

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT DIABETES CARE INC. and	)	
ABBOTT DIABETES CARE LIMITED,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 21-977 (KAJ)
	)	
DEXCOM, INC.,	)	
	)	
Defendant.	)	
	)	

PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

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DEXCOM EXHIBIT 1066
Dexcom v. Abbott
IPR2023-01251

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70	The New Penguin English Dictionary (2000) (excerpt)
71	The James Spring & Wire Company, "What is a Coil Spring?" (May 10, 2018), https://www.jamesspring.com/news/what-is-a-coil-spring/
72	Alexander Blake, Practical Stress Analysis In Engineering Design, Second Edition, Revised and Expanded (1990) (excerpt)
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86	Peter Scallan, Process Planning (2003) (excerpt)
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88	U.S. Publication No. 2018/0368771
89	U.S. Publication No. 2011/0082484
90	U.S. Patent No. 7,946,984
91	U.S. Publication No. 2005/0239154
92	U.S. Publication No. 2007/0173706
93	U.S. Patent No. 7,885,698

¹ Exhibits 1-67 were submitted with the Joint Claim Construction Chart (D.I. 120) and have not been resubmitted. Exhibits 68-100 are new and are being submitted herewith.

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94	WO Publication No. 2007/120363
95	WO Publication No. 2013/152090
96	U.S. Publication No. 2006/0020189
97	U.S. Publication No. 2004/0133164
98	L.J. Watson, “ <i>Traction Engine Governors</i> ,” The Threshermen’s Review, Vol. XX No. VII, July 1911 (excerpt)
99	Springs & Things Inc., “ <i>Spiral Torsion Springs</i> ”
100	U.S. Publication No. 2009/0099521

TABLE OF ABBREVIATIONS

Abbreviation	Description
Abbott	Plaintiffs Abbott Diabetes Care Inc. and Abbott Diabetes Care Limited
DexCom	Defendant DexCom Inc.
443 patent	U.S. Patent No. 10,973,443 (D.I. 120, Ex. 2)
649 patent	U.S. Patent No. 10,945,649 (D.I. 120, Ex. 3)
440 patent	U.S. Patent No. 11,013,440 (D.I. 120, Ex. 4)
341 patent	U.S. Patent No. 10,881,341 (D.I. 120, Ex. 5)
654 patent	U.S. Patent No. 10,959,654 (D.I. 120, Ex. 6)
216 patent	U.S. Patent No. 11,000,216 (D.I. 120, Ex. 7)
842 patent	U.S. Patent No. 10,820,842 (D.I. 120, Ex. 8)
653 patent	U.S. Patent No. 10,952,653 (D.I. 120, Ex. 9)
954 patent	U.S. Patent No. 10,827,954 (D.I. 120, Ex. 10)
338 patent	U.S. Patent No. 10,874,338 (D.I. 120, Ex. 11)
644 patent	U.S. Patent No. 10,966,644 (D.I. 120, Ex. 12)
647 patent	U.S. Patent No. 10,945,647 (D.I. 120, Ex. 13)
POSITA	Person of ordinary skill in the art
Leinsing Decl.	Declaration of Karl R. Leinsing, MSME, PE
Sarrafzadeh Decl.	Declaration of Majid Sarrafzadeh, Ph.D.
Smith Decl.	Declaration of John L. Smith, Ph.D.

**** All emphasis added unless otherwise indicated.***

TABLE OF DISPUTED TERMS AND PROPOSED CONSTRUCTIONS²

Claim Term	Patent(s)	Abbott's Construction	DexCom's Construction
<i>"first spring"</i>	443 patent	Plain and ordinary meaning (no construction needed or "first spring")	Compression spring loaded along its axis
<i>"first spring in a loaded position"</i>	341, 653 & 216 patents	Plain and ordinary meaning (no construction needed or "first spring that is loaded")	Compression spring loaded along its axis
<i>"slot"</i>	649 & 440 patents	Plain and ordinary meaning ("a narrow opening, groove, or channel")	Narrow opening through the first slidable body, through which the rotor follower projection extends
<i>"rotor comprising a cylindrical shape"</i>	649 & 440 patents	Plain and ordinary meaning ("rotor having an overall cylindrical shape")	Plain and ordinary meaning
<i>"processing/process the sensor data"</i>	842 & 653 patents	Converting/convert the sensor data into calibrated analyte values	Plain and ordinary meaning
<i>"data indicative of the sensed glucose level"</i>	842 & 653 patents	Calibrated glucose values	Plain and ordinary meaning
<i>"failure mode condition"</i>	842 & 653 patents	Condition that adversely affects function	Condition that requires disabling of the output of sensor data
<i>"chemically bonded"</i>	954 patent	Bonded by attractive forces between atoms or molecules	Plain and ordinary meaning
<i>"insertion mechanism configured to position the sensor subassembly against the base of the transmitter mount by causing movement of the sensor subassembly"</i>	647 patent	Plain and ordinary meaning (no construction needed or "a mechanism that inserts a sensor into position for use that is configured to position the sensor subassembly against the base of the transmitter mount by causing movement of the sensor subassembly")	112(6) / Means-plus-function Function: positioning the sensor subassembly against the base of the transmitter mount by causing movement of the sensor subassembly Corresponding structure: none disclosed, or alternatively 420 in Figures 4D and 4E and 550 in Figure 5B

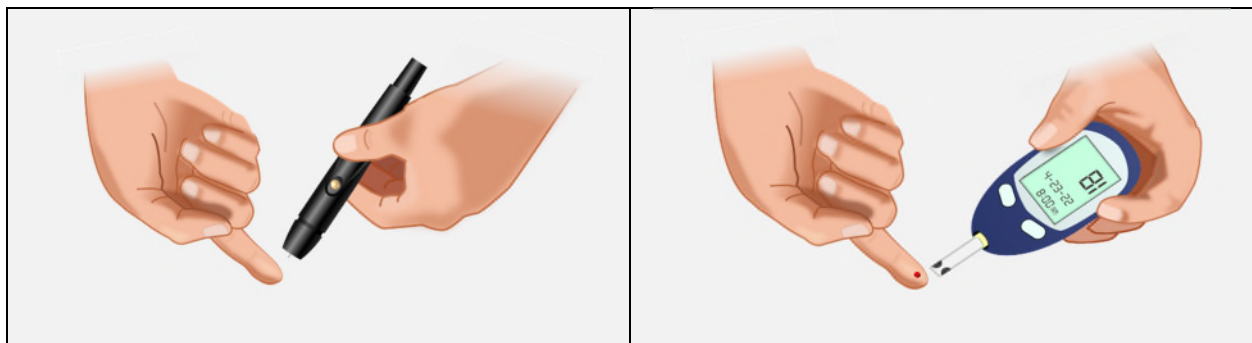
² For the 341, 654, and 216 patents, DexCom is no longer arguing indefiniteness for the term *"wherein the glucose sensor is a first glucose sensor . . ."* Accordingly, it is not necessary for the Court to construe this term.

I. INTRODUCTION

Abbott's proposed claim constructions are consistent with the ordinary meaning of the disputed terms in light of the intrinsic and extrinsic evidence. In some instances, no construction is necessary because the claim language is straightforward and readily understood. In contrast, DexCom imports limitations that are refuted by the intrinsic and extrinsic evidence. For several terms, DexCom did not propose a construction when the parties met and conferred, merely stating "plain and ordinary meaning" without saying what that meaning is. (D.I. 120, Ex. 1 (JCCC).) DexCom should not be permitted to now propose constructions that it failed to disclose.

II. BACKGROUND OF THE PATENTED INVENTIONS

Abbott asserts that DexCom infringes 12 patents covering improvements to continuous glucose monitoring ("CGM") systems. Diabetes patients and healthcare providers traditionally monitored blood glucose levels using "fingerstick" methods. (D.I. 108, ¶17.) This involved pricking a finger to obtain blood, placing blood on a test strip, and inserting the test strip into a monitor to receive a blood glucose value. (*Id.*) Fingersticks were inconvenient and painful, and provided only a single glucose value at one point in time.



Various companies developed CGM products as an alternative to fingerstick measurements. (*Id.* ¶18.) CGM systems typically include an inserter (or applicator), a glucose sensor, a transmitter (or electronics unit), and a display device. Abbott's FreeStyle Libre (top) and DexCom's G6 (bottom) are shown below:

Inserters	Sensor and Transmitter	Display Device
		 
		 

The inserter is a mechanism that implants the glucose sensor partially beneath the skin and into contact with interstitial fluid. The sensor may be held in place with a mount adhered to the patient's skin. In many systems such as DexCom's G6, the transmitter snaps into the mount where it makes electrical contact with the sensor. The transmitter receives electrical signals from the sensor and, in turn, wirelessly transmits data to the display device.

Early CGM products had significant drawbacks that were solved by Abbott's patented inventions, as discussed below.

Abbott's Patented Inserter Designs. Inserters in early commercial CGM systems were complicated and awkward. For example, some required the user to pinch skin between their fingers and then stab themselves at a 45° angle with a needle to insert the sensor. Others required the user to manually operate the inserter to plunge a needle and sensor combination into their skin. A retaining mechanism would then hold the sensor under the skin while the user manually

withdrew the needle. These insertion procedures were intimidating, painful, and prone to human error.

Six of Abbott's patents in this case revolutionized inserters. The 443 patent is generally directed to an inserter with a mount coupled to its end. (Ex. 2 at claim 1.) With the mount pressed against the skin, the simple push of a button initiates a series of automated actions: a needle (sometimes called a "sharp" or "introducer") pierces the skin, the glucose sensor is partially implanted, and the needle is retracted. This makes sensor placement easy, accurate, and less intimidating. (*Id.*)

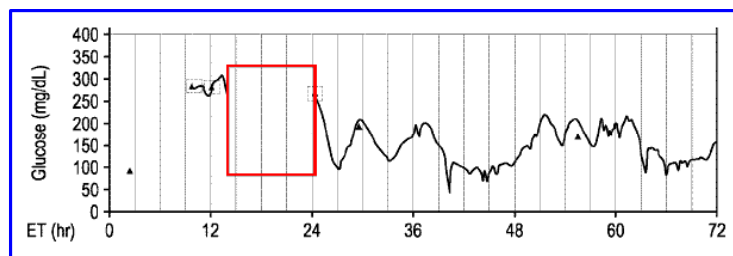
Abbott's 649 and 440 patents further improved inserter technology. These patented designs use, *inter alia*, a torsion spring with a rotor, which provides the force necessary for needle and sensor insertion. (Ex. 3 at claim 1.) The torsion spring is configured to cause rotation of the rotor, which causes first and second slidable bodies and the glucose sensor to advance within the inserter housing in a linear direction, thereby inserting the sensor. (*Id.*) Compared to early CGM inserters, Abbott's patented inserter designs are able to deliver a quick and less painful insertion.

Abbott's 341, 654, and 216 patents take advantage of multiple axes for the insertion process that minimize the overall size of an inserter. The user presses a button along a first axis, which releases a spring from a loaded position. (Ex. 5 at claim 1.) This causes a sliding member to move within a straight track along a second axis. (*Id.*) Movement of the sliding member results in the advancement of the needle and sensor in a direction along a third, insertion axis. (*Id.*) These innovations provide a compact, easy-to-use, and relatively pain-free inserter.

Abbott's Patented Seal Carrier Locks. For some CGM products, the insertion process involves locking a sensor subassembly into a mount. Abbott's 647 patent claims an inserter configured to position the sensor subassembly against the base of the mount by causing movement

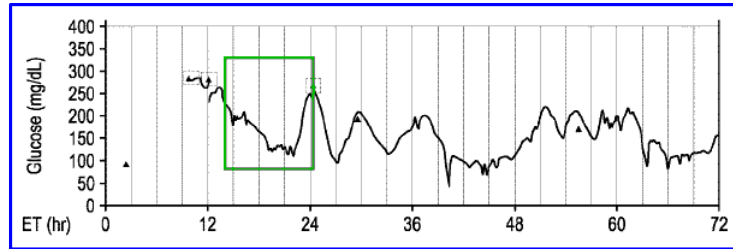
of the sensor subassembly until a locking mechanism engages the sensor subassembly. (Ex. 13 at claim 1.) Movement of the sensor subassembly is impeded while the locking mechanism is engaged, holding the sensor in place for a good, clean connection to the transmitter. (*Id.*)

Abbott's Patented Backfilling Technology. CGM systems are designed to report continuous glucose information to the patient. The information can take the form of a numerical value, a trend arrow, or a graph of glucose concentration over time. There are times, however, when the system cannot report accurate information. For example, early CGMs required the user to periodically re-calibrate the glucose sensor by taking fingerstick measurements. But if a periodic calibration measurement was not made, or if the measurement was erroneous, the system could not report data. This caused a data gap (in red below) in the user's glucose data.



(Ex. 8 at FIG. 7A.) Several different failure mode conditions can cause data gaps, including, an “inability to promptly calibrate the sensor, system malfunction, sensor dislodging, signal errors associated with the sensor, transmitter unit, receiver unit, and the like.” (*Id.* at 13:21-24.)

Abbott's 842 and 653 patents solved the data-gap problem. For example, when a calibration measurement fails, the data gap can be filled by processing uncalibrated data using calibration parameters from a subsequent successful calibration event. (*Id.* at 12:47-54.) Then, “the gap in [the] output display ... may be filled.” (*Id.* at 12:59-61.)



(*Id.* at FIG. 7B.)

Abbott’s Patented Drift Correction. Early CGM systems required periodic re-calibration at least in part due to a phenomenon known as drift. (Ex. 10 at 3:27-38.) Drift can be understood as a change over time to the relationship between the glucose concentration and the sensor signal. To reduce inaccuracies, sensors had to be re-calibrated repeatedly during the wear life, typically involving fingerstick measurements. (*Id.*)

Abbott’s 954 patent addressed this problem with, *inter alia*, a drift profile programmed into memory, where the drift profile represents drift as a function of time. (*Id.* at claim 1.) Using the drift profile, the system determines a drift correction factor to compensate for drift and produce more accurate glucose concentration readings, even without re-calibration. (*Id.*) This technology supports CGM systems that do not require any user calibration during an extended wear life.

III. LEGAL PRINCIPLES

“[T]he words of a claim ‘are generally given their ordinary and customary meaning,’” which “is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention,” when read “in the context of the entire patent.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005).

When construing claims, courts should first look to the intrinsic evidence: the claims, specification, and prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The specification is “the single best guide to the meaning of a disputed

term.” *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). The Federal Circuit has strongly cautioned, however, that “limitations from the specification are not to be read into the claims.” *Teleflex, Inc. v. Ficos N. Am. Corp.*, 299 F.3d 1313, 1326 (Fed. Cir. 2002). The claims themselves also “provide substantial guidance as to the meaning of particular claim terms.” *Phillips*, 415 F.3d at 1314. Courts “should also consider the patent’s prosecution history,” which “provides evidence of how the PTO and the inventor understood the patent.” *Id.* at 1317.

Courts can also consult extrinsic evidence. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). “[D]ictionaries, and especially technical dictionaries, ... have been properly recognized as among the many tools that can assist the court in determining the meaning of particular terminology.” *Phillips*, 415 F.3d at 1318.

IV. DISPUTED CLAIM TERMS

A. 443 Patent

1. “first spring”

Abbott’s Proposed Construction	DexCom’s Proposed Construction
Plain and ordinary meaning (no construction needed or “first spring”)	Compression spring loaded along its axis

“Spring” is a common, everyday term.³ It is readily understandable not only to POSITAs, but to lay people as well. Springs are basic elastic elements that have existed for centuries. They provide a force via stored energy. Common examples include compression, extension, and torsion springs (among others). (Leinsing Decl. ¶¶45-50.)

³ The word “first” in “first spring” is merely a numerical identifier and non-limiting. *Free Motion Fitness, Inc. v. Cybex Int’l, Inc.*, 423 F.3d 1343, 1348 (Fed. Cir. 2005).

The Federal Circuit has made clear that common, generic terms like “spring” typically do not require construction. *Phillips*, 415 F.3d at 1314 (some terms “may be readily apparent even to lay judges”). Indeed, courts specifically have declined to construe “spring” for this reason. *See, e.g., Ethicon Endo-Surgery, Inc. v. Covidien, Inc.*, 2017 WL 1313851, *3-4 (S.D. Ohio Apr. 10, 2017) (ordinary meaning of “spring” is apparent; rejecting attempt to narrow its meaning by importing a limitation from an embodiment).

Abbott submits that “spring” requires no construction. DexCom agrees that the word “spring” need not be construed, including “spring” in its construction. Instead, DexCom seeks to add narrowing limitations not found in the claim language (i.e., “compression” spring “loaded along its axis”). Specifically, DexCom argues that the general term “spring” means only one type of spring (compression)—to the exclusion of all others—contrary to the ordinary meaning of “spring.” DexCom also argues that “spring” requires the spring to be “loaded along its axis” even though the claim language says nothing about loading, let alone a specific way of loading.⁴ DexCom’s attempt to inject non-existent limitations into the general term “spring” is improper. *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330-31 (Fed. Cir. 2007) (“[The Court] cannot endorse a construction analysis that does not identify a ‘textual reference in the actual language of the claim with which to associate a proffered claim construction.’”); *Shire ViroPharma Inc. v. CSL Behring LLC*, 2019 WL 6118253, *10-11, 13 (D. Del. Nov. 18, 2019) (refusing to limit “pharmaceutical composition” to **only liquid** pharmaceutical compositions because, *inter alia*, “the claim language neither expressly nor implicitly teaches a limitation to a

⁴ Further showing the flaws in DexCom’s position, DexCom argues the same construction for “first spring” and “first spring **in a loaded position**,” despite the differences in language. *See infra* § IV.B.1.

liquid pharmaceutical composition”; “[The Court cannot] add a narrowing modifier before an otherwise general term that stands unmodified in a claim.”).

DexCom’s motive is clear. Its accused products use a first spring. It is a torsion spring, not a compression spring. That is why DexCom seeks to improperly narrow the ordinary meaning of the generic term “spring.”

As shown herein, DexCom’s construction is refuted by the intrinsic and extrinsic evidence and violates fundamental claim construction principles. Abbott’s plain-and-ordinary-meaning construction should be adopted.

Claim construction starts with—and remains centered on—the claims themselves. The claims of the 443 patent—alone—are decisive.

Independent claims 1 and 13 of the 443 patent recite “a first spring” with no restriction as to spring type or loading. Dependent claims 3 and 15 restrict the “first spring” to “a coil spring.” (Ex. 2 at claims 3 & 15.) Under the doctrine of claim differentiation, dependent claims 3 and 15 provide “strong evidence” that “first spring” in the independent claims is not limited to a specific spring type. *Netflix, Inc. v. Divx, LLC*, 2022 WL 2298983, *4 (Fed. Cir. June 27, 2022); *Invisible Fence, Inc. v. Perimetre Techs., Inc.*, 2006 WL 1443399, *7 (N.D. Ind. May 25, 2006) (“**Through the doctrine of claim differentiation, the term ‘a spring’ as used in claim 9 is broad enough to cover various types of springs**” where a dependent claim recited a specific spring type). Moreover, these dependent claims confirm that “first spring” includes coil springs. Importantly, two of the most common examples of coil springs are extension and torsion springs, neither of which are “compression springs loaded along their axis.” (Leinsing Decl. ¶¶47, 53; Ex. 71 (discussing the “History of the Coil Spring” and noting that “Three common types of coil spring designs are compression, extension, and torsion.”)); *Ethicon*, 2017 WL 1313851, *4

(refusing to limit ordinary meaning of “spring” where the claims mention “springs that are not limited to [the spring type advocated by defendant].”). Thus, these dependent claims strongly indicate that DexCom’s restrictive construction is incorrect.

The specification likewise confirms Abbott’s position. For example, the specification broadly teaches using a wide variety of drivers for advancing the “introducer” (needle) and sensor into the skin (like the “first spring” of the 443 patent). (Ex. 2 at 7:62-8:2.) Examples include “a spring” generally and a “wound spring” more specifically among other options:

The carrier 204 drives the sensor 42 and, optionally, the introducer 120 into the skin of the patient using, **for example**, a cocked or **wound spring**, a burst of compressed gas, an electromagnet repelled by a second magnet, **or the like**, within the insertion gun 200. In some instances, **for example**, when using **a spring**, the carrier 204 and introducer 120 may be moved, cocked, or otherwise prepared to be directed towards the skin of the patient.

(*Id.*) The specification emphasizes the breadth of its teachings by using terms like “for example” and “or the like.” Moreover, “wound springs” (as specifically recited) include springs that are not “compression springs loaded along their axis.” (Leinsing Decl. ¶54.) One example is a torsion spring (considered to be both a coil spring and a wound spring). (*See, e.g., id.*; Ex. 75 (torsion springs are “wound” springs having “active coils”); Ex. 99.)

The specification elsewhere teaches that a drive force can be provided via “stored potential energy” (citing a coil spring as an example). (Ex. 2 at 13:1-14; *see also id.* at 18:34-39 (referring generally to the use of “spring forces” for an insertion force).) The specification nowhere states that only specific springs (compression or otherwise) can be used with the claimed inventions. Further, consistent with the ordinary meaning of “spring,” the specification describes and/or depicts multiple exemplary springs. (*Id.* at 7:62-66 (“wound” spring), Figs. 12, 16.)

Contrary to fundamental claim construction law, DexCom apparently seeks to narrow “spring” by importing a limitation from exemplary figures. *Enercon GmbH v. Int’l Trade Comm’n*, 151 F.3d 1376, 1384 (Fed. Cir. 1998) (“Generally, particular limitations or embodiments ... will not be read into the claims.”). For example, Figure 16 depicts an embodiment of the claims. The “first spring” depicted in that figure (item 336) is a compression spring. But that does not mean “first spring” is limited to only compression springs. *Id.* (even where a patent describes only a single embodiment, claims should not be read restrictively). Indeed, in the textual description of that embodiment, the specification uses the broad term “**drive spring**” (not “compression” spring) to describe the spring (i.e., “drive spring 336”). (Ex. 2 at 14:3-8.)

The file history of the 443 patent is also instructive. During prosecution, pending claim 17 recited “a spring.” (Ex. 14 at 2.) The examiner rejected this claim based on the prior art’s teaching of a wound spring. (Ex. 15 at 4 (addressing pending claims 17 & 18).) In other words, consistent with the ordinary meaning of “spring,” the Examiner understood the genus term “spring” to include the species of “wound” springs, which (as noted above), include springs that are not “compression springs loaded along their axis.”

Finally, extrinsic evidence confirms that POSITAs would not understand the general term “first spring” to be limited only to “compression springs loaded along their axis.” (Leinsing Decl. ¶¶42-61.)

B. 341, 654, and 216 Patents

1. “first spring in a loaded position”

Abbott’s Proposed Construction	DexCom’s Proposed Construction
Plain and ordinary meaning (no construction needed or “first spring that is loaded”)	Compression spring loaded along its axis

Like “first spring” above, “first spring in a loaded position” is a common term that does not require construction. Both parties agree that “first spring in a loaded position” is a loaded spring. But DexCom again seeks to add limitations with no basis in the claim language, asserting that the general term “spring” means only one type of spring (compression) and the general term “loaded” means the spring can be loaded only one way (along its axis). This is improper. *MBO Labs.*, 474 F.3d at 1330-31; *Shire*, 2019 WL 6118253, *10-11, 13 (improper to “add a narrowing modifier before an otherwise general term”). Abbott’s view is confirmed, and DexCom’s view refuted, by the intrinsic and extrinsic evidence.

The claims alone are dispositive. “First spring in a loaded position” appears in the independent claims of all three patents from this family. (Ex. 5 at claims 1, 26; Ex. 6 at claims 1, 20; Ex. 7 at claims 1, 26.) Because these patents all stem from the same parent, the term should be construed the same in all three. *Samsung Elecs. v. Elm 3DS Innovations*, 925 F.3d 1373, 1378 (Fed. Cir. 2019). In the 341 patent, dependent claims 4 and 27 state “**wherein the first spring is a torsion spring.**” Given these dependent claims, DexCom’s construction cannot be correct because a torsion spring is not a “compression spring loaded along its axis.” *Ethicon*, 2017 WL 1313851, *4 (refusing to limit ordinary meaning of “spring” where “springs that do not fit [defendant’s proposed construction] are contemplated in the various patent claims.”); *Shire*, 2019 WL 6118253, *7, 11 (dependent claim cannot be broader than the independent claim); *Littlefuse, Inc. v. Mersen USA EP Corp.*, 29 F.4th 1376, 1379-80 (Fed. Cir. 2022) (constructions that exclude a dependent claim are “disfavored” and “should be avoided when possible”). Also, under claim differentiation, these dependent claims strongly suggest that “spring” in the independent claims is not limited to a specific type of spring. (*See supra* § IV.A.1.)

Additionally, “the context of the surrounding words of the claim also must be considered.” *Phillips*, 415 F.3d at 1314. Each independent claim recites “a first spring” and “a second spring.” (Ex. 5 at claims 1, 26; Ex. 6 at claims 1, 20; Ex. 7 at claims 1, 26.) Each one further specifies that “the second spring is a compression spring” but does not limit the “first spring.” (*Id.*) In other words, when the independent claims were intended to limit “spring” to a compression spring, they were drafted so expressly.

The common specification of all three patents likewise confirms Abbott’s proposed construction. For example, the specification includes a “Summary” section. (Ex. 5 at 2:58-4:54.) The “Summary” broadly describes inserters that utilize “a second driver” to facilitate advancement of the sharp (like the “first spring” of the asserted patents). (*Id.* at 2:60-3:18.) The “Summary” then teaches that the “second driver” can be a “torsion spring,” “compression spring,” or a variety of other options. (*Id.* at 3:19-22.)

Other general teachings support a broad construction of “spring.” Specifically, the specification also includes an “Insertion Assembly” section that generally describes the inserters of the patent. (*Id.* at 22:24-23:67.) The specification again broadly teaches that the inserters may have “[a] **driver** ... for advancing the sharp and/or analyte sensor/support structure” without limiting the type of “driver.” (*Id.* at 23:17-19.) That same section broadly teaches that the inserters likewise may have a “drive assembly” for retracting the sharp away from the skin, wherein “the drive assembly may include **a spring** [without restricting the spring type], motor, hydraulic piston, etc.” (*Id.* at 23:42-47.) In short, the specification teaches broadly, rather than restrictively, with respect to the source of drive forces. (Leinsing Decl. ¶¶74-76.)

The original claims of the earliest priority application—which form part of the specification⁵—are consistent with the above specification teachings. Original independent claim 1 recites “an apparatus for inserting a medical device” that includes “a second driver for advancing the sharp support towards” the skin. (Ex. 36 at claim 1.) The Examiner thereafter found that this “generic” claim 1 encompassed multiple embodiments in the specification, including the embodiment in Figs. 25-31 (a sample embodiment covered by asserted claims). (Ex. 37 at 2.) Notably, the original claims expressly teach that the inserters of original claim 1 could use a torsion spring (claim 3), compression spring (claim 5), or other options (claims 2 and 4) as part of the “second driver.” (Ex. 36 at claims 2-5.)

As with the 443 patent, and contrary to fundamental claim construction law, DexCom apparently seeks to narrow the ordinary meaning of “spring” by importing a limitation from an exemplary embodiment. *Enercon*, 151 F.3d at 1384. As noted above, Figures 25-31 depict a sample embodiment. The “first spring” depicted in those figures (item 3714) is a compression spring. But that does not mean “first spring in a loaded position” is limited to a compression spring. *Id.* (claims generally will not be read restrictively even where the patent describes only a single embodiment). Indeed, in the textual description of that sample embodiment, the specification uses the broad terms “**drive spring** 3714” and “**spring** 3714” to describe the first spring. (Ex. 5 at 29:16-19; Leinsing Decl. ¶80.)

As for the file histories, the Examiner never found that the generic term “first spring” in the independent claims was limited to any type of spring. Moreover, in connection with the 341 patent, the Examiner expressly found that “first spring” includes torsion springs (as reflected by the allowed “torsion spring” dependent claims). In the 654 and 216 file histories, the

⁵ *Scriptpro LLC v. Innovation Assoc., Inc.*, 833 F.3d 1336, 1341-42 (Fed. Cir. 2016).

Examiner did question whether there was sufficient written description to specifically claim a “torsion spring”—in dependent claims—in conjunction with the other claim elements. (*See, e.g.*, Ex. 45 at 3.) Abbott expressly disagreed (indeed, Abbott had already obtained similar claims reciting a “torsion spring” in the 341 patent without objection from the Examiner). (*See, e.g.*, Ex. 46 at 9.) Nevertheless, as is common prosecution practice, Abbott decided to, “without prejudice,” cancel the species dependent claims “for the sole purpose of advancing prosecution, and without conceding the merits of the rejection under Section 112, first paragraph.” (*Id.*) This is not remotely a disclaimer of the scope of “spring” in the independent claims of the 654 and 216 patents (to the extent DexCom tries to so argue). *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045-47 (Fed. Cir. 2016) (prosecution disclaimer cannot be found unless the disclaimer is “clear and unmistakable” – a “high” burden to prove); *Epistar Corp. v. Int’l Trade Comm’n*, 566 F.3d 1321, 1334-35 (Fed. Cir. 2009) (to “overcome [the] heavy presumption that claim terms carry their full ordinary and customary meaning,” there must be “a clear disavowal of claim scope” by “expressions of manifest exclusion or restriction”). Indeed, courts in this District have repeatedly found that canceling claims under similar circumstances is not a disclaimer. *Enzo Life Sci., Inc. v. Gen-Probe, Inc.*, 2015 WL 4101205, *6-7 (D. Del. July 7, 2015) (“Defendants have failed to persuade the Court that the patentee’s tactical decision to cancel claims expressly covering partial strandedness means that the claims it was issued require the Court to construe ‘double stranded’ in a manner that excludes partial strandedness.”); *Ondeo Nalco Co. v. EKA Chem., Inc.*, 2003 WL 1524661, *1 n.2 (D. Del. Mar. 21, 2003) (“The court concludes ... that the patentee’s agreement to cancel claim 4 in order to allow claim 1 to issue was not an express disavowal of the claim scope sought by Eka now.”).

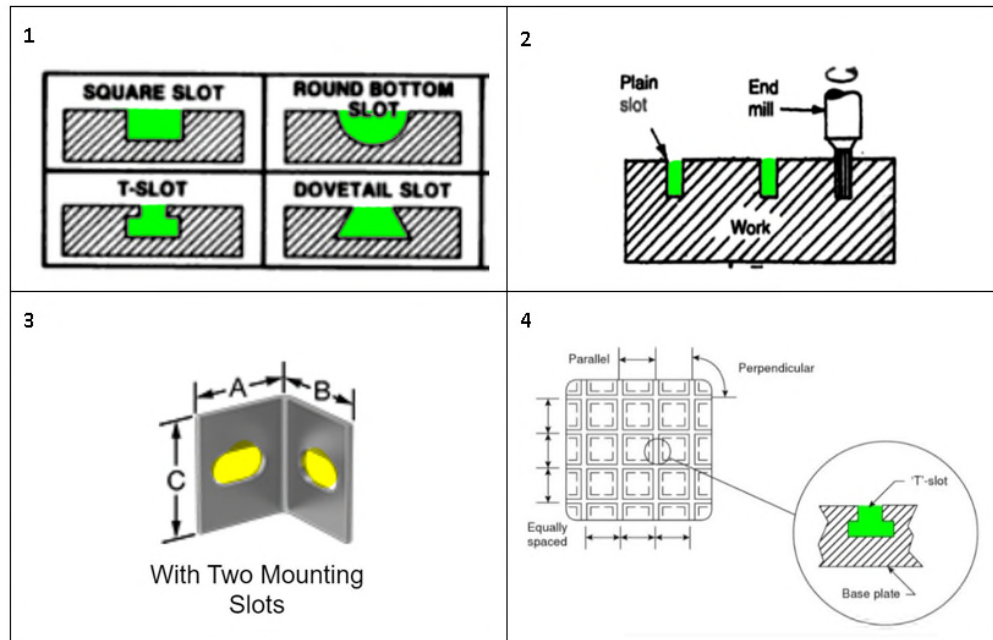
Finally, the extrinsic evidence confirms that POSITAs would not understand (a) the term “first spring” to be limited only to compression springs or (b) the term “in a loaded state” to be limited only to “loaded along its axis.” (Leinsing Decl. ¶¶65-82.)

C. 649 and 440 Patents

1. “slot”

Abbott’s Proposed Construction	DexCom’s Proposed Construction
Plain and ordinary meaning (“a narrow opening, groove, or channel”)	Narrow opening through the first slidable body, through which the rotor follower projection extends

Like “spring,” “slot” is a common everyday word. The ordinary meaning of “slot” is “a narrow opening, groove, or channel.” (Leinsing Decl. ¶88.) This is confirmed by numerous dictionaries. (*See, e.g.*, Ex. 76 at 1342 (“a narrow, elongated depression, groove, notch, slit, or aperture”); Ex. 79 at 642 (“a narrow opening through which something is to be put [A] groove or channel or slit into which something fits.”); Exs. 76-82; Leinsing Decl. ¶¶109-116.) Standard technical guides and literature likewise confirm this ordinary meaning. For example, here are sample “slots” depicted in such documents:



(Leinsing Decl. ¶¶117-122 (citing, *e.g.*, “Comprehensive Basic Mechanical Engineering” and “Manufacturing Processes Reference Guide”).) Consistent with the ordinary meaning of “slot,” the above examples include slots that go all the way through an object (“through-slots”) (see example 3 in yellow) and others that do not (“non-through-slots”) (see examples 1, 2, and 4 in green). (See also *id.*)

Contrary to the ordinary meaning of “slot,” DexCom asserts that “slot” in the 649 and 440 patents is limited to only one subset of slots, *i.e.*, through-slots. DexCom has taken that position in its pending IPR petitions against these patents. (See, *e.g.*, Ex. 87 at 47.) Specifically, DexCom’s proposed construction is limited only to an “opening” “through” a slidable body “through which” a rotor follower projection extends.

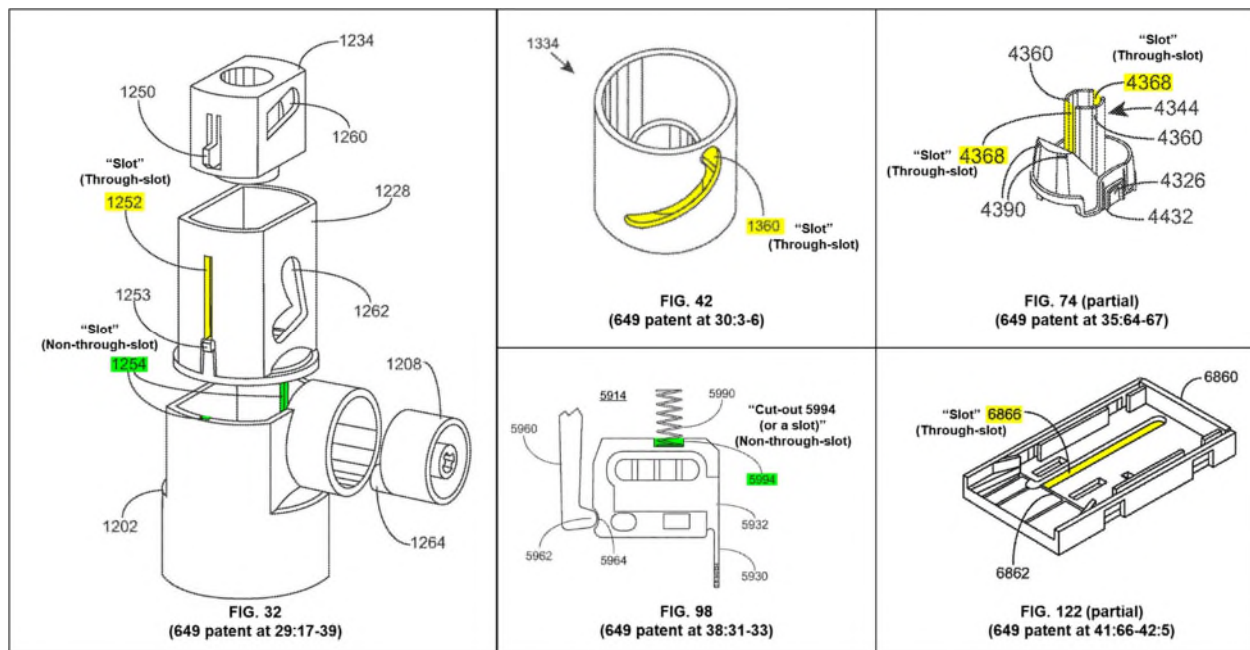
Fundamentally, the parties’ dispute is whether, in accordance with its ordinary meaning, the term “slot” encompasses both through-slots and non-through-slots. Or alternatively, whether “slot” is narrowly restricted to only one type of slot (through-slots) contrary to its ordinary meaning. As shown below, the intrinsic evidence is dispositive in Abbott’s favor.

The claim language is highly instructive. The claim term simply recites a “slot.” It does not say “through” slot or use any other modifying term to narrow the ordinary meaning of “slot.” *Shire*, 2019 WL 6118253, *10-11, 13 (refusing to limit “pharmaceutical composition” to only liquid compositions: “Notably absent from [the claim] language is any requirement that the ‘composition’ be a liquid.”).

For additional reasons, the claim language shows that DexCom’s construction is incorrect. DexCom’s construction states that the slot is “through the first slidable body, through which the rotor follower projection extends.” But there is no textual basis in “slot” for this part of DexCom’s construction. *MBO Labs.*, 474 F.3d at 1330-31. The term “slot” says nothing about a “first slidable body” or “rotor follower projection.” Moreover, to the extent there are any required structural relationships between the “slot” and those claimed components, they are expressly addressed in other parts of the claim and should not be read into the general term “slot.” *See, e.g., Greatbatch Ltd. v. AVX Corp.*, 2015 WL 1383656, *3 (D. Del. Mar. 20, 2015) (declining to read structural limitations into a term because the claim elsewhere expressly recites any required structural limitations), *aff’d*, 813 Fed. Appx. 609 (Fed. Cir. 2020).

The specification is dispositive. It uses the term “slot” multiple times. And “[i]t is well-established ... that claim terms are to be construed consistently throughout a patent.” *Phil-Insul Corp. v. Airlite Plastics Co.*, 854 F.3d 1344, 1359 (Fed. Cir. 2017); *Eli Lilly & Co. v. Eagle Pharms., Inc.*, 2019 WL 1299212, *2, 4 (D. Del. Mar. 21, 2019) (“administration” not limited to “liquid administration” because the specification also discloses non-liquid administration and noting that claim terms should be construed consistently throughout a patent). Importantly, consistent with the ordinary meaning of “slot,” the specification uses “slot” to describe both

through-slots and non-through-slots. Here are several examples (with through-slots in yellow and non-through-slots in green):



(Ex. 3 at Figures 32, 42, 74, 98, 122 (annotated).) In light of these examples, “slot” cannot be limited to only a through-slot as DexCom urges. *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (“[I]f an apparatus claim recites a general structure (*e.g.*, a noun) without limiting that structure to a specific subset of structures (*e.g.*, with an adjective), we will generally construe the claim to cover all known types of that structure that are supported by the patent disclosure.”); *Shire*, 2019 WL 6118253, *10-11, 13 (improper to “add a narrowing modifier before an otherwise general term that stands unmodified in a claim.”).

For another reason, the above disclosed “slot” examples show that DexCom’s construction is wrong. Many of them are neither “through a first slidable body” nor does a rotor follower projection extend through them (as DexCom’s construction requires). (Leinsing Decl. ¶108.) Thus “slot”—as used throughout the 649 and 440 patents—cannot mean what DexCom says.

DexCom again apparently seeks to narrow the ordinary meaning of a claim term by importing a limitation from an embodiment. Figures 37-46 of the 649 and 440 patents depict an embodiment of the claims. The “slot” in the first slidable body of that example (item 1360) is a through-slot. But under basic claim construction law, that is not a proper basis for limiting “slot” to a through-slot. *Enercon*, 151 F.3d at 1384. Here, nothing in the specification nor anywhere else “clearly and unmistakably” disclaims non-through-slots. Quite the opposite, as shown above, the specification expressly discloses **both** through-slots and non-through-slots.

Finally, as shown above, the extrinsic evidence—including dictionaries, scientific literature, and expert testimony—supports Abbott’s construction. (Leinsing Decl. ¶¶86-123.)

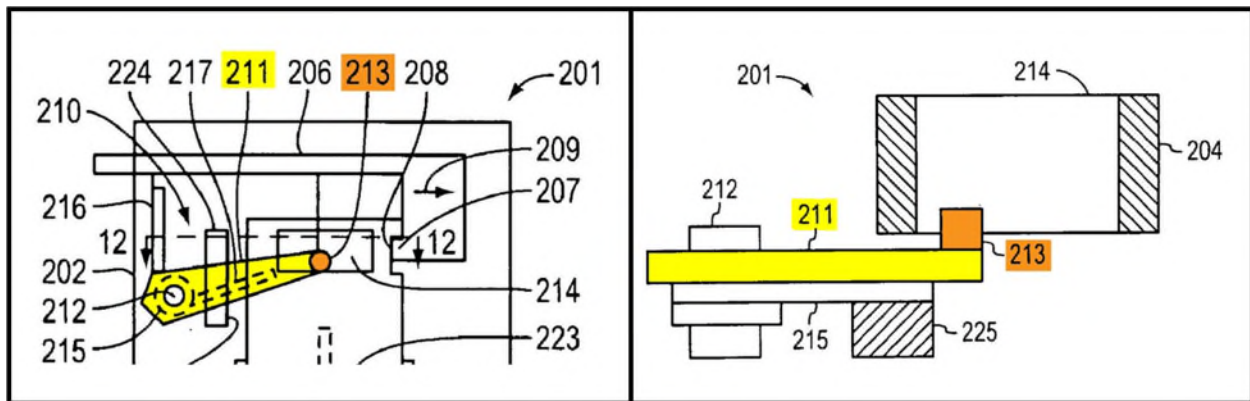
2. “rotor comprising a cylindrical shape”

Abbott’s Proposed Construction	DexCom’s Proposed Construction
Plain and ordinary meaning (“rotor having an overall cylindrical shape”)	Plain and ordinary meaning

The claim term “rotor comprising a cylindrical shape” is straightforward. It means the rotor itself has a cylindrical shape, but can have other features as well. MPEP §2111.03 (“comprising” is open-ended and means, *inter alia*, “characterized by”).) This is the logical and natural reading of the term, especially in light of the intrinsic evidence. (Leinsing Decl. ¶¶124-144.) As shown below, the Examiner understood the same.

DexCom, on the other hand, offers no construction but instead says “plain and ordinary meaning.” However, based on DexCom’s IPR petitions filed against the 649 and 440 patents, DexCom apparently will assert that a “rotor comprising a cylindrical shape” means the rotor **or any sub-component of the rotor** has a cylindrical shape. The reason for DexCom’s strained construction arises out of necessity. DexCom’s primary prior art reference in its IPR petitions does not have a cylindrically-shaped rotor (but its alleged “rotor” has a small sub-

component that is cylindrically shaped). Specifically, DexCom alleges that “lever 211” (highlighted in yellow) in the image below is a “rotor comprising a cylindrical shape”:



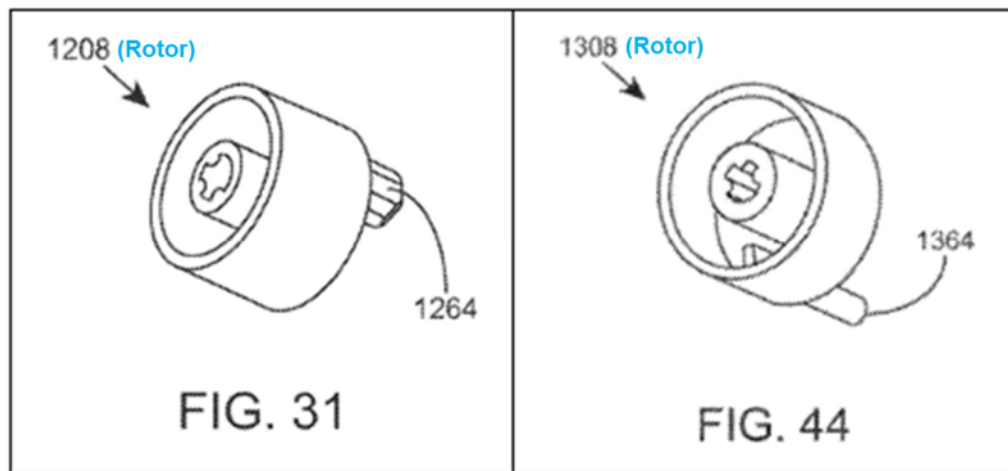
(Ex. 100 at Figs. 9 (partial) & 12 (highlighting added); Ex. 87 at 38-39.) Clearly, lever 211 is not cylindrical. Nevertheless, attempting to meet the claim language, DexCom alleges lever 211 (yellow highlighting) “compris[es] a cylindrical shape” because there is a small cylindrical nub (“rod 213”) extending from one end of the lever (orange highlighting). (Ex. 87 at 38-39.) That is not credible.

As an initial matter, the claim language is clear. It says the **rotor itself** comprises a cylindrical shape (i.e., the claim refers to the overall shape of the rotor). The claims do not say either the rotor itself **or a sub-component thereof** comprises a cylindrical shape. And the use of the open-ended “comprises” makes sense given the surrounding claim language. Beyond having a cylindrical shape, the claims further specify that the rotor “comprises” (or has) an additional feature, namely, “a rotor follower projection.” (Ex. 3 at claim 1; Ex. 4 at claim 1.) Here is an example from claim 18 of the 649 patent:

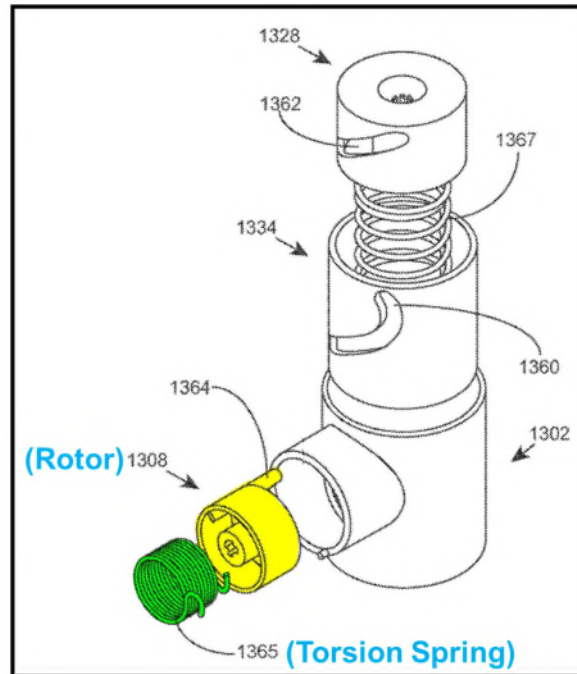
[An] inserter assembly comprising ... a rotor comprising a cylindrical shape, ... and wherein the rotor comprises a rotor follower projection

(Ex. 3 at claim 18.) In both instances, the term “rotor” is plainly referring to the rotor itself, not a sub-component thereof. (Leinsing Decl. ¶130.)

The specification also comports with Abbott’s construction. Although the phrase “cylindrical shape” does not appear in the specification, the claim term is supported by multiple figures. The specification depicts two rotors. Although neither is perfectly cylindrical (e.g., they have projections 1264 and 1364 extending from them), they both have an overall cylindrical shape:

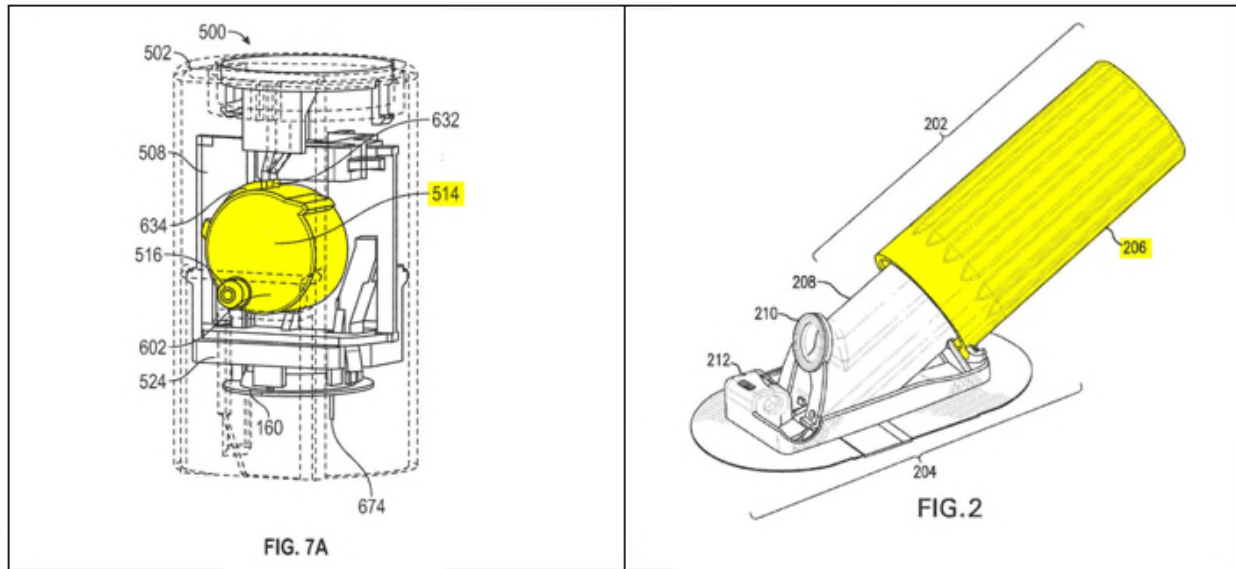


(Ex. 3 patent at Figs. 31, 44 (annotated).) Moreover, the specification and surrounding claim language provide a strong reason for having a cylindrically-shaped rotor—namely, to receive a torsion spring (which often has a generally cylindrical profile), *e.g.*, see annotated Figure 45:



(See also Ex. 4 at claim 1 (“a torsion spring received within the rotor”) Leinsing Decl. ¶137.)

The file history also supports Abbott, showing that the Examiner understood “rotor comprising a cylindrical shape” to refer to the overall shape of the rotor. Specifically, in the Notice of Allowance for the 440 patent, the Examiner discussed the “most relevant” art (citing three references). (Ex. 30 at 2-3.) The Examiner found that two of the references disclose “a cylindrical rotor” (*i.e.*, the Examiner equated a “rotor comprising a cylindrical shape” with a “cylindrical rotor”). (*Id.* at 3.) And notably, the “cylindrical rotors” cited by the Examiner (items 514 and 206) have an overall cylindrical shape (albeit not perfectly cylindrical, *e.g.*, they have projections/flanges or ridges)—see the yellow highlighting below:



(*Id.*; Ex. 88 at Fig. 7A; Ex. 89 at Fig. 2.)

DexCom’s own actions also support Abbott’s view. In its IPR petitions, DexCom asserts two grounds—a primary ground and an “alternative” second ground. (*See, e.g.*, Ex. 87 at ii-iii (Section VII & VIII headings).) In DexCom’s first ground, the alleged “rotor” in the cited prior art (which is really a lever) does not have an overall cylindrical shape. Knowing that its primary Ground 1 rests on a strained construction of a “rotor comprising a cylindrical shape,” DexCom advances an “alternative[]” Ground 2 “***to the extent the claims are interpreted as requiring ... a rotor having an overall cylindrical shape***” (*Id.* at 93.) DexCom then cites additional art purportedly disclosing—using DexCom’s words—“a rotor having an overall cylindrical shape” or “cylindrical shaped rotor.” (*Id.* at 95-96, 98; *see also id.* at 40 (referring to “cylindrical rotors,” “cylindrically shaped rotors,” and rotors “having an overall cylindrical shape”).) In short, DexCom itself acknowledges that Abbott’s proposed construction is, at the very least, a plausible plain and ordinary meaning of the term.

Finally, consistent with the evidence above, Abbott’s expert confirms that POSITAs would understand the term to refer to the overall shape of the rotor. (Leinsing Decl. ¶¶124-144.)

D. 842 and 653 Patents

1. “processing/process the sensor data”

Abbott’s Proposed Construction	DexCom’s Proposed Construction
Converting/convert the sensor data into calibrated analyte values	Plain and ordinary meaning

In the 842 patent, the terms “processing ... the sensor data” (claim 1), “processing the sensor data” (claim 8), and “process the sensor data” (claim 14) refer to converting/convert the sensor data into calibrated analyte values, which are then displayed to the user. (Sarrafzadeh Decl. ¶56.) The intrinsic evidence confirms this, beginning with the plain language of the claims.

For example, claims 1 and 14 of the 842 patent recite that “sensor data [is] received from the analyte sensor” and stored. (Ex. 8 at claim 1.) This sensor data is then “process[ed].” (*Id.*) The claims further recite that the “processed stored sensor data [is output] to the display of the analyte monitoring system.” (*Id.*) Thus, what the user views on the display is processed sensor data. (Sarrafzadeh Decl. ¶60.)

In analyte monitoring systems, data received from an analyte sensor, which typically comprises electrical signals, must be converted into a corresponding analyte level to be interpretable and useful to the user and their physician. (Sarrafzadeh Decl. ¶¶61-62.) To achieve this, analyte sensors are calibrated such that a relationship is determined between the measured electrical signals and corresponding analyte levels. (Sarrafzadeh Decl. ¶63.) As a result, the user sees analyte concentration values on the display.

The specification teaches that “[p]eriodic calibration of the sensor unit 101 (FIG. 1) of an analyte monitoring system 100 ... may be required for accurate calculation of a user’s analyte level.” (Ex. 8 at 10:59-61.) “Calibration ... is used to ensure the analyte related data signals received at a transmitter unit 102 ... are correctly converted to corresponding analyte levels.” (*Id.* at 10:62-66.)

The specification further teaches that calibrated sensor data is output to the display and thus equates “processing the sensor data” with converting the sensor data into calibrated analyte values. (Sarrafzadeh Decl. ¶66.) For example, the specification explains that if a calibration event is unsuccessful, “the receiver unit may no longer display the monitored and processed glucose information.” (Ex. 8 at 11:16-18.) However, “once the system recovers after a successful calibration event, **the calibrated sensor data** is once again displayed.” (*Id.* at 12:45-47.)

Other parts of the specification also teach that “processing the sensor data” refers to converting the sensor data into calibrated analyte values to be output to the display. (Sarrafzadeh Decl. ¶68.) The Abstract, for example, explains that the disclosure provides “methods and apparatus for receiving sensor data from an analyte sensor of a sensor monitoring system, processing the received sensor data with time corresponding calibration data, [and] outputting the processed sensor data.” (Ex. 8 at Abstract.) As another example, the specification explains that after a failure mode condition is corrected:

the subset of analyte related sensor data that were previously unprocessed or uncalibrated due to unsuccessful contemporaneous calibration may be processed using, for example, calibration data such as the sensitivity ratio determined from the most recent successful calibration event, and thereafter, the gap in output display illustrating the processed and calibrated signals may be filled.

(*Id.* at 12:54-61; Sarrafzadeh Decl. ¶67.)

And while the specification uses the term “processing” to include other types of actions such as “filtering and encoding” (Ex. 8 at 5:59), “data decoding, error detection and correction, data clock generation, and data bit recovery” (*id.* at 6:30-33), the specific type of processing claimed must refer to converting the sensor data into calibrated analyte values because only calibrated analyte values are output to the display, which the claims refer to as “processed sensor data.” (Sarrafzadeh Decl. ¶¶59-60, 69.)

2. “data indicative of the sensed glucose level”

Abbott’s Proposed Construction	DexCom’s Proposed Construction
Calibrated glucose values	Plain and ordinary meaning

The claims of the 653 patent use terminology that differs from the 842 patent, but for the same reasons explained above, “data indicative of the sensed glucose level” refers to “calibrated glucose values.”⁶ (Sarrafzadeh Decl. ¶71.)

In particular, claim 1 of the 653 patent recites “a glucose sensor, a portion of which is configured to be positioned under skin of the user and sense a glucose level of the user.” (Ex. 9 at claim 1.) The system of claim 1 includes “a data processing and transmitter unit coupled with the glucose sensor, wherein the data processing and transmitter unit is configured to transmit ***data indicative of the sensed glucose level*** over a Bluetooth wireless communication link.” (*Id.*) The “data indicative of the sensed glucose level” is then output “to a display of the receiver unit.” (*Id.*)

As explained above, the user views calibrated glucose levels on the display. (Sarrafzadeh Decl. ¶73.) Therefore, “data indicative of the sensed glucose level” must mean “calibrated glucose values.” (*Id.*)

⁶ The claims of the 842 patent are directed to analyte monitoring systems whereas the claims of the 653 patent are directed specifically to glucose monitoring systems.

3. “*failure mode condition*”

Abbott’s Proposed Construction	DexCom’s Proposed Construction
Condition that adversely affects function	Condition that requires disabling the output of sensor data

The claims, specification, and file histories support construing “failure mode condition” to mean a condition that adversely affects function. (Sarrafzadeh Decl. ¶75.) Claim 1 of the 842 patent is directed to “[a] method of backfilling one or more sensor data gaps” and includes “detecting ... a *failure mode condition*, wherein the *failure mode condition* causes one or more sensor data gaps to be outputted to a display.” (Ex. 8 at claim 1; *see also id.* at claim 14 (“detect a failure mode condition, wherein the failure mode condition causes one or more sensor data gaps to be outputted to a display of the analyte monitoring system”).) When the disputed term is read within the full context of the claim, it is clear that a “condition that adversely affects function” “*causes* one or more sensor data gaps to be outputted to a display.” (Sarrafzadeh Decl. ¶¶76-77); *Phillips*, 415 F.3d at 1314 (“[T]he context of the surrounding words of the claim also must be considered.”).

Various different types of failure mode conditions that can cause data gaps are expressly recited in the specification. These examples include an “inability to promptly calibrate the sensor, system malfunction, sensor dislodging, signal errors associated with the sensor, transmitter unit, receiver unit, and the like, or any other variables or parameters that result in the inability of the analyte monitoring system to display or output the real-time monitored analyte level.” (Ex. 8 at 13:21-27.) Each of these recited failure mode conditions is a condition that adversely affects the functioning of the system, consistent with Abbott’s construction. (Sarrafzadeh Decl. ¶81.)

The specification also uses the term “adverse condition” in a manner consistent with “failure mode condition.” For example, it teaches that, in some embodiments, “one or more detected adverse conditions may include one or more of a sensor instability condition, a calibration failure condition, or a monitoring system failure condition.” (Ex. 8 at 13:60-62.) “The calibration failure condition may include one or more of an analyte level exceeding a predetermined threshold, a rate of change of an analyte level exceeding a predetermined threshold, a signal error associated with the reference data, a data unavailability condition, or a combination thereof.” (*Id.* at 14:1-5; *see also id.* at 14:26-27 (“The condition unsuitable for calibration may include one or more of a failure mode of a sensor, ...”); Sarrafzadeh Decl. ¶83.)

Indeed, during prosecution of the 842 patent, the Examiner understood “failure mode condition” to be a condition that adversely affects function. In issuing a double-patenting rejection, the Examiner found that the claims of the 842 patent differed from three related patents “in that the instant claims recite ‘failure mode condition’, whereas the U.S. Patent[s] recite[] an ‘adverse condition’.” (Ex. 54 at 3-4.) The Examiner explained, “[h]owever, **a failure mode condition may be interpreted as a form of an adverse condition effecting an analyte monitoring system.**” (*Id.*; Sarrafzadeh Decl. ¶¶84-86.)

Abbott’s construction also comports with extrinsic evidence. For example, the book, *Guidelines for Failure Modes & Effects Analysis for Medical Devices*, defines a “potential failure mode” as “the manner in which a failure can occur i.e. **the ways in which the reviewed item can fail to perform its intended design function**, or perform the function but fail to meet the objective.” (Ex. 68; Sarrafzadeh Decl. ¶¶87-90.)

DexCom’s proposed construction, on the other hand, is an attempt to backdoor limitations from the specification into a different part of the claims. Instead of addressing what a

failure mode condition is, DexCom’s construction targets how sensor data gaps can be output to a display. (Sarrafzadeh Decl. ¶94.) According to DexCom, data gaps can be output to a display only by “disabling the output of sensor data.” DexCom’s construction is wrong for several reasons.

First, this construction must be rejected in light of the plain language of the claims because “sensor data” is not output to the display in either the 842 or the 653 patent. (Sarrafzadeh Decl. ¶93.) Rather, according to claims 1 and 14 of the 842 patent, “***processed*** stored sensor data” is output to the display, not sensor data. (Ex. 8 at claim 1.) Similarly, claim 1 of the 653 patent recites outputting “data indicative of the sensed glucose level,” not sensor data. (Ex. 9 at claim 1.) On this basis alone, DexCom’s construction must be rejected. (Sarrafzadeh Decl. ¶93.)

Second, DexCom’s construction renders other parts of the claims redundant (and in a limiting way). The claims already recite that a failure mode condition “***causes*** one or more sensor data gaps to be outputted to a display.” (Ex. 8 at claim 1; Sarrafzadeh Decl. ¶99.) However, substituting DexCom’s construction into claim 1 of the 842 patent, for example, yields: “detecting ... a [condition that requires disabling the output of sensor data], wherein the [condition that requires disabling the output of sensor data] causes one or more sensor data gaps to be outputted to a display.” DexCom’s construction adds no clarity to the claims and instead imports limitations from the specification, which relate to one manner in which data gaps can be displayed, into a different part of the claim. *See Novartis Pharms. Corp. v. Actavis, Inc.*, 2013 WL 6142747, *4 (D. Del. Nov. 21, 2013) (rejecting construction that “would render other portions of the claim redundant and inject confusion, rather than clarity, into the understanding of this term’s meaning”).

Third, DexCom’s construction is incorrect in light of the specification. While the specification describes embodiments that can include disabling the output of sensor data, the specification also explains that “gaps in monitored analyte levels” can be “due to, for example, ...

the inability of the analyte monitoring system to display or output the real-time monitored analyte level.” (Ex. 8 at 13:20-27; *see also id.* at 11:13-18 (explaining that “the receiver unit *may no longer display* the ... glucose information” if calibration is unsuccessful); Sarrafzadeh Decl. ¶¶101-102.); *Enercon*, 151 F.3d at 1384 (“Generally, particular limitations or embodiments ... will not be read into the claims.”). Considering that an example failure mode condition includes “signal errors associated with the ... transmitter unit [or] receiver unit” such as when the transmitter and receiver are out of range or when there is wireless interference, the data gap is caused by the receiver being *unable* to display the data because it would not have received it, which is consistent with the specification’s broad teachings. (Ex. 8 at 13:25-27 (“inability ... to display or output the real-time monitored analyte level”); Sarrafzadeh Decl. ¶103.)

Accordingly, a POSITA would understand a “failure mode condition” to be a condition that adversely affects function, which in a separate limitation “causes one or more sensor data gaps to be outputted to the display.” (Sarrafzadeh Decl. ¶104.)

E. 954 Patent

1. “chemically bonded”

Abbott’s Proposed Construction	DexCom’s Proposed Construction
Bonded by attractive forces between atoms or molecules	Plain and ordinary meaning

The intrinsic and extrinsic evidence supports construing “chemically bonded” to mean “bonded by attractive forces between atoms or molecules.” (Smith Decl. ¶46.) In particular, as the term is used in the 954 specification, chemical bonds can occur at the atomic level (by attractive forces between atoms) and at the molecular level (by attractive forces between molecules). DexCom asserts that “chemically bonded” should have its plain and ordinary meaning,

but takes no position on what that meaning is and has not identified any “plain and ordinary meaning” that is different than Abbott’s construction.

“Chemically bonded” appears in claim 17 of the 954 patent, which depends from claim 16, which in turn depends from claim 1. (Ex. 10 at claims 1, 16, 17.) Claim 16 provides that “the analyte sensor” of claim 1 “comprises ... a working electrode comprising an analyte-responsive enzyme **bonded** to a polymer disposed on the working electrode.” (*Id.* at claim 16.) Claim 17 adds that “the analyte-responsive enzyme is **chemically bonded** to the polymer.” (*Id.* at claim 17.) Accordingly, claim 16 recites that the enzyme is bonded to a polymer, whereas claim 17 specifies that the enzyme is chemically bonded to the polymer.

The 954 specification describes chemical bonds that a POSITA would understand occur at both the atomic level and the molecular level. (Smith Decl. ¶45) For example, the specification of the 954 patent states that in one embodiment “[a] glucose-sensing layer is constructed by crosslinking together”: (1) a “redox polymer” and (2) an enzyme (“glucose oxidase”). (*Id.* at 18:42-47.) Crosslinking is where molecules are linked together by multiple chemical bonds. (Smith Decl. ¶39.) This example, therefore, describes an analyte-responsive enzyme chemically bonded to a polymer. These chemical bonds involve attractive forces between molecules at the molecular level and attractive forces between atoms at the atomic level. (Smith Decl. ¶45.)

In another example, “glucose oxidase enzyme molecules” are “crosslinked” with “Osmium-based mediator molecules” which are in turn chemically bonded “to a polymeric backbone.” (Ex. 10 at 18:15-17.) In this example, the three types of molecules (enzymes, mediators, and polymers) are all chemically bonded together, forming a multi-molecular structure.

(Smith Decl. ¶44.) This also describes an analyte-responsive enzyme chemically bonded to a polymer. (Smith Decl. ¶44.)

In other examples where enzymes are chemically bonded to polymers in the 954 patent, both the enzyme and polymer are molecules. (Smith Decl. ¶45; *see also* Ex. 10 at 18:15-50; 26:39-50.) Given these examples, a POSITA would understand that where “the analyte-responsive enzyme is chemically bonded to the polymer” as required by claim 17, the chemical bond refers to “attractive forces between atoms or molecules.” (Smith Decl. ¶46.)

Abbott’s construction also comports with the extrinsic evidence. For example, *Merriam-Webster’s Collegiate Dictionary*, 10th ed. (1999), defines “bond” in the chemical context as “an attractive force that holds together the atoms, ions, or groups of atoms in a molecule or crystal” (Ex. 69 at 130; *see also* Ex. 70 at 153 (defining “bond” in the chemical context as “a force of attraction by means of which atoms, ions, or groups of atoms are held together in a molecule or crystal”).) Thus, a chemical bond refers to an “attractive force” between either “atoms” or “groups of atoms” (*i.e.*, molecules). (Smith Decl. ¶¶40-42.)

For the foregoing reasons, a POSITA would understand “chemically bonded” to mean “bonded by attractive forces between atoms or molecules.” (Smith Decl. ¶46.)

F. 647 Patent

1. ***“insertion mechanism configured to position the sensor subassembly against the base of the transmitter mount by causing movement of the sensor subassembly”***

Abbott’s Proposed Construction	DexCom’s Proposed Construction
Plain and ordinary meaning (no construction needed or “a mechanism that inserts a sensor into position for use that is configured to position the sensor subassembly against the base of the transmitter mount by causing movement of the sensor subassembly”)	Subject to 35 U.S.C. § 112(f) Function: positioning the sensor subassembly against the base of the transmitter mount by causing movement of the sensor subassembly Corresponding structure: none disclosed, or alternatively 420 in Figures 4D and 4E and 550 in Figure 5B

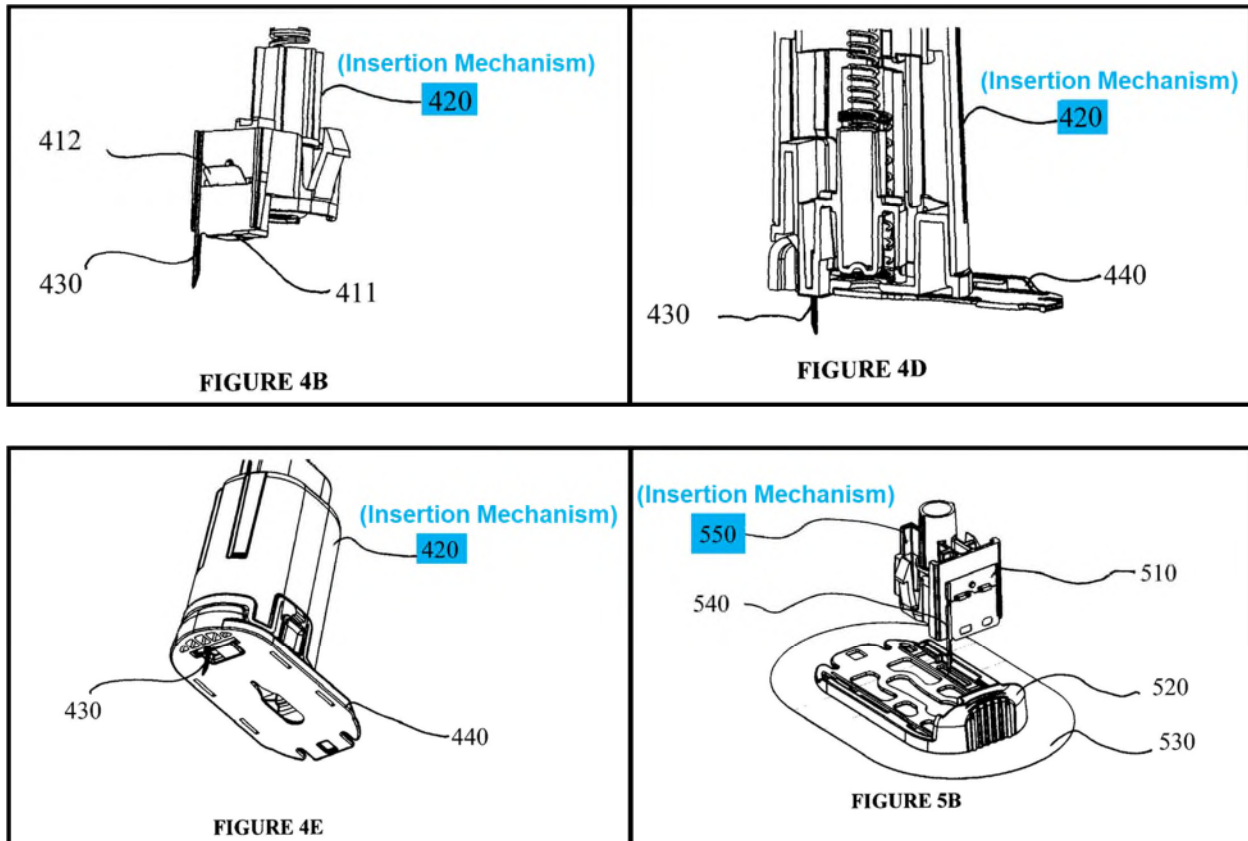
This term should be given its plain and ordinary meaning, and it is not a means-plus-function term under 35 U.S.C. § 112(f).

a. Plain and Ordinary Meaning

The first part of the disputed term, “insertion mechanism,” is readily understood by POSITAs as a class of structures for inserting a sensor into position for use, including positioning a portion of the transcutaneous sensor through the skin. (Leinsing Decl. ¶152.) DexCom argues that the remainder of the disputed term merely recites a function. To the contrary, the remainder of the disputed term recites additional structural components using terminology (e.g., sensor subassembly and transmitter mount) readily understood by POSITAs, and no construction is necessary. (Leinsing Decl. ¶159.) For example, the “sensor subassembly” comprises “an analyte sensor and a sensor seal,” both of which a POSITA would be familiar with. (Ex. 13 at claim 1; 5:37-43; 8:51-55; Leinsing Decl. ¶160.) The same is true of “transmitter mount,” which is well-described in the specification. (Ex. 13 at 6:22-67; Leinsing Decl. ¶161.)

The intrinsic record shows that the plain meaning of “insertion mechanism” is a mechanism that inserts a sensor into position for use. For example, the specification explicitly

identifies different embodiments of an “insertion mechanism” as shown below. (Ex. 13 at Figs. 4B, 4D, 4E, and 5B; 6:23-67 (identifying elements 420 and 550 as an “insertion mechanism”).)



Further, the specification explains that, with respect to the example in FIG. 4C, “the transmitter mount 440 [is] in cooperation with the *insertion mechanism 420* having the sensor 410 loaded in the introducer 430 before the sensor is placed in the patient.” (*Id.* at 6:44-47). And it explains that “the *insertion mechanism 420* [is] coupled with the transmitter mount 440 after the insertion mechanism has deployed the introducer 430 so as to place at least a portion of the sensor 410 in fluid contact with the patient’s analytes” and also positions the sensor “relative to the transmitter mount 520 ... to securely retain the sensor 510 in position relative to the transmitter unit 102 being mounted on the transmitter mount.” (*Id.* at 6:47-51; 6:58-67). The various embodiments of insertion mechanisms are thus described as mechanisms for placing the sensor

into position for use, *e.g.*, part of the sensor is inserted within the host's body and part of the sensor is ready to be coupled with a transmitter unit. (*Id.* at 6:47-51; 6:58-67).

Abbott's plain-and-ordinary construction of insertion mechanism also aligns with the extrinsic evidence. For example, patents and applications in the relevant field filed around the priority date of the 647 patent use the term "insertion mechanism" consistently with Abbott's construction of the term. (Leinsing Decl. ¶¶153-155; Exs. 90-95.) A POSITA would have a clear understanding of what an insertion mechanism is. (Leinsing Decl. ¶¶152-158.)

b. The Disputed Term Is Not Subject To § 112(f)

DexCom contends that the disputed claim term is a means-plus-function term under 35 U.S.C. § 112(f). To the contrary, the term is not means-plus-function because it (1) does not use the statutory term "means" or an equivalent, (2) recites structural components using language readily understood by POSITAs, including insertion mechanism, sensor subassembly, and transmitter mount (and more specifically the base of the transmitter mount), and (3) provides further structural detail by reciting how the components are arranged and interact.

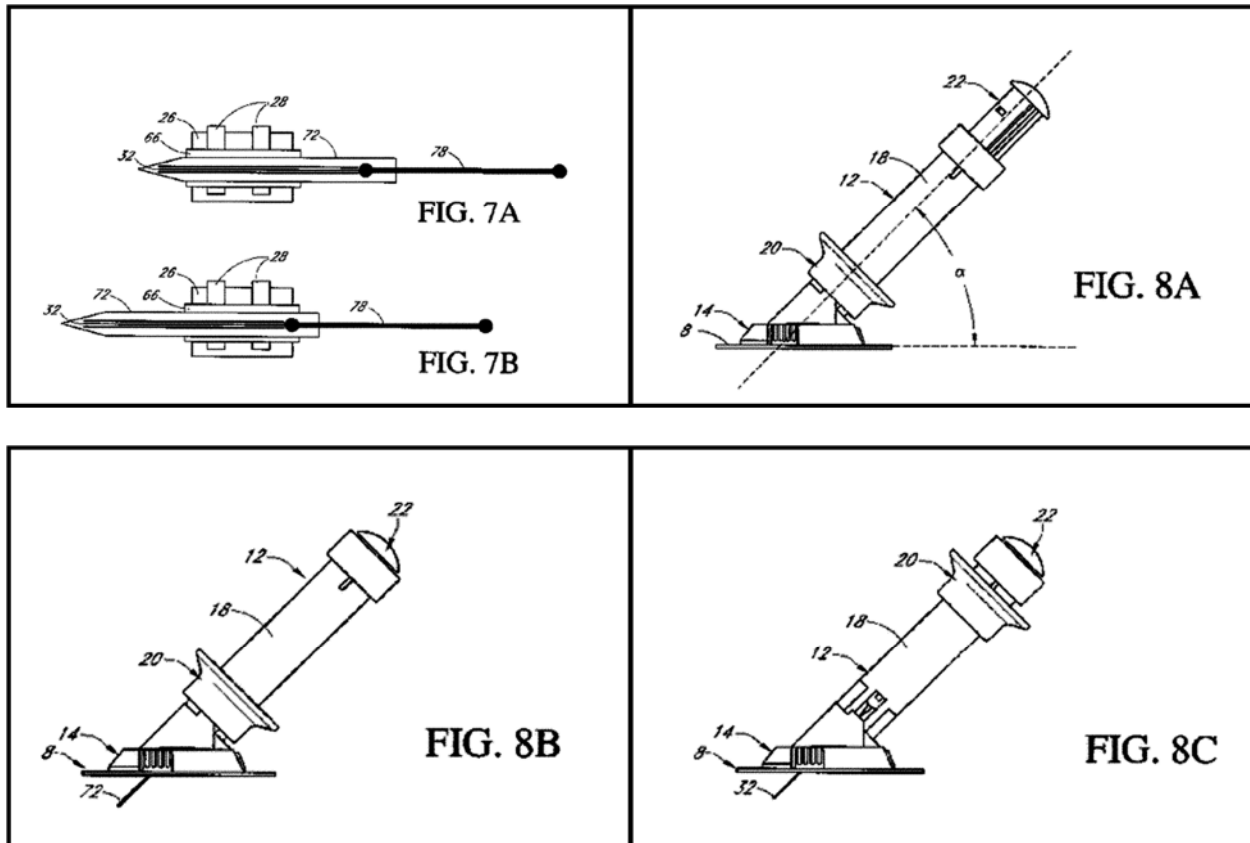
When determining whether § 112(f) applies, "[t]he standard is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). The absence of the word "means" in the claim term creates a presumption that § 112(f) does not apply. *Id.* at 1349. That presumption can be overcome only "if the challenger demonstrates that the claim term fails to 'recite[] sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'" *Id.* at 1348 (citations omitted). In this case, no such showing can be made.

"To determine whether the claim limitation at issue connotes sufficiently definite structure to a person of ordinary skill in the art, [courts] look first to intrinsic evidence, and then,

if necessary, to the extrinsic evidence.” *TEK Global, S.R.L. v. Sealant Sys. Int’l, Inc.*, 920 F.3d 777, 785 (Fed. Cir. 2019).

Notably, section 112(f) does not apply where a disputed term “is used in common parlance or by persons of skill in the pertinent art to designate structure, even if the term covers a broad class of structures and even if the term identifies the structures by their function.” *Skky, Inc. v. MindGeek, s.a.r.l.*, 859 F.3d 1014, 1019 (Fed. Cir. 2017) (citations omitted). That is the case here. As explained above, “insertion mechanism” is a term used by POSITAs to designate a class of structures that can be used to insert a sensor into position for use in the context of transcutaneous devices. (Leinsing Decl. ¶¶152-158, 167-168.) The term, along with similar terms like inserter or applicator, are commonly used and understood by POSITAs as designating structure, even if the particular details of the insertion mechanism may vary. (*Id.*); cf. *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996) (finding “detent mechanism” to not be means-plus-function where it “denotes a type of device with a generally understood meaning in the mechanical arts, even though the definitions are expressed in functional terms”) (collecting cases); see also MPEP § 2181(I)(C) (“[A]lthough a generic placeholder like ‘mechanism’ standing alone may invoke 35 U.S.C. § 112(f) when coupled with a function, it will not invoke 35 U.S.C. § 112(f) when it is preceded by a structural modifier (e.g. ‘detent mechanism’).”) (citing *Greenberg*, 91 F.3d at 1583).

The file history provides further evidence because the Examiner also understood the plain meaning of “insertion mechanism” to designate a class of structures. During prosecution, the Examiner relied on U.S. Pub. No. 2006/0020189 (“Brister”) when rejecting the pending claims, identifying Brister’s “applicator” (as shown in figures 7A-B and 8A-C) as an insertion mechanism. (See Ex. 66 at 2-5; Leinsing Decl. ¶¶ 170-171, 175).



The Brister “applicator” is used to insert the sensor into position for use, although it is different in some respects than the exemplary insertion mechanisms described in the 647 patent. The Examiner’s understanding of “insertion mechanism” during prosecution is therefore indicative of, and consistent with, a POSITA’s understanding as designating structure. *Phillips*, 415 F.3d at 1317 (“[T]he prosecution history provides evidence of how the PTO and the inventor understood the patent.”); *see also* Ex. 67 at 4 (regarding a related application, mapping the claimed insertion mechanism to the “sensor inserter” component 310 of U.S. Pub. No. 2004/0133164, which is the device that inserted the sensor into position for use); Leinsing Decl. ¶¶173-175.)

DexCom argues that the remainder of the disputed term following “insertion mechanism” merely recites a function. To the contrary, as discussed above, the remainder of the disputed term recites additional structural components (e.g., sensor subassembly and transmitter mount) that would be readily understood by a POSITA. Moreover, the claims further describe the

structure by reciting how the components are arranged and interact together. For example, in claim 1, the disputed term teaches that the insertion mechanism, sensor subassembly, and transmitter mount are structurally related so that the insertion mechanism can cause movement of the subassembly until it is positioned against the base of the transmitter mount. (Ex. 13 at claim 1.) Claim 1 also recites that the insertion mechanism is “further configured to be removed from the transmitter mount after the second portion of the analyte sensor is inserted through the skin surface and in fluid contact with the bodily fluid of the user.” (*Id.*; *see also id.* at claims 5, 12; Leinsing Decl. ¶¶165-166.) These detailed descriptions of how the components are arranged and interact further supports finding that the disputed term is not means-plus-function. *See Uni-Sys, LLC v. US Tennis Ass’n Nat’l Tennis Center Inc.*, 2020 WL 3960841, *13 (E.D.N.Y. July 13, 2020) (“retention mechanism” not means-plus-function in part because the claim “provide[d] sufficient detail as to how the retention mechanism interacts with other components ... in a way that informs the structural character of the retention mechanism”).

DexCom might argue that the disputed term includes some functional language. But “the mere fact that the disputed limitations incorporate functional language does not automatically convert the words into means for performing such functions.” *Zeroclick, LLC v. Apple, Inc.*, 891 F.3d 1003, 1008 (Fed. Cir. 2018); *see also Greenberg*, 91 F.3d at 1583 (“[T]he fact that a particular mechanism ... is defined in functional terms is not sufficient to convert a claim element containing that term into a ‘means for performing a specified function’ within the meaning of section [112(f)]. Many devices take their names from the functions they perform.”); *SoundView Innovations, LLC v. Facebook, Inc.*, 2007 WL 2221177, *5 (D. Del. May 19, 2017) (“‘Controller’ may be a class of structures, rather than one specific structure, and may be defined with functional terms, but that does not make it means-plus-function.”) (citing *Personalized Media Commc’ns, LLC v. ITC*, 161

F.3d 696, 705 (Fed. Cir. 1998) (“[N]either the fact that a ‘detector’ is defined in terms of its function, nor the fact that the term ‘detector’ does not connote a precise physical structure in the minds of those of skill in the art detracts from the definiteness of structure.”)).

V. CONCLUSION

For the foregoing reasons, the Court should adopt Abbott’s proposed constructions.

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CERTIFICATE OF COMPLIANCE

I hereby confirm that this brief complies with the word limitation of 10,000 words as set forth in the Court's Scheduling Order. (See D.I. 35 at 8.) I certify that this brief contains 9,953 words, which were counted using Microsoft Word's word counting feature. The word count does not include the cover page, table of contents (page i), table of authorities (pages ii-iv), table of additional exhibits (pages v-vi), table of abbreviations (page vii), table of disputed terms and proposed constructions (page viii), or the counsel blocks.

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CERTIFICATE OF SERVICE

I hereby certify that on July 13, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 13, 2022, upon the following in the manner indicated:

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