see also* EX1004, [0045] (describing benefits of “smaller profile” on-body unit). Specifically, on-body-units were known to have a height profile of 10 mm or below. *See e.g.*, EX1012, [0334] (“the overall height of the sensor system, including the housing and electronics, is no more than about 0.350 [8.89 mm], 0.300 [7.62 mm], 0.250 [6.35 mm], 0.200 [5.08 mm], 0.150 [3.81 mm], 0.100 [2.54 mm], or most preferably 0.075 inches [1.905 mm] in its smallest dimension.”); EX1013, [0425] (“the mounting unit 316/electronics unit 314 subassembly has ... a thickness of less than about 10 mm.”); EX1014, [0074] (“the on-skin sensor control unit 44 has a height of ... preferably 0.7 cm or less”); EX1015, 29:63-64 (same); EX1016, 30:33-34 (same).

5. It Was Known To Protect Needles And Avoid Needle Sticks

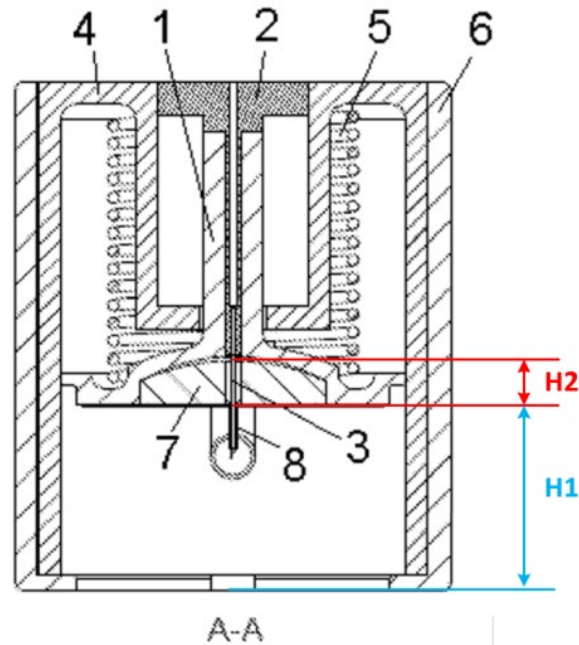
36. Designing inserters to conceal the needle and prevent needle sticks was also well-known. *See, e.g.*, EX1009, [0127] (“needle 1112 can be protected both before and after insertion ... to prevent accidental needle sticks”).

37. It was known to implement a needle/sharp extending past the distal tip of a transcutaneous device to protect the transcutaneous device (*see e.g.*, EX1004, FIG. 2; EX1005, FIG. 6A) and to shroud the needle within the inserter prior to and after insertion to minimize anxiety and avoid inadvertent needle-sticks. EX1005, [0005], [0235].

38. It was well-known that, to insert a transcutaneous device using an inserter, the needle and the on-body unit must travel a distance (“distance of travel”) that is at least equal to an implantable length of the transcutaneous device in order for the transcutaneous device to be fully inserted into the skin. *See, e.g.*, EX1017, [0027] (“the distance traveled ... is equal to at least a distance required to fully insert the insertion set in the patient’s skin that is at least equal to an implantable length of the piercing member.”).

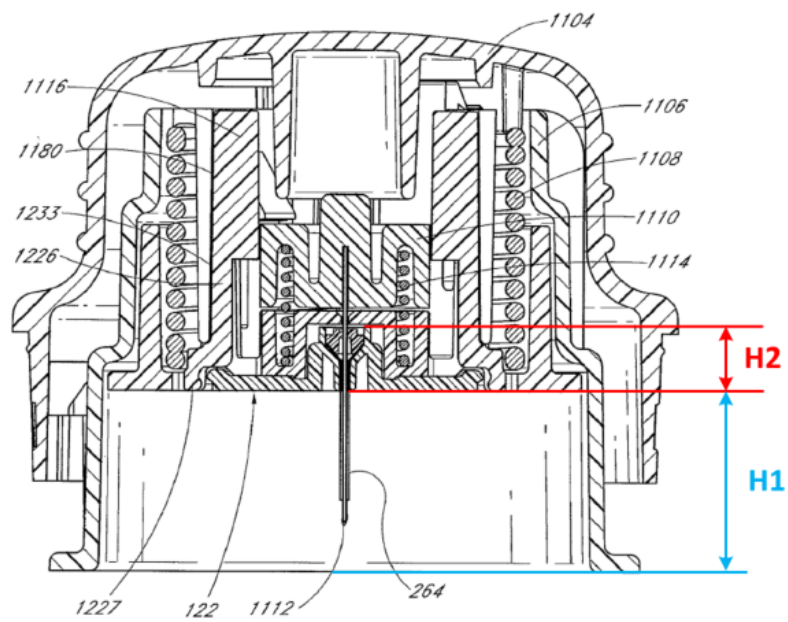
39. Relatedly, it was routine for this distance of travel (“H1”) to be greater than a height of the housing of the on-body unit (“H2”), again to prevent the transcutaneous device and/or needle from being exposed at the distal end of the inserter for the reasons mentioned above. As shown below, Hasted (EX1011),

Raymond (EX1009), Kovelman (EX1020), and Cote (EX1005) disclose on-body medical devices (*e.g.*, glucose sensors, infusion sets, etc.) with travel distances greater than the heights of their housings.

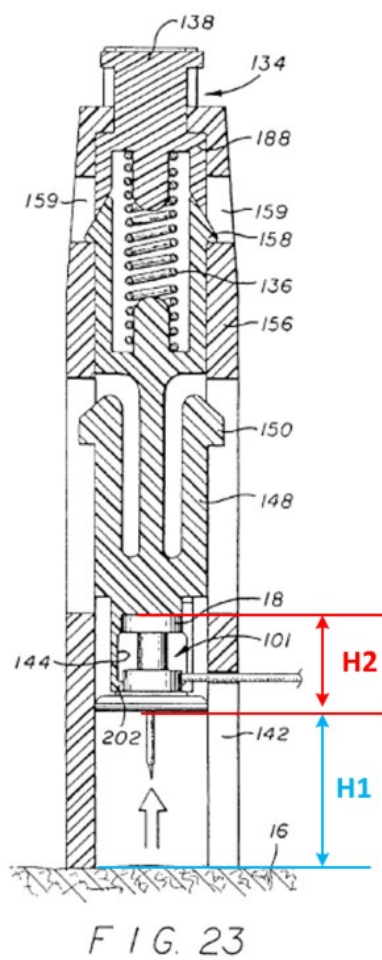


Hasted, FIG. 1 (partial, annotated)¹

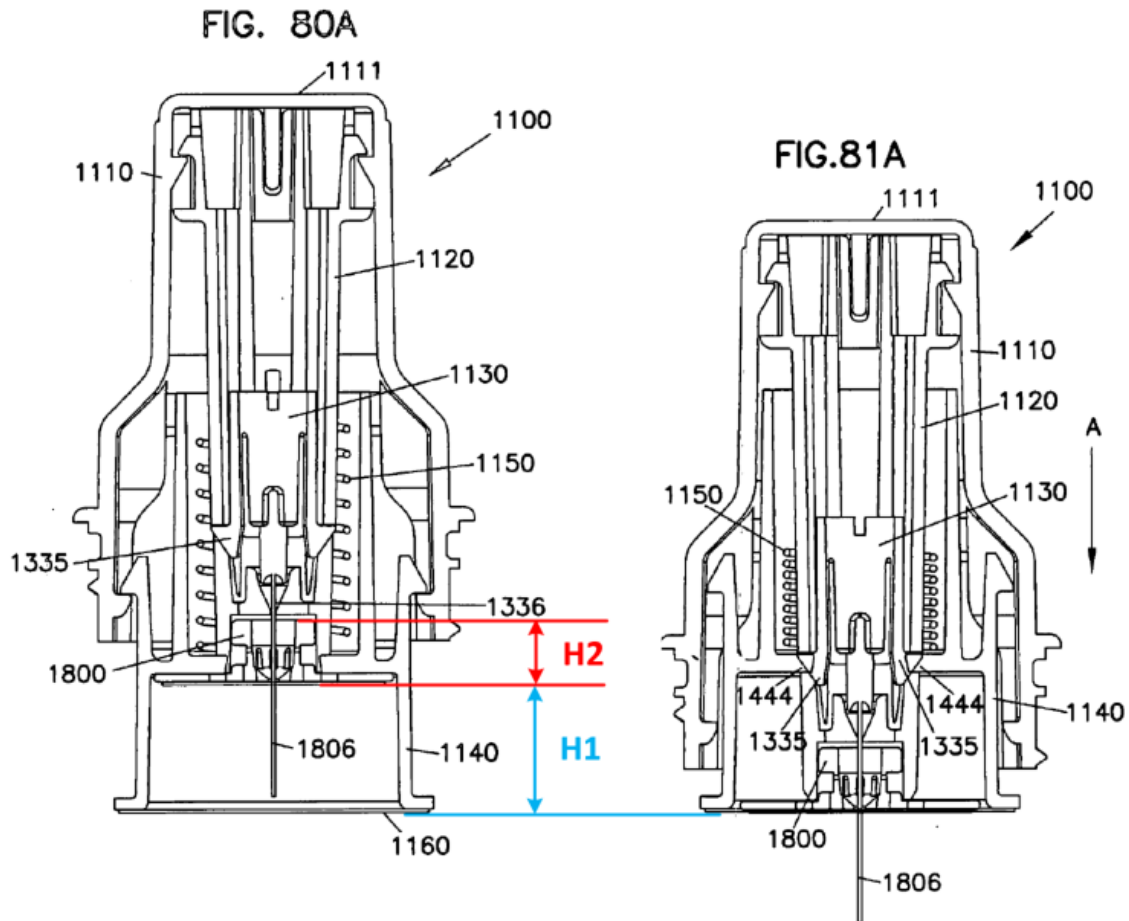
¹ Unless otherwise noted, all color annotations to the FIGS. throughout this petition are added.



Raymond, FIG. 29 (annotated)



Kovelman, FIG. 23 (annotated)

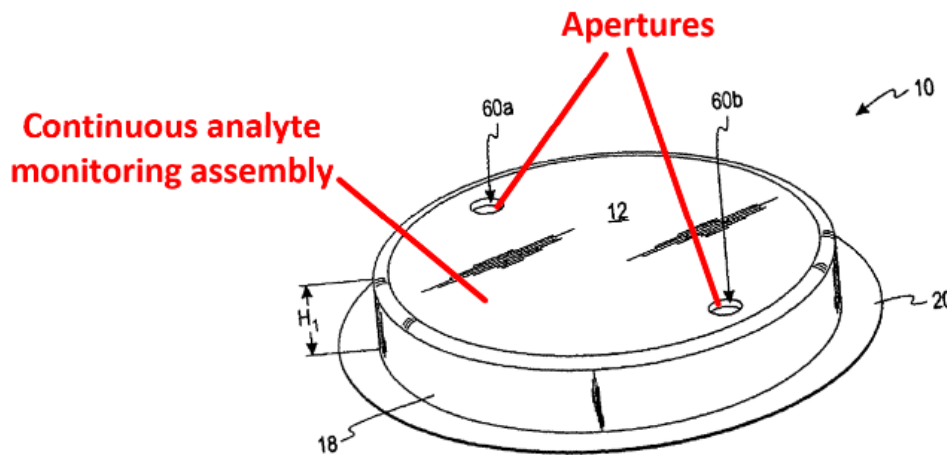


Cote, FIGS. 80A, 81A (annotated)

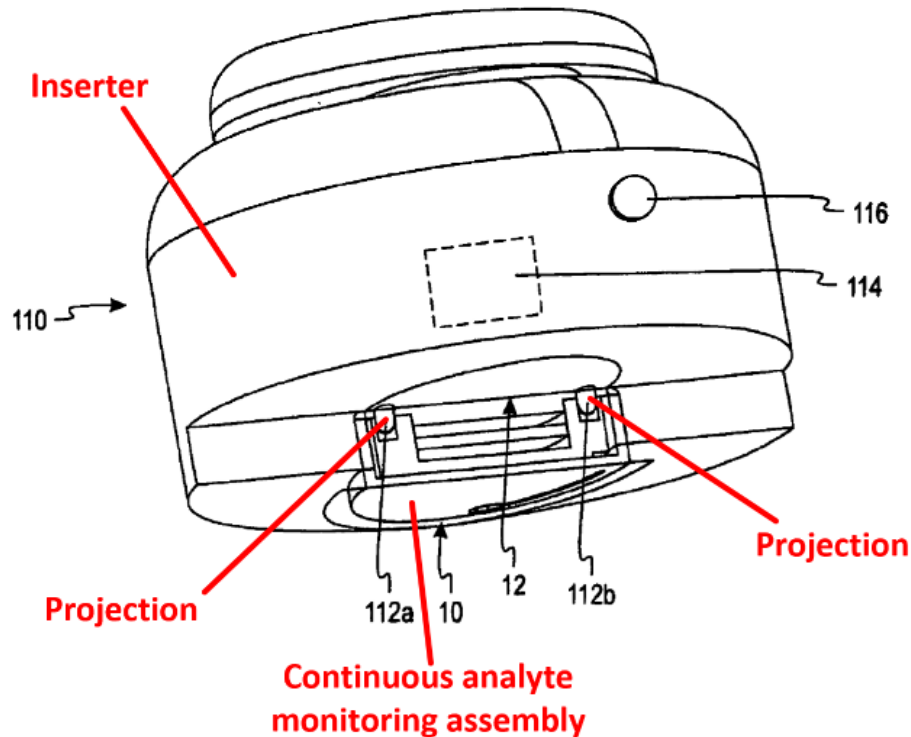
40. Accordingly, it was understood that the distance of travel should be greater than the implantable length of the transcutaneous device such that the needle is not exposed at the distal end of the inserter prior to use thereby avoiding unwanted needle sticks prior to insertion. A POSITA would have understood that the optimal insertion depth for a transcutaneous glucose sensor was typically greater than the desired small height of “low-profile” on-body units.

**6. It Was Known To Couple The On-Body Unit
To The Inserter By Using Peripheral Apertures On
The Unit That Engaged With Projections On The Inserter**

41. Using peripheral apertures on an on-body unit configured to engage corresponding features of an inserter to secure the on-body unit (and a transcutaneous medical device coupled thereto) to the inserter were known. For example, as shown below, Brenneman (EX1040) discloses peripheral apertures 60 which engage projections 112 of inserter 110 to couple the continuous analyte monitoring assembly 10 (“on-body unit”) to the inserter. EX1040, ¶ 0042, FIGS. 1, 8; *see also* EX1007, [0069] (peripheral recesses 77 engage protrusions 71).



Brenneman, FIG. 1 (annotated)



Brenneman, FIG8 (annotated)

VII. CLAIM CONSTRUCTION

42. I understand that for inter partes review, claim terms should be given the ordinary meaning that the terms would have to a person of ordinary skill in the art (“POSITA”) on the earliest effective filing date, in view of the specification and file history.

43. Unless otherwise noted, I am applying the plain and ordinary meaning to a POSITA of all claim terms below.

**VIII. GROUND 1: CLAIMS 1-6, 9-14, 16-24, 27, 29-30
ARE UNPATENTABLE OVER STAFFORD IN VIEW OF COTE**

44. A POSITA would have been motivated, with a reasonable expectation of success, to combine the teachings of Stafford and Cote in implementing an inserter device like that taught by Cote to insert and position an analyte sensor and associated on-body unit like that taught by Stafford. Stafford expressly describes the desire to avoid unwanted needle sticks (*e.g.*, EX1004, [0003], [0022]) and to provide “simple and accurate sensor deployment to the desired subcutaneous position” on a patient (*e.g.*, *id.*, [0007]). A POSITA implementing Stafford would seek out other complementary teachings that further these goals and readily appreciate the benefits of Cote, which teaches an insertion device that further reduces the risk of accidental needle-sticks and provides quick, accurate insertion and positioning of the sensor and associated on-body unit while minimizing pain and anxiety of the patient. EX1005, [0005], [0235]-[0236].

A. Stafford

45. U.S. Publication No. 2008/0097246 (“Stafford,” EX1004) published April 24, 2008, from an application filed September 10, 2006.

46. Stafford describes an assembly comprising an analyte sensor and a data processing unit coupled thereto for processing analyte level measurements. *See, e.g.*, EX1004, [0036]. As shown below, the data processing unit comprises a data

processing unit housing mounted on the skin and an analyte sensor underneath the skin. *See, e.g., id.*, FIG. 4A, [0027].

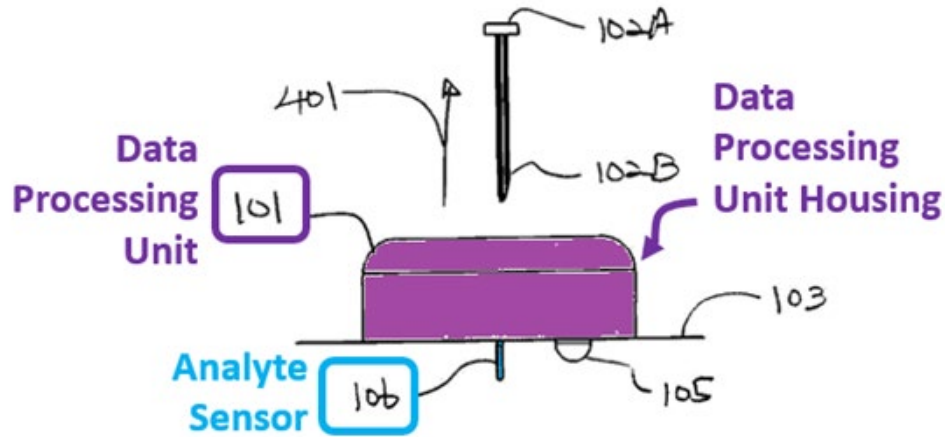
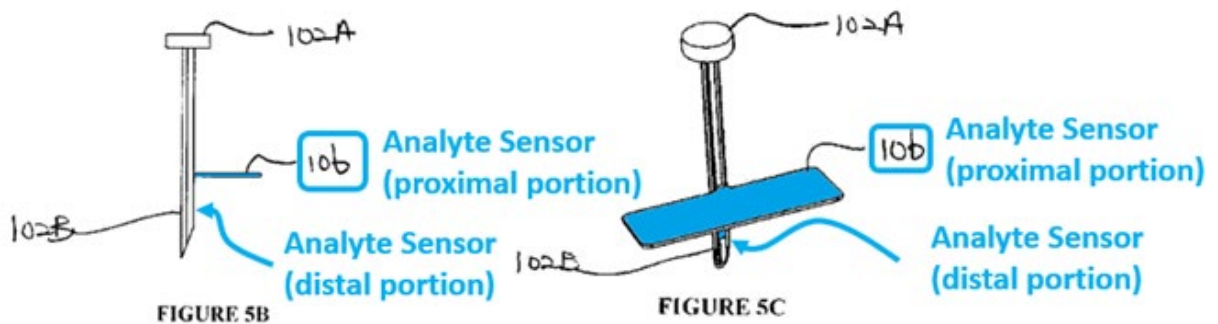
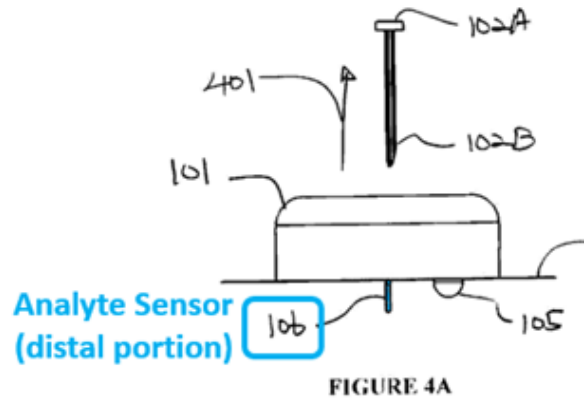


FIGURE 4A

Stafford, FIG. 4A (annotated)

47. Stafford's sensor (shown in blue, below) may be a glucose sensor. *Id.*, [0051], [0029]-[0030] (explaining that glucose is one of the analytes that may be monitored using its system). Stafford's sensor comprises a distal portion perpendicular to the subject's skin surface and a proximal portion parallel to the subject's skin:



Stafford, FIGS. 4A, 5B, 5C (annotated)

48. Stafford further describes an introducer comprising a needle-like lower portion that pierces the skin of the subject to insert a portion of the sensor coupled to the data processing unit into the subject. *Id.*, [0021] (“[T]he lower portion 102B of the introducer is configured with a sharp tip to facilitate puncturing or piercing through the surface of the subject”), [0024] (“[T]he user ... places the entire analyte sensor delivery and data processing unit assembly 100 on the surface of the subject ... with sufficient force applied on the upper surface of the data processing unit 101 such that the lower portion 102B of the introducer is pierced through the skin layer of the patient.”), FIG. 4A. Subsequently, the introducer is withdrawn from the

subject, leaving part of the sensor within the skin. *Id.*, [0024] (“Thereafter, the introducer may be removed to detach or decouple from the data processing unit 101 by, for example, pulling at the upper portion 102A of the introducer, thereby withdrawing the introducer from the patient”).

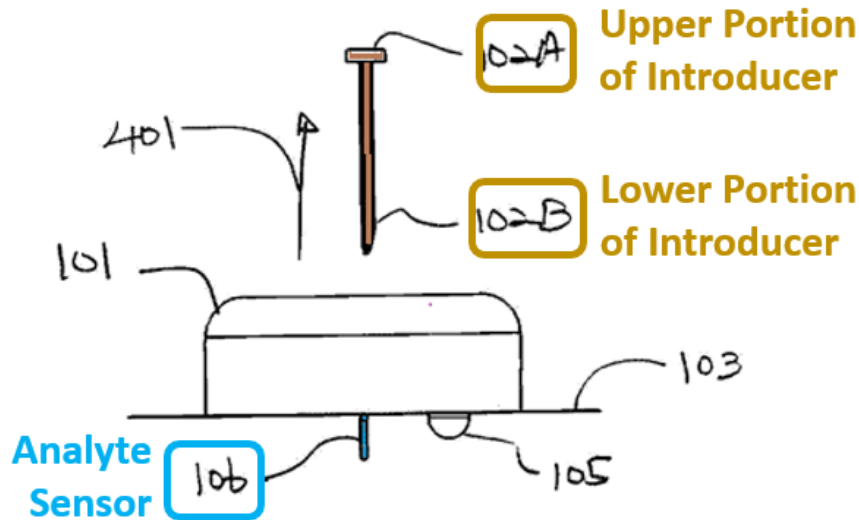


FIGURE 4A

Stafford, FIG. 4A (annotated)

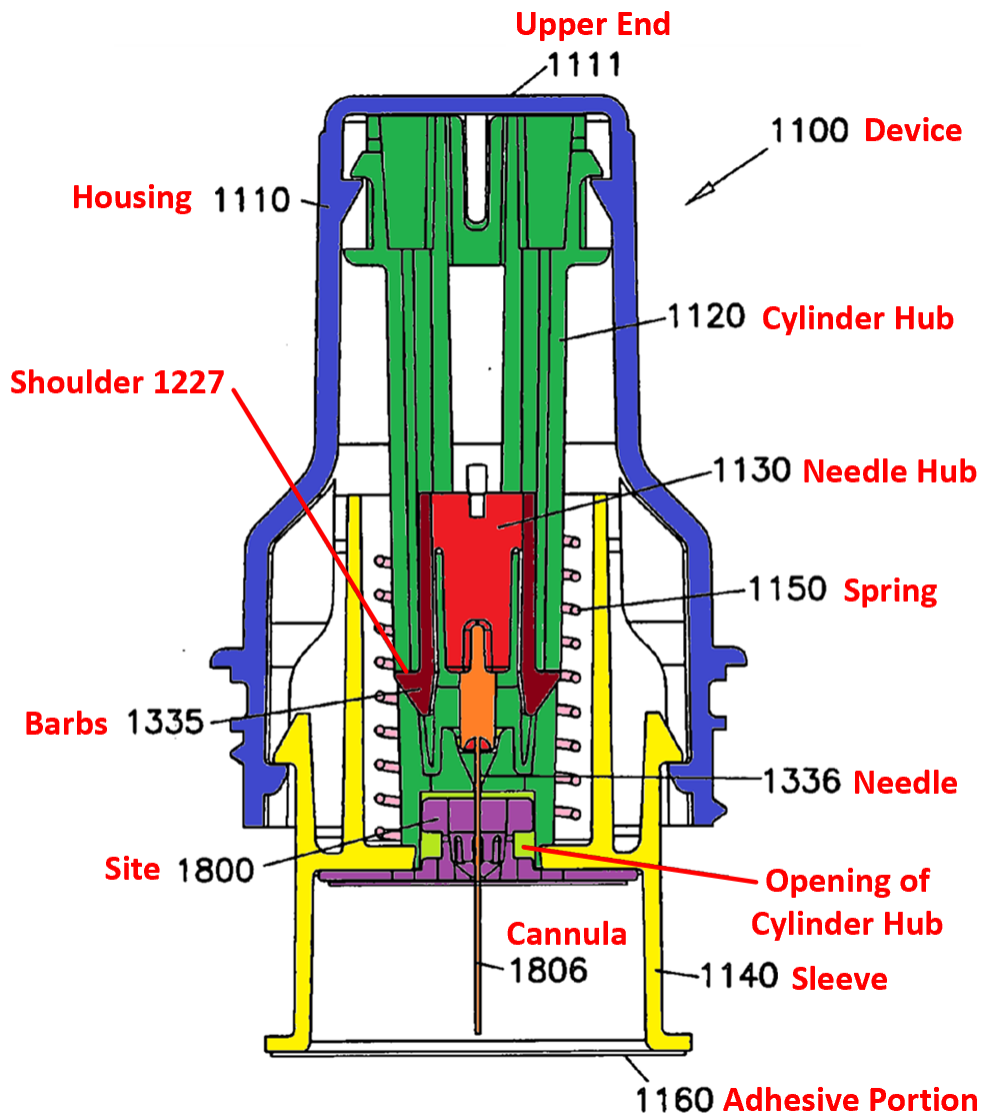
49. Stafford explains that withdrawing and discarding the introducer “requires a level of care” to avoid injury from an introducer’s sharp tip and that “particular precautions” should be taken to avoid contact with the sharp tip (*e.g.*, lower portion), after it has contacted the subject’s biological fluids. *Id.*, [0003] (“Further, since the tip of the inserter has come into fluid contact with the patient’s biological fluids, it is important to take particular precautions in the handling of the inserter”).

B. Cote

50. U.S. Publication No. 2005/0101932 (“Cote,” EX1005), published May 12, 2005, from an application filed November 10, 2003.

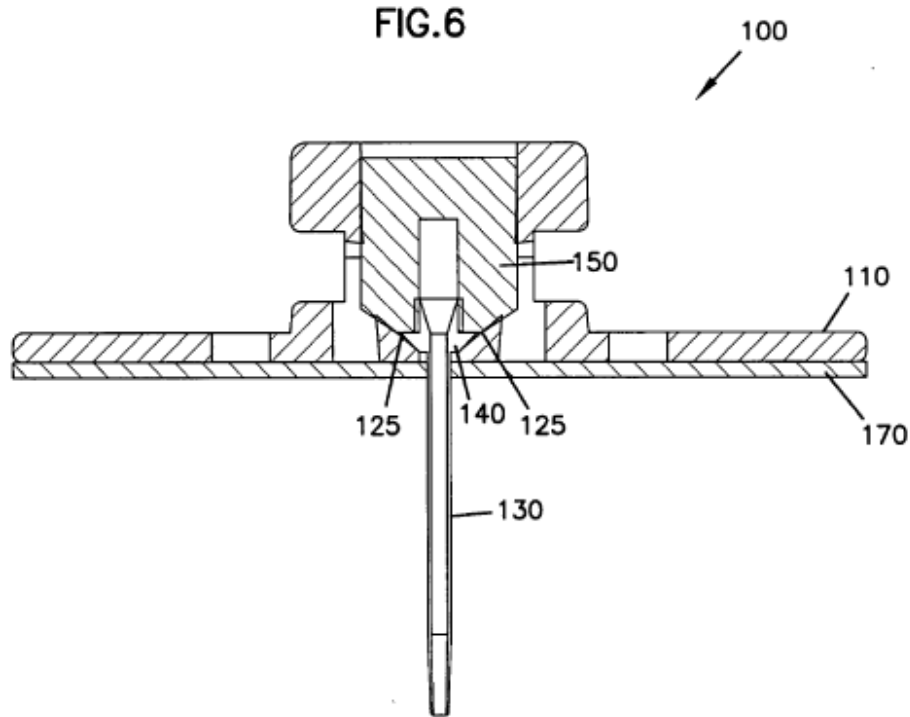
51. Cote teaches a device that uses an automatically retractable needle to insert a cannula of an infusion device into a patient’s skin. EX1005, [0179], [0236]. As shown below, Cote’s insertion device generally includes a housing (blue), a cylinder hub (green), a needle hub (red) including needle (orange), a sleeve (yellow), and a spring (pink). *Id.*, [0180], FIG. 80A.²

² For clarity purposes, only the cross-sectional surfaces of housing 1110 and sleeve 1140 are annotated in color.



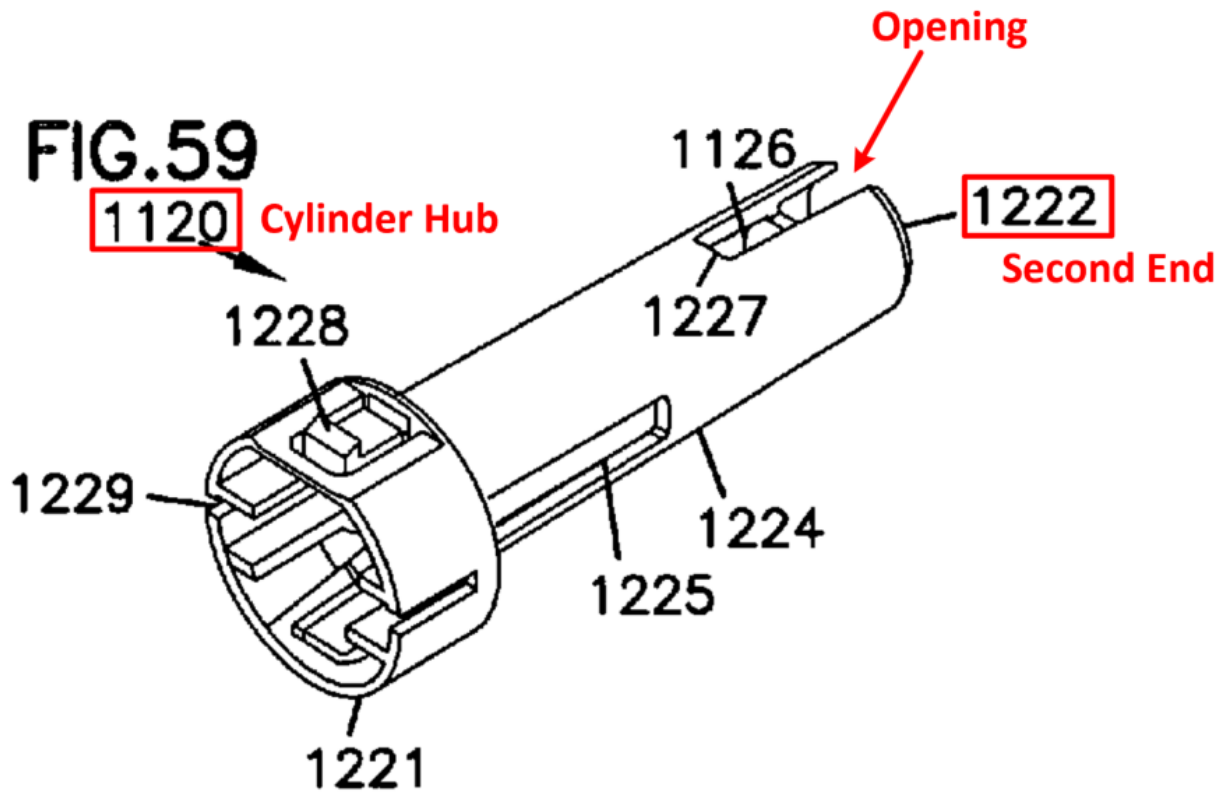
Cote, FIG. 80A, “delivery state” (annotated)

52. Cote explains how the cannula is part of a “site,” an on-body unit that also includes a base “coupled to the skin of the patient.” *E.g., id.*, [0134], [0195]. Cote FIG. 6A shows an exemplary on-body site with transcutaneous cannula 130, base 110, and adhesive portion 170 for affixing the site to the patient’s skin:



Cote, FIG. 6A, cross-section of a “site” device

53. In Cote’s pre-insertion “delivery state,” the needle extends through the site and cannula (*id.*, [0205]), with the site disposed within an opening at the distal end of the cylinder hub. *See also id.*, FIG. 59 (below), [0182] (opening at “second end 1222”). As shown above in FIG. 80A, in this position the needle is within and shrouded by the rest of the inserter.



Cote, FIG. 59 (annotated)

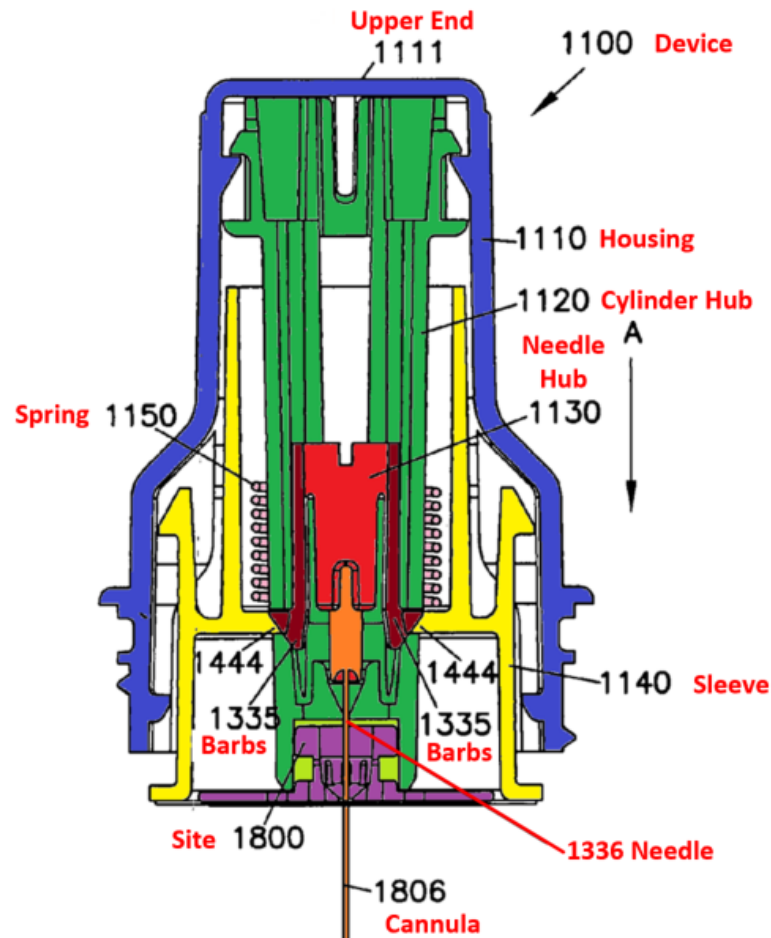
54. To retain the site within the opening of the cylinder hub within the inserter, an elastomeric diaphragm of the site is positioned on the needle to frictionally engage with the needle, as shown in FIG. 6A (below). *Id.*, [0145], [0205]. *See also id.*, [0165] (describing diaphragm resealing itself once needle is removed).

55. Considering the inserter's construction and the diaphragm's structure and material properties, a POSITA reading Cote would understand that once the needle presses through the diaphragm and the cannula, the frictional engagement between the needle and the diaphragm maintains the positioning of the site relative to the needle prior to and during delivery.



Page 39

of a patient,” “the patient applies pressure to the upper end 1111 of the housing 1110 to move the housing 1110 and associated structures including the cylinder hub 1120 and needle hub 1130 (including needle 1336 and site 1800) in a direction A with respect to the sleeve 1140 and toward the skin 1900 of the patient.” EX1005, [0012], [0203] [0207].

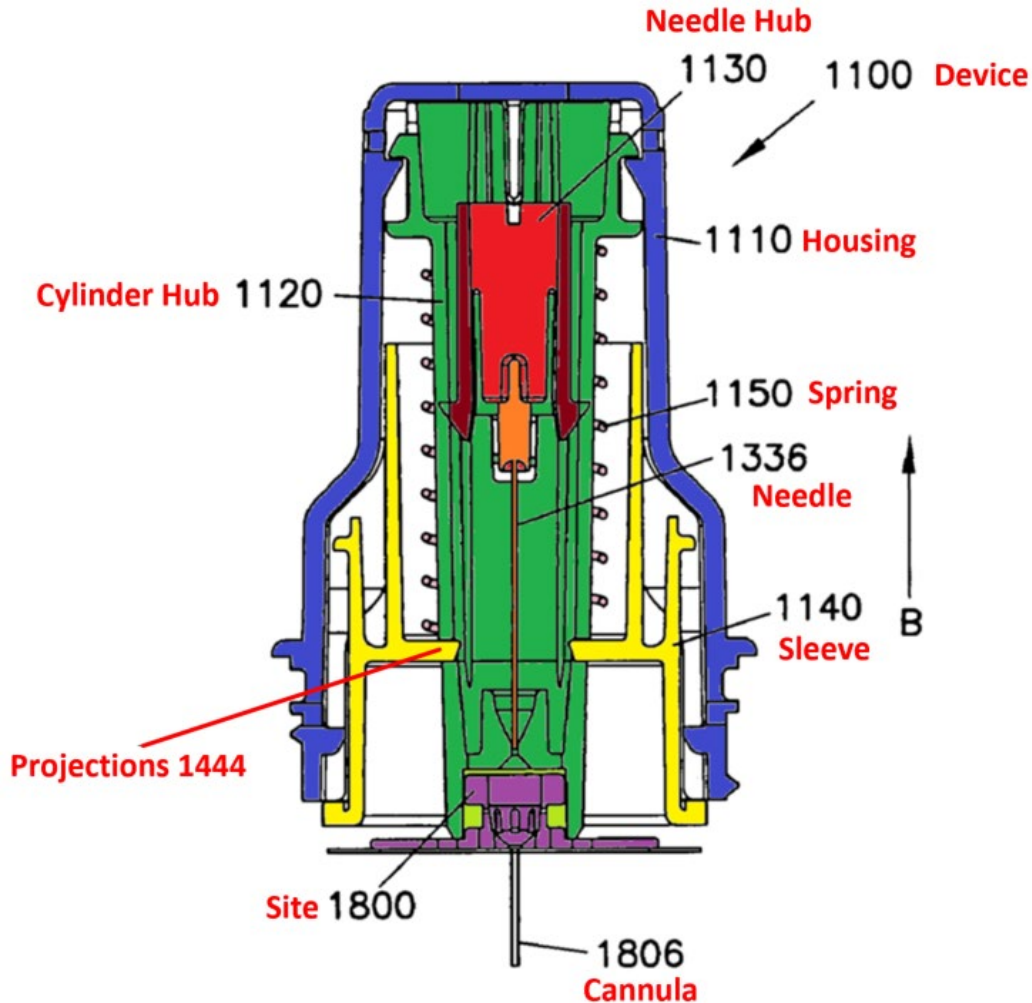


Cote, FIG. 81A, “trigger state” (annotated)

58. Specifically, several structures (housing, cylinder hub, needle hub) move together relative to the sleeve as the device is transitioned from the delivery state to the trigger state. EX1005, [0183], [0185]. For example, the cylinder hub is

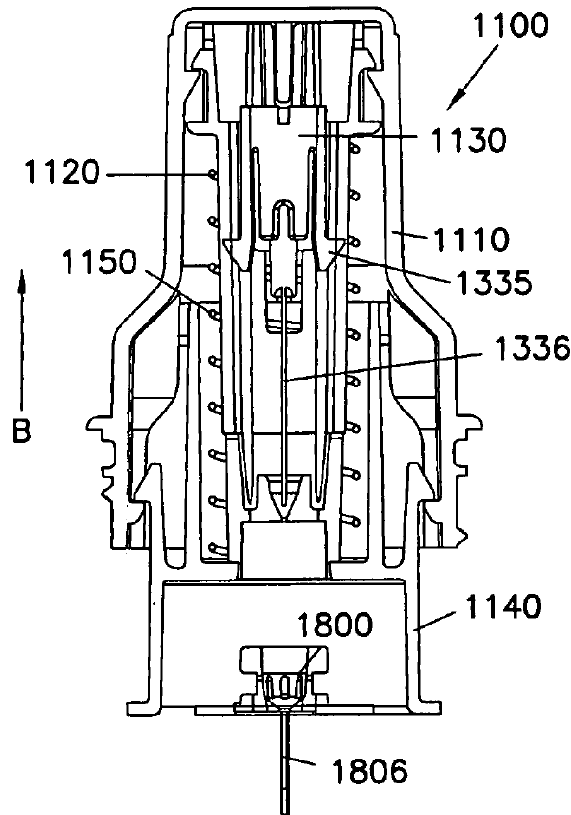
held in a fixed position relative to the housing, and the needle hub is held in a fixed position relative to the cylinder hub by barbs 1335 (burgundy) of the needle hub that are positioned against a shoulder of the cylinder hub. EX1005, [0183], [0185], FIG. 59. As such, movement of the housing in direction A results in movement of the needle and the site, as well as compression of the spring. *Id.*, [0207].

59. As the device is moved to a release state (FIG. 82A, below), the barbs are pushed inwards by projections 1444 of sleeve 1140, and thus uncoupled from the cylinder hub. *Id.*, [0211]. The spring can then propel the needle hub and associated needle “in the direction B” up through the cylinder hub into the upper end of the housing. *Id.* As shown in FIG. 82A (below), the cylinder hub and the site remain down during retraction of the needle, with the site adhered to the patient’s skin, overcoming the frictional engagement between the needle and the diaphragm of the site so that “the site 1800 and associated cannula 1806 are held on the skin 1900 of the patient.” *Id.*; *see also id.*, FIGS. 82A, 82B.



Cote, FIG. 82A, “needle hub retracted” (annotated)

60. Thereafter, the device “automatically retract[s] the needle while leaving the site placed on the skin, thereby reducing the patient’s contact with the exposed needle.” *Id.*, [0236]. Thereafter, “the patient removes pressure from the upper end 1111 of the housing 1110, the spring 1150 causes the housing 1110 and cylinder hub 1120 to move in the direction B as shown in FIGS. 83A and 83B to a fully retracted state.” *Id.*, [0212]. Finally, the distal end of the inserter is removed from the patient’s skin. *Id.*, [0213].



Cote, FIG. 83A, “fully retracted state”

C. Combining The Teachings Of Stafford And Cote

61. A POSITA would have been motivated, with a reasonable expectation of success, to combine Stafford’s teachings on an analyte sensor, introducer (“sharp”), and data processing unit (“on-body unit”) with Cote’s teachings on automatically-retracting insertion devices (“inserters”). A skilled artisan would have combined these respective teachings into an improved design (hereinafter, “Stafford+Cote”), that included benefits from each reference and adjusted the inserter and/or on-body unit as needed for them to cooperate and function as intended, as discussed below.

62. The resulting combination has the following elements cooperating as follows:

- A data processing unit as taught by Stafford, including:
 - a housing with openings in the top and bottom surfaces;
 - an analyte sensor, *e.g.*, a glucose sensor; and
 - electronics coupled with the analyte sensor;
- an introducer sharp configured to insert a portion of the analyte sensor into a subject, the sharp extending through the data processing unit and integrated within a Cote-like inserter device; and
- a device for insertion as taught by Cote, including the inserter's needle-based insertion and automatic retraction mechanisms.

63. Stafford+Cote includes an inserter as taught by Cote integrated with Stafford's introducer sharp and configured to advance Stafford's data processing unit and introducer from a first position to a second position such that Stafford's data processing unit is secured to the skin of the user in a second position. Stafford+Cote is further configured to retract Stafford's introducer sharp entirely into the interior of the inserter leaving a part of the sensor in the user's skin.

64. A POSITA would have been motivated, with a reasonable expectation of success, to combine Stafford and Cote by implementing a Cote-like inserter to deploy Stafford's on-body unit and analyte sensor for at least the following reasons.

65. *First*, Cote improves upon an aspect of insertion specifically identified by Stafford, namely to prevent accidental needle sticks when withdrawing the needle from the subject. EX1004, [0003], [0022]. Stafford lacks a way to prevent contact with the introducer's exposed lower portion after the guard is removed prior to insertion and also once the introducer is withdrawn from the subject. Cote, in turn, teaches an inserter that guards the needle not only prior to insertion but also "protect[s] against inadvertent contact with the needle" during insertion of a medical device into a subcutaneous layer of skin. EX1005, [0235]. Cote also teaches a type of automatic retraction that withdraws the sharp back into the inserter after insertion (*id.*, abstract, [0236]), thus avoiding undesired contact with "the tip of [Stafford's] inserter [that] has come into fluid contact with the patient's biological fluids." EX1004, [0003], *see id.* FIGS. 5B-5C. Thus, a POSITA would be motivated to obtain the benefits of Cote's teachings on a specific inserter device that shrouds the needle both prior to and after insertion. EX1005, [0235]-[0236]. Indeed, these benefits overcome problems identified, but not fully addressed, by Stafford, which does not clearly address problems with post-insertion needlesticks.

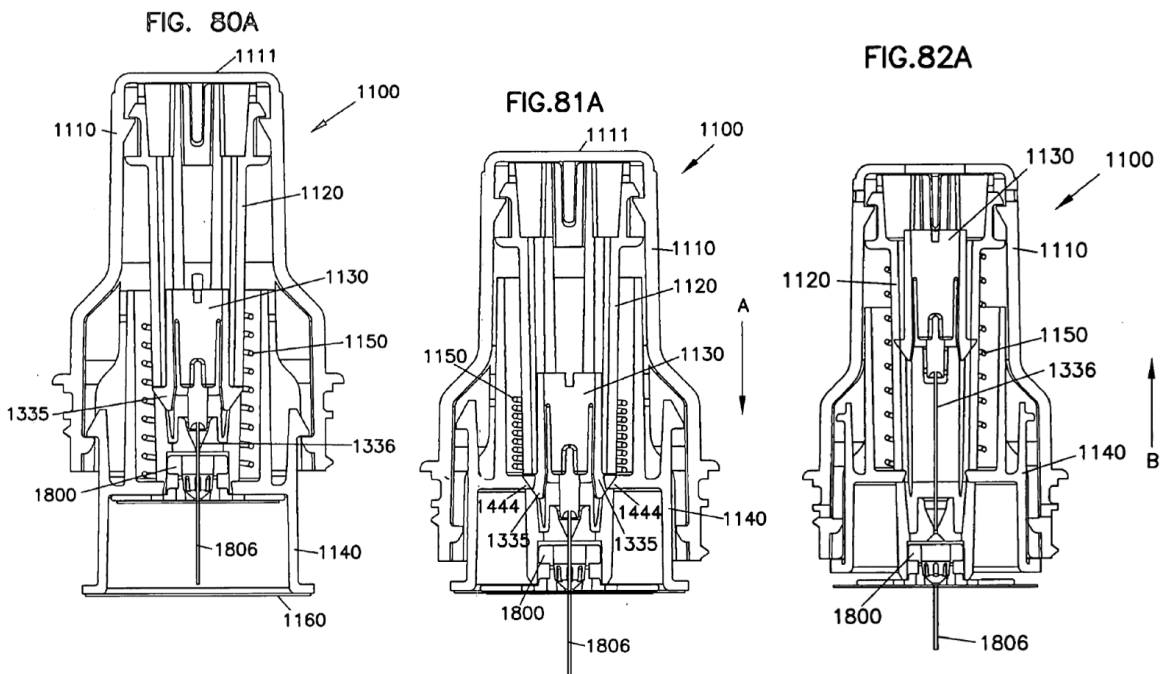
66. *Second*, and relatedly, a POSITA would have recognized the benefits of using a shrouded and automatically-retracting inserter to minimize any pain or anxiety of the patient due to use of a needle-implanted device such as the one described in Stafford.

67. *Third*, the teachings complement one another, as Cote teaches an all-in-one insertion assembly that comes with the on-body unit pre-loaded with the inserter and that separates from the on-body unit only after insertion. This aligns with Stafford's goal of "a single disposable assembly" that does not require "a *separate* sensor introducing device." EX1004, [0044].³ A POSITA would recognize that such all-in-one systems provided benefits over other assembly-required systems that used a separate insertion device, e.g., the insertion gun of Say referenced in Stafford (EX1008, 2:66-3:15), which the user had to align with and affix to the on-body unit prior to insertion. Like Stafford, Cote teaches an inserter assembly that obviates the need for users to perform these additional, potentially intimidating steps.

68. Similarly, Cote teaches an insertion assembly that is easily graspable and operable by a single hand, and notes the advantages of such an assembly. EX1005, [0234], [0181], [0197]. This aligns with Stafford's teachings on an assembly that "may be easily operated using one hand by the user or the patient," EX1004, [0007], thus further motivating a POSITA to combine the two teachings to implement an inserter like that taught by Cote for inserting a glucose sensor as taught by Stafford.

³ Emphases throughout are added, unless otherwise noted.

69. *Finally*, a POSITA would have had a reasonable expectation of success in combining the teachings of Stafford and Cote. Stafford describes a transcutaneous medical device comprising an analyte sensor used in connection with infusion devices. *Id.*, [0032], [0042]. Cote describes an inserter for a transcutaneous infusion device configured to deliver medications. EX1005, [0002]. Since both references are directed to the deployment of transcutaneous medical devices and use of infusion devices, the teachings in these references complement one another and combining their teachings would have yielded nothing more than predictable results.



Cote, FIGS. 80A, 81A, 82A

70. As shown in Stafford's FIG. 4A and Cote's FIGS. 79A–83B, both Stafford's introducer and Cote's device comprise a needle (*e.g.*, lower portion of Stafford's introducer and Cote's needle, respectively) configured to actuate in a

direction substantially perpendicular to the subject's skin to deploy a subcutaneous device. Since a POSITA would have realized that the lower portion of Stafford's introducer and the needle of Cote's device perform the same function with similar structures, a POSITA would have easily combined the teachings to create an insertion assembly that would position Stafford's on-body unit and sensor using Cote's insertion device.

71. For at least these reasons, a POSITA would have naturally implemented an insertion assembly that incorporated Cote's teachings on an inserter device with Stafford's teachings on a sensor device with a partially implantable sensor and an on-body unit with associated sensor electronics. As explained in the following sections, such an insertion assembly meets all elements of the independent claims and many dependent claims.

72. Like the '591 patent, Stafford and Cote are each directed to the insertion of transcutaneous medical devices for diabetes treatments. Thus, Stafford and Cote are analogous art to the claimed invention of the '591 patent.

1. Claims 1/19⁴

[1.1]/[19.1]⁵ An insertion assembly, comprising:

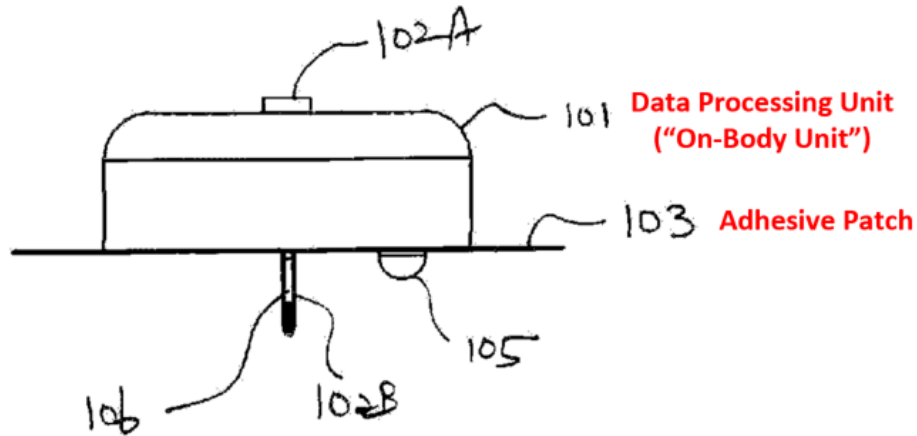
73. To the extent the preamble is limiting, the Stafford and Cote combination described above (hereinafter, “Stafford+Cote”) includes an insertion assembly.

[1.2]/[19.2] (a) an on-body unit, comprising:

74. Stafford+Cote includes an on-body unit based on Stafford’s teachings related to an on-body data processing unit that adheres to a patient’s body. EX1004, [0019] (describing use of “adhesive patch 103” to “securely attach ... the data processing unit 101 on a surface of a subject such as the skin of a patient.”), FIG. 2.

⁴The elements of claim 19 that correspond to those of claim 1 are mapped herein with claim 1, the remaining elements are mapped with claims 3, 4, 5, and 14.

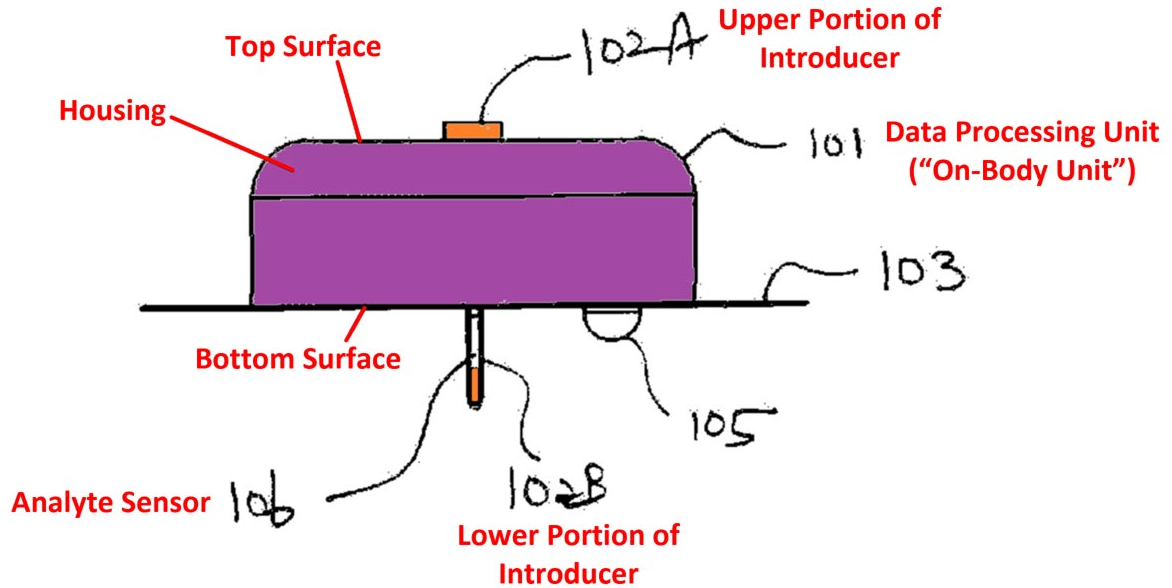
⁵ Reference numbers in the format of [claim#.limitation#] are added throughout for ease of reference.



Stafford, FIG. 2 (annotated)

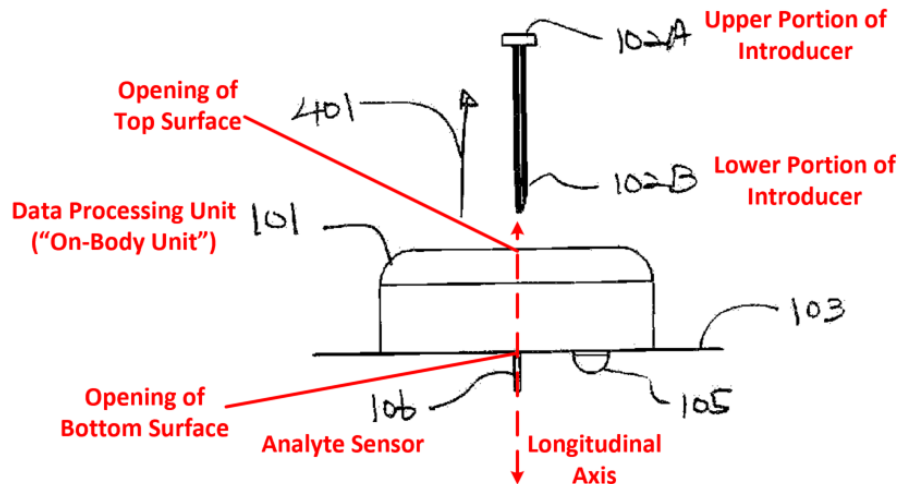
[1.3]/[19.3] a housing comprising a top surface and a bottom surface, wherein the top surface comprises an opening of the top surface, wherein the bottom surface comprises an opening of the bottom surface, and wherein a longitudinal axis extends through the opening of the top surface and the opening of the bottom surface;

75. The Stafford+Cote on-body unit includes a “housing” (purple) comprising an “upper surface” (top surface) and a “bottom surface,” as taught by Stafford. *E.g.*, EX1004, [0020].



Stafford, FIG. 2 (annotated)

76. Each of these top and bottom surfaces comprises an opening, and a longitudinal axis extends through the opening of the top surface and the opening of the bottom surface, which allows the introducer 102A/B (orange) to extend through the housing from top to bottom, as shown in FIG. 2. *Id.*, [0020] (“the introducer in one embodiment is coupled to the housing of the data processing unit 101 such that the upper portion 102A of the introducer protrudes from an upper surface of the data processing unit 101, while the lower portion 102B of the introducer is configured to protrude downwardly from the bottom surface of the data processing unit 101.”), FIG. 2.



Stafford, FIG. 4A (annotated)

77. Stafford FIG. 4A (above) shows how the introducer may be removed through this longitudinal axis in the housing, confirming that the longitudinal axis extends through the two openings. *Id.*, [0026].

[1.4]/[19.4] a glucose sensor; and

78. Stafford+Cote's on-body unit includes an "analyte sensor," shown as 106 in at least FIGS. 2 and 4A-4B of Stafford. *E.g.*, EX1004, [0023]. Stafford teaches that "[t]he analyte sensor may include a glucose sensor." *Id.*, [0051]. A POSITA knew that a glucose sensor was a common—if not the most common—type of analyte sensor. Thus, it was obvious to implement the Stafford+Cote insertion system with an on-body unit comprising a glucose sensor as the analyte sensor.

[1.5]/[19.5] sensor electronics disposed within the housing and coupled with the glucose sensor; and

79. Stafford+Cote's on-body unit includes sensor electronics disposed within the housing. EX1004, [0006] ("a data processing unit substantially disposed within the housing"); [0040] ("components in the data processing unit 101"). Stafford teaches sensor electronics that include a processor ("processor 704"), a power source ("power supply 707"), an analog interface ("analog interface 701"), and wireless communication circuitry ("RF transceiver 706") configured to communicate data indicative of a glucose level. *Id.*, [0039]-[0040], [0052], FIG. 7. These sensor electronics are coupled with the glucose sensor. *Id.*, [0028] ("a single integrated unit with the analyte sensor 106 in electrical contact with the data processing unit 101.") [0039] (describing data processing unit's "analog interface 701 configured to communicate with the sensor 106 (FIG. 2)"). *See also id.*, [0036], [0039]-[0043], FIG. 7.

[1.6]/[19.7] (b) an inserter, comprising:

80. Stafford+Cote includes a Cote-like inserter (*e.g.*, similar to Cote's "device 1100") configured to insert a portion of an on-body unit into the skin of a patient and place a portion of the on-body unit on the skin of the patient. EX1005, [0202] ("device 1100 can be used to insert a cannula 1806 of an infusion device, such as site 1800, into the subcutaneous layer of skin of a patient").

FIG.54

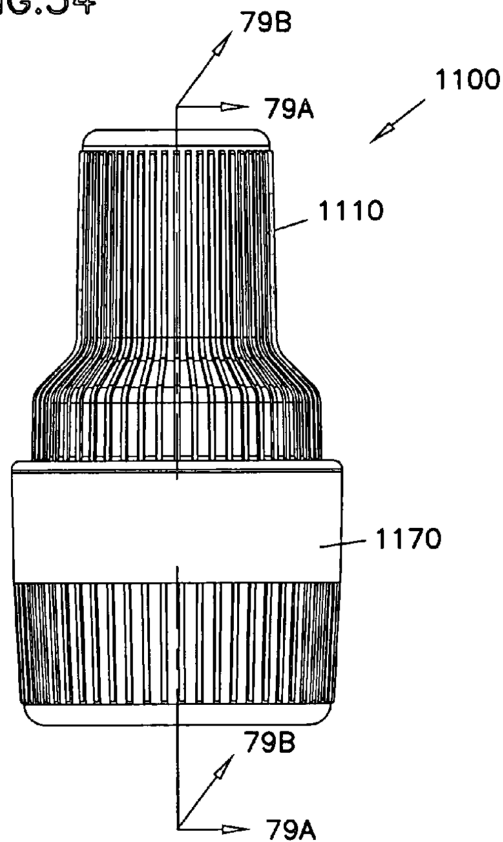
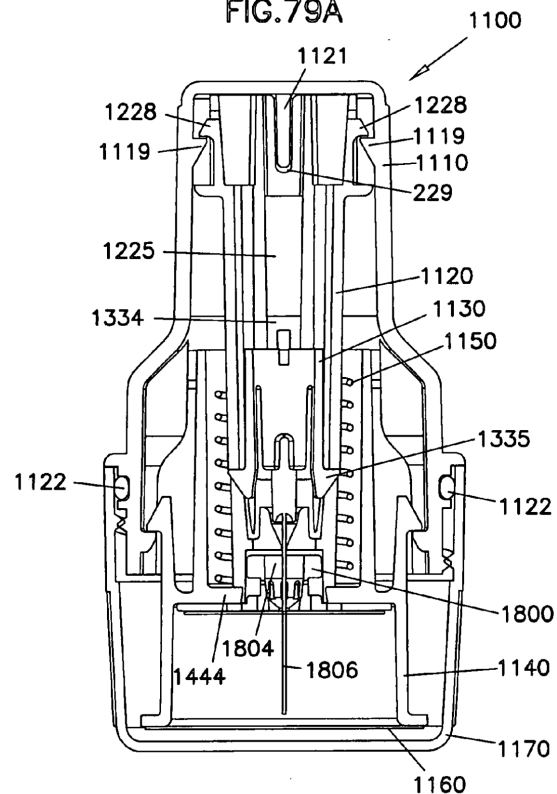


FIG.79A

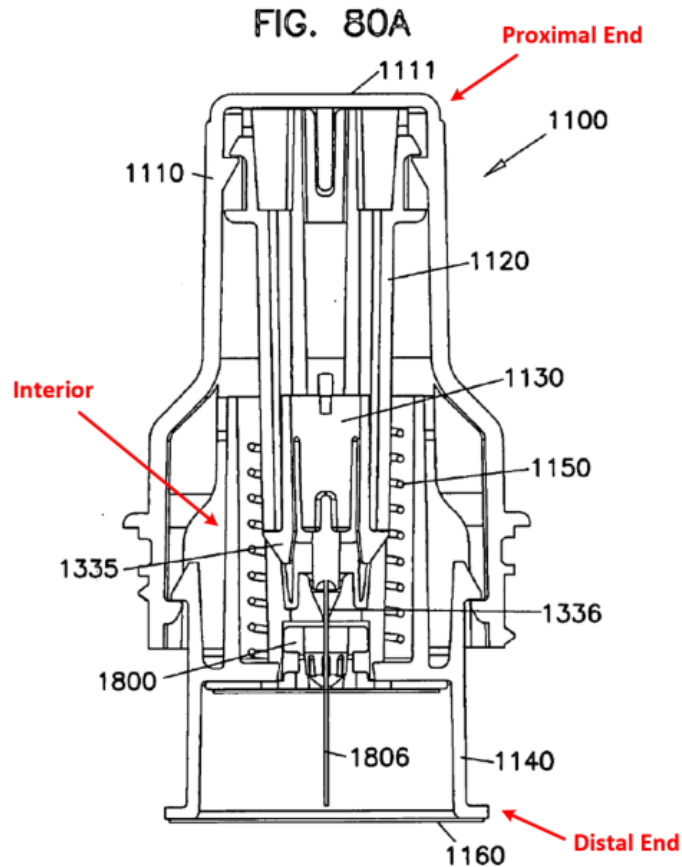


Cote, FIGS. 54 and 79A

81. In Stafford+Cote, an inserter like that taught by Cote deploys an on-body unit and analyte sensor as taught by Stafford. As explained in the following paragraphs, the Stafford+Cote inserter includes all the features recited in claim 1.

[1.7]/[19.8] a proximal end, a distal end, and an interior; and

82. Stafford+Cote's inserter includes a proximal end, a distal end, and an interior, as taught by Cote, e.g., with respect to Cote inserter 1100. EX1005, FIG. 80A, below.

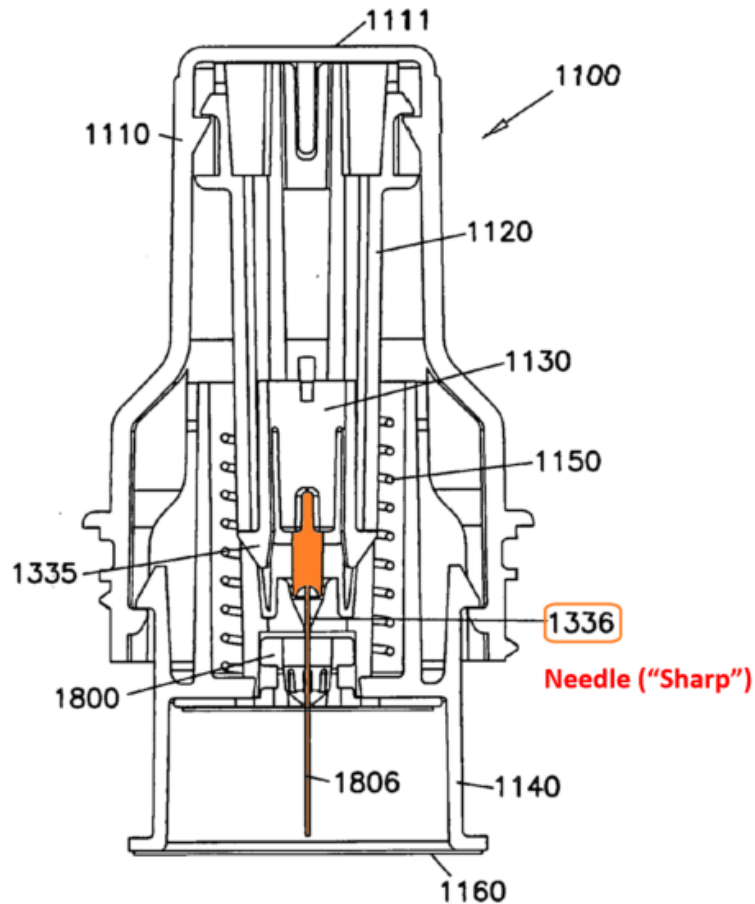


Cote, FIG. 80A (annotated)

[1.8]/[19.9] a sharp,

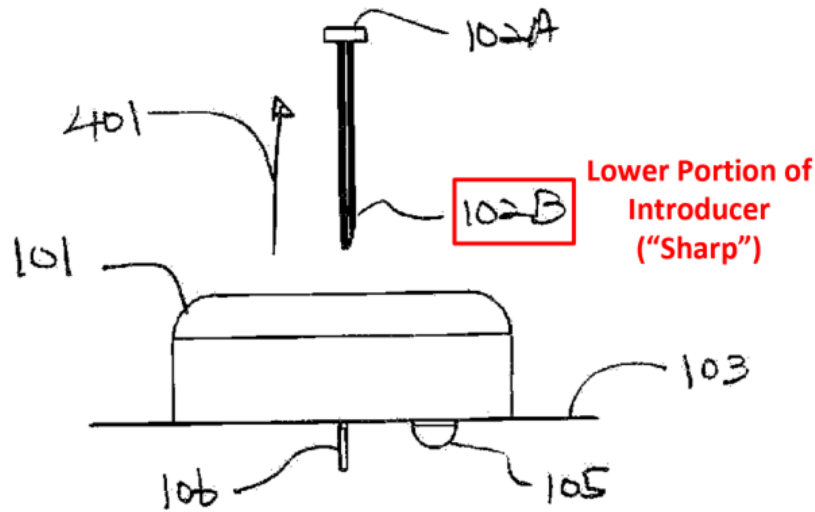
83. Stafford+Cote includes a sharp like that taught by Stafford, with at least a lower portion having a channel / U-shaped cross-section for properly surrounding and guiding the in-body portion of the sensor during insertion. *See, e.g.,* EX1004, [0021] (“[T]he lower portion 102B of the introducer is configured with a sharp tip to facilitate puncturing or piercing through the surface of the subject such as the skin of the patient.”); FIGS. 4A, 5C; *see also* EX1005, [0184] (“needle 1336 (hollow or

solid))), [0207] (“the needle 1336 ... [is] introduced into the skin 1900 of the patient.”).

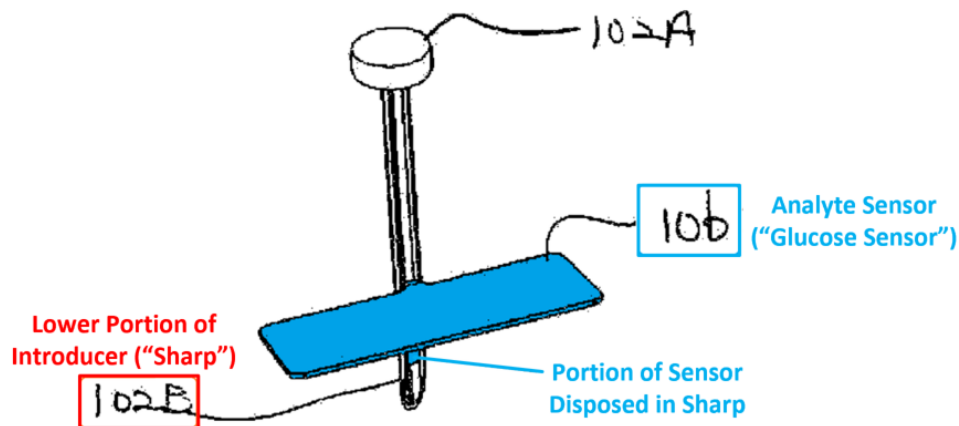


Cote, FIG. 80A (annotated)

84. Stafford FIG. 4A and FIG. 5C (annotated versions below) show the sharp’s channel / U-shaped cross-section that accommodates a portion of the sensor. Thus, during insertion, “a portion of the analyte sensor 106 is disposed within the lower portion 102B of the introducer such that, the user or patient may easily, and accurately position the analyte sensor 106 under the skin layer.” EX1004, [0028]; *see also id.*, [0002] (“introducer includes a sharp needle shaped inserter”).



Stafford, FIG. 4A (annotated)



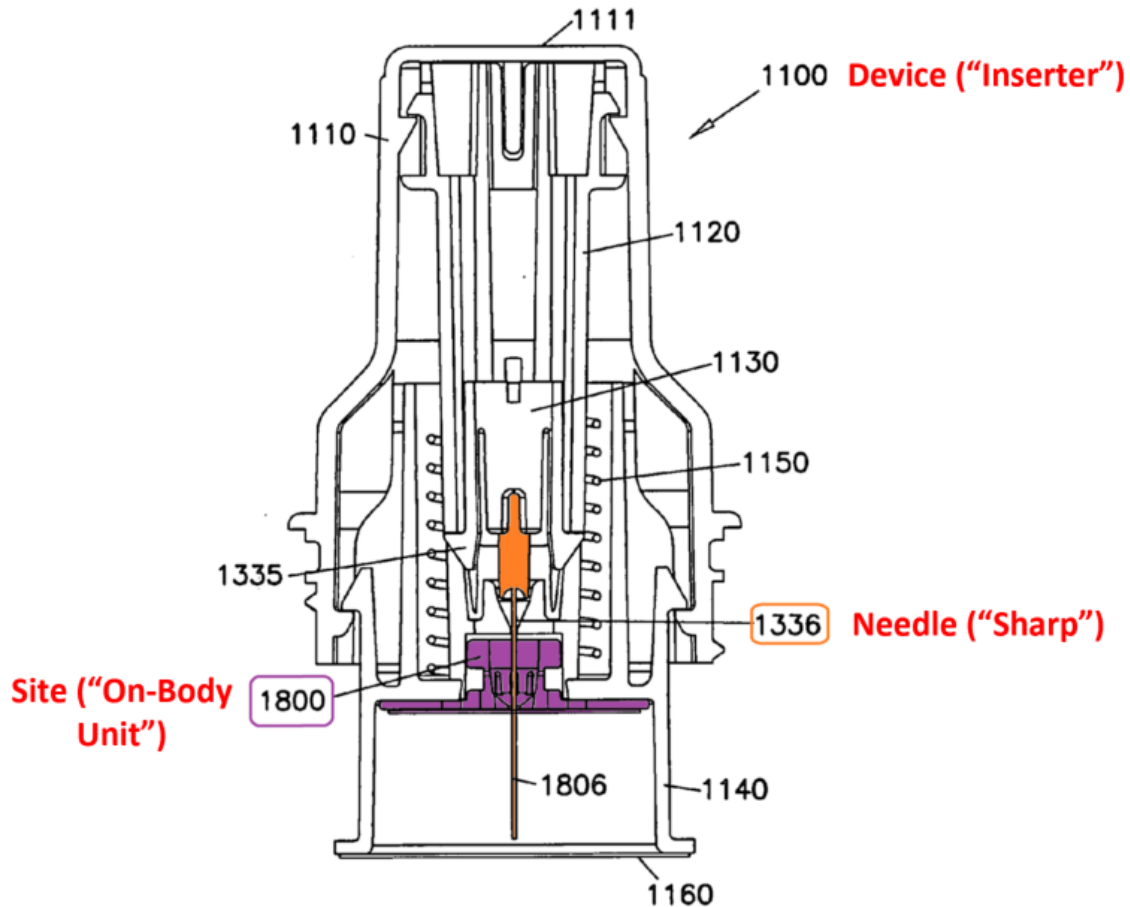
Stafford, FIG. 5C (annotated)

85. Cote itself recognizes the use of either solid or hollow needles for insertion (EX1005, [0184], [0207]; EX1004, [0021]), confirming that a POSITA would have naturally implemented the Stafford+Cote sharp insertion assembly with a sharp having a channel / U-shaped cross-section for surrounding and guiding the sensor during insertion, as taught by Stafford. EX1008, FIGS. 13B-C, 27:63-66

(prior art patent incorporated into Stafford, reflecting knowledge in art of sharp insertion devices that “support the sensor ... during insertion”).

[1.9]/[19.10] wherein the on-body unit and the sharp are entirely disposed in the interior of the inserter,

86. In Stafford+Cote’s insertion assembly, the on-body unit and sharp are disposed entirely within the interior of the inserter, as taught in Cote and shown below. Cote teaches the on-body unit and sharp are entirely disposed in the interior of the inserter. EX1005, [0198] (“the internal components of the device 1100 (e.g., needle 1336 and site 1800)”; FIG. 80A (below). *See also id.*, [0215] (“sleeve 1140 [functions] to shroud the needle 1336 prior to insertion”).



Cote, FIG. 80A (annotated)

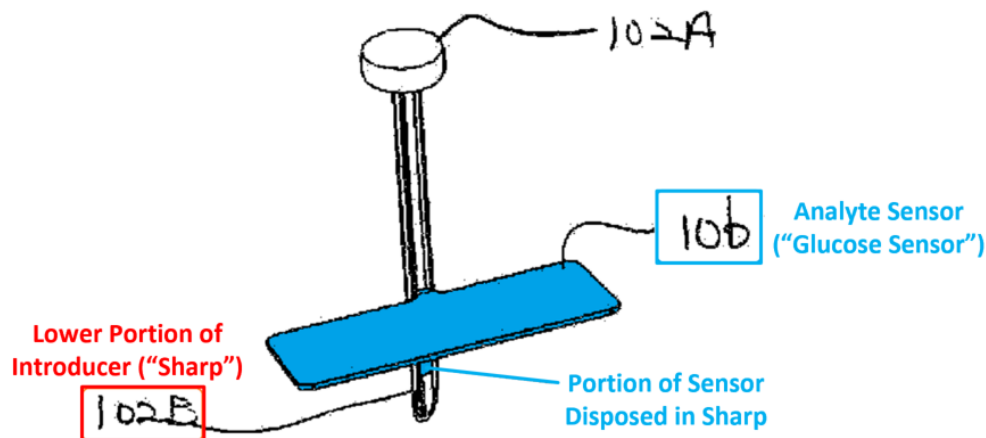
87. Cote teaches the benefits of this implementation, *e.g.*, “the internal components of the device 1100 (*e.g.*, needle 1336 and site 1800) can be maintained in a substantially sterile state” (EX1005, [0198]) and “cover[ing] or hid[ing] the needle prior to insertion of the site ... protect[s] against inadvertent contact with the needle.”)]. EX1005, [0235].

88. Stafford+Cote thus has its on-body unit and sharp/needle disposed entirely within the inserter. In such a combination, the on-body unit is disposed, *e.g.*, within an opening at the distal end of Cote’s cylinder hub. A POSITA would

understand how to modify the distal end of Cote's cylinder hub to receive the shape of Stafford's on-body unit. A POSITA would be motivated to modify Cote's cylinder hub in this way, with a reasonable expectation of success, as this minor change in size or shape is a simple design choice.

[1.10]/[19.11] wherein at least a portion of the glucose sensor is disposed in the sharp,

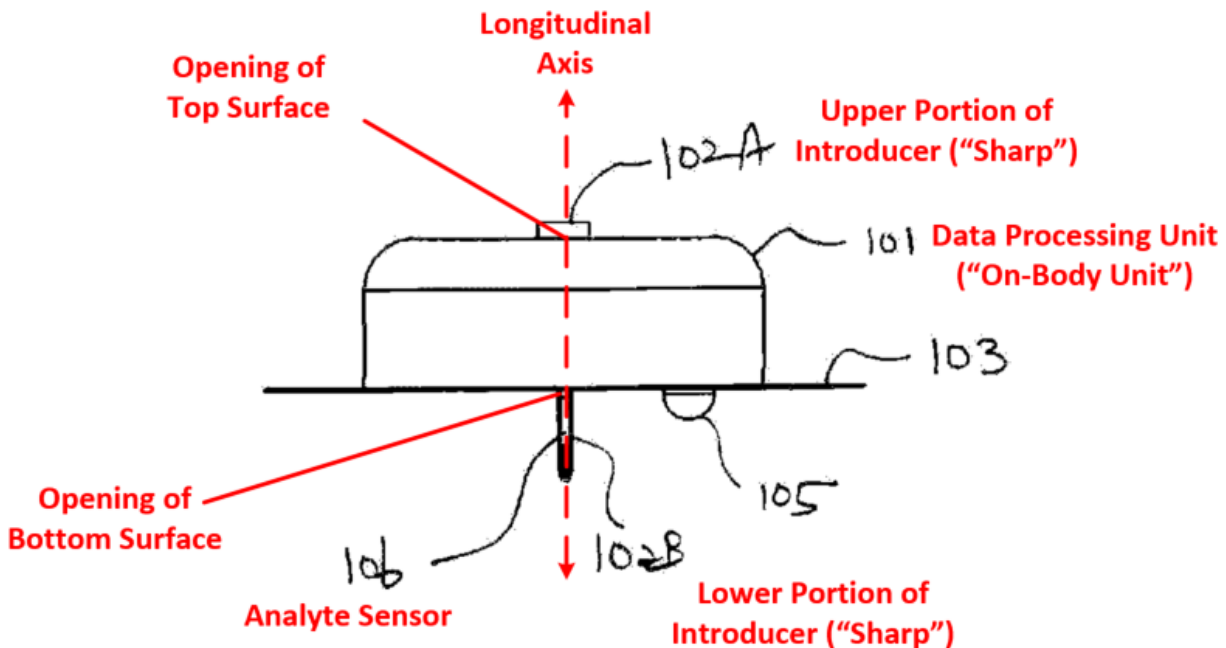
89. In the Stafford+Cote insertion assembly, a portion of the glucose sensor is disposed in the sharp, i.e., within the channel of the lower portion of the sharp, as taught by Stafford. EX1004, [0028], FIG. 5C (below). *See supra* Section [1.8]/[19.9].



Stafford, FIG. 5C (annotated)

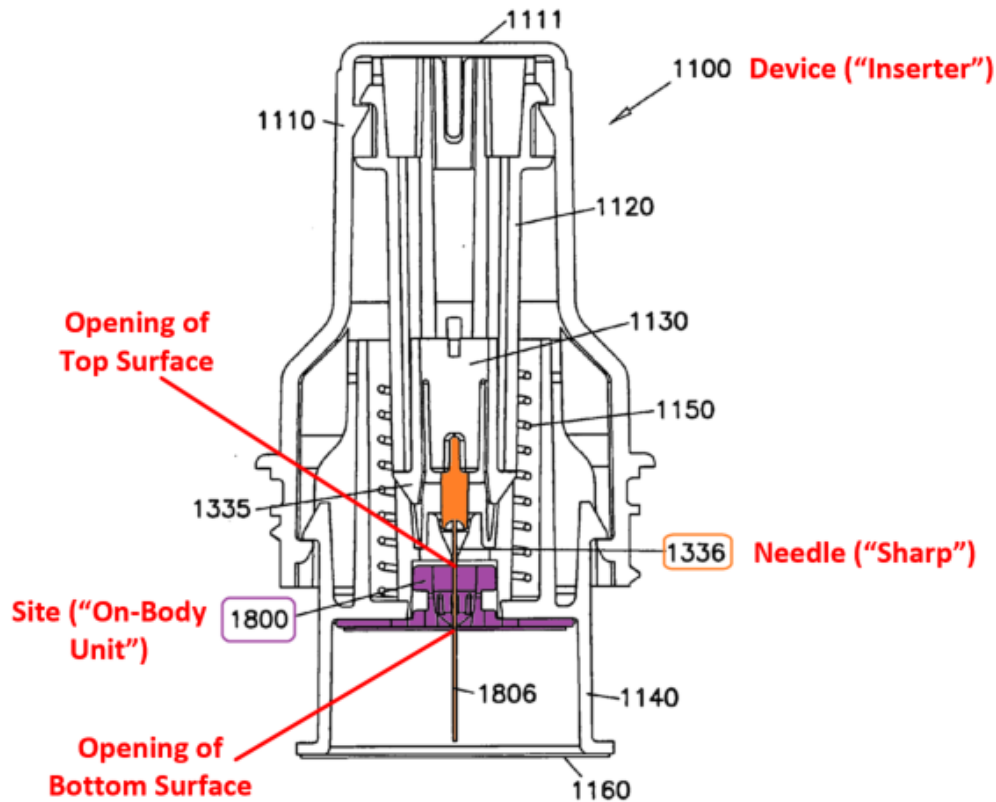
[1.11]/[19.16] wherein the sharp extends through the opening of the top surface and the opening of the bottom surface along the longitudinal axis when the on-body unit is in [a]/[the] first position,

90. In the Stafford+Cote insertion assembly, the sharp extends through openings in the top and bottom surfaces of the housing, along the longitudinal axis, when the on-body unit is in a first position, as taught by both Stafford and Cote. Stafford teaches and shows this. *E.g.*, EX1004, [0020]; FIG. 2 (below); *see supra* Section [1.3]/[19.3].



Stafford, FIG. 2 (annotated)

91. Cote also teaches this. EX1005, FIG. 80A, [0135], [0137], [0202].



Cote, FIG. 80A (first position, annotated)

92. As shown and taught by Cote, in its pre-insertion “delivery state,” the on-body unit is in a first position and the sharp extends longitudinally through the openings in both top and bottom surfaces. EX1005, FIG. 80A (above), [0139], [0205]. Specifically, Cote’s sharp extends through an elastomeric diaphragm that is retained within the opening of the top surface and through a cannula positioned within the opening of the bottom surface. *Id.*, [0139], [0143], [0145], [0165], [0205].

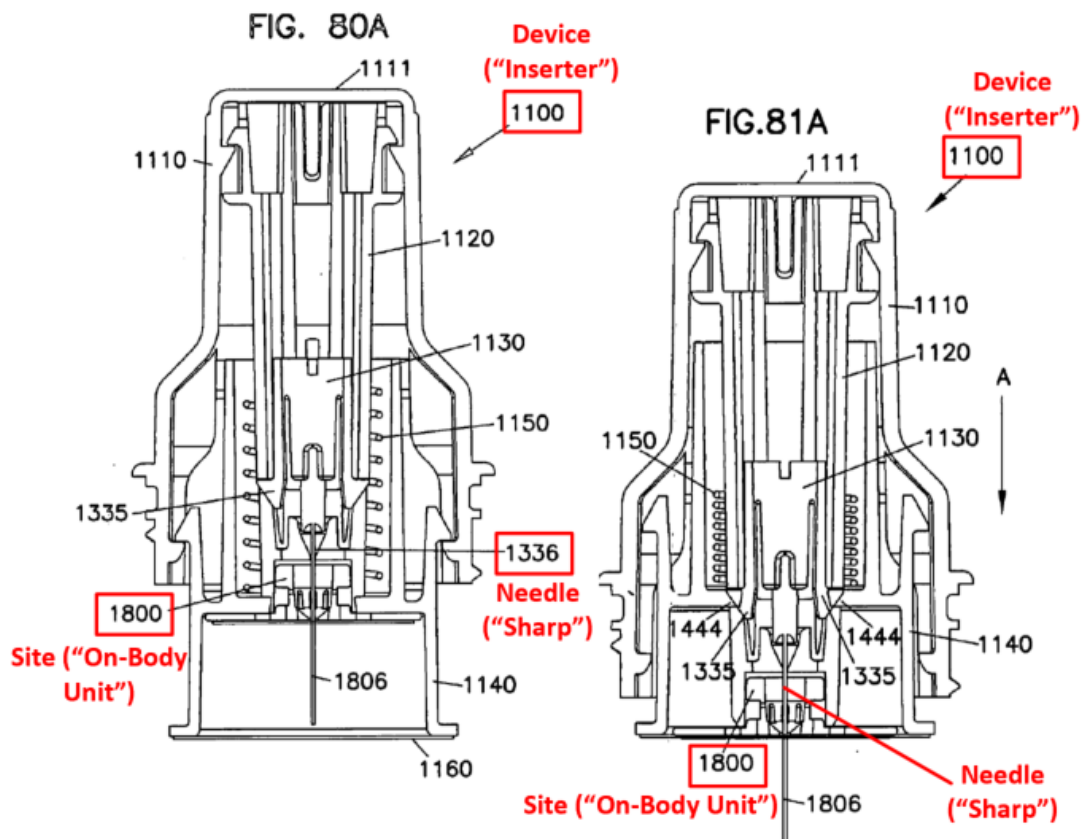
93. Cote’s sharp extends through and is frictionally engaged with a diaphragm retained in Cote’s on-body unit to maintain the vertical positioning of

Cote's site relative to the sharp. *Supra* VIII.B. Cote teaches that the diaphragm and opening define a self-sealing aperture that "reseals itself" when the sharp is removed from the diaphragm. EX1005, [0165]. Stafford also teaches that its upper opening is "a self-sealing aperture." EX1004, [0027]. Accordingly, a POSITA would recognize that the Stafford sharp would extend through and frictionally engage with the self-sealing aperture of Stafford's on-body unit in the same manner as Cote's sharp engages with the diaphragm, e.g., to maintain the vertical positioning of Stafford's on-body unit relative to the Stafford sharp prior to deployment. *Id.*, [0027], FIG. 2. For example, a POSITA would understand that the frictional engagement between the self-sealing aperture and Stafford's sharp would be sufficient to maintain the relative vertical positioning between the on-body unit and the inserter, e.g., to prevent the sharp from separating from the on-body unit prior to insertion or falling out of the device if a user orients the device upside down (opposite to what is shown in Stafford FIG. 2 and Cote FIG. 80A).

[1.12]/[19.12] wherein the inserter is configured to advance the on-body unit and the sharp in a linear direction from [the]/[a] first position to a second position such that the sharp pierces skin of a user and the housing of the on-body unit is secured to the skin of the user in the second position,

94. The Cote-like inserter of the Stafford+Cote insertion assembly is configured to advance the on-body unit and sharp from the first position ("delivery state") to a second position ("trigger state"), as taught by Cote. EX1005, [0012] ("a

device is configured to move a needle and associated cannula of an infusion device from a delivery state to a trigger state at which the cannula of the infusion device is inserted into the skin of a patient”), [0203], FIGS. 77, 80A-80B (“delivery state”), FIGS. 78, 81A-81B (“trigger state”). *See also* Section VIII.B (describing operation of Cote’s device).



Cote, annotated FIGS. 80A (first position) and 81A (second position)

95. Cote teaches that, as the inserter goes from the delivery state to the trigger state, associated structures, including the sharp and the on-body unit, move in direction A “toward the skin 1900 of the patient.” EX1005, [0207]. The inserter is thus configured to advance the on-body unit and the sharp in a linear direction

(“direction A”) from the first position (“delivery state,” *e.g.*, FIG. 80A) to the second position (“trigger state,” *e.g.*, FIG. 81A); *id.*, [0203], [0207].

96. In the second position, Cote’s sharp pierces the skin and the housing of the on-body unit is secured to the skin. EX1005, [0203], [0236] (“a trigger state, or the state at which the needle 1336 and the cannula of the site 1800 have been fully inserted into the subcutaneous layer of skin of the patient, and the needle hub 1130 and associated needle 1336 are about to be retracted.” “[D]evices disclosed herein can automatically retract the needle while leaving the site placed on the skin.”). *Id.*, [0012], [0203], [0207], FIGS. 80A, 81A.

97. Stafford+Cote includes an adhesive that secures the on-body unit to the skin of the patient in the second position, as taught by both Stafford and Cote. *E.g.*, EX1004, [0019] (describing “adhesive patch” on bottom of on-body unit that provides “sufficient adhesive strength ... to securely attach the adhesive patch 103 and the data processing unit 101 on a surface of a subject such as the skin of a patient”); *id.*, [0025], [0047]; EX1005, [0237] (“In addition, the action of inserting the needle into position on the skin using the devices disclosed herein can function to hold the site on the surface of the skin during needle retraction. This can assist in adherence of the adhesive portion to the skin and reduce the chances of separation between the adhesive portion and site and the skin during needle retraction.”); *see also id.*, [0191], [0210], FIGS. 81A, 81B, and 81C; *infra* Section [2.1]/[20.1]. A

POSITA would understand from the disclosure in Cote that the adhesive forces provided by the adhesive portion in the Stafford+Cote combined system are strong enough to overcome the forces holding Stafford's on body unit within inserter such that when the needle retracts the on-body unit remains on the skin.

98. Stafford+Cote maintains the on-body unit in position prior to insertion, *e.g.*, by using a diaphragm and / or other frictional engagement between Stafford's sharp carried by Cote's needle hub and the self-sealing aperture of Stafford's on-body unit. EX1004, [0027]; EX1005, [0189]. The POSITA also would have been motivated to incorporate a diaphragm-like device as taught by Cote, either combining it with the self-sealing aperture or in addition thereto.

99. Cote further teaches that the inserter "hold[s] the site on the surface of the skin during needle retraction" and "assist[s] in adherence of the adhesive portion to the skin." EX1005, [0237], FIG. 81A.

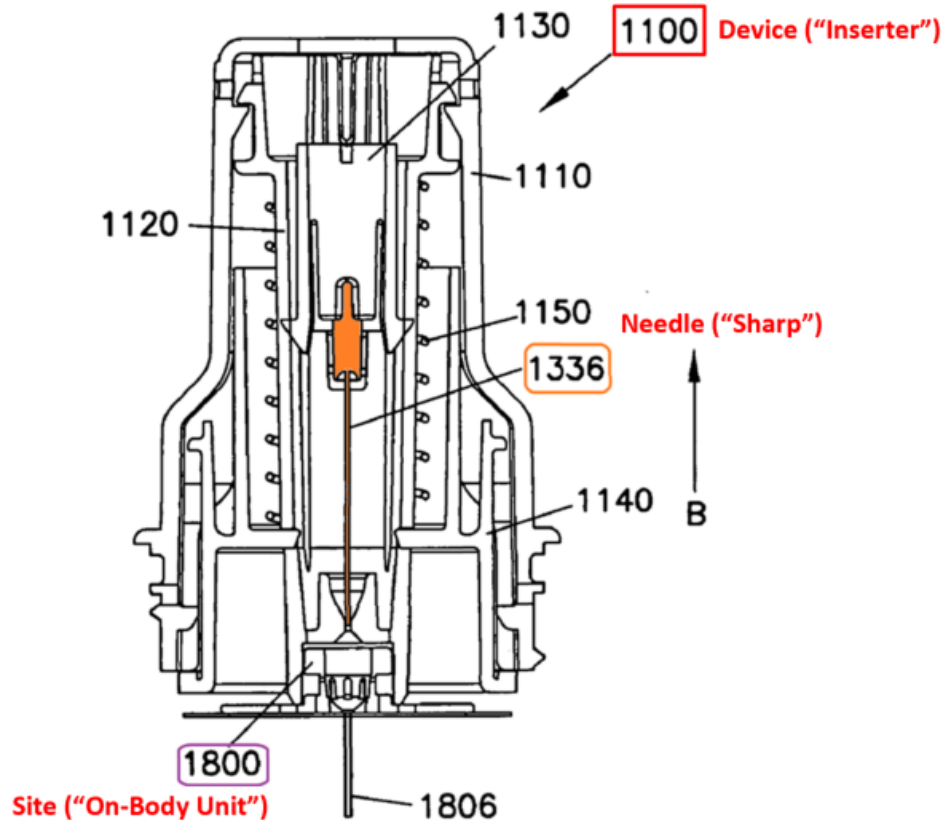
[1.13]/[19.17] wherein the distal end of the inserter is configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp,

100. Stafford+Cote includes a distal end of the inserter configured to be positioned on the skin of the user before advancement of the on-body unit and the sharp, as taught by Cote. EX1005, [0206]-[0207] ("[A]nd the sleeve 1140 of the device 1100 is positioned so that the adhesive portion 1160 (*i.e.*, surface 1668) contacts the skin 1900 of the patient. See FIGS. 77, 80A, and 80B. Next, in the

illustrated preferred embodiment, the patient applies pressure to the upper end 1111 of the housing 1110 to move the housing 1110 and associated structures including the cylinder hub 1120 and needle hub 1130 (including needle 1336 and site 1800) in a direction A with respect to the sleeve 1140 and toward the skin 1900 of the patient.”).

[1.14]/[19.18] wherein the inserter is further configured to automatically retract the sharp from within the user and entirely into the interior of the inserter and leave a part of the glucose sensor in the skin of the user, and

101. As the Stafford+Cote inserter is advanced in the linear direction, the needle hub becomes uncoupled from engagement with the cylinder hub, allowing the needle hub and sharp to be automatically retracted by a spring, while the cylinder hub and site remain down in an extended position, as taught by Cote. EX1005, [0211]. Specifically, the “spring 1150 ... propels the needle hub 1130 and associated needle 1336 in the direction B up through the cylinder hub 1120 into the upper end 1111 of the housing 1110, while the site 1800 and associated cannula 1806 are held on the skin 1900 of the patient, as shown in FIGS. 82A and 82B.” *Id.* After this automatic retraction of the sharp, the sharp is entirely within the interior of the inserter and a portion of the on-body unit’s sensor is left in the user’s skin. *Id.*, FIG. 82A (below), [0236] (“devices disclosed herein can *automatically retract the needle while leaving the site placed on the skin*, thereby reducing the patient’s contact with the exposed needle.”).



Cote, FIG. 82A (annotated)

102. In inserting Stafford+Cote’s on-body unit, then, a portion of the on-body unit’s sensor is left in the user’s skin when the needle retracts. By leaving a portion of the glucose sensor within the user’s skin, the Stafford+Cote insertion assembly allows the sensor to “maintain fluid contact with the patient’s analyte,” as taught in Stafford. EX1004, [0027] (“When the introducer is removed, . . . the portion of the analyte sensor 106 is retained in the subcutaneous position so as to maintain fluid contact with the patient’s analyte.”).

103. In addition to the adhesive holding the on-body unit to the skin during needle retraction, Cote teaches implementing the inserter to press the on-body unit

against the skin as the sharp is retracted. *See* EX1005, FIGS. 81A, 82A. Thus, in Stafford+Cote, the inserter maintains the on-body unit against the skin as the sharp is retracted. “In addition, the action of inserting the needle into position on the skin using the devices disclosed herein can function to hold the site on the surface of the skin during needle retraction. This can assist in adherence of the adhesive portion to the skin and reduce the chances of separation between the adhesive portion and site and the skin during needle retraction.” *Id.* [0237].

[1.15]/[19.19] wherein the distal end of the inserter is further configured to be removed from the skin of the user after automatic retraction of the sharp from within the user.

104. In the Stafford+Cote insertion assembly, the distal end of the inserter is configured to be removed from the skin of the user after automatic retraction of the sharp, as taught by Cote. EX1005, [0213] (“Finally, the sleeve 1140 is removed from contact with the skin 1900, and the cap 1170 can be replaced onto the threaded portion 1113 of the housing 1110 of the device 1100.”).

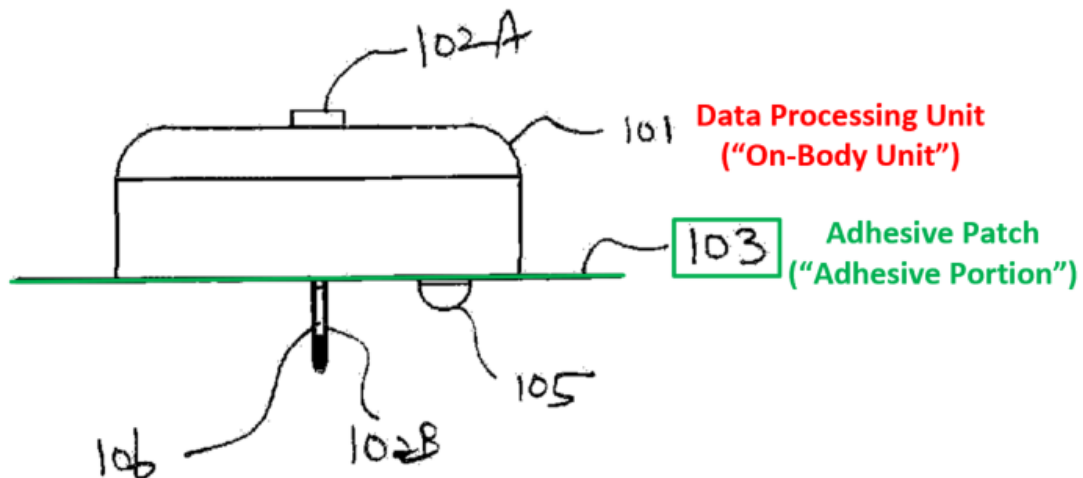
2. Claims 2/20

[2.1]/[20.1] The insertion assembly of claim [1/19], further comprising an adhesive portion configured to secure the housing to the skin of the user, wherein the adhesive portion is further configured to extend outwardly beyond the bottom surface of the housing along the skin in all directions when the housing is secured to the skin of the user.

105. The Stafford+Cote insertion assembly includes an adhesive portion extending outwardly beyond the bottom surface of the housing to secure the unit to

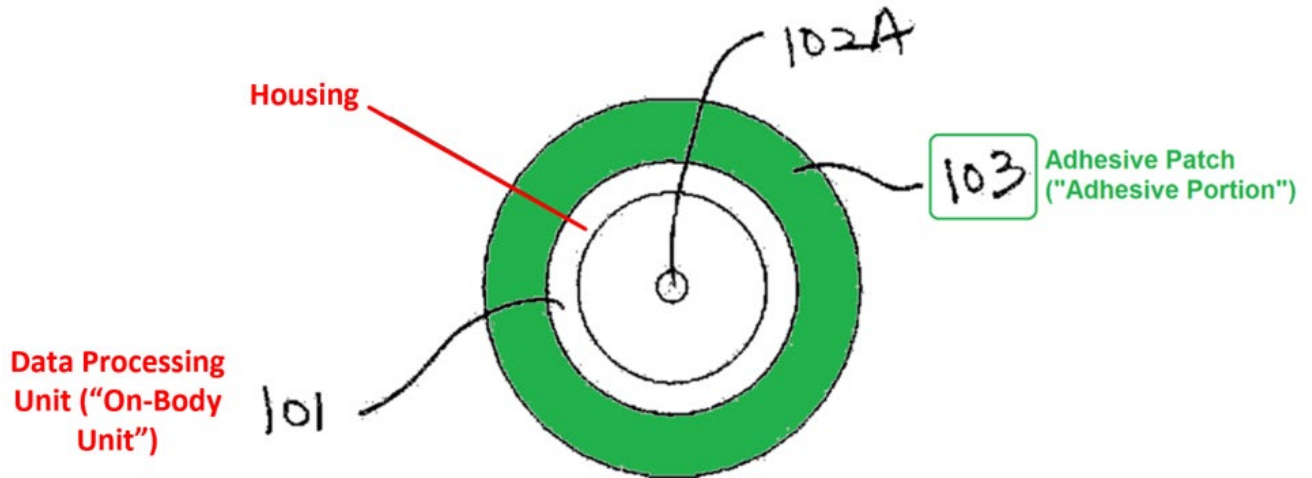
the user's skin, as taught by both Stafford and Cote. EX1004, [0019]; EX1005, [0195].

106. Both Stafford and Cote teach adhesive portions (“adhesive patch 103” and “adhesive portion 1160,” respectively) for securing the on-body unit to the user. EX1004, [0019] (“adhesive patch 103 in one embodiment is provided with an adhesive material ... on its bottom surface that is configured to securely attach the adhesive patch 103 and the data processing unit 101 on a surface of a subject such as the skin of a patient.”); EX1005, [0195] (“the adhesive portion 1160 includes adhesive on one or more of surfaces 1668 and 1669 to allow the adhesive portion 1160 to be coupled to the sleeve 1140, site, and/or to the skin of the patient.”). Stafford teaches that the adhesive portion and the on-body unit are coupled together prior to insertion of the on-body unit. EX1004, FIGS. 1-2, [0025].

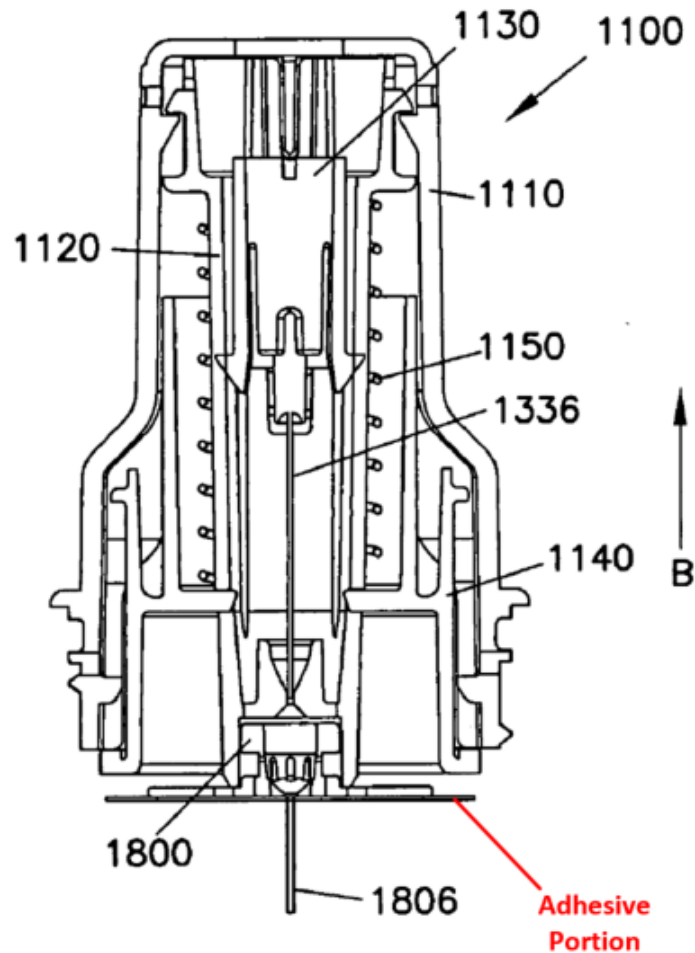


Stafford, FIG. 2 (annotated)

107. Both Stafford's and Cote's adhesive portions extend outwardly beyond the bottom surface of the housing of the on-body unit in all directions, at least when the housing is secured to the patient's skin. EX1004, FIG. 3B (below); EX1005, FIG. 82A (further below).



Stafford, FIG. 3B (annotated)



Cote, FIG. 82A (annotated)

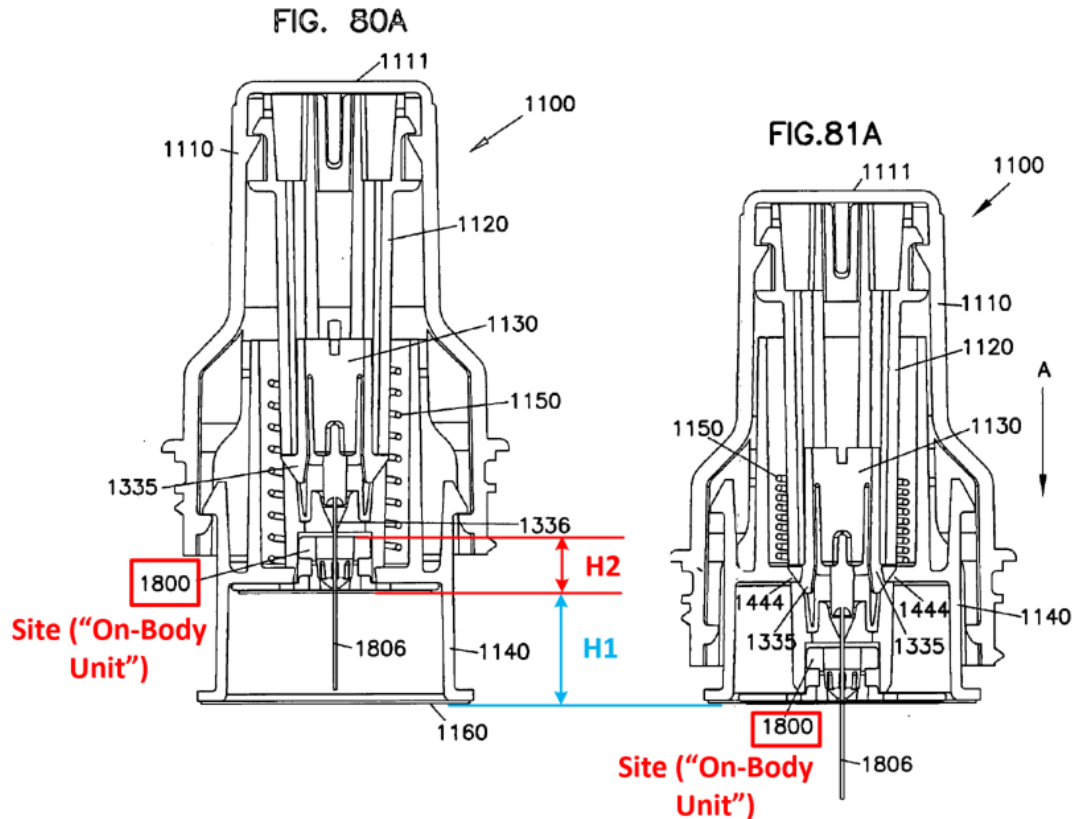
108. Cote teaches that the adhesive portion is coupled to the bottom surface of the on-body unit's housing during insertion. EX1005, [0209]. A POSITA using Cote to insert/apply the Stafford sensor device would have thus at least found it obvious to use an adhesive portion extending outwardly beyond the bottom surface of the on-body unit housing to secure the unit to the user's skin. EX1004, [0019]; EX1005, [0195].

3. Claims 3/19

[3.1]/[19.13] [The insertion assembly of claim 2,] wherein a distance between the housing when the on-body unit is in the first position and the housing when the on-body unit is in the second position is greater than a maximum height of the housing[.]/[.,]

109. Stafford+Cote includes an on-body unit in the first position when the inserter is in a delivery state (similar to, *e.g.*, Cote's inserter in FIGS. 77, 80A-80B) and in the second position when in a trigger state (similar to, *e.g.*, Cote's inserter in FIGS. 78, 81A-81B), as taught by Cote. EX1005, [0203].

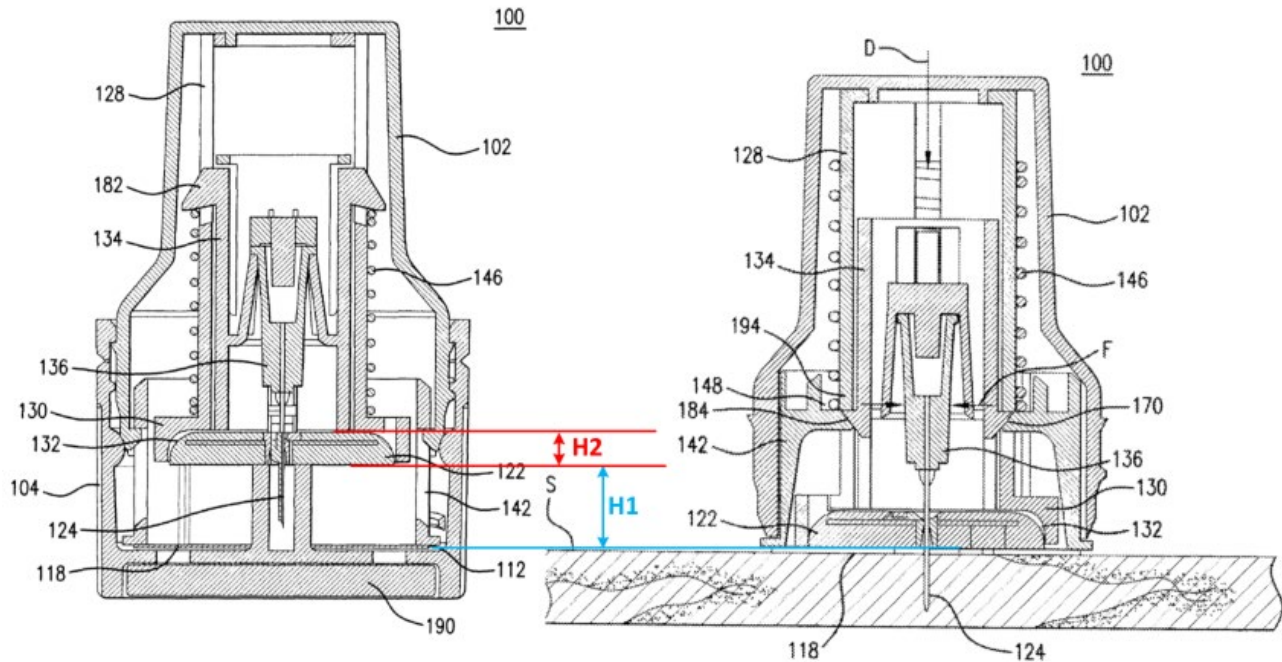
110. As shown below, Cote teaches that the distance ("H1," blue arrow) between an infusion device's site ("on-body unit") in the first position (FIG. 80A) and the second position (FIG. 81A) is greater than a maximum height ("H2," red arrow) of the site. *Id.*, FIGS. 80A, 81A. Since Cote's figures clearly illustrate the relationship between travel distance and housing height, Cote discloses this limitation. Based on Cote's teachings, a POSITA would have configured the travel distance of Stafford's on-body unit ("H1") to be greater than the height of the on-body unit's housing ("H2").



Cote, FIG. 80A (first position), FIG. 81A (second position)⁶ (annotated)

⁶ FIG. 80A (delivery state) is compared to FIG. 81A (trigger state, without “over-travel”). A POSITA would understand that while the on-body unit must travel beyond the distal end of Cote’s inserter to enable automatic retraction of the sharp (EX1005, [0209]-[0211]), Fig. 81C—which purports to show this trigger state with “over-travel” for the 1100 device—is incorrectly labeled. Rather, FIG. 81C illustrates over-travel for the 1100” device of FIGS. 85-91, which replaces sleeve 1140 with trigger 1140’. EX1005, [0215]. As such, A POSITA would recognize that “over-travel” would further increase the distance H1 shown above.

111. Cote's disclosure of the relative dimensions is at least equivalent to what is described in the '591 patent. *Compare*, Cote, FIGS. 80A, 81A (above) with EX1001, FIGS. 28, 30 (below).



'591 patent, FIGS. 28, 30 (annotated)

112. In particular, the specification of the '591 patent does not describe a distance between the housing when the on-body unit is in the first position and when the on-body unit is in the second position, let alone that this distance is greater than the height of the housing. Rather, such disclosure appears to come exclusively from its figures, *e.g.*, FIGS. 28 and 30, above.

113. Even without Cote's express teachings, it was an obvious design choice to configure Stafford+Cote such that the on-body unit's travel distance is greater than the height of the on-body unit. As discussed *infra*, *e.g.*, in Section VIII.C.12

addressing elements [14.1]/[19.14], a POSITA would find a low-profile on-body unit desirable, and both Stafford and Cote describe their on-body units as such. EX1005, [0228]; EX1004, [0045]. A POSITA additionally would have found it desirable for the needle to extend past a distal end of the sensor to protect the tip of the sensor during insertion.

114. Further, a POSITA understood that transcutaneous devices (*e.g.*, sensors or cannulas) routinely had an *in vivo* portion that was longer than the on-body portion was tall. *See e.g.*, EX1006, FIG. 1A, [0034]; EX1018, FIG. 3; EX1038, FIGS. 6-11; EX1021, 8:53-55, 16:3-5, 17:11-12. A POSITA would thus have found it at least an obvious design choice in Stafford+Cote to implement the sensor with an *in vivo* length longer than the on-body unit is tall.

115. Additionally, it was routine and desirable to position the sharp up within the inserter device (*i.e.*, well away from the distal end of the inserter) to avoid needle sticks. EX1005, [0235]. Further, such positioning allows the needle to accelerate prior to hitting the skin, which can be beneficial for patients with higher-than-average skin thickness and/or skin density. EX1042, [0004]. Thus, it would have been obvious to a POSITA to position the Stafford+Cote sharp some distance away from the distal end of the inserter, thus requiring some initial travel before the sharp contacts the user's skin, *e.g.*, to "shroud" the needle prior to insertion, as taught in Cote. EX1005, [0215].

116. This obvious implementation of the on-body electronics unit (with the length of the *in vivo* sensor portion greater than the height of the low-profile housing) and the inserter device (with the needle extending past the end of the sensor and the needle point withdrawn from the distal end of the inserter prior to insertion) results in a travel distance H_1 greater than the height of the housing H_2 . Such a configuration for inserter devices was well-known in the art. *See supra* Section VI.B.5. This is consistent with what is depicted in Cote's Figures 80A and 81A, namely, that the travel distance (H_1) is greater than the height of the housing (H_2).

117. Nothing in the '591 patent indicates that the relative dimensions are a critical aspect of the claimed invention. To the extent the claimed relative dimensions suggest a low-profile on-body unit and/or protection against the sharp, these features are known in the art and taught by Stafford and Cote.

118. Accordingly, the claimed height dimensions are not patentably distinct from the prior art. *see supra* Sections VI.B.4 and VI.B.5.

4. Claims 4/19

[4.1]/[19.6] [The insertion assembly of claim 3,] wherein the sensor electronics comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level[.]/[; and]

119. Stafford's sensor electronics ("components in the data processing unit 101") include a processor ("processor 704"), a power source ("power supply 707"), an analog interface ("analog interface 701"), and wireless communication circuitry ("RF transceiver 706") configured to communicate data indicative of a glucose level. EX1004, [0039]-[0040], [0052], FIG. 7.

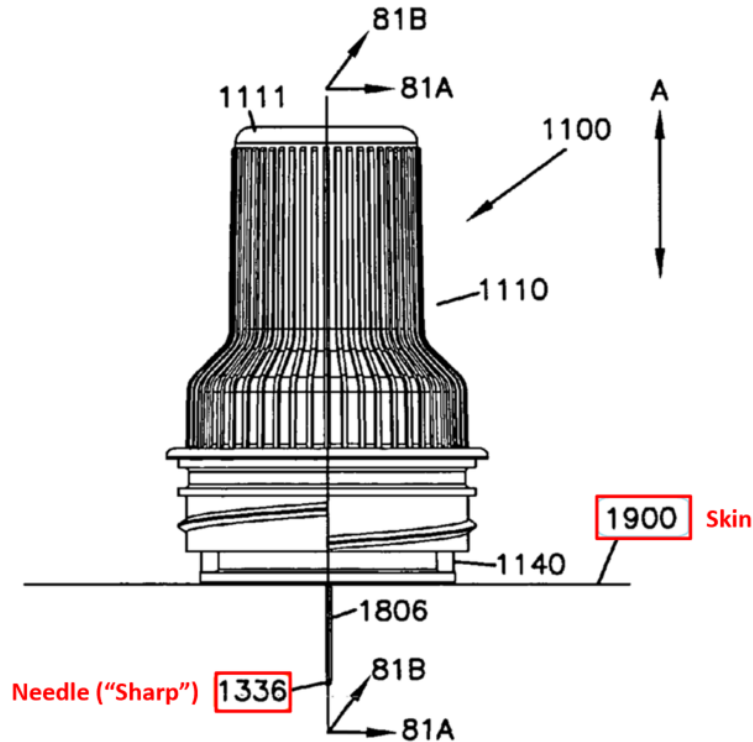
120. A POSITA also knew that a data storage unit would be required for the data processing unit to store incoming data, use for working data, and store output data. Stafford teaches that the data processing unit 101 can be configured to perform data processing such as filtering or encoding and can transmit the encoded data at one-minute intervals. EX1004, [0036]-[0037]. A POSITA would recognize this lag between when sensor data is measured and when processed/encoded data is transmitted requires that the data be stored in a data storage unit to allow for processing. *See e.g.*, EX1034, 509 (acknowledging the role of data storage in executing processing routines (such as encoding)). *See also*, EX1035, 23-25 (describing the use of stored data in an exemplary digital signal processing system).

121. Further, Stafford teaches that additional details on the data processing unit are disclosed in Say, which teaches that the on-skin sensor control unit electronics (“sensor electronics”) optionally include a data storage unit. EX1004, [0043]; EX1008, 44:54-45:7 (“The on-skin sensor control unit 44 may include an optional data storage unit 102 The data storage unit 102 typically includes a readable/writeable memory storage device”), 36:40-43 (“The on-skin sensor control unit 44 also typically includes at least a portion of the electronic components that operate the sensor 42”). Thus, use of a data storage unit would have at least been an obvious design choice for a POSITA implementing the Stafford+Cote inserter.

5. Claims 5/19

[5.1]/[19.15] [The insertion assembly of claim 3,] wherein the sharp is configured to pierce the skin of the user at an angle substantially perpendicular to the skin of the user[.]/[.]

122. Stafford+Cote’s Cote-like inserter is configured to advance the Stafford sharp in the linear direction A perpendicular to the skin of the user, as taught by Cote. EX1005, FIG. 78 (below). As such, the Cote-like inserter advances the sharp such that it pierces the skin at a substantially perpendicular angle.



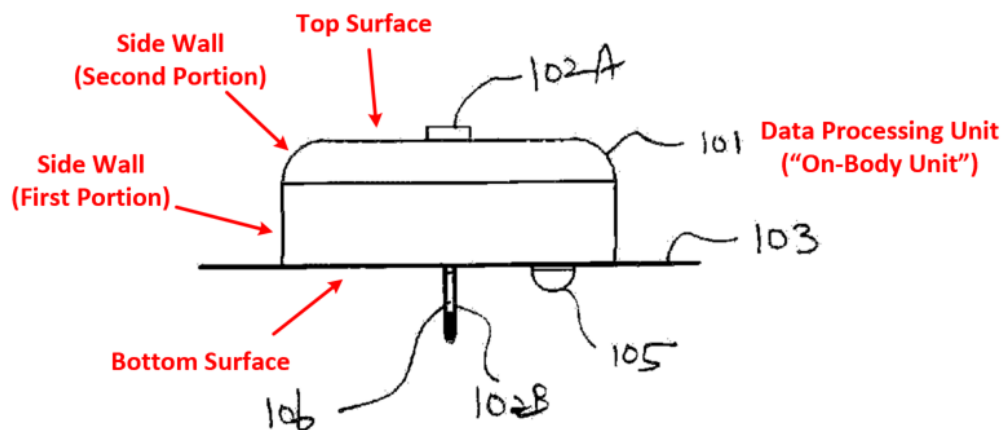
Cote, FIG. 78 (annotated)

123. Similarly, Stafford's sharp is introduced in a perpendicular orientation. EX1004, FIGS. 2, 4A, [0026]. Thus, in combination, it would be obvious to introduce Stafford's on-body unit using the Cote-like inserter by inserting Stafford's sharp into the skin of the patient in a perpendicular orientation.

6. Claims 6/27

[6.1]/[27.1] The insertion assembly of claim [3/23], wherein the on-body unit further comprises a side wall of the housing, wherein the side wall is located between the top surface and the bottom surface, wherein the side wall comprises a first portion and a second portion, and wherein the second portion of the side wall defines a non-orthogonal angle relative to both the first portion of the side wall and the top surface of the housing.

124. The housing of Stafford's on-body unit includes a side wall located between top and bottom surfaces of the housing. EX1004, FIG. 2. As shown below, a second portion of the side wall defines a non-orthogonal angle (*i.e.*, an angle other than a right angle) relative to both a first portion of the side wall and the top surface of the housing.



Stafford, FIG. 2 (annotated)

125. Orthogonal surfaces contact one another at a right angle (*i.e.*, a 90 degree angle). Non-orthogonal surfaces contact one another at a non-90 degree angle. As shown in Stafford's FIG. 2, the second portion of the side wall contacts both the top surface and the first portion of the side wall at non-90 degree angles,

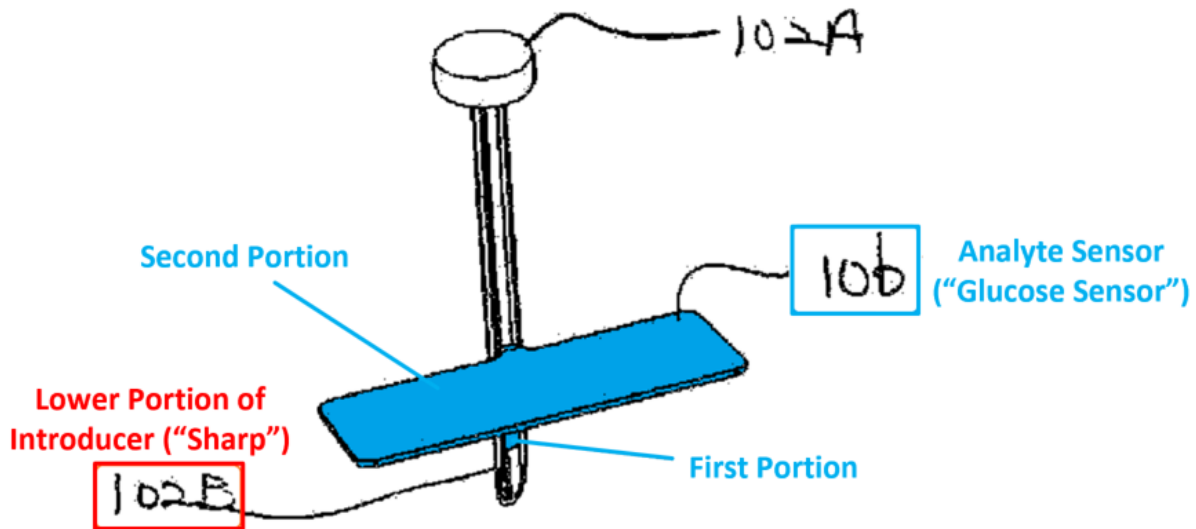
and thus defines a non-orthogonal angle relative to both the first portion of the side wall and the top surface of the housing.

7. Claims 9/22

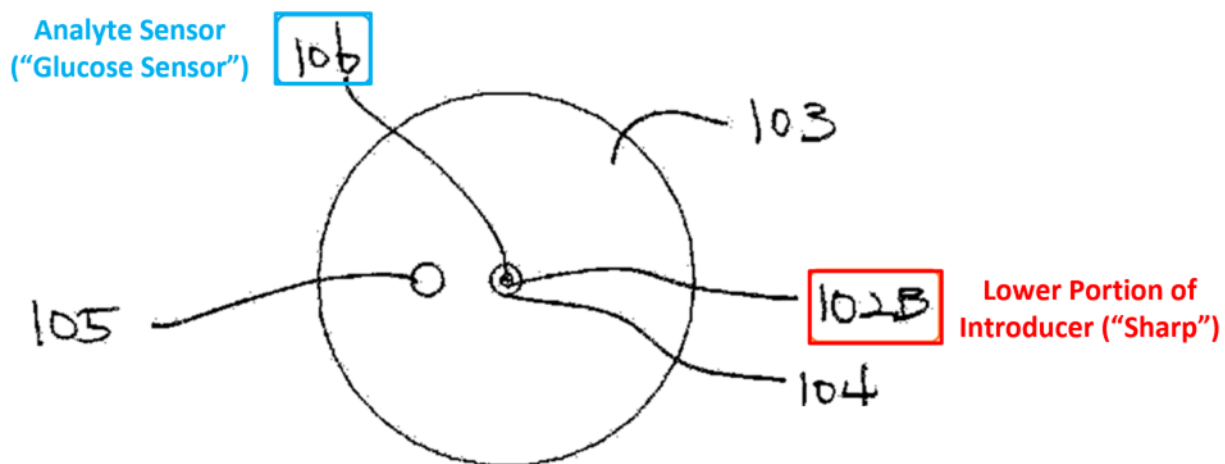
[9.1]/[22.1] The insertion assembly of claim [3/21], wherein the sensor electronics further comprise an opening of the sensor electronics along the longitudinal axis, and wherein the sharp extends through the opening of the sensor electronics when the on-body unit is in the first position.

126. Stafford+Cote includes sensor electronics provided by Stafford's data processing unit, which comprises sensor electronics (components of "data processing unit 101"). *See* Section [1.5]/[19.5].

127. Stafford's sensor has a first or lower portion that is "disposed within the lower portion 102B of the introducer" and a second or upper portion that is "disposed within the housing and in electrical communication with the data processing unit." EX1004, [0028], [0006]. To make electrical contact, a POSITA would understand that the upper portion of the sensor physically contacts the sensor electronics, and that adjacent to this area of physical contact, the sharp holds the lower portion of the sensor. *Id.*, [0028].



Stafford, FIG. 5C (annotated)



Stafford, FIG. 3C (showing skin-side of on-body unit, annotated)

128. A POSITA would understand that while the upper portion of the sensor contacts the sensor electronics (*e.g.*, a circuit board), the adjacent lower portion of the sensor, contained within the sharp, extends out of the on-body unit to contact the subject. It was well-known in the art at the time to include an opening in the sensor electronics to allow a sharp including a portion of an analyte sensor to pass through,

allowing the sensor to contact both the electronics and the subject. *See e.g.*, EX1006, FIG. 6.

129. To achieve the benefit of minimal size, and avoid any wasted space, the POSITA would have implemented the on-body unit such that the housing was no larger than the electronics; in other words, the electronics would occupy the entirety of the cavity within the housing. Such a configuration was known in the art, for example as shown in Shah. EX1006, FIG. 6. And as in Shah, the electronics would include a hole through the middle aligned with the hole in the housing, such that the Stafford-like u-shaped needle passed through the on-body unit to partially surround the in-vivo portion of the sensor.

130. To the extent there was any other way to implement the electronics, an implementation as in Shah was at the very least the most obvious design choice as it minimized the amount of space needed for the housing by leaving no wasted space within that housing. This obvious design choice allowed the upper portion of the sensor to contact the sensor electronics while allowing the needle to pass through the on-body unit and into the subject, thus facilitating insertion. The sensor must contact the sensor electronics to function, which is easily accomplished if the sensor extends through an opening in the sensor electronics board. An alternate design choice is for the sensor to contact the sensor electronics along an outer edge of the sensor electronics board. A POSITA would understand that having an opening

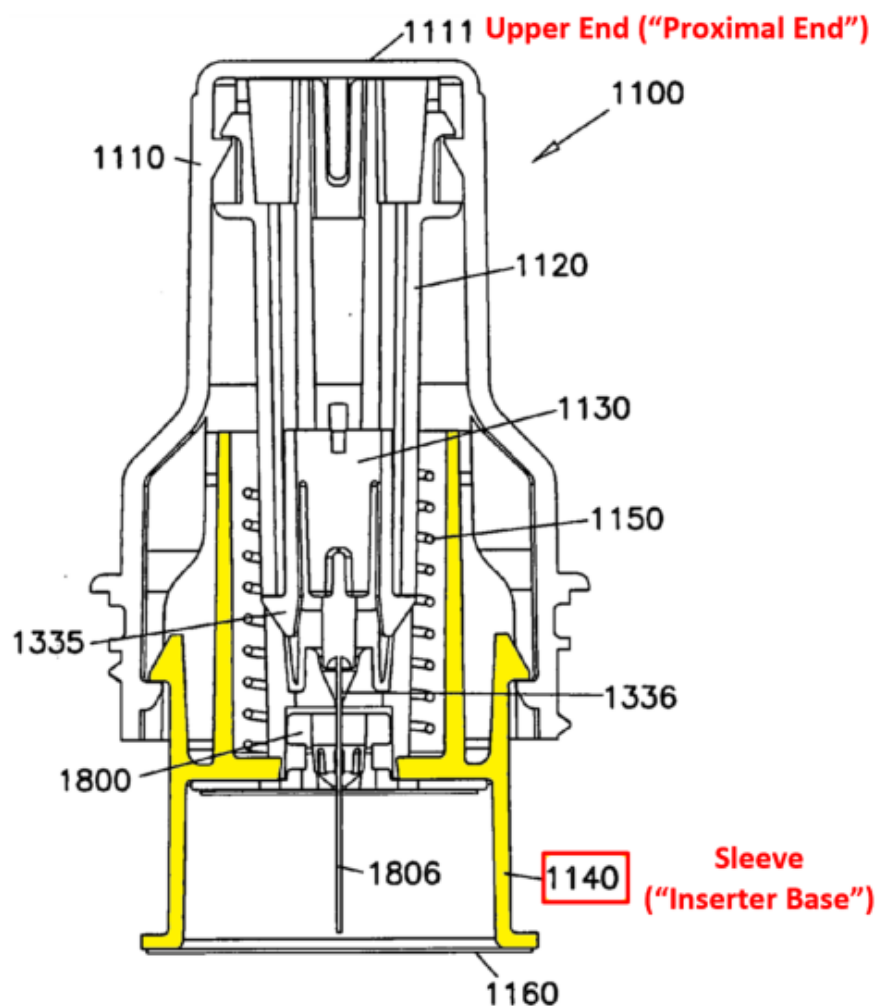
through the sensor electronics where the sensor contacts the sensor electronics, rather than making contact along an outer edge of the sensor electronics board, reduces effects of any sensor insertion forces on the sensor electronics board (e.g., reducing the chance of bending or damaging the electronics board).

131. Thus, a POSITA would have found it obvious to implement Stafford+Cote with an opening in the sensor electronics along the longitudinal axis, through which the sharp extends when the on-body unit is in the first position.

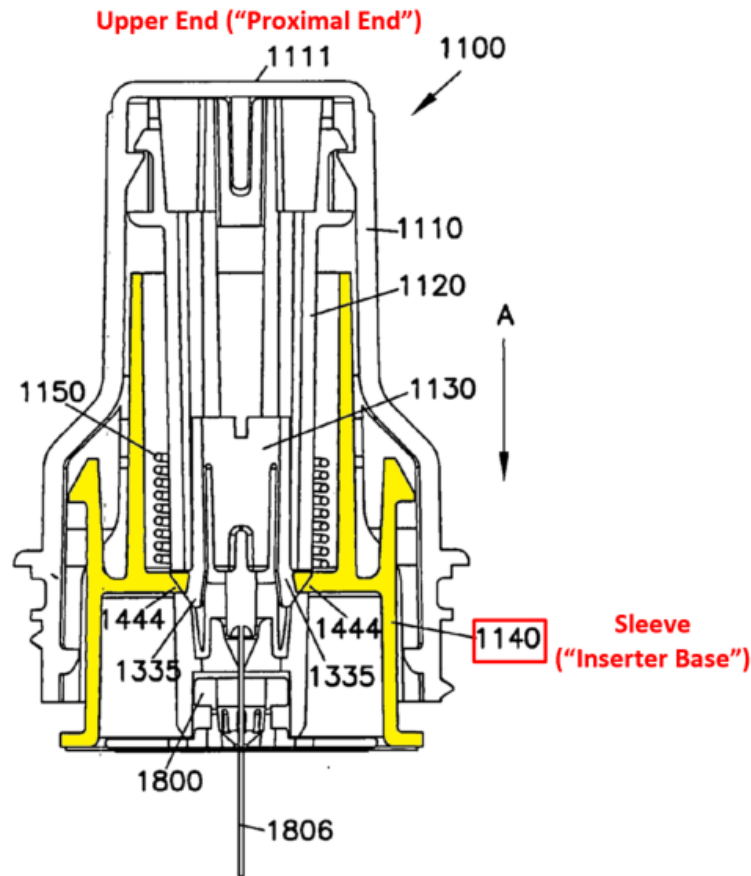
8. Claims 10/24

[10.1]/[24.1] The insertion assembly of claim [3/23], wherein the inserter further comprises an inserter base, and wherein the proximal end of the inserter is configured to move in a downward direction toward the skin of the user relative to the inserter base in response to an application of force on the proximal end of the inserter[.]/[, and]

132. Stafford+Cote's inserter includes an inserter base, such as taught in Cote. As further illustrated below, Cote's inserter includes an inserter base ("sleeve 1140"). The proximal end of Cote's inserter ("upper end 1111") is configured to move in a downward direction ("direction A") relative to the inserter base (towards the skin of the user) in response to an application of force to the proximal end of the inserter. EX1005, [0207] ("the patient applies pressure to the upper end 1111 of the housing 1110 to move the housing 1110 and associated structures ... in a direction A with respect to the sleeve 1140 and toward the skin 1900 of the patient."). *See* EX1005, FIGS. 80A and 81A, below.



Cote, FIG. 80A (annotated)

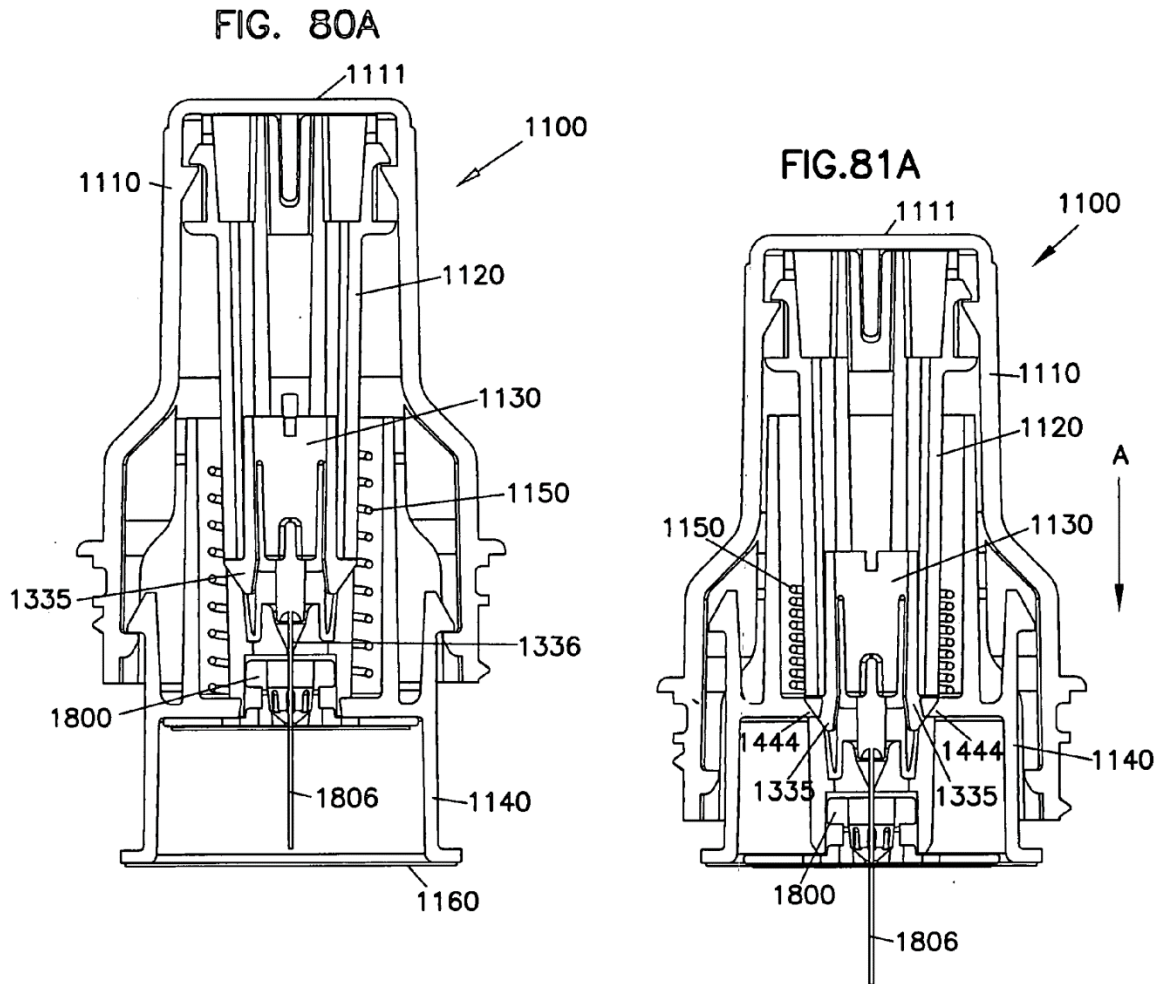


Cote, FIG. 81A (annotated)

9. Claims 11/24

[11.1]/[24.2] [The insertion assembly of claim 10,] wherein the inserter is configured to advance the on-body unit and the sharp from the first position to the second position after the application of force on the proximal end of the inserter.

133. Stafford+Cote includes an inserter that advances the on-body unit and the sharp from the first position to the second position after the application of force on the proximal end of the inserter, as taught by Cote. EX1005, [0207], FIGS. 80A (first position)-81A (second position).



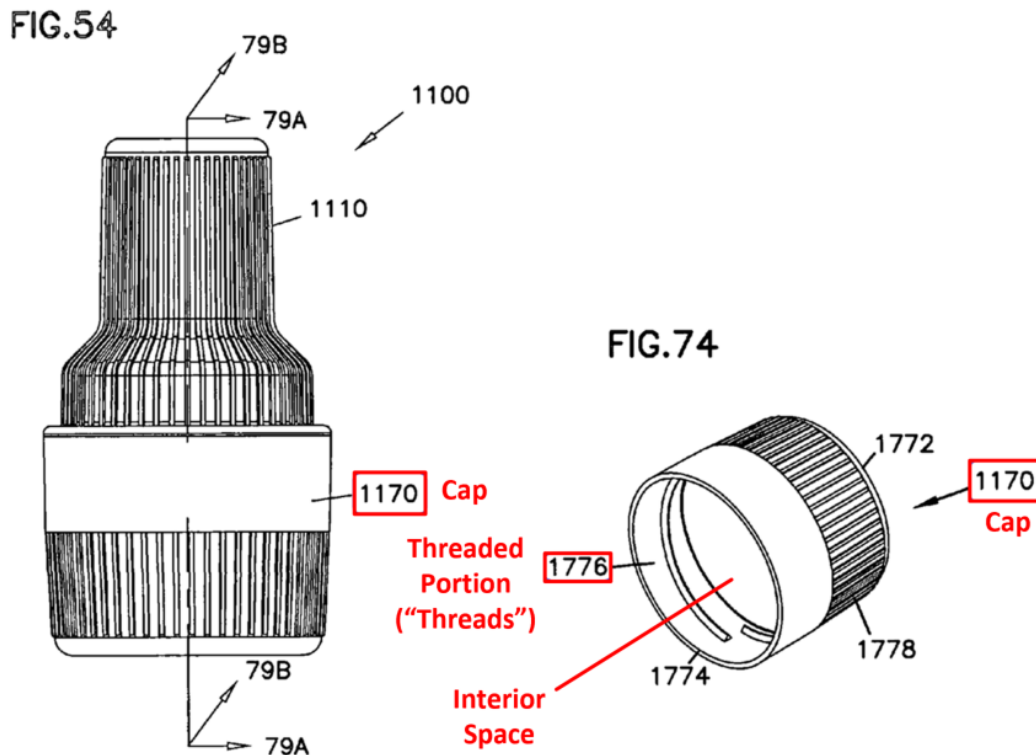
Cote, FIG. 80A (first position), FIG. 81A (second position)

10. Claims 12/29

[12.1]/[29.1] The insertion assembly of claim [3/23], further comprising a cap removably attached to a distal portion of the inserter by a plurality of threads, and wherein the cap comprises an interior space comprising a sterile environment.

134. Stafford+Cote's inserter includes a cap removably attached to a distal portion of the inserter by a plurality of threads, similar to cap 1170 taught in Cote which includes a threaded portion 1776 for attaching to a distal portion of the

inserter. EX1005, [0197] (“[T]he interior of the cap 1170 includes a threaded portion 1776 positioned adjacent the open second end 1774 so that the threaded portion 1776 can be threaded onto the threaded portion 1113 of the housing 1110 to seal the device 1100.”); FIGS. 54, 57, 74. Cote teaches that the cap maintains the internal components in a “substantially sterile state”. *Id.*, [0198] (“In this manner, the internal components of the device 1100 (e.g., needle 1336 and site 1800) can be maintained in a substantially sterile state prior to removal of the cap 1170.”). A POSITA would thus understand that in the Stafford+Cote inserter, the cap comprises an interior space comprising a sterile environment.

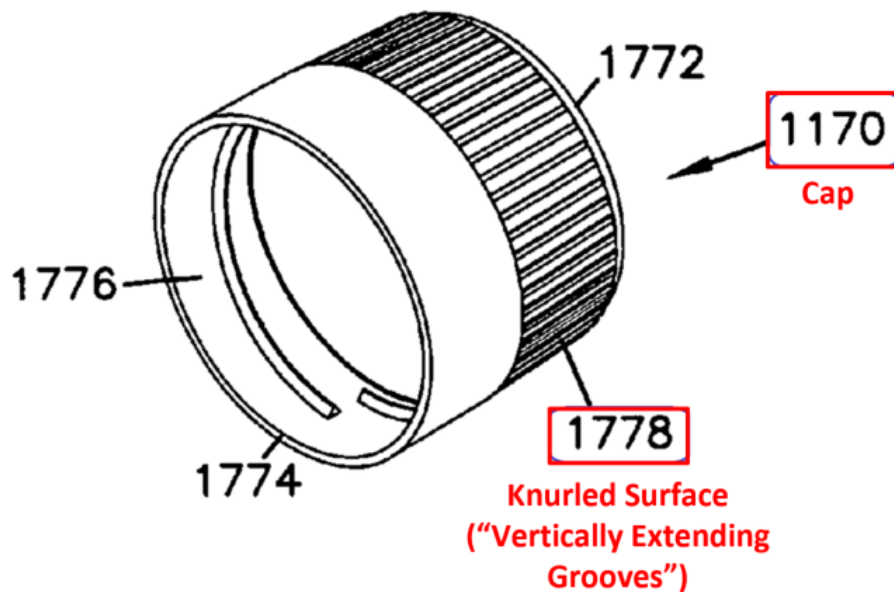


Cote, FIGS. 54, 74 (annotated)

11. Claims 13/30

[13.1]/[30.1] The insertion assembly of claim [12/29], wherein the cap further comprises a plurality of vertically extending grooves spaced apart around an outer perimeter surface of the cap.

135. Stafford+Cote's inserter's cap includes a plurality of vertically extending grooves spaced apart around an outer perimeter surface of the cap, as taught by Cote ("knurled surface 1778"). EX1005, [0197] ("The cap 1170 preferably includes an exterior with a knurled surface 1778 to enhance the patient's grip on the cap 1170."); FIG. 74.



Cote, FIG. 74 (annotated)

12. Claims 14/19

[14.1]/[19.14] [The insertion assembly of claim 3,] wherein a height profile of the housing is less than or equal to approximately 10 millimeters[.]/[.,]

136. A POSITA would have found it obvious to configure the Stafford+Cote on-body unit housing to have a height profile of 10 mm or less. Stafford and Cote both teach that the housing for the on-body unit has a low height profile. *See, e.g.*, EX1005, [0228] (site “preferably configured to have a low profile to be unobtrusive to the patient.”); EX1004, [0045] (describing “smaller profile” as a benefit). Additionally, it was well-known in the art for such low height profile housings to be approximately 10 mm or less. *See* Section VI.B.4.

137. The ’591 patent does not describe the claimed height as affecting the performance of the device in any way, but merely states that the data processing unit has a reduced height to “provide a low-profile when sitting on the skin of the subject.” EX1001, 14:4-5.

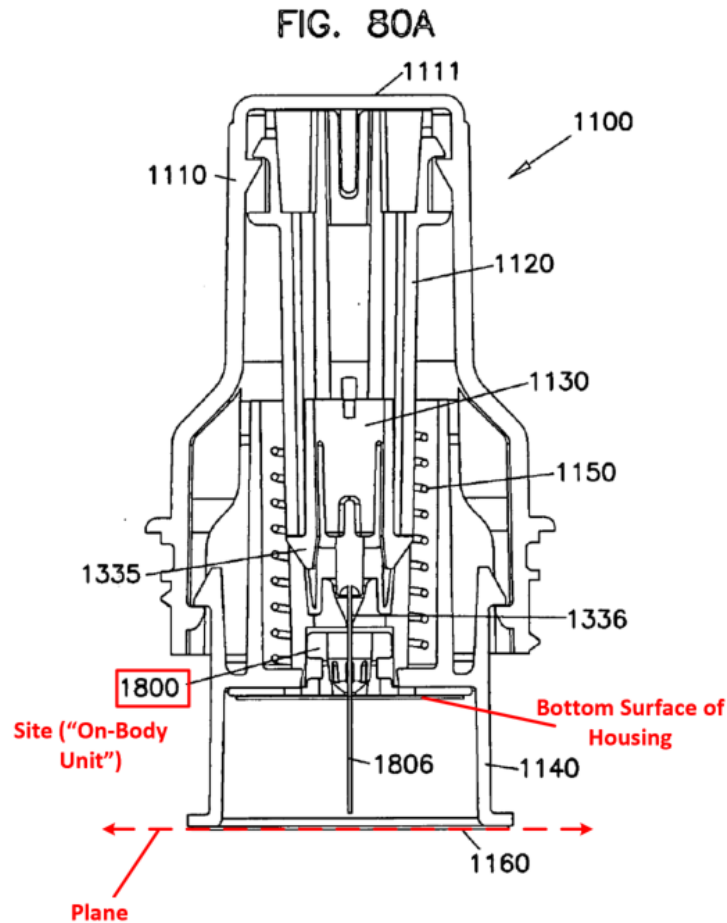
138. Even assuming a “low-profile” affects performance of the device, the height profile of the housing is not a critical aspect of the claimed invention, as providing a “low-profile” is well-known in the art. *See, e.g.*, EX1005, [0228]; EX1004, [0045]; Section VI.B.4.

13. Claims 16/23

[16.1]/[23.1] The insertion assembly of claim [3/22], wherein the distal end of the inserter defines a plane, and wherein the bottom surface of the housing is parallel to the plane when the on-body unit is in the first position.

139. In the Stafford+Cote combined system, a POSITA would position Stafford's on-body unit within the inserter such that the bottom surface of Stafford's housing is parallel to a plane defined by the distal end of the inserter, as taught in Cote (EX1005, *e.g.*, FIG. 80A) and would have a reasonable expectation of success in doing so.

140. Cote teaches that the distal end of the inserter defines a plane and that the bottom surface of the housing of the on-body unit is parallel to the plane when the on-body unit is in the first position. EX1005, FIG. 80A.



Cote, FIG. 80A (first position, annotated)

141. The specification of the '591 patent does not describe the bottom surface of the housing being parallel to a plane defined by the distal end of the inserter, such disclosure appears to come exclusively from its figures, *e.g.*, FIGS. 28 and 30, which provides nothing more than from Cote's disclosure of this feature.

14. Claim 17

[17.1] The insertion assembly of claim 3, wherein the on-body unit is configured to be disposed after a single use.

142. Stafford teaches that the on-body unit is disposable. EX1004, [0044] (“a single disposable assembly”). Cote also teaches disposable devices. EX1005, [0238] (“The configuration and disposable nature of the devices further allow ease in discarding of the devices after use.”), [0241] (“single use devices”).

143. Thus, Stafford+Cote teaches an on-body unit configured to be disposed after a single use to “allow ease in discarding of the device[] after use,” as taught in Cote. *Id.*, [0238].

15. Claims 18/21

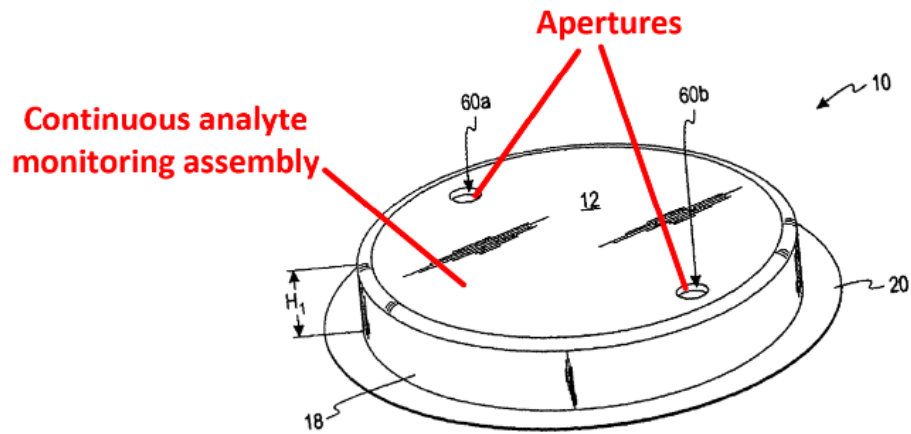
[18.1]/[21.1] The insertion assembly of claim [2/20], wherein the opening of the top surface is a first opening of the top surface, wherein the top surface further comprises a second opening of the top surface,

144. As described above, Stafford teaches an on-body unit with an opening in the top surface of the housing. EX1004, [0020], [0027] (“the housing of the transmitter unit 101 is provided with a self-sealing aperture (not shown) through which the introducer may be removed.”). In Stafford+Cote, a POSITA would understand that the sensor assembly as taught by Stafford should remain fixed relative to the insertion device to maintain the position of the on-body unit relative to the inserter and prevent unintended movement and potential damage during

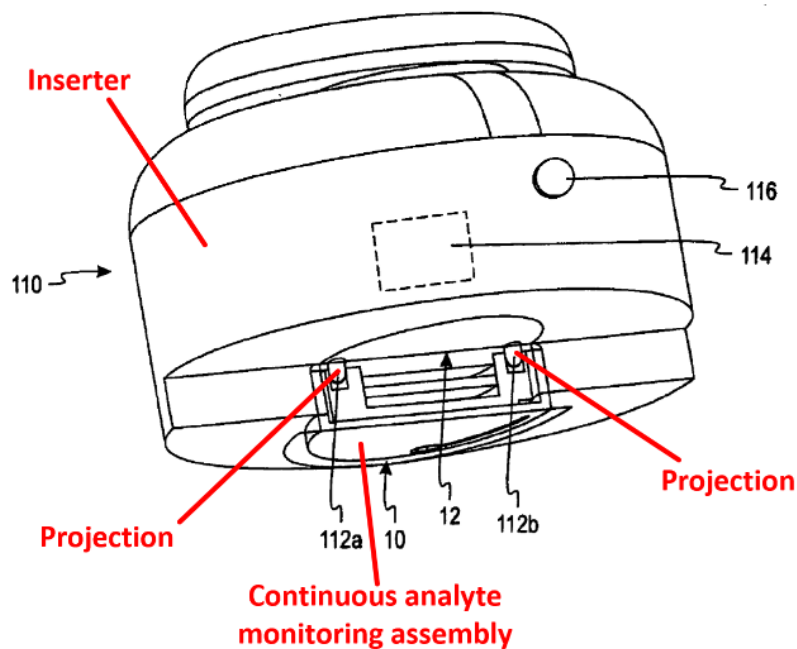
shipment or use. The POSITA also knew how to add peripheral apertures to the outer edges of the top surface of Stafford's housing to interface with corresponding protrusions on the insertion device for the aforementioned purposes.

145. The utility and desirability of adding apertures to the outer periphery of an on-body unit is reflected in, for example, Brenneman⁷ EX1040, FIGS. 1, 8, [0042] (which teach projections/pins 112 that interface with apertures 60 in the outer periphery of the top surface 12 of the continuous analyte monitoring assembly 10 to “form a snug fit therein to couple the continuous analyte monitoring assembly 10 and the inserter 110”). Positioning the apertures on a periphery of the top surface desirably secures the outer edges of the on-body unit within the inserter, e.g., the “snug fit” aids in maintaining the on-body unit within the housing prior to insertion. The POSITA would also recognize that this helps maintain alignment and reduces tipping/tilting of the on-body unit within the inserter.

⁷For purposes of Ground 1, Brenneman and Turner are relied on as background references that reflect the state of the art and knowledge of the POSITA.



Brenneman, FIG. 1 (annotated)

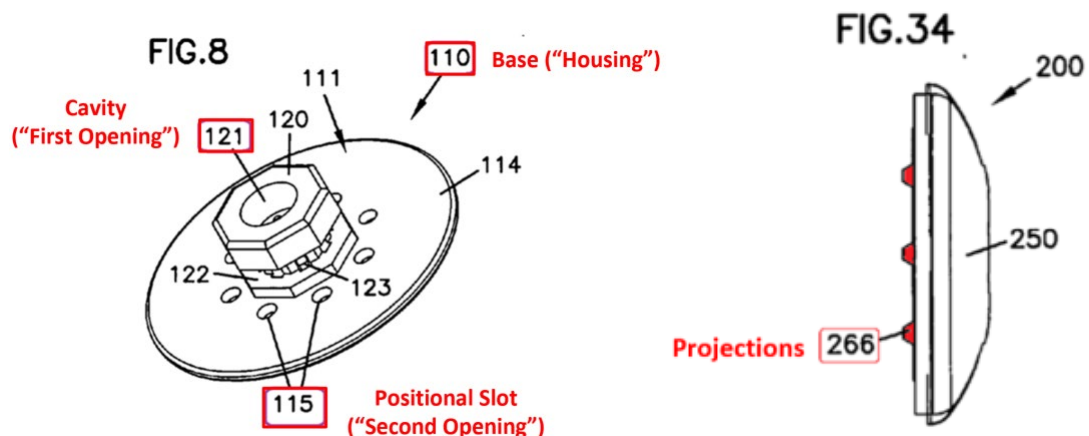


Brenneman, FIG. 8 (annotated)

146. The POSITA would recognize the further benefit of the peripheral apertures taught by Brenneman, as those peripheral apertures and associated pins would also assist in avoiding rotation of the on-body unit. The desire to avoid

rotation is reflected in, e.g., Turner, which teaches recesses and associated protrusions to avoid rotation. EX1007, [0068]-[0069], FIG. 3, (protrusions 71 on the insertion device interface with complementary recesses 77 “to prevent rotation of the insertion device relative to body 20 [of the on-body unit].”).

147. Accordingly, a POSITA would have been motivated to add peripheral apertures to the top surface of Stafford+Cote’s on-body unit to better couple the on-body unit to the inserter in a desired position and retain it there, as taught by Brenneman and Turner. The POSITA would have reasonably expected success in adding such peripheral apertures as evidenced by the fact that both Brenneman and Turner did so, and further as confirmed by Cote itself which teaches use of similar concepts for a slightly different purpose, namely openings (“positional slots” 115 on the base 110) that interface with corresponding projections 266 to maintain alignment between the different portions of the infusion device. EX1005, [0135], [0137], [0168], FIGS. 8 and 34 (below).



Cote, FIGS. 8, 34 (annotated)



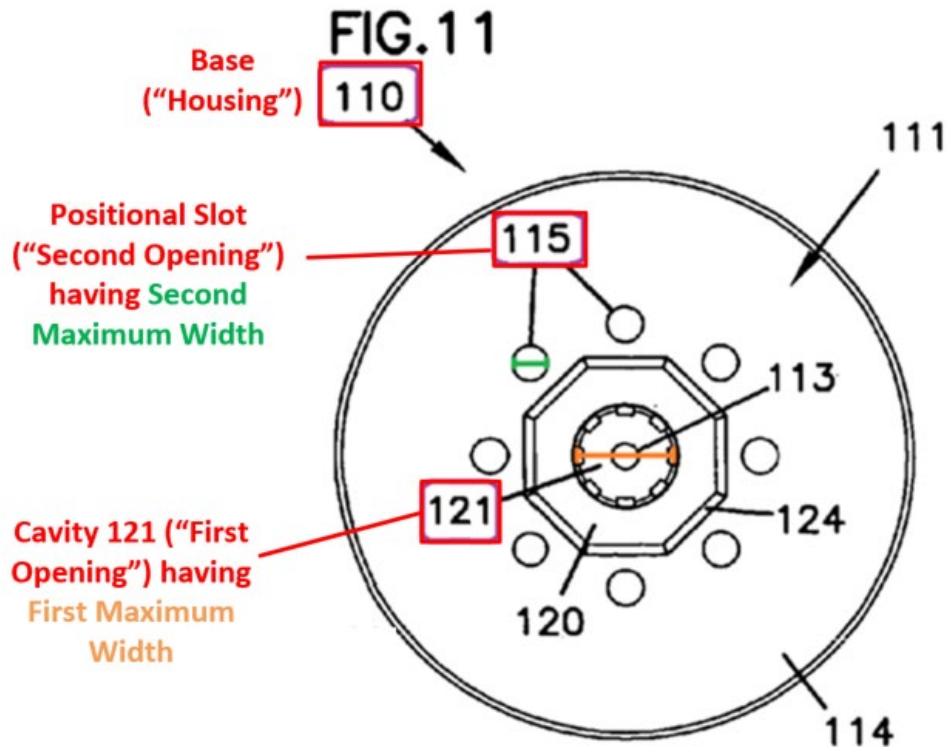
149. Thus, a POSITA would be motivated, with a reasonable expectation of success, to add at least one peripheral aperture (“second opening”) to the top surface

of the Stafford+Cote on-body unit to maintain the position of the on-body unit relative to the inserter.

[18.2]/[21.2] wherein the first opening of the top surface has a first maximum width, and wherein the second opening of the top surface has a second maximum width less than the first maximum width.

150. As discussed *supra* in Section [18.1/21.1], in Stafford+Cote, Stafford's on-body unit includes Stafford's self-sealing aperture ("first opening") and peripheral apertures ("second openings") on the top surface of the housing, as taught by, e.g., Brennaman. A POSITA would have found it obvious to configure the peripheral apertures with a smaller maximum width than Stafford's aperture ("first opening") (EX1004, [0027], FIG. 2). Such a configuration is an obvious design choice and one of a finite number of solutions for adding aperture(s) to the top surface. Further, this simple design choice is explicitly shown in Cote. EX1005, FIGS. 8, 11.

151. Cote teaches a first opening ("cavity 121") having a first maximum width and a second opening ("positional slots 115") having a second maximum width less than the first maximum width. *Id.*, FIG. 11, [0135], [0137].



Cote, FIG. 11 (annotated)

152. Furthermore, the '591 patent does not describe the claimed relative widths affecting the performance of the device in any way, but merely depicts the housing 122 with circles of smaller size than its central opening on its top surface. EX1001, FIG. 23 (below).

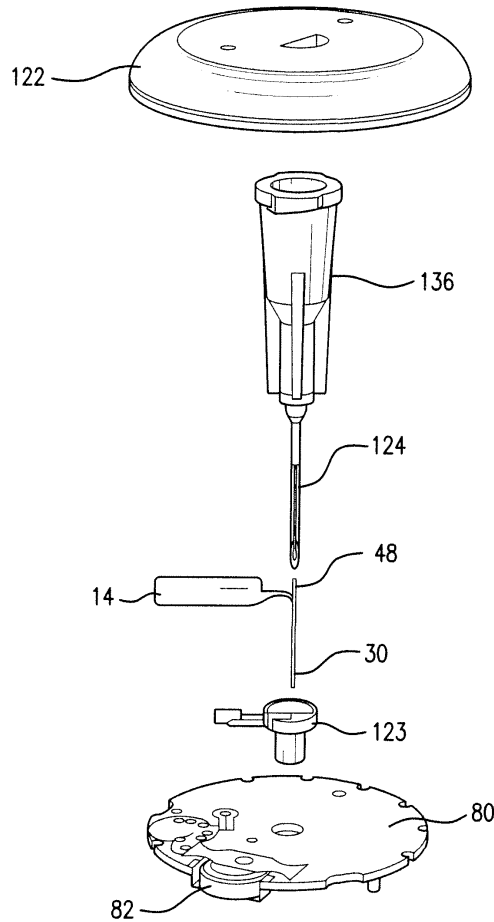


FIG. 23

'591 patent, FIG. 23

16. Claim 19, 20-24, 27, 29-30

153. Claim 19 is similar to claim 1, except that it adds limitations similar to those in claims 3-5, and 14, which are also taught or suggested by Stafford+Cote, as described in Sections VIII.C.1, VIII.C.3- VIII.C.5, and VIII.C.12, above.

154. Each of claims 20-24, 27, 29-30 depends from claim 19, and recites elements taught or suggested by Stafford+Cote. *See* Sections VIII.C.2, VIII.C.6- VIII.C.11, VIII.C.13, and VIII.C.15.

155. To the extent Patent Owner argues certain claims are not obvious over Stafford+Cote, these claims are also obvious over Stafford+Cote, further in view of Say, Brenneman, and/or Shah, as set forth below.

IX. GROUND 2: STAFFORD+COTE+SAY (CLAIMS 4, 7-8, 14-15, 19-30)

156. Dependent claims 4, 7-8, 14-15, 19, 25-26, and 28 each recite elements that, to the extent Patent Owner argues are not obvious over Stafford+Cote alone, are further obvious over Say. Claims 20-21, 23-30 depend directly or indirectly from claim 19 and are also obvious over Stafford+Cote in view of Say.

A. Say

157. U.S. Patent No. 6,175,752 (EX1008, “Say”) issued January 16, 2001.

158. Say describes a glucose monitoring system including a sensor control unit (functionally similar to Stafford’s data processing unit) that can include a memory. EX1008, 5:25-28, 44:54-45:7 (“The on-skin sensor control unit 44 may include an optional data storage unit 102 The data storage unit 102 typically includes a readable/writeable memory storage device”).

159. Say also describes that the sensor control unit’s sensor electronics can enter a “sleep mode” prior to use to conserve battery power. *Id.*, 31:41-62 (“The on-skin sensor control unit 44 optionally remains in a sleep mode prior to use to conserve the battery’s power”).

160. Say further describes its sensor control unit as being “thin” to “enhance concealment” and specifically teaches that the on-body unit “has a height of ... preferably 0.7 cm [7 mm] or less.” *Id.*, 29:38, 29:45-47.

161. Say further teaches that a support can be disposed within a housing of the sensor control unit to promote adequate contact between an analyte sensor and electrical contacts of the sensor electronics. *Id.*, 34:53-35:5.

B. Combining The Teachings Of Stafford+Cote+Say

162. Say (disclosing a transcutaneous medical device for diabetes treatments) is analogous art to the claimed invention of the '591 patent and is further analogous art to Stafford and Cote.

163. Stafford expressly discloses that additional details of its data processing unit are disclosed in Say. EX1004, [0043]. Thus, a POSITA implementing Stafford+Cote would have been motivated to consult Say and incorporate its beneficial teachings on (1) memory for storing instructions or sensor data, (2) promoting adequate contact between a sensor and associated sensor electronics, and (3) conserving battery power. A POSITA reading Say would, with a reasonable expectation of success, be motivated to add Say's memory, support, and sleep mode functionality to Stafford's data processing unit to further improve Stafford's data processing unit.

1. Claims 7/25

[7.1]/[25.1] The insertion assembly of claim [3/23], wherein the sensor electronics are in a sleep mode or an idle mode when the on-body unit is in the first position.

164. Say teaches that on-skin sensor control units (“on-body units”) optionally remain in sleep mode prior to use. EX1008, 31:45-47 (“The on-skin sensor control unit 44 optionally remains in a sleep mode prior to use to conserve the battery’s power.”). A POSITA would understand that “prior to use” of Stafford’s on-body unit (i.e., prior to insertion of the sensor), Stafford’s on-body unit is in the first position within the inserter.

165. Accordingly, in Stafford+Cote+Say, Stafford’s sensor electronics are in a sleep mode while Stafford’s on-body unit is in the first position within the inserter. It would have been obvious to a POSITA to make such a modification to “conserve the battery’s power,” as taught in Say (EX1008, 31:45-47).

2. Claims 8/26

[8.1]/[26.1] The insertion assembly of claim [3/23], wherein the sensor electronics are configured to be activated when the on-body unit is at or near the second position.

166. While the ’591 patent does not provide a specific definition of the term “activated,” the specification uses the term “activating” synonymously with “switching on”: “thereby closing the circuit to/from the battery/power source and thus *activating or switching on* the sensor electronics.” EX1001, 22:9-10.

Accordingly, a POSITA would understand that the claim limitation is met if the sensor electronics are switched on when the on-body unit is at or near the second position.

167. In Stafford+Cote, Stafford's on-body unit is in a "second position" when Stafford's on-body unit is secured to the skin of a user and Stafford's sharp pierces the user's skin. *See* Section [1.12]/[19.12].

168. Stafford teaches that "the data processing unit 101 may be configured to transmit the encoded sampled data signals ... *after the completion of the initial power on procedure.*" EX1004, [0037]. A POSITA would therefore understand that Stafford's data processing unit is powered on (*i.e.*, activated) when transmitting data (*i.e.*, when the sensor has been inserted). Thus, Stafford's data processing unit ("sensor electronics") is activated when at the second position (on the patient's skin).

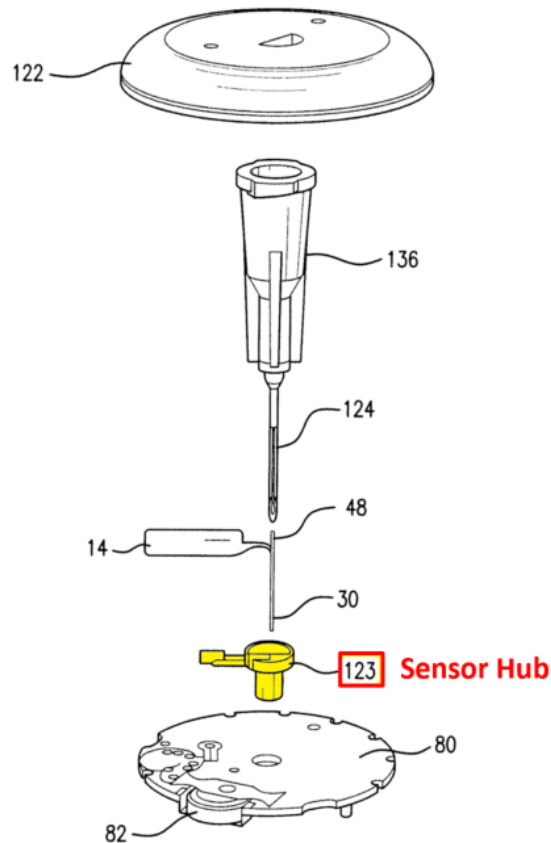
169. Additionally, Say teaches sensor electronics that remain in sleep mode to conserve battery power and that "[t]he on-skin sensor control unit 44 detects that it is being used and activates itself. Detection of use may be through a number of mechanisms." EX1008, 31:45-49. In view of this, a POSITA would understand that, to conserve battery life, it is advantageous to activate the sensor electronics once Stafford's on-body unit is at or near the second position, *i.e.*, on or near the patient's skin. Accordingly, a POSITA would have found it obvious in Stafford+Cote to configure Stafford's sensor electronics to be activated when at or near the second

position. It was known in the art to have on-body units that did not activate until they were in position on the skin. *See, e.g.*, EX1019, [0084], [0086]-[0087] (disclosing an on-skin treatment element wherein “the attachment of treatment element 1210 to the tissue is configured to activate it automatically...”).

3. Claims 15/28

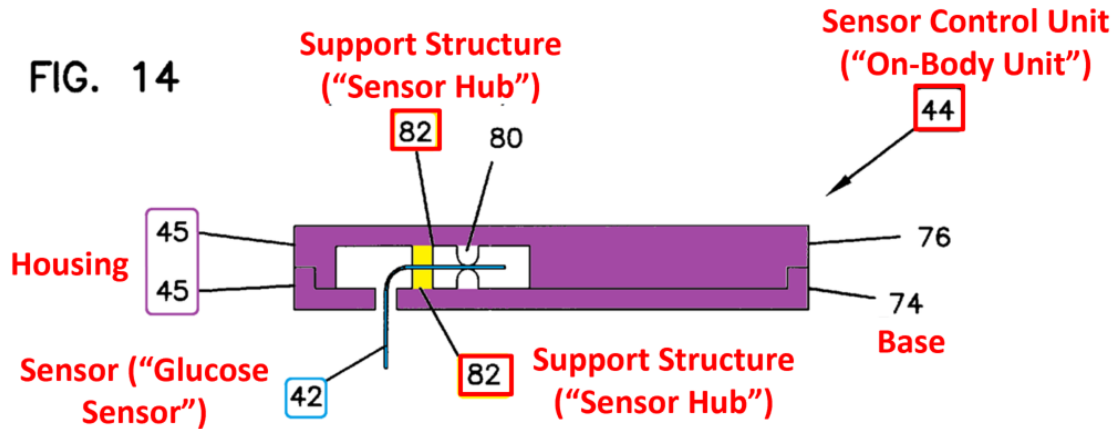
[15.1]/[28.1] The insertion assembly of claim [3/23], further comprising a sensor hub,

170. Claims 15 and 28 require a “sensor hub,” which is not a term of art. However, the '591 patent discloses that the sensor hub includes a structure positioned within the housing of the on-body unit which supports the portion of the sensor that is electrically coupled to electrical contacts. *See, e.g.*, EX1001, FIG. 23 (element 123), 17:56-59 (“sensor hub 123 [is] positioned within sensor housing 122.”), [15.3]/[28.3].

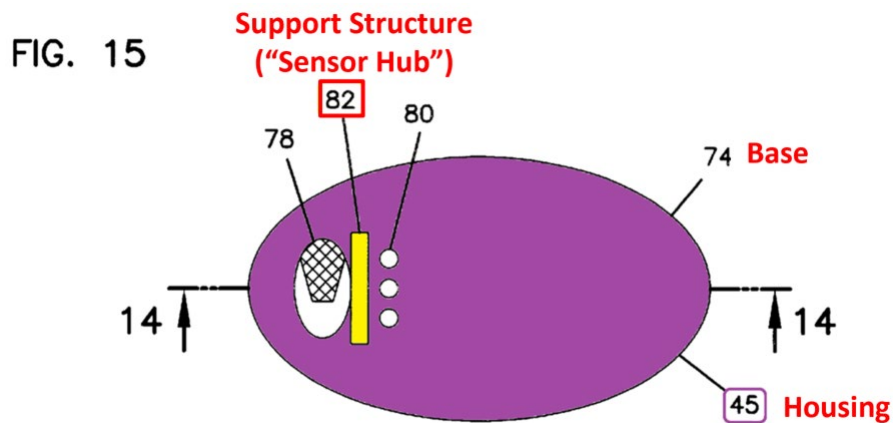


'591 patent, FIG. 23 (annotated)

171. While the internal components of Stafford's on-body unit are not explicitly shown, Say teaches a sensor control unit ("on-body unit") containing a support structure ("sensor hub") to "hold, support, and/or guide the sensor 42 into the correct position." EX1008, 34:50-52, FIGS. 14-16. The support structure is "provided under the sensor 42 to promote adequate contact between the contact pads 49 on the sensor 42 and the pins 84." *Id.*, 34:59-61. "In one embodiment, the conductive contacts 80 are pins 84," *Id.* 34:54-55. *See also id.*, FIG. 19A.



Say, FIG. 14 (annotated)



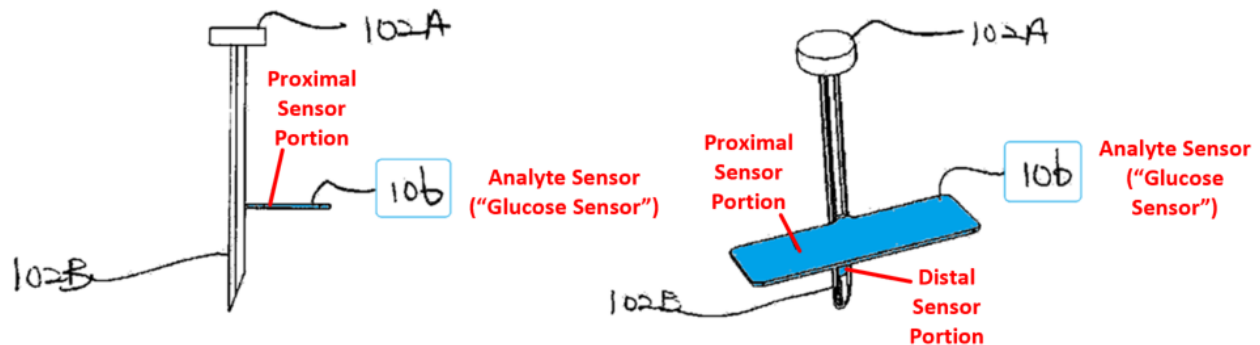
Say, FIG. 15 (annotated)

172. A POSITA would therefore understand Say's support structure to be a "sensor hub" because, like the sensor hub 123 of Figure 23 of the '591 patent, Say's structure is within the housing of the on-skin sensor control unit ("on-body unit") and supports the proximal portion of the sensor.

173. The most natural understanding of Say's support structure is that item 82 is indeed a separate structure that satisfies the claimed "sensor hub."

[15.2]/[28.2] 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 user,

174. Stafford's sensor has a first portion ("distal sensor portion") "configured for subcutaneous placement and in fluid contact with an interstitial fluid of a subject," and a second portion ("proximal sensor portion") "disposed within the housing and in electrical communication with the data processing unit." EX1004, [0006]. Stafford's distal sensor portion senses a patient's analyte (*id.*, [0028] "[The distal sensor portion] is disposed within the lower portion 102B of the introducer such that, the user or patient may easily, and accurately position the analyte sensor 106 under the skin layer to establish fluid contact with the patient's analyte.") and that analyte is glucose. EX1004, [0029], FIGS. 5B, 5C.



Stafford, FIGS. 5B, 5C (annotated)

175. Thus, the distal sensor portion of Stafford's sensor is configured to sense a glucose level of the user.

[15.3]/[28.3] wherein the proximal sensor portion is engaged with the sensor hub, and

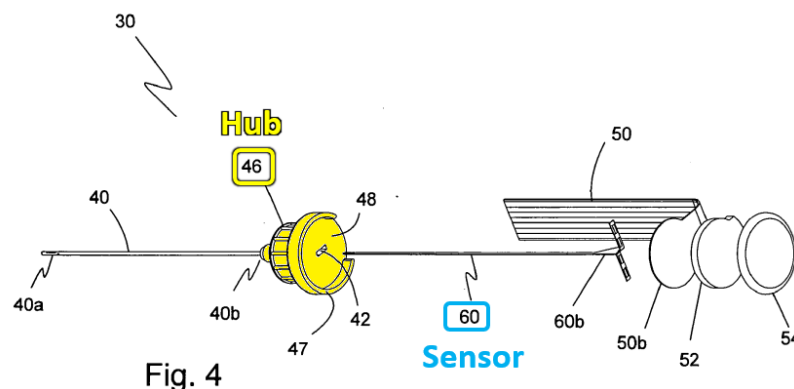
176. Say teaches that the proximal portion of the sensor is engaged with a support structure. EX1008, 34:50-52 (“The on-skin sensor control unit 44 may optionally contain a support structure 82 to hold, support, and/or guide the sensor 42 into the correct position.”), 34:59-61 (“A support 82 may be provided under the sensor 42 to promote adequate contact between the contact pads 49 on the sensor 42 and the pins 84.”), FIG. 14. *See* Section [15.1]. Thus, in Stafford+Cote, a POSITA would be motivated to hold or support the proximal sensor portion of Stafford’s sensor with a support structure to “hold, support, and/or guide the sensor [...] into the correct position,” as taught by Say, *e.g.*, having it engaged with Say’s support structure. *Id.*, 34:51-62.

177. A POSITA would further have been motivated to add Say’s support structure to Stafford’s on-body unit to help promote adequate electrical contact between Stafford’s proximal sensor portion and Stafford’s sensor electronics, as taught by Say. EX1004, claim 1 (“...wherein the second portion of the analyte sensor is in electrical contact with the data processing unit...”); EX1008, 34:59-61 (“A support 82 may be provided under the sensor 42 to promote adequate contact between the contact pads 49 on the sensor 42 and the pins 84.”). A POSITA would have a reasonable expectation of success in making the combination because Say’s

sensor and Stafford's analyte sensor have similar shapes and the proximal sensor portion of each would be supported in a similar fashion.

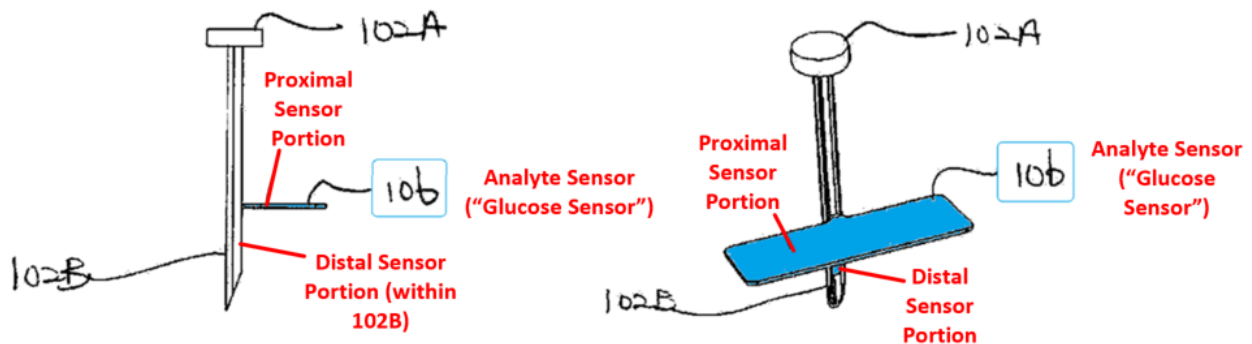
178. Accordingly, a POSITA would have found it obvious to modify Stafford to have a proximal portion of Stafford's sensor engaged with a support structure ("sensor hub"), as such a configuration is explicitly taught by Say.

179. Moreover, it was well-known for proximal sensor portions to be engaged with sensor hubs. For example, Bickoff (EX1018) teaches a hub 46 configured to receive a proximal portion of a sensor 60. EX1018, [0034] ("Sensor assembly 30 includes a sensor sheath 40 sealingly connected to a sensor hub 46 from which sensor cable 50 extends."), [0035] ("Sensor 60 has a shank proximal end 60b that is received within hub 46"), FIG. 4 (below). The hub 46 retains the sensor 60 therein and applies pressure against the sensor 60 to maintain good electrical contact between the electrical contact of the sensor electronics. *Id.*, [0038].



Bickoff, FIG. 4 (annotated)

[15.4]/[28.4] wherein the distal sensor portion is substantially orthogonal to the proximal sensor portion.



Stafford, FIGS. 5B, 5C (annotated)

180. In Stafford+Cote, the distal sensor portion of Stafford's sensor is substantially orthogonal to the proximal sensor portion, as taught by Stafford and as shown above. EX1004, FIGS. 5B, 5C.

4. Claims 4/19, 14/19

[4.1]/[19.6] [The insertion assembly of claim 3,] wherein the sensor electronics comprise a processor, a power source, an analog interface, a data storage unit, and wireless communication circuitry configured to communicate data indicative of a glucose level[.]/[; and]

181. As to claims 4 and 19, to the extent not already expressly disclosed, a POSITA would have been motivated to include a data storage unit as taught by Say to Stafford+Cote to store collected sensor data and/or instructions for operating Stafford's on-body unit.

182. Specifically, Say describes that the on-skin sensor control unit electronics ("sensor electronics") include a data storage unit. EX1008, 44:54-45:7

(“The on-skin sensor control unit 44 may include an optional data storage unit 102 The data storage unit 102 typically includes a readable/writeable memory storage device”), 36:40-43 (“The on-skin sensor control unit 44 also typically includes at least a portion of the electronic components that operate the sensor 42”). A POSITA would be motivated to include a data storage unit in Stafford’s sensor electronics to hold data (*e.g.*, measurements from the sensor or processed data) for analysis by the processor, as taught in Say. *Id.*, 44:54-45:7.

[14.1]/[19.14] [The insertion assembly of claim 3,] wherein a height profile of the housing is less than or equal to approximately 10 millimeters[.]/[.,]

183. As to claims 14 and 19, Say describes its on-body unit as being “thin” to “enhance concealment” and specifically teaches that the on-body unit “has a height of ... preferably 0.7 cm [7 mm] or less.” EX1008, 29:38, 29:45-47. Accordingly, in further view of Say, a POSITA would have found it obvious to configure the housing of Stafford’s on-body unit in Stafford+Cote to have a height profile of 7 mm or less.

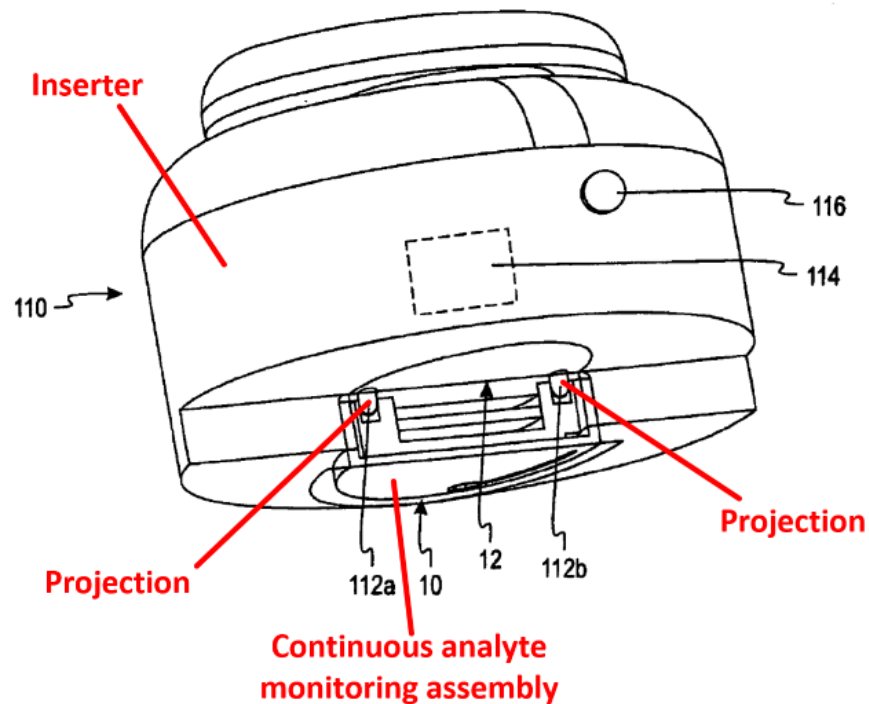
5. Claims 20-30

184. Each of claims 20-30 depends from claim 19, and recites elements that are substantially identical to those in claims already shown to be obvious over Stafford and Cote (Section VIII), and/or in further view of Say (Sections IX.B.1-4).

X. GROUND 3:
STAFFORD+COTE+BRENNEMAN (CLAIMS 18, 21-24, 27, 29-30)

A. Brenneman

185. PCT Publication No. WO2008/115409 (“Brenneman,” EX1040) published on September 25, 2008, from an application filed March 14, 2008. Brenneman describes an insertion device 110 for delivering a continuous analyte monitoring assembly 10 to the skin of a subject, glucose being one of the measured analytes. EX1040, [0023], [0041]-[0048].



Brenneman, FIG. 8 (annotated)

186. As shown above, Brenneman’s insertion device 110 comprises a plurality of projections 112, each of which engages a corresponding one of a

plurality of peripheral apertures 60 disposed on a top surface of the cover 12 of the continuous analyte monitoring assembly 10. EX1040, [0028], [0041].

B. Combining The Teachings Of Stafford+Cote+Brenneman

187. Brenneman (directed to the insertion of transcutaneous analyte sensors for diabetes treatments) is analogous art to the claimed invention of the '591 patent and to Stafford, Cote, and Say.

188. A POSITA implementing Stafford+Cote would have been further motivated to use Brenneman's teachings on mechanisms for coupling an on-body unit to an inserter, which are complementary to Cote's teachings. For example, Cote teaches an on-body unit that is retained within the inserter using frictional engagement between a diaphragm of the on-body unit and a needle of the inserter. EX1005, [0205]. Likewise, Brenneman's peripheral apertures "form a snug fit" with the projections "to couple the continuous analyte monitoring assembly 10 and the inserter 110." EX1040, [0042], FIG. 8.

189. A POSITA knew it was desirable to secure the on-body unit within the inserter in Stafford+Cote in a desired position, for example, to prevent dislodging of the on-body unit during shipping and/or reduce tipping/tilting of the on-body unit within the inserter. *Supra* Section VI.B.6. A POSITA understanding this need and reading Brenneman would, with a reasonable expectation of success, implement Stafford+Cote with peripheral apertures on the top surface of the on-body unit, as

taught by Brenneman, and corresponding projections on the insertion device (*e.g.*, at the distal end of the cylinder hub), as taught by Brenneman, such that the on-body unit remains in a desired position within the inserter. EX1040, [0042]; *see also* EX1007, [0069] (which teaches the use of corresponding recesses and protrusions to maintain the on-body unit and inserter in a desired position relative to one another).

190. Brenneman thus further reinforces that a POSITA would have found it obvious to include peripheral aperture(s) on a top surface of an on-body unit in Stafford+Cote to couple the on-body unit and inserter to one another.

1. Claims 18, 21-24, 27, 29-30

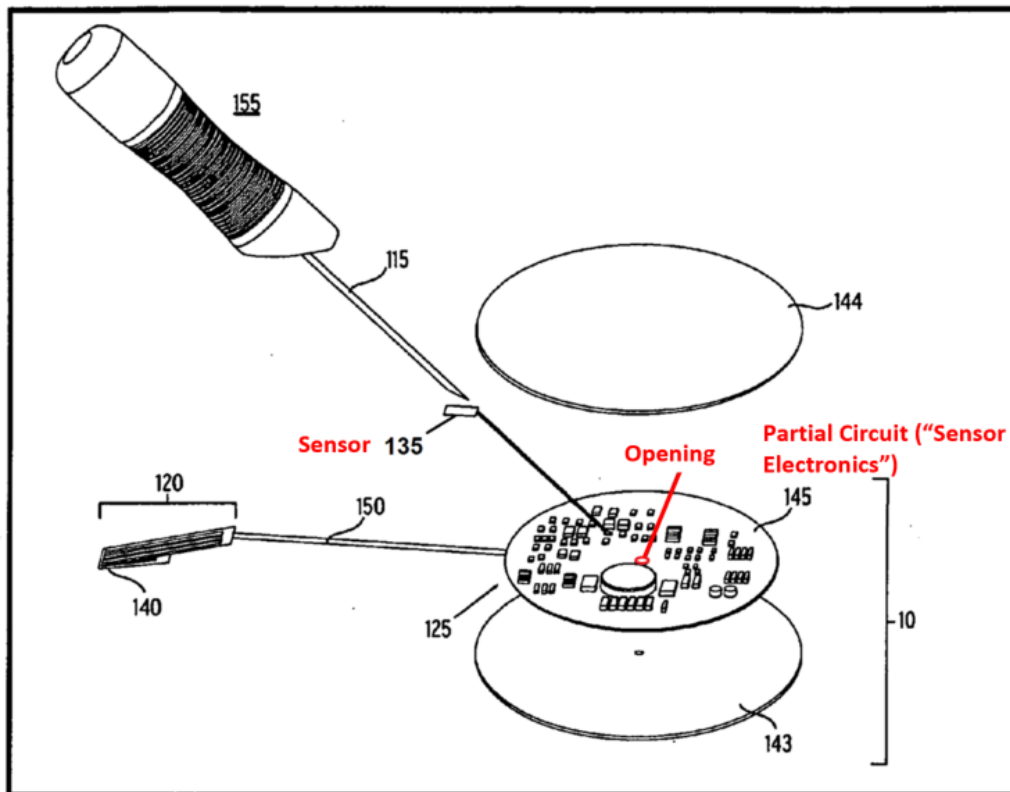
191. Dependent claims 18 and 21 each recite “a second opening on the top surface.” This was obvious in view of Stafford+Cote, as described above. *See* Section VIII.C.15. To the extent Patent Owner argues otherwise, Brenneman—presented here in Ground 3 as part of the combination itself (and not merely as a background reference)—confirms obviousness, as it teaches peripheral apertures (*e.g.*, a “second opening”) positioned on a top surface of an on-body unit, *e.g.*, coupling the on-body unit with an inserter. EX1040, [0042], FIGS. 1, 8.

192. Claims 22-24, 27, 29-30 depend directly or indirectly from Claim 21, and the Stafford+Cote combination teaches the additional limitations of these claims. *See* Sections VIII.C.6-VIII.C.11, and VIII.C.13.

**XI. GROUND 4:
STAFFORD+COTE+SHAH (CLAIMS 9, 22-24, 27, 29-30)**

A. Shah

193. U.S. Publication No. 2007/0073129 (“Shah,” EX1006), published on March 29, 2007, from an application filed September 23, 2005.



Shah, FIG. 6 (annotated)

194. Shah teaches a transcutaneous analyte sensor coupled to a flexible partial circuit with an opening (red) through which the sensor and needle pass. EX1006, [0045] (“The insertion needle 115 is adapted to extend through the ... flexible mounting base 10”), [0046], FIG. 6.

B. Combining The Teachings Of Stafford+Cote+Shah

195. Shah (disclosing a transcutaneous medical device for diabetes treatments) is analogous art to the claimed invention of the '591 patent and is further analogous to Stafford and Cote.

196. A POSITA would have been motivated to implement Shah's teachings in Stafford+Cote, to include an opening in Stafford's sensor electronics allowing passage of the sensor and sharp therethrough.

197. Specifically, Stafford teaches a data processing unit comprising sensor electronics and an introducer configured to extend through a central portion of the data processing unit. EX1004, FIGS. 2-4A. Likewise, Shah teaches a flexible mounting base (functionally similar to Stafford's data processing unit) comprising a flexible partial circuit having an opening and an insertion needle configured to extend partially through the opening in the central portion of the mounting base. EX1006, [0045] FIG. 6.

198. Given that Stafford does not explicitly show the arrangement of the sensor electronics within the on-body unit, a POSITA would have naturally turned to other sensor disclosures on specific electronics arrangements. The POSITA would have understood that one implementation of the electronics would be as in Shah, with a printed circuit board that occupies the entire cavity within Stafford's housing. A POSITA would have implemented this PCB with a hole aligned with the hole in

Stafford's housing, so that Stafford's introducer extended through both the housing and electronics, as taught by Shah.

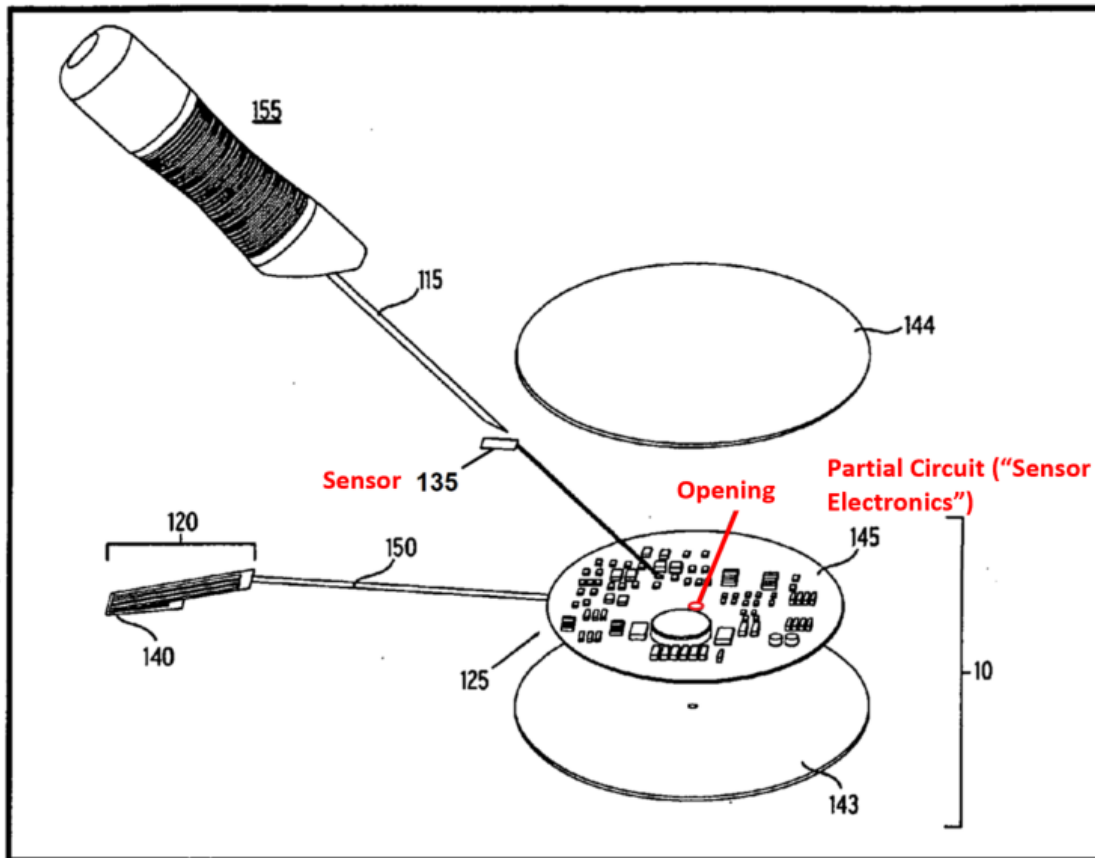
199. There was a reasonable expectation of success in such an arrangement, because Shah depicts it functioning for another type of on-body unit with a housing and an in-vivo portion. Further, adding an opening to the circuit board is an obvious design choice and one of a finite number of solutions for positioning the sharp such that it extends through the on-body unit.

200. Thus, a POSITA would be motivated to combine the teachings of Stafford, Cote, and Shah (hereinafter "Stafford+Cote+Shah") with a reasonable expectation of success.

1. Claims 9, 22, 23-24, 27, 29-30

201. Claims 9 and 22 depend from claims 3 and 21, respectively, which are obvious in view of Stafford+Cote. *See* Sections VIII.C.3 and VIII.C.15.

202. Shah teaches a partial circuit ("sensor electronics") having an opening through which an insertion needle ("sharp") extends. EX1006, [0045], FIG. 6. An opening in the sensor electronics would thus have been an obvious variation in shape in view of Shah.



Shah, FIG. 6 (annotated)

203. Moreover, Shah teaches that “the sensor electronics may be contained in a housing.” EX1006, [0046]. As such, Shah’s sensor electronics are expressly contemplated as being positioned within a housing, such as the housing of Stafford’s on-body unit.

204. A POSITA would have thus been motivated to combine Stafford+Cote with Shah’s teachings of an opening of the sensor electronics, with a reasonable expectation of success. Claims 23-24, 27, 29-30 depend directly or indirectly from

Claim 22. Stafford+Cote teaches the additional limitations of these claims. *See* Sections VIII.C.6, VIII.C.8-VIII.C.11, and VIII.C.13.

XII. GROUND 5-8

A. Ground 5: +Brenneman To Ground 2 (claims 21-30)

205. Claim 21 depends from claim 20, which, as shown in Ground 2, is obvious over Stafford+Cote+Say. *See* Section IX.B.5. As described in Ground 3, Brenneman further demonstrates the obviousness of the additional limitations of claim 21. A POSITA would have been motivated to further combine Brenneman's teachings with those of Stafford+Cote+Say, with a reasonable expectation of success. *See* Section X.B.

206. Claims 22-30 depend directly or indirectly from Claim 21. As shown above, Stafford+Cote and/or Stafford+Cote+Say satisfy these claims' added limitations. *See* Sections VIII.C.6-VIII.C.11, VIII.C.13, and IX.B.2-IX.B.4.

B. Grounds 6-8: +Shah To Grounds 2, 3, And 5

207. As explained in Ground 4, Shah teaches use of printed circuit board electronics that, when combined with Stafford+Cote, further renders claim 22 obvious. A POSITA would have been motivated with a reasonable expectation of success to incorporate Shah's teachings into Stafford+Cote, with or without the other references' teachings combined therewith. *See* Section XI.B.

1. Ground 6: Stafford+Cote+Say+Shah (claims 25-26, 28)

208. As explained above in Ground 2, Stafford, Cote, and Say render obvious *inter alia* claim 21, from which claim 22 depends, as well as claims 25-26, and 28, which depend indirectly from claim 22. *See* Sections IX.B.1-5. As noted in Ground 4, a POSITA would have been motivated with a reasonable expectation of success to incorporate Shah's teachings into Stafford+Cote+Say, thus further rendering obvious claims 25-26 and 28. *See* Section XI.B, XI.B.1.

**2. Ground 7:
Stafford+Cote+Brenneman+Shah (claims 22-24, 27, 29-30)**

209. As explained above in Ground 3, Stafford, Cote, and Brenneman render obvious *inter alia* claim 21, from which claim 22 depends, as well as claims 24, 27, 29, and 30, which depend indirectly from claim 22. *See* Section X.B.1. A POSITA would have been motivated with a reasonable expectation of success to incorporate Shah's teachings into Stafford+Cote+Brenneman, thus further rendering obvious claims 22-24, 27, 29, and 30. *See* Section XI.B, XI.B.1.

**3. Ground 8:
Stafford+Cote+Say+Brenneman+Shah (claims 25-26, 28)**

210. As explained above in Ground 5, Stafford, Cote, Say, and Brenneman render obvious *inter alia* claim 21, from which claim 22 depends, as well as claims 25-26, and 28, which depend indirectly from claim 22. *See* Section XII.A. A POSITA would have been motivated with a reasonable expectation of success to

incorporate Shah's teachings into Stafford+Cote+Say+Brenneman, thus further rendering obvious claims 25-26 and 28. *See* Section X I.B, XI.B.1.

XIII. NO OBJECTIVE INDICIA OF NON-OBVIOUSNESS

211. I am unaware of any secondary considerations of non-obviousness that would refute the showing of obviousness set forth above.

XIV. CONCLUSION

212. In my opinion, a POSITA would have viewed claims 1-30 of the '591 patent as being obvious in view of the cited references, whether alone, or in the combinations described herein.

XV. AVAILABILITY FOR CROSS-EXAMINATION

213. In signing this declaration, I recognize that the declaration may be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case. If cross examination is required of me, I will cooperate to the best of my ability to appear for cross examination by video or in person during the time allotted for cross examination.

A. Right to Supplement

214. I reserve the right to supplement my opinions in the future to respond to any arguments that the Patent Owner raises and to take into account new information as it becomes available to me.

B. Signature

215. I, Dr. Gary D. Fletcher, do hereby declare and state, that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: October 10, 2023



Signature

APPENDIX A

GARY D. FLETCHER, Ph.D.

241 Indian Lane
Media, PA 19063
215-704-3960

gary.fletcher@rnddx.com

<https://www.linkedin.com/in/garyfletcher>

R&D ENGINEERING PRODUCT DEVELOPMENT EXECUTIVE | IP EXPERT WITNESS

Entrepreneurial executive with expanding R&D roles in business, technology, and new product development leadership and execution, building and guiding teams in both Fortune 500 and startup companies. Yale Ph.D. in physics with proven record of leadership in creating innovative new businesses and products in healthcare, medical devices, diagnostics, life, materials, and optical sciences.

- **New Product Development and R&D Leadership** - Managing, planning, budgeting, financing, recruiting, and leading internal and external research and product development programs in medical device, diagnostics, optical devices, point-of-care and blood sample testing; championing technology development and product development stage-gate process implementation.
- **New Business and Technology Due Diligence** - Strategic assessment, customer discovery, ideation, product design, usability, technology assessment, business development, and marketing of new products and business opportunities.
- **Strategic Innovation** – Building and communicating business strategy and technology cases; identifying industry trends, technology trends, market trends, translating into business development, technology roadmaps, implementing product portfolio management.
- **IP Assessment & Development** - Defining intellectual property strategy, conducting due diligence, implementing a major IP portfolio in start-up new technology company, negotiating licensing agreements, Expert Witness, 23 issued patents and 25 patent applications.

PROFESSIONAL EXPERIENCE

RAVEN BIOMATERIALS LLC, Pennington, NJ (2020 – present)

Founder & COO -- biotech startup developing greatly improved cell separation / enrichment processes for cell therapy manufacturing, cell-based diagnostics, protein and vaccine manufacturing.

- Conducted customer discovery, built business models and case, developed investor presentations, performed due diligence, set up laboratory and operations, conducted proof of feasibility experiments, developed patent strategy.

RnDDx SOLUTIONS LLC, Media, PA (2015 – present)

Founder & Principal – Expert Witness in Patent Litigation | Medical Device Business & Product Development Consultant

- Expert Witness in patent litigation involving blood collection, blood separation, and blood preparation for clinical diagnostics, and cell and platelet therapy.
 - Successfully represented respondents as Expert Witness in International Trade Commission, Inv. No. 337-TA-1147, providing expert opinion on infringement, validity, and enforceability of US patent; included two declarations for Markman hearing, expert witness

report, rebuttal expert report, 9-hour deposition, expert witness statement and rebuttal statement. The technical case was so strong that Complainant withdrew complaint and requested stay of hearing. (2019)

- Retained as Expert Witness for the defendant in a patent dispute before the USDC in Delaware, involving four patents in the area of blood collection and processing. I reviewed drafts of the Petition for IPR, involving two of the four patents, informing defendant's counsel that I believed the arguments presented in the draft IPR Petition were not strong. I was not asked to prepare an IPR Expert Declaration, nor did I review the final IPR Petition. (2020)
- Retained as Expert Witness for the defendant in a patent infringement case before USDC in Delaware, involving two patents in the area of medical diagnostic testing fluidic systems and methods of sample processing, and point-of-care diagnostic fluidic systems and uses. I reviewed prior art, and the plaintiff dismissed their suit. (2020)
- Retained as Expert Witness for the defendant in a patent infringement case before USDC in Western District of Texas, involving two patents in the area of preparing blood samples for analysis of circulating nucleic acids using chemical agents that inhibit blood cell lysis. I prepared a declaration supporting defendant's responsive claim construction brief, and I was deposed by plaintiff regarding the declaration. (2021)
- Retained as Expert Consultant for counsel developing patent litigation strategy for client in glucose monitoring space, assisting in preparation of five (5) IPR Petitions. (2021)
- Expert video commentary for episode of Advancements TV with Ted Danson, discussing engineering challenges in developing comprehensive point-of-care testing systems, for point-of-care testing diagnostic company.
- Consultant to startup medical device company, providing product development and product optimization of chemical attributes of blood separation devices.
- Consultant and advisor to startup medical device company, providing business development, competitive analysis, and product development expertise in blood separation devices for point-of-care testing.
- Consultant to startup medical diagnostics company, providing technical due diligence, product design, development, and testing of blood sampling methods.
- Consultant to startup medical device company developing blood microcollection device and diagnostics, providing expertise in the field of blood diagnostic products and services.
- Consultant to startup medical device company developing blood collection device, providing project management and product advisory services.
- Consultant to Fortune 100 Healthcare Provider, delivered Point-of-Care-Testing Growth Opportunity Assessment and Emerging Technology Landscape, with actionable targets.
- Lean Startup Coach within Program Management Office of Fortune 1000 data analytics company, developing repeatable Lean Startup process around Customer Discovery and Validation, training materials for workshops.
- Mentored four early stage companies, building business models, plans, and funding presentations.
- Guided technology companies through Lean Startup, Business Model Canvas, and national NSF I-Corps business development efforts.
- Conducted customer discovery, built business models and case, developed investor presentations, performed due diligence, set up operations, and initiated licensing negotiations with academic inventors, for U. of Pennsylvania life sciences startup developing super-resolution fluorescent microscopy for cell analysis.
- Maven consultations
 - Phone consultation for confidential entity regarding emerging companies and technologies in in vitro diagnostics and point-of-care diagnostics and needs for outsourced contract design, development, and manufacturing.
- Guidepoint consultations
 - Phone consultation for confidential entity regarding remote blood collection devices.
 - Phone consultation for confidential entity regarding biospecimen users and purchasers.

- Phone consultation for confidential entity regarding remote blood collection space.
- Phone consultations for confidential entity regarding medical device supply chain and product development.
- Phone consultation for confidential entity regarding microfluidics and medical devices.
- Phone consultation for confidential entity regarding healthcare in vitro diagnostics.
- Survey for confidential entity regarding medical technology OEMs.
- Gerson Lehrman Group consultations
 - Completed survey on MedTech Services for confidential entity
- Reviewer for NSF SBIR/STTR Phase I and Phase II proposals

BECTON DICKINSON, Franklin Lakes, NJ (2004 – 2014)

BD is a global medical technology company with products in drug delivery, life sciences tools, and disease management in diabetes, women's health and cancer, and infection control.

Leader, Technology Innovation, R&D (2010 – 9/2014)

Responsible for identifying adjacent business opportunities, building compelling business cases, and leading product development in new business spaces. Moved into this role to address critical need to identify higher growth business opportunities for low-single-digit growth business.

- Developed and executed two adjacent market business plans and technology strategies, achieving \$2M internal investment for medical device technology development, in: 1) Tissue collection and preservation for improved cancer diagnostics; and 2) Point of care blood collection and diagnostic testing, managing consultants and partnerships in microfluidics technologies.
- Led product development of first tissue collection product to manufacturing release.
- Initiated customer discovery, developed Key Opinion Leader relationships with surgical and clinical pathologists and Point of Care Coordinators to understand cancer diagnostic and blood testing needs. Set up expert focus group panels at international conferences.

Technology Leader, Advanced Technology, R&D (2006 – 2010)

Moved into new innovation strategy role; charged with identifying and leading technology and product development of new-to-business concepts to reinvigorate core business.

- Developed business unit technology and innovation strategy.
- Developed and led technology scouting, due diligence, and innovation processes for new medical devices.
- Completed “deep dive” technology assessment in blood fractionation technologies, leveraging and contracting academic experts in materials and fluidics; led development effort assessing primary blood separation technologies. Effort to develop rapid noncentrifugal blood separation challenging and continues to present.

Director, Core Technologies, R&D (2004 – 2006)

Based on interest and experience in medical device product development, hired at Director level into Preanalytical [Vacutainer] business at BD to bring innovative new product development leadership and vision to legacy business.

- Reporting to VP R&D, led 5-member technology development group, executing technology strategy to support medical device blood specimen collection and preservation business.

- Built team key technical capabilities to support innovation of current and next generation products; interfacing R&D with clinical affairs, regulatory, Program Management Office.
- Led R&D teams resolving manufacturing problems in core plastic blood collection products, identified and solved vendor plastic materials changes, material coatings changes, manufacturing process changes.
- Led Business Unit R&D rollout of Technology Development stage-gate process, initiated prior to formal New Product Development stage-gate process, to reduce technology risk in New Product Development.
- Taught, on ongoing basis, 2-day BD University course on “Managing for Performance Excellence” to managers.

SARNOFF CORPORATION, Princeton, NJ (2001 – 2004)

Sarnoff [previously RCA Laboratories, now part of SRI] was a contract research laboratory executing both government and commercial research and new product development contracts in hardware, software, image analysis, and market analysis. Hired to expand Sarnoff's commercial medical device and diagnostic product development contract business, and to create patentable internal product development capabilities which could be licensed or spun-out as startup companies.

Technical Manager, Healthcare Products (2001 – 2004)

- Reporting to Technical Director, directed 12-member multidisciplinary group as product development program manager of new painless minimally invasive blood glucose monitor; achieved successful spinout as medical device startup. Managed 8-month, \$2M budget.
- Functionally manage 7-member scientific and engineering staff involved in multiple medical device product development contracts.
- As Co-Principal Investigator, prepared successful Department of Homeland Security research grant funding product development for rapid detection of airborne biological weapons, based on electrostatic particle collection and Raman spectroscopy detection.

CYTOMETRICS, INC., Philadelphia, PA (1996 – 2001)

Cytometrics was a medical imaging and diagnostic startup commercializing a platform miniature optical reflectance microscope for human in vivo assessment of circulation perfusion and noninvasive measurement of whole blood count parameters, using hemoglobin optical absorption spectroscopy.

Vice President, Advanced Technology (1998 – 2001)

Asked to lead innovative team developing additional clinical applications for the platform optical imaging instrument in circulation perfusion assessment.

- Reporting to CEO, led team of five scientists evaluating technical feasibility of new product concepts, identified new applications of core technology, and assessed competitive technology.
- Managed the development of a novel noninvasive technology platform, achieving product introduction 18 months after concept definition.
- Led research, medical imaging analysis, and clinical groups, demonstrating clinical efficacy of noninvasive blood analysis and microcirculation imaging instrument, generating \$41M in capital for continued development.
- Managed company intellectual property portfolio, resulting in filing of 14 major patent applications.
- Developed corporate R&D strategy. Negotiated external university research contracts and funding, resulting in 10 study reports and 8 manuscripts submitted for publication. Directed technical consultants.
- Collaborated in the ISO implementation and manufacturing start-up.

Vice President, Engineering (1996 – 1998)

Hired as employee #6 to lead product development and build the product development team for the core noninvasive WBC [whole blood count] application.

- Reporting to CEO, led optical, mechanical, electrical, software image analysis, and clinical team, and developed product prototypes.
- Built a high-performance team of scientists and engineers with a driven-to-execute innovation culture
- Led research, development, and clinical testing of 4 generations of prototype video reflectance microscopes for noninvasive blood analysis, resulting in performance improvements and sensor miniaturization, which generated \$10M in angel investment for continued development.

BIOCONTROL TECHNOLOGY, INC., Indiana, PA (1996)

Biocontrol Technology was established medical device company developing noninvasive glucose measurement based in near infrared skin reflectance spectroscopy. Hired to lead product development.

Manager, Engineering (1996)

- Reporting to President, managed 25 electrical, mechanical, optical, and software engineers developing noninvasive glucose sensor utilizing diffuse reflectance near-infrared spectroscopy.
- Led cross-functional teams to refocus technical effort, resulting in greater interaction between engineering, research, data analysis, clinical, and manufacturing departments and faster sensor performance improvements.

ANDROS, INC., Berkeley, CA (1993-1996)

Andros, Inc. was an OEM supplier of gas analysis instruments based on infrared absorption spectroscopy to the automotive and medical device markets. I was hired to expand development of new anesthetic and respiratory gas analyzers.

Senior Physicist and Manager, Advanced R&D (1993-1996)

- Reporting to VP Engineering, managed development of nondispersive infrared [NDIR] absorption anesthetic and respiratory gas analyzers, resulting in new OEM agreements with medical patient monitoring companies.
- Assessed and tested biomedical and automotive sensor technologies, including low cost gas analyzer based on quenching of fluorescent radiation excited by blue LEDs, and portable gas analyzer based on solid-state IR sources and nonimaging IR optics.

MEASUREX CORPORATION, Cupertino, CA (1991-1993)

Measurex Corporation provided process control sensors and instrumentation for the pulp and paper, and plastics industries. I was hired to develop and commercialize new infrared and x-ray sensor technology.

Staff Physicist (1991-1993)

- Reporting to Manager of Sensor Engineering, developed, field tested, and released to manufacturing new IR moisture sensor for paper industry use, requiring fewer calibrations and generating greater customer acceptance.
- Researched and led customer acceptance tests of 10 and 30 keV x-ray sensors as thickness monitors, generating new sales in aluminum industry.

LAWRENCE LIVERMORE NATIONAL LABORATORY, Livermore, CA (1986-1991)

LLNL is a Department of Energy national lab dedicated to research and development of energy, weapons, laser, defense, and biological technologies. I was hired into the Physics Department to understand and develop rapid laser and x-ray technologies.

Physicist (1986-1991)

- Designed and fielded subnanosecond time-resolving crystal x-ray spectrometers to measure temperature and density of laser-produced plasmas, which provided data for modeling and development of x-ray lasers.
- Formulated new nuclear test experiment, involving 2-dimensional x-ray imaging.

UNIVERSITY OF VIRGINIA, Charlottesville, VA (1983-1986)

Assistant Professor of Physics and Research Associate in Physics (1983-1986)

- Reporting to Prof. Daniel Larson, mentored seven graduate students, resulting in 6 peer-reviewed publications.
- Designed and executed precision measurements in high field nuclear magnetic resonance spectroscopy of laser optically pumped atomic rubidium and laser photodetachment studies of atomic negative ions confined in Penning trap, discovering new effects.
- Taught undergraduate introductory physics laboratory course.

YALE UNIVERSITY, New Haven, CT (1976-1983)

Research Assistant in Physics (1976-1983)

- Under the direction of Prof. Vernon Hughes and Prof. Michael Lubell, upgraded experimental lab, measured spin dependence in electron-hydrogen atom collisions, wrote dissertation and 4 peer-reviewed publications.

EDUCATION

Doctor of Philosophy in Physics, Yale University, New Haven, CT

Bachelor of Arts in Physics and Mathematics, DePauw University, Greencastle, IN

HONORS

1999 -- Cytometrics Founders' Award, "for outstanding contributions to the furtherance of Cytometrics' mission."

1975 -- Elected to Phi Beta Kappa, with 4.0 GPA

PROFESSIONAL ACTIVITIES

Member, American Association for Clinical Chemistry (AACC)

Member, American Chemical Society (ACS)

PUBLICATIONS

1. G.D. Fletcher et al., "Measurement of Spin-Exchange Effects in Electron-Hydrogen Collisions: 90° Elastic Scattering from 4 to 30 eV," Phys. Rev. Lett. **48**, 1671, (1982).
2. T. J. Gay, G. D. Fletcher, M. J. Alguard, V. W. Hughes, P. F. Wainwright, and M. S. Lubell, "Measurement of spin-exchange effects in electron-hydrogen collisions: Further studies of impact ionization," Phys. Rev. **A 26**, 3664 (1982).
3. G.D. Fletcher et al., "Experimental study of spin-exchange effects in elastic and ionizing collisions of polarized electrons with polarized hydrogen atoms," Phys. Rev. **A 31**, 2854 (1985).
4. G. D. Fletcher, T. J. Gay, and M. S. Lubell, "New insights into Mott-scattering electron polarimetry," Phys. Rev. **A 34**, 911 (1986).

5. S.J. Lipson, G.D. Fletcher, and D.J. Larson, "Observation of Quadrupole and Dipole Diamagnetic Shifts in Atomic Ground State Hyperfine Structure, Phys. Rev. Lett. **57**, 567 (1986).
6. R.E. Elmquist, C.J. Edge, G.D. Fletcher, and D.J. Larson, "Observation of Resolved Zeeman Thresholds in Photodetachment in a Magnetic Field," Phys. Rev. Lett. **58**, 333 (1987).
7. G.D. Fletcher, S.J. Lipson, and D.J. Larson, "Observation of a Magnetic Field Dependent g-Factor Ratio," Phys. Rev. Lett. **58**, 2535 (1987).
8. R. Trainham, G.D. Fletcher, N.B. Mansour, and D.J. Larson, "Photodetachment Threshold Shift in a Strong Laser Field," Phys. Rev. Lett. **59**, 2291 (1987).
9. N. B. Mansour, G. D. Fletcher, and D. J. Larson, "Laser photodetachment spectroscopy of S—near the D1 threshold," Phys. Rev. A **35**, 2321 (1987).
10. R Trainham, G D Fletcher and D J Larson, "One- and two-photon detachment of the negative chlorine ion," Journal of Physics B **20**, L777 (1987).

CONFERENCE ORGANIZER

- **D2H2 [Distributed Diagnosis and Home Healthcare] Conference**, Program Committee, Session Organizer and Session Chair, Chair—Home Devices, April 2006.
- **NIST Cross-Industry Issues in Nanomanufacturing**. Workshop Organizer, Plenary Speaker, and Report Co-author; Organized and chaired session – "Surfaces, Interfaces, and Non-bonded Interactions of Nanomaterials." Plenary Speaker – "Pharmaceuticals and Medical Devices." May 2008. http://www.nist.gov/mml/upload/nano_small_web-4.pdf

CONFERENCE PROCEEDINGS

1. Rusty Trainham, G. D. Fletcher and D. J. Larson, "Laser photodetachment spectroscopy of the negative chlorine ion," AIP Conf. Proc. **146**, 385 (1986); <http://dx.doi.org/10.1063/1.35750>
2. O. Genzel-Boroviczeny, A. G. Harris, G. D. Fletcher, and F. Christ, "Non-invasive determination of hemoglobin in neonates with orthogonal polarization spectral (ops) imaging," Pediatric Research **47**(4), 332A–332A (2000). Part 2 Suppl. S.

GRANTED PATENTS

EP1983891B1	System and method for blood collection devices
EP2986220B1	Biological fluid collection device and biological fluid collection and testing system
EP2986221B1	Biological fluid sampling device
EP2986222B1	Biological fluid sampling transfer device and biological fluid separation and testing system
EP2986223B1	Blood sampling transfer device
EP2986383B1	Biological fluid separation device and biological fluid separation and testing system
EP2986384B1	Biological fluid sampling transfer device and biological fluid separation and testing system
EP3169236B1	Lancet device with first-drop removal
EP3513727B1	Biological fluid sampling device

EP3598944B1	Lancet device with first-drop removal
US 9,380,972	Biological Fluid Collection Device and Biological Fluid Collection and Testing System
US 9,380,973	Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System
US 9,408,568	Biological Fluid Sampling Device
US 9,549,700	Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System
US 9,724,690	Blood Collection Device, Method, and System for Using the Same
US 9,743,876	Lancet Device with First-Drop Removal
US 9,808,192	Biological fluid sampling transfer device and biological fluid separation and testing system
US 10,154,808	Biological fluid separation device and biological fluid separation and testing system
US 10,194,851	Blood sampling transfer device and blood separation and testing system
US 10,342,471	Biological fluid transfer device and biological fluid sampling system
US 10,682,085	Lancet Device with First-Drop Removal
US 10,791,975	Biological fluid transfer device and biological fluid sampling system
US 10,925,530	Blood Sampling Transfer Device

PATENT APPLICATIONS

US20040058311A1	Method and apparatus for measuring the hemoglobin concentration and/or hematocrit in whole blood using diffuse light
WO2004091693A2	Body fluid sampling constructions and techniques
US20050070819A1	Body fluid sampling constructions and techniques
WO2007092585A2	Biological specimen collection and storage devices
WO2007092586A2	Blood collection device, method, and system for using the same
WO2007092587A2	Improved label processor and method relating thereto
US20090130646A1	BLOOD COLLECTION DEVICE, METHOD, AND SYSTEM FOR USING THE SAME
US20100217155A1	BODY FLUID SAMPLING CONSTRUCTIONS AND TECHNIQUES
US20100279397A1	Biological specimen collection and storage devices
US20140305197A1	Biological Fluid Separation Device and Biological Fluid Separation and Testing System
US20140305823A1	Blood Sampling Transfer Device
US20140308164A1	Biological Fluid Transfer Device and Biological Fluid Sampling System
US20140308166A1	Blood Sampling Transfer Device and Blood Separation and Testing System
US20140308167A1	Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System
US20140309556A1	Biological Fluid Collection Device and Biological Fluid Collection and Testing System
US20140309557A1	Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System
US20140309558A1	Biological Fluid Sampling Device
US20140328734A1	Biological Specimen Collection and Storage Devices
US20160015305A1	Lancet Device with First-Drop Removal

US20170095191A1	Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System
US 62/302,296	Biological Fluid Separation Device
US20170319120A1	Lancet Device with First-Drop Removal
US20190274609	Biological Fluid Transfer Device and Biological Fluid Sampling System
US20200397359	Biological Fluid Transfer Device and Biological Fluid Sampling System
US20210137434	Blood Sampling Transfer Device