

United States District Court,
D. Delaware.

MEDTRONIC MINIMED INC,
Plaintiff and Counter-defendant.

v.

SMITHS MEDICAL MD INC,
Defendant and Counterclaimant.

No. Civ.A. 03-776-KAJ

June 1, 2005.

Karen Jacobs Louden, Julia Heaney, Kristen Healey, Philip H. Bangle, Morris, Nichols, Arsht & Tunnell, Wilmington, Delaware, for Plaintiff, Terrence P. McMahon, McDermott Will & Emery, Palo Alto, CA, Jon B. Dubrow, McDermott Will & Emery, Washington, DC, David M. Beckwith, McDermott Will & Emery, San Diego, CA, Daniel Floyd, Gibson Dunn & Crutcher, Los Angeles, CA, of counsel.

Richard D. Kirk, Cheryl Siskin, Wilmington, Delaware, for Defendant, Anthony C. Roth, Thomas E. Nelson, Corinne A. Niosi, J. Clayton Everett, Jr., Morgan, Lewis & Bockius LLP, Washington, DC, of counsel.

MEMORANDUM OPINION

JORDAN, J.

I. INTRODUCTION

This is a patent infringement case. Medtronic MiniMed, Inc. ("MiniMed" or "Plaintiff") alleges that Smiths Medical MD, Inc. ("Smiths" or "Defendant") infringes two of its patents, U.S. Patent No. 6,665,065 (issued September 9, 1997) (the "'065 patent") and U.S. Patent No. 6,241,798 (issued June 5, 2001) (the "'798 patent"). (Docket Item ["D.I."] 25.) Smiths in turn alleges that MiniMed infringes a patent Smiths owns, U.S. Patent No. 6,241,704 (issued June 5, 2001) (the "'704 patent"). (D.I. 28 at 27-28.)

Presently before me are the parties' requests for construction of the disputed claim language in these patents, pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The parties have fully briefed and argued their positions. Jurisdiction is proper under 28 U.S.C. s. 1338.

II. BACKGROUND

A. Procedural Background

MiniMed filed a complaint for infringement of the '065 patent and the '798 patent against Smiths on August

8, 2003. FN1 (D.I.1.) MiniMed subsequently filed an amended complaint on October 13, 2003, alleging that Smiths also directly infringed, induced infringement, and contributorily infringed the '065 patent and the '798 patent. (D. I. 25.) Smiths filed an answer to MiniMed's amended complaint on November 17, 2003 and asserted a counterclaim for direct infringement of the '704 patent. (D.I. 28 at 27-28.) Smiths also asserted various antitrust counterclaims against MiniMed. (*Id.* at 24-27.) On December 19, 2003, MiniMed filed a reply to Smiths' counterclaims. (D.I.30.) On April 14, 2005, I granted Summary Judgment dismissing all of Smiths' antitrust counterclaims. (D.I.271.) MiniMed and Smiths are scheduled to try this case before a jury beginning on July 7, 2005. (D.I.47.)

FN1. MiniMed originally filed suit against Deltec, Inc., Smiths Medical LTD, and Smiths Group PLC. (D.I. 25 at 1.) In its First Amended Complaint, MiniMed removed Smiths Medical LTD from the case and replaced it with Smiths Group North America, Inc. *Id.* On February 24, 2004, the parties entered into a stipulation dismissing without prejudice Smiths Group North America, Inc. and Smiths Group PLC and noting that Deltec Inc. had changed its corporate name to Smiths Medical MD, Inc., which is now the sole remaining defendant in this case. (D.I.38.)

B. The Disclosed Technology

1. The State of the Art FN2

FN2. In this section, I have cited to both parties' Markman presentations. There are no issues in dispute with respect to this section and no inferences should be drawn from the use of one party's presentation over another party's presentation at any particular point.

"Diabetes is a disease that causes the body not to produce or properly use insulin." (Smiths' *Markman* Presentation at Tab 1, pg 1.) Insulin is used by the body to "convert sugar, starches and other food into energy...." (*Id.*) Currently it is estimated that around 18.2 million Americans or 6.3% of the population have diabetes, with one third of that population, 5.2 million people, being unaware that they have the disease. (*Id.* at 1-2.) Diabetes can lead to serious health consequences such as blindness, cardiovascular disease, kidney disease, and nerve disease. (*Id.*)

There are two types of diabetes. "Type 1 diabetes results from the body's failure to produce insulin...." (*Id.* at 2.) "Insulin is a hormone, produced in the pancreas, that is needed to convert sugar, starches and other food in energy...." (*Id.* at 1.) As a result, Type 1 diabetics cannot covert sugar into energy, resulting in high levels of blood sugar. (*Id.*) In Type 2 diabetes, the patient produces a sufficient amount of insulin; however, the patient is unable to utilize the insulin to metabolize carbohydrates. (*Id.*) This inability to utilize insulin is referred to as "insulin resistance." (*Id.*)

To treat people with Type 1 diabetes, and some people with Type 2 diabetes, insulin injections are given. ('798 patent, col. 1:21-22.) Ordinarily, insulin is administered by injection because it is not as effectively delivered in an oral form. (*Id.* at 22-23.) There are two main ways in which injection is accomplished. The patient may use a syringe, which is the traditional and most common method. (*Id.* at 22-23, 29-31.) A newer method employs an external infusion pump that delivers the insulin "via a catheter with a percutaneous needle or cannula placed in the subcutaneous tissue." (*Id.* at 26-27.) Most infusion pumps are comprised of a body that houses a reservoir to hold the liquid insulin and a small motor that pushes the insulin into the catheter that delivers it to the body. (Smiths' *Markman* Presentation at Tab 1, pg 7.)

Using the traditional syringe method, the patient must try to predict how much insulin he will need throughout the day and periodically inject the appropriate amount. Too little insulin, and the patient could become hyperglycemic, *i.e.*, have high blood sugar; too much insulin and the patient could become hypoglycemic, *i.e.*, have low blood sugar. Either condition can result in coma, seizures, or even death. (Smiths' *Markman* Presentation at Tab 1, pg 4.) Conversely, administering the proper amount of insulin to avoid such complications can help to prevent many of the long-term negative health consequences of diabetes. (*Id.*)

In order to ensure that they have the proper amount of insulin, patients often take blood glucose readings to see if their blood sugar is too high or too low. (*Id.* at 5.) If a patient's blood glucose level is too high, he will often inject extra insulin to lower his blood sugar. This is referred to as a "correction bolus." (MiniMed's *Markman* Presentation at 8.) Alternatively, if a patient knows he will be eating a large meal, especially one high in carbohydrates, he will inject insulin before eating to prevent high blood sugar. This is referred to as a "meal bolus." (*Id.* at 6.) To calculate a bolus, the patient has to engage in mathematical computations, which are dependent on a number of factors. (*Id.* at 6-9.) For a meal bolus, the patient must know how much insulin is needed to metabolize one gram of carbohydrates, and then divide the number of carbohydrates by that number to arrive at the correct meal bolus. (*Id.* at 6-7.) A correction bolus can be more difficult to calculate because the patient must take into account numerous factors, such as his current blood glucose level, his desired blood glucose level, his insulin sensitivity, and any active insulin in his body. (*Id.* at 8-9.) Electronic bolus calculators can be used to help patients make these calculations. (*Id.*) Patients using insulin pump therapy often use a correction or meal bolus for the same reasons as a patient using the traditional syringe method. (*Id.* at 6-9.)

One of the major differences between these two therapeutic methods is how patients supply their baseline insulin, *i.e.*, insulin needed for normal functioning of the body without food. (*Id.* at 1-2.) Patients using a syringe to periodically inject their insulin use long acting insulin because of the gap in time between injections. (*Id.* at 1.) Patients using insulin pump therapy, on the other hand, use a short acting insulin because it is delivered continuously throughout the day. (*Id.* at 2.)

Insulin pump therapy has the advantage of more accurately simulating normal pancreatic insulin delivery. (*Id.*) The major drawback to insulin pump therapy is the need to always have the pump attached to the patient. ('798 patent, col. 1:45-47.) There has been progress in the miniaturization of insulin pumps so that patients can more readily conceal them under their clothing. (*Id.*; MiniMed's *Markman* Presentation at 10-11.) As pumps have become smaller and more easily hidden from view, there has also been an effort to make the controls and communication between the pump and user more convenient. ('798 patent, col. 1:45-54.) This has been accomplished by, among other things, the use of remote control devices and alarms. (*Id.*)

2. The '704 Patent FN3

FN3. I have found it most convenient to address the counterclaimant's patent first, which implies nothing about the relative importance of the parties' patents or the merits of their positions.

The '704 patent discloses a programmable pump, that contains a communications port to allow the pump to be programmed with therapy protocols for pumping the desired fluid into the patient. ('704 patent, Abstract.) Smiths has asserted Claims 6 and 11 against MiniMed in this litigation. (D.I. 28 at 21-23.) Specifically,

Claim 6 is directed to a pump containing a port for communicating with another device. ('704 patent, col. 47:11-25.) Claim 11 is directed to a pump which, *inter alia*, uses an access code to gain access to the control panel of the pump. (*Id.*, col. 47:40-60.)

3. The '065 Patent

The '065 patent relates to a medical infusion pump that allows for the input of blood and other data and then recommends a delivery schedule for dispensing of medication from the pump. ('065 patent, Abstract.) MiniMed has asserted Claims 1-3, 9-11, 13, and 19-21 against Smiths. (D.I. 25 at 11-12.)

4. The '798 Patent

The '798 patent relates, *inter alia*, to an infusion system that can be hidden from view and commanded remotely, and an infusion system that utilizes a bolus estimator. ('798 patent, col. 19:13-35, Abstract.) MiniMed has asserted Claims 1-5, 7, 9, 10, 12, 17, 22-28, and 35-40 against Smiths. (D.I. 25 at 9-10.) All of the claims are also directed to an infusion system that integrates a bolus estimator. ('798 patent, col. 30:26-34:35.)

III. APPLICABLE LAW

Patent claims are construed as a matter of law. *Markman*, 52 F.3d at 979. A court's objective is to determine the ordinary and customary meaning, if any, that those of skill in the art would apply to the language used in the patent claims. *Waner v. Ford Motor Co.*, 331 F.3d 851, 854 (Fed.Cir.2003) (citing *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed.Cir.2001)). In this regard, pertinent art dictionaries, treatises, and encyclopedias may assist a court. *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202-03 (Fed.Cir.2002). The intrinsic record, however, is the best source of the meaning of claim language. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996). Therefore, patent claims are properly construed only after an examination of the claims, the specification, and, if in evidence, the prosecution history of the patent. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1324 (Fed.Cir.2003) (citing *Vitronics*, 90 F.3d at 1582).

The intrinsic record is also of prime importance when claim language has no ordinary meaning in the pertinent art, *see Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1269-70 (Fed.Cir.2001) (determining that claim language could only be construed with reference to the written description) (citation omitted), and where claim language has multiple potentially applicable meanings, *Texas Digital, Inc.*, 308 F.3d at 1203.

If patent claim language has an ordinary and accustomed meaning in the art, there is a heavy presumption that the inventor intended that meaning to apply. *Bell Atl. Network Servs., Inc.*, 262 F.3d at 1268 (citing *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed.Cir.1999)). Thus, unless the inventor has manifested an express intent to depart from that meaning, the ordinary meaning applies. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed.Cir.2002) (citation omitted).

To overcome that presumption, an accused infringer may demonstrate that "a different meaning is clearly set forth in the specification or ... the accustomed meaning would deprive the claim of clarity." *N. Telecom Ltd. v. Samsung Elecs. Co., Ltd.*, 215 F.3d 1281, 1287 (Fed.Cir.2000). However, the presumption may not be rebutted "simply by pointing to the preferred embodiment...." *Teleflex, Inc.*, 299 F.3d at 1327. It may be rebutted, though, where "the patentee ... deviate[d] from the ordinary and accustomed meaning ... by

redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Id.*

If claim language remains unclear after review of the intrinsic record, a court "may look to extrinsic evidence to help resolve the lack of clarity." *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1332 (Fed.Cir.2001). The use of extrinsic evidence in the claim construction process, however, is "proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence." *Id.* (citation omitted). A court may not use extrinsic evidence to contradict the import of the intrinsic record, and if the intrinsic record is unambiguous, extrinsic evidence is entitled to no weight. *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed.Cir.1997).

IV. CLAIM CONSTRUCTION

Smiths alleges that MiniMed directly infringes Claims 6 and 11 of the '704 patent. (D.I. 28 at 27-28.) MiniMed alleges that Smiths directly infringes, induces infringement, and contributorily infringes Claims 1-3, 9-11, 13, and 19-21 of the '065 patent and Claims 1-5, 7, 9, 10, 12, 17, 22-28, and 35-40 of the '798 patent. (D.I. 25 at para. 14; D.I. 138 at 4.) Each claim will be discussed in turn, according to the claim terms in dispute.

A. '704 Patent

1. Claim 6

Claim 6 of the '704 patent reads as follows:

A pump apparatus for pumping fluid to a patient, comprising:

a pump mechanism for pumping fluid;

a memory for storing operational data for said pump mechanism;

processor means electrically connected to said memory for retrieving said operational data to control the operation of said pump mechanism; and

at least one port means operable as either a communications port for effecting communication with a device external of said pump mechanism or as an input port for receiving input from the patient or a user for specifying the amount of fluid to be pumped by said pump mechanism.

('704 patent, col. 47:11-25.)

a. The Preamble

i. The Parties' Proposed Constructions

Smiths argues that the preamble is limiting and therefore requires construction. (D.I. 190 at 5-8.) Smiths asserts that the preamble "provides meaning for other terms recited in the body of each claim and should not be ignored in construing the claims." (D.I. 190 at 6.) Specifically, Smiths asserts that the preamble serves as an antecedent basis for the term "patient" used in one of the claim limitations of Claim 6. (*Id.*)

Additionally, Smiths argues that the preamble should be construed to mean "a drug delivery device external to the patient that pumps fluid to the patient." (D.I. 213 at 2.) To support its construction, Smiths relies on the specification and the file history of applications related to the '704 patent. (D.I. 190 at 6-8.)

MiniMed argues that the "mere fact that the preamble may provide antecedent basis ... does not require the preamble ... to be read as a limitation." (D.I. 214 at 2.) Further, MiniMed argues that "the inclusion of the word 'patient' in the preamble adds [nothing] ... to the interpretation of Claim 6. Rather, 'the body of the claim sets out the complete invention.'" (*Id.* at 2-3 (citing *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371 (Fed.Cir.2003).) FN4 With respect to the construction of the preamble, if it is considered limiting, MiniMed argues that the plain meaning should apply. (*Id.*) MiniMed asserts that there is no clear disavowal of claim scope" in the "prosecution history or in the specification." (*Id.*)

FN4. MiniMed also points out that although Claim 11 has the same preamble it does not contain any terms that rely on the preamble as an antecedent basis. (D.I. 214 at 3.)

ii. The Court's Construction

A preamble is only limiting where "it recites essential structure or steps, or if it is necessary to give 'life, meaning, and vitality' to the claims." *Intertool, Ltd. v. Texar Corp.*, 369 F.3d 1289, 1295 (Fed.Cir.2004) (internal citations omitted). If deletion of the preamble "does not affect the structure or steps of the ... invention," it should not be considered limiting, unless there is "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art." *Id.* (internal quotations and citations omitted).

In this claim, the preamble's deletion would affect "the structure of the invention," and, therefore, is limiting. *See id.* The body of the claim does not set out the complete invention and as such, the language of the preamble is not superfluous. Specifically, the preamble utilizes the phrase "pumping fluid to a patient." (*Id.*, col. 7:11.) In a later element of the claim, the term "patient" is again referred to when the device is described as "receiving input from the patient or a user." (*Id.*) To understand this later use of the term "patient," it is necessary to know that the "patient" is receiving the fluid from the apparatus. Without the context supplied by the preamble, the use of the term "patient," lacks meaning and the claim terms do not have their intended effect. *See Intertool, Ltd. v. Texar Corp.*, 369 F.3d at 1295.

The same preamble is also at issue in Claim 11. (D.I. 213 at 5.) The limitations in that claim do not, however, rely on the preamble to give them "life, meaning, and vitality." *See Intertool, Ltd. v. Texar Corp.*, 369 F.3d at 1295. Unlike Claim 6, none of the claim terms in Claim 11 rely on the preamble as an antecedent basis. Because "the body of the claim sets out the complete invention" in Claim 11, the preamble in that claim is not limiting. *See Altiris*, 318 F.3d at 1371.

Because the preamble of Claim 6 is limiting, I must construe it. The thrust of Smiths' arguments is that the word "to," as in pumping the fluid "to a patient," necessarily means that the pump is external to the patient." (D.I. 190 at 6-8.) However, the relevant dictionary definition of "to" is "used as a function word to indicate movement or an action of condition suggestive of movement toward a place, person or thing reached." *Merriam-Webster Dictionary*, 1234 (10th ed.2001). This definition includes implanted pumps that pump fluid from within a reservoir toward the tissue surrounding it. The use of the word "to" in this fashion is similar to its use in a sentence such as "I am walking from the confines of my home 'to' the outside

environment." Smiths has not cited anything that would overcome the general rule that "terms in the claim are to be given their ordinary and accustomed meaning." See *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1362 (Fed.Cir.1999). I construe the preamble to have its plain meaning. Therefore, the preamble does not limit the invention to an external infusion device.

b. "processor means electronically connected to said memory for retrieving said operational data to control the operation of said pump mechanism"

i. The Parties' Proposed Constructions

Smiths argues that "processor means" should be construed according to its plain meaning. (D.I. 220 at 8.) It is unclear if Smiths is disputing that this is a means-plus-function limitation or if Smiths is arguing that it is a means-plus-function limitation whose terms should be construed to have their plain meaning. Smiths entire argument amounts to four sentences wherein it cites MiniMed's brief. (*Id.*) The relied on language states, "Smiths approach is to analyze the term 'processor means' under a plain meaning approach. It is anticipated that no real dispute exists with respect to the construction of this term." (*Id.* (citing D.I. 167 at 11, n. 2.)) MiniMed argues that "[t]he use of the term 'processor means' invokes the presumption that 35 U.S.C. s. 112, para. 6 applies when construing this claim" and that the presumption stands un rebutted. (D.I. 167 at 11.)

ii. The Court's Construction

The patent statute allows for a claim limitation to be drafted in means-plus-function format. 35 U.S.C. s. 112 para. 6.FN5 A means-plus-function claim recites a function to be performed rather than a definite structure or the materials required to perform that function. *See id.* Such a claim limitation is typically identified by the presence of the introductory term "means," *Micro Chem., Inc. v. Great Plains Chem. Co., Inc.*, 194 F.3d 1250, 1257 (Fed.Cir.1999), which creates a presumption that section 112, paragraph 6 applies. *York Prods., Inc. v. Cent. Tractor Farm & Family Center*, 99 F.3d 1568, 1574 (Fed.Cir.1996). That presumption is rebuttable, however, "where a claim uses the word 'means,' but specifies no corresponding function for the 'means' ... [or] where a claim recites a function, but then goes on to elaborate sufficient structure, material, or acts within the claim itself to perform entirely the recited function...." *Sage Prods., Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1427 (Fed.Cir.1997) (internal citations omitted).

FN5. 35 U.S.C. s. 112 para. 6 provides that "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof."

Once a means-plus-function term is identified, its interpretation by the court is a two-step process. *Sage Prods.*, 126 F.3d at 1428. First, the court must identify the function recited by the claim. *See id.* Second, the court must identify the structure(s) in the specification of the patent necessary to perform the recited function. *Id.* Structure, material, or acts are deemed "corresponding" where the "specification or prosecution history clearly links or associates that structure to the function recited in the claim." *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed.Cir.1997). The court, however, "may not import functional limitations that are not recited in the claim, or structural limitations from the written description that are unnecessary to perform the claimed function." *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed.Cir.2001) (citing *Mico Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258

(Fed.Cir.1999)).

If Smiths is arguing that this is not a means-plus-function limitation it has done nothing to rebut the presumption that the use of the word "means" creates a means-plus-function limitation, and I find nothing in the claim to rebut that presumption either. Consequently, the claim term is a means-plus-function limitation. The function is "retrieving said operations data to control the operation of said pump mechanism." The corresponding structure is microprocessor 182. (*See, e.g.*, '704 patent, col. 5:21-22.)

c. "at least one port means operable as either a communications port for effecting communication with a device external of said pump mechanism or as an input for receiving input from the patient or a user for specifying the amount of fluid to be pumped by said pump mechanism."

i. The Parties' Proposed Constructions

Smiths asserts that this claim element is not a means-plus-function limitation and that I should give it its plain meaning. (D.I. 190 at 9-12.) Specifically, Smiths argues that this limitation is not a means-plus-function limitation because "it does not recite a function for the 'means'" and because the "clause recites sufficient structures." (*Id.* at 9.) With respect to the argument that the limitation does not recite a function for the "means," Smiths notes that the "word 'operable' as used after the noun 'means' is an adjective, not a verb denoting a function for the 'means.'" (*Id.*) Furthermore, Smiths argues the two functions recited in the claim, " 'for effecting communication' and 'for receiving input,' refer to the 'communication port' and 'input port' structures, respectively, not the term 'port means.'" (*Id.*) With respect to its second argument, Smiths states that the term port "connotes a particular electronic interface structure" that is sufficient to rebut the presumption that 35 U.S.C. 112 para. 6 applies. (*Id.* at 9-10.)

MiniMed argues, in essence, that the assertion that the word "operable" cannot be functional language is semantic misdirection. (D.I. 214 at 4.) MiniMed argues that "operable as" could have been replaced by a verb such as "operates as" and the meaning would not have changed. (*Id.*) Furthermore, MiniMed argues that it is clear that "port means" has two alternative functions clearly linked through the term "operable as." (*Id.*) As to the sufficiency of the structure disclosed in "port means," MiniMed argues that "port" is not a sufficient statement of a structure because "port" is defined "by the way the device is used and *not* by its structure alone." (*Id.* at 6 (citing Authoritative Dictionary of IEEE Standards Terms, 844 (7th ed.2000) (emphasis added by MiniMed)).)

ii. The Court's Construction

I agree with MiniMed that this claim term is governed by 35 U.S.C. s. 112 para. 6 and is a means-plus-function limitation. Smiths' argument that "operable as" is simply an adjective and cannot act as functional language is unpersuasive. "Operable as" denotes what the "port means" is used for and, therefore, is functional in nature. Moreover, in each of the alternative limitations, the term "for" reinforces the conclusion that the language following the term "port means" is functional in nature. The claim states two functional limitations. The first function is "operable as a communications port for effecting communication with a device external of said pump mechanism." The second function is "operable as an input for receiving input from the patient or a user for specifying the amount of fluid to be pumped by said pump mechanism."

Smiths is also unpersuasive in its argument that this is not a means-plus-function claim because the claim contains sufficient structure. "The recitation of some structure ... does not preclude the applicability of section 112(6) [when it] merely serves to further specify the function of the means." *Laitram Corp. v.*

Rexnord, Inc., 939 F.2d 1533, 1536 (Fed.Cir.1991); *see also* Unidynamics Corp. v. Automatic Prods. Int'l, 157 F.3d 1311, 1318-19 (Fed.Cir.1998) (holding that the addition of the word "spring" to a means-plus-function limitation did not add sufficient structure to overcome the presumption that 112 para. 6 applied).

Here, the addition of the term "port" and the additional structure contained in each of the alternative functions for the "port means," are insufficient to overcome the means-plus-function presumption. The term "port" merely acts to further describe how the means communicates or receives data. The terms "communications" and "input" only restate what is already contained in their respective functions, namely to communicate and receive. Consequently, the "port means" limitation does not contain sufficient structure to overcome the presumption that this is a means-plus-function limitation.

As to the corresponding structures, the specification describes the communications port 132 as a structure that "allows for communication with pump 100 from an external device located either locally or remotely relative to pump 100." ('704 patent, col. 4:30-34.) This structure corresponds with one of the functions of the "port means," which is "operable as a communications port for effecting communication with a device external of said pump mechanism." Consequently, this is a corresponding structure for the "port means."

In the specification, the remote dose port 234 is described as permitting the patient to "remotely press or simulate pressing a key on keyboard 122, such as the key which manually operates the pumping mechanism, via a signal from a remote switch sent through remote dose cord port 234 to processor 182." (*Id.*, col. 7:51-55 .) This structure corresponds to the "input port" function which is "operable as an input for receiving input from the patient or a user for specifying the amount of fluid to be pumped by said pump mechanism." Consequently, remote dose port 234 is a corresponding structure of the "port means" limitation.

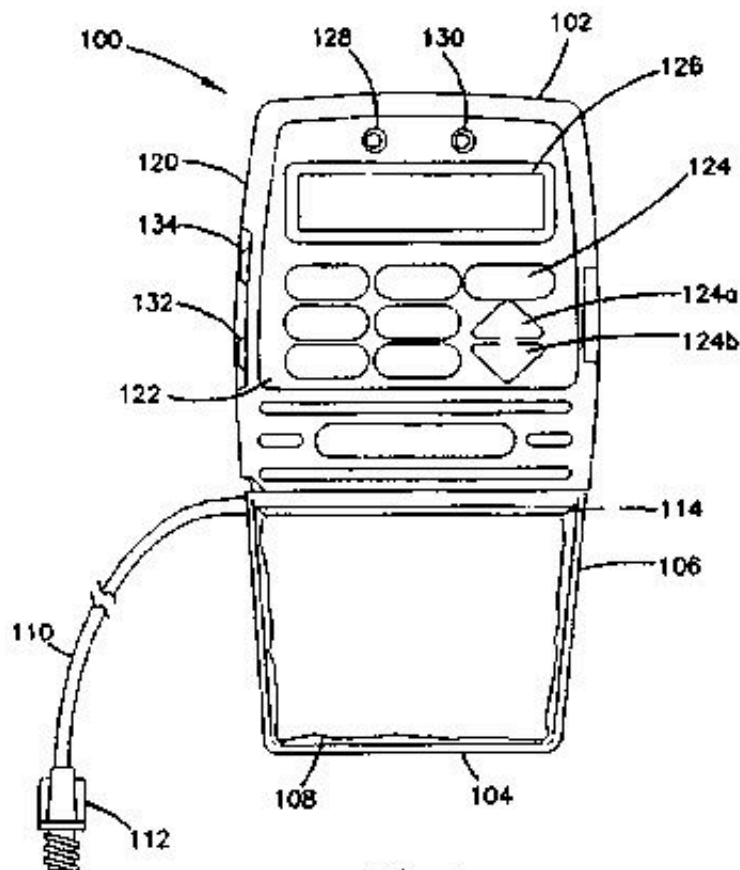


FIG. 1

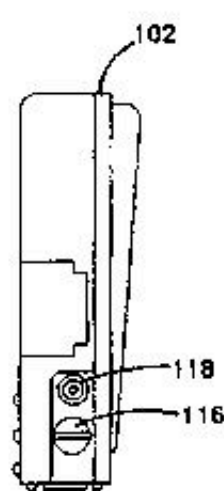


FIG. 1A

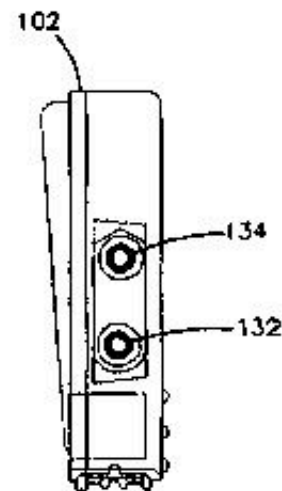


FIG. 1B

The parties also dispute whether the term "or" as used in this limitation is conjunctive or disjunctive. In this limitation the term "or" is used with "either" in an "either ... or" fashion, and thus is clearly meant to be disjunctive. *See In re Hyatt*, 708 F.2d 712, 714 (Fed.Cir.1983) (stating that "[a] claim must be read in accordance with the precepts of English grammar").

2. Claim 11

Claim 11 of the '704 patent reads as follows:

A pump apparatus for pumping fluid to a patient, comprising:

a pump mechanism for pumping fluid;

a memory;

at least one operations program for controlling the operation of said pump mechanism and an access code program stored in said memory;

controller means utilizing said operations program for controlling the operation of said pump, said controller means having a locked state and an unlocked state, wherein, to prevent any tampering with the operation of

said pump mechanism, an access code is required to place said controller means in the unlocked state from the locked state before the operations controlled by said operations program could be altered;

a keyboard, wherein said access code required for altering the operations of said operations program is entered via said keyboard, wherein said access code program places said controller means in the locked state after the operations controlled by said operations program has been altered.

('704 patent, col. 47:41-56.)

a. "controller means utilizing said operations program for controlling the operation of said pump"

Both parties agree that this claim limitation must be interpreted under s. 112 para. 6 as a means-plus-function limitation. (D.I. 213 at 6.) They disagree, however, on the function associated with the "controller means." MiniMed argues that the function of the "controller means" is "controlling the operation of the pump utilizing said operations program," whereas Smiths argues that the function of the "controller means" is "utilizing the operations program and controlling the operation of the pump." (*Id.*)

As previously stated, a means-plus-function claim recites a function to be performed rather than a definite structure or the materials required to perform that function. *See* 35 U.S.C. s. 112 para. 6. The "controller means" by definition "controls." The function of that means is "controlling the operation of said pump." "Utilizing said operations program" does not further describe the function of controlling. Instead, "utilizing said operations program" describes how the "controller means" accomplishes that function. As the function of a means-plus-function limitation does not include the structure required to perform the function, FN6 "utilizing said operations program" is not part of the function. Consequently, the full function is "controlling the operation of said pump."

FN6. Instead, the corresponding structure is a separate aspect of the limitation and is found in the specification. *Sage Prods.*, 126 F.3d at 1428 (stating that "[a]fter identifying the "specified function" of the unrecited means, a court must consult the specification to define the structure, material or acts corresponding to this claimed function").

The specification states that "[m]icroprocessor 182 and a memory 184 programmable with selected functions [are used] for controlling operation of pump mechanism 140 and the other features of pump 100." ('704 patent, col. 5:22-24.) Therefore, the corresponding structure is microprocessor 182 used in conjunction with memory 184.

b. "access code"

i. The Parties' Proposed Constructions

MiniMed argues that the term "access code" should be construed to mean "a secret sequence of characters including a password which an authorized user must enter to gain access to the controller means ." MiniMed cites the dictionary definitions of "access" and "code," to support what it contends is a common usage of the term "access code." Specifically, MiniMed states that access is defined as "to get at: gain access to" and code is defined as a "system of symbols (as letters or numbers) to represent assigned and often secret meanings." (D.I. 167 at 32 (citing Merriam-Webster Dictionary, 6, 221 (10th ed.2001)).) Moreover, MiniMed argues that the term "access code" and the term "password" are used consistently in the

specification. (Id.)

Smiths argues that "access code" should be given its plain meaning and argues that MiniMed selectively chooses definitions to support its proposed construction. Smiths also notes that the same dictionary also defines "code" as "a system of principals or rules ... a system of signals or symbols for communication." (D.I. 220 at 13-14 (citing Merriam-Webster Dictionary, 6 (10th ed.2001)).)

ii. The Court's Construction

I have concluded that MiniMed's definition of the term "access code" is correct. An additional dictionary definition, not cited by either party, captures the common and ordinary meaning of the phrase: "[a]n alphanumeric sequence that permits access to an electronic network, such as a telephone network or an automated teller machine." The American Heritage Dictionary of the English Language (4th ed.2000). Although this definition refers to gaining access to a network, it supports the idea that preventing use by unauthorized people is integral to the meaning of the term "access code." Consequently, I construe the term "access code" to mean "a sequence of characters used as a password which an authorized user must enter to gain access to the controller means."

The rest of the disputed terms FN7 have their plain and ordinary meaning and require no further construction.

FN7. The remaining disputed terms are "locked state," "unlocked state," "wherein said access code required for altering the operations of said operations program is entered via said keyboard," and "wherein said access code program places said controller means in the locked state after the operations controlled by said operations program has been altered."

B. '065 Patent

1. Claim 1

Claim 1 of the '065 patent reads as follows:

A medication infusion device, comprising:

reservoir means for receiving and storing a supply of a selected medication;

delivery means for delivering a selected dosage of the medication from said reservoir means to a patient;

controller means for automatically controlling said delivery means to deliver the selected medication dosage to the patient according to a first medication dispensing protocol; and

means for inputting blood data to said controller means, said data being representative of a current patient condition parameter, said controller means including means responsive to said data for recommending a second medication dispensing protocol;

said controller means including patient accessible manual set means for enabling said controller means to deliver the medication to the patient according to a selected one of said first and second medication

dispensing protocols.

('065 patent, col. 6:2-21.)

a. "dispensing protocol" FN8

FN8. This discussion is applicable to three claim terms "first medication dispensing protocol," "second medication dispensing protocol," and "third manually inputted medication dispensing protocol."

i. The Parties Proposed Constructions

Smiths argues that I should construe "dispensing protocol" to mean "dosage rate." (D.I. 190 at 17.) To support its argument, Smiths cites the specification of the '065 patent, which notes the timing of the dosage as one of the critical characteristics of the dispensing protocol. (*Id.* at 16 (citing '065 patent, col. 1:54-56, col. 2:14-20, col. 5:1-14).) Smiths also argues that the prosecution history of the '065 patent supports the construction it proposes. (*Id.*) Smiths cites an office action in which the patentee argued that a piece of prior art is distinguishable from his invention because the prior art does not teach a "response to a patient parameter to alter or to *recommend alteration of a preexisting dosage rate.*" (*Id.* 16-17 (citing D.I. 192, Ex. 26 at 6 (emphasis added by Smiths)).) Smiths further notes that the patentee pointed out to the examiner that the "range" taught by the prior art was "not a dispensing rate or dispensing protocol." (*Id.* 17 (citing D.I. 192, Ex. 26 at 7).) Lastly, Smiths argues that MiniMed's own expert bolsters their construction of the term. (*Id.* 17 (citing D.I. 193, Ex. 44 at 44, 55).)

MiniMed counters that "dispensing protocol" has a plain and ordinary meaning. It argues that the plain meaning of "dispensing protocol" is "a regimen of therapy." (D.I. 214 at 13 (citing PDR Medical Dictionary, 1446 (1st ed.1995).) MiniMed further argues that the specification of the '065 patent support this construction. (*Id.* at 14.) It cites many of the same portions of the specification cited by Smiths. It argues that frequency and timing are discussed with respect to a "dispensing protocol," thus demonstrating that "dispensing protocol" is not merely a dosage rate. (*Id.* at 14 (citing '065 patent, col. 1:37-41, col. 1:54-56 col. 2:15-20, col. 5:3-14).) Further, MiniMed argues that the prosecution history relied upon by Smiths was taken out of context. (*Id.*)

ii. The Court's Construction

I construe the term "dispensing protocol" in this context to mean "a plan or regimen for the delivery of medication." The general rule is that terms in the claim are to be given their ordinary and accustomed meaning." *K-2 Corp.*, 191 F.3d at 1362. To overcome this presumption, the patentee must "clearly and deliberately set forth [an alternate meaning] in the intrinsic materials." (*Id.*) Further, in order to narrow a claim term from its ordinary meaning the patentee must have "demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed.Cir.2004) (internal citation omitted).

Although Smiths argues that MiniMed has offered a "myriad" of conflicting definitions for the term "dispensing protocol," the definition appears straightforward. The PDR Medical Dictionary lists only one definition for "protocol": "a precise and detailed plan for the study of a biomedical problem or for a regimen of therapy." PDR Medical Dictionary, 1446 (1st ed.1995). Further, Merriam-Webster's Dictionary lists only one definition of protocol applicable to the medical field; "a detailed plan of ... treatment, or procedure."

Merriam-Webster's Collegiate Dictionary, 936 (10th ed.2002). The ordinary meaning of "dispensing protocol" in this context is a "a plan or regimen for the delivery of medication."

Smiths' argument that the intrinsic evidence supports its more narrow construction is unconvincing. Nowhere in the specification has the patentee "demonstrated a clear intention to limit the claim scope." Liebel-Flarsheim, 358 F.3d at 906. Smiths relies on a statement in the specification, that "[t]he medication dosage and frequency are, of course, developed according to a dispensing protocol to meet the needs of each patient" to show that the patentee narrowed the scope of "dispensing protocol" to "dosage rate." (D.I. 190 at 16 (citing '065 patent, col. 1:54-56, col. 2:14-20, col. 5:1-14).) Frequency and dosage are apparently two of the factors considered when creating a dispensing protocol. Therefore, such language is consistent with the plain meaning of "dispensing protocol."

With respect to the prosecution history, the one excerpt on which Smiths relies is taken out of context and is inconsequential. In the office action in question, the patentee distinguished the prior art by noting that it did not recommend a dosage rate. (D.I. 192, Ex 26, at 6.) As a "dispensing protocol" is made up of a series of "dosage rates" and could presumably be just one "dosage rate," in some instances, it is axiomatic that if the prior art did not suggest a "dosage rate" it also could not suggest a "dispensing protocol" because "dispensing protocol" encompasses "dosage rate ." Therefore, the patentee was not limiting the definition of "dispensing protocol."

As to Smiths' last argument, that MiniMed's own expert supported Smiths' construction of the term in question, the quote relied on again appears to be taken out of context. During a deposition, the expert was asked the question "what did the algorithms recommend? Did they recommend a pattern?" (D.I. 193, Ex. 44 at 44.) In response, he answered "No. They recommend a rate." (Id.) It appears, however, that the expert was addressing one embodiment of the invention where the invention is continually changing the dosage rate throughout the day in response to blood glucose readings and not the meaning of "dispensing protocol" as used in Claim 1. (Id . at 44-45, 54-55.)

b. "automatically control" FN9

FN9. This line of reasoning also applies to the term "automatically operate" found in Claim 10. Therefore, it also carries its plain meaning.

i. The Parties' Proposed Constructions

Smiths argues that "automatically control" means "to automatically control in response to a blood glucose reading." (D.I. 165 at 2.) Smiths states that:

[i]n each initial usage of the term "automatic" or "automatically," it is used in the context of operating the infusion pump in response to a blood glucose reading. As such, the term 'automatically controlling' as recited in claims 1 and 19 means to 'automatically control' in response to a blood glucose reading.

(D.I. 190 at 19.) Smiths further argues that where I to construe "automatically controlling" without reference to a blood glucose reading such construction would constitute new matter not disclosed in the '065 patent application. (Id.) Therefore, Smiths argues, its construction is necessary to avoid invalidity of the patent.

MiniMed contends that the term "automatically control" is part of the function of the "controller means"

limitation. (D.I. 214 at 17.) Consequently, it contends, adding the "responding to a blood glucose reading" limitation impermissibly adds a functional limitation to the term "control means." (D.I. 214 at 17 (citing *Wenger Mfg., Inc. v. Coating Mach. Sys., Inc.*, 239 F.3d 1225, 1233 (Fed.Cir.2001) (holding "a court may not import functional limitations that are not recited in the claim"))).

ii. The Court's Construction

Contrary to MiniMed's assertion, Smiths is not arguing for the importation of functional limitations into the claim. Smiths is arguing that one of ordinary skill in the art would understand "automatically controlling" to mean "automatically controlling in response to a blood glucose reading." (D.I. 218 at 3.) That being said, I nevertheless reject the argument that one of ordinary skill in the art would understand "automatically controlling" to have that meaning.

"The general rule is that terms in the claim are to be given their ordinary and accustomed meaning." *K-2 Corp.*, 191 F.3d at 1362. Neither party has argued that there is any ambiguity as to the meaning of "automatically controlling." The fact that "automatically" was used in a different context in the prosecution history is of little significance. Smiths does not even argue that the patentee acted as his own lexicographer and redefined the word "automatic" or the phrase "automatically controlling." (D.I. 190 at 18-19.)

I also find unpersuasive Smiths' argument that giving "automatically controlling" its plain meaning would raise issues of invalidity. "Claims can only be construed to preserve their validity where the proposed claim construction is 'practicable,' is based on sound claim construction principles, and does not revise or ignore the explicit language of the claims." *Generation II Orthotics, Inc. v. Medical Tech., Inc.*, 263 F.3d 1356, 1365 (Fed.Cir.2001). Smiths' proposed construction of "automatically controlling" is not based on "sound claim construction principals," and must be rejected. *See id.* Consequently, I find the term has its plain meaning.

c. "controller means for automatically controlling said delivery means to deliver the selected medication dosage to the patient according to a first medication dispensing protocol"

i. The Parties' Proposed Constructions

The parties agree that this is a means-plus-function limitation governed by 35 U.S.C. 112 para. 6. They also agree on the language in the claim that comprises the function and that the structure corresponding to the function is controller 24.FN10 (D.I. 190 at 22; D.I. 169 at 7.) The parties disagree, however, as to what the corresponding structure in the specification encompasses. (*Id.*)

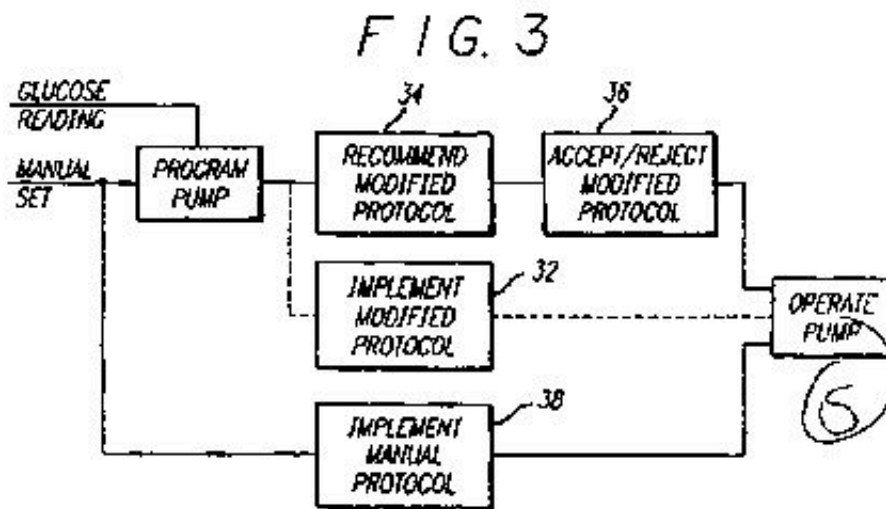
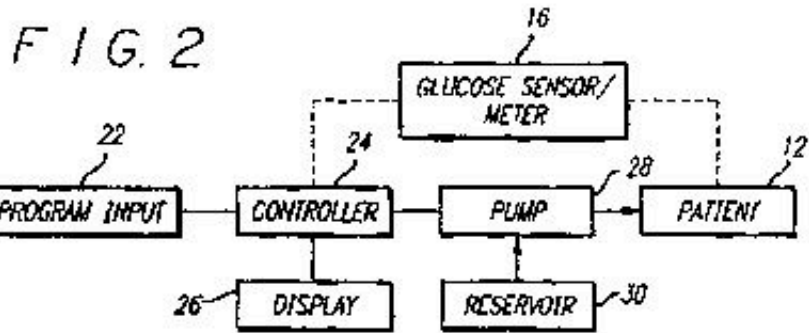
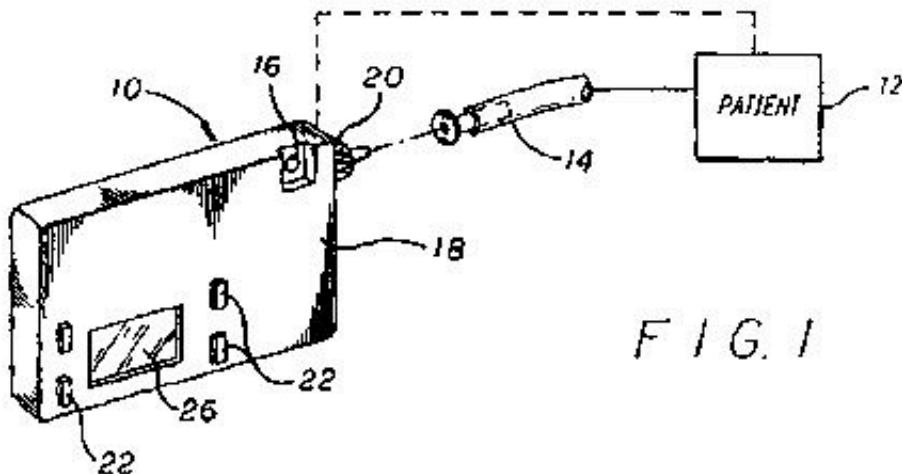
FN10. The parties do not agree as to the proper construction of "dispensing protocol," "first medication dispensing protocol," and "automatically controlling." (D.I. 165 at 2-3.) I have already construed these disputed terms, however, *see supra*, Part IV.B.1.a-b, and they have those same meanings here.

Smiths argues that controller 24 "is limited by its disclosed algorithm." (D.I. 190 at 22 (quoting *WMS Gaming Inc. v. International Game Tech.*, 184 F.3d 1339, 1348 (Fed.Cir.1999) (stating "[t]he structure of a microprocessor programmed to carry out an algorithm is limited by the disclosed algorithm"))). Specifically, Smiths argues that "[t]he algorithm of controller 24 is clearly illustrated in Figure 3, which is described in the '065 patent specification as 'a flow chart illustrating operation of the pump controller and recommended dispensing protocol in response to a current patient parameter.'" (*Id.* (citing '065 patent, col. 3:37-39).)

Smiths asserts that block 32 shows the only automatic operation contemplated for controller 24. (D.I. 218 at 15. (citing '065 patent, col. 4:51-60).) Smiths proceeds to note that block 34 only recommends a protocol and block 38, by definition, requires manual implementation of the protocol. (*Id.* (citing '065 patent, col. 4:44-49, 4:65-5:5).) Therefore, it argues that "automatically controlling" is limited to block 32. (*Id.* (citing '065 patent, col. 4:41-49).) MiniMed responds that Figure 3 shows other algorithms that can be used for "automatically controlling said delivery means." (D.I. 214 at 23-25.) Therefore, it contends that the corresponding structure, controller 24, is not limited to block 32 as Smiths asserts. (*Id.*)

ii. The Court's Construction

At the heart of Smiths' argument is the assumption that the "automatically controlling" part of the "controller means" function must be completed at the second step of Figure 3, *i.e.*, at the stage when the decision is made by the user or the machine to implement the "medication dispensing protocol." This is clear because Smiths restricts its discussion of "automatically controlling" to blocks 32, 34, and 38, all of which represent the second step in Figure 3. (D.I. 190 at 22-23.) I have already rejected Smiths argument that "automatically controlling" means "automatically controlling in response to a blood glucose reading." *See supra*, Part IV.B.1.b. Therefore, there is nothing in the function that dictates that "automatically controlling" occur at the second step of Figure 3 as opposed to the last step, where controller 24 actually controls the pump.



The next question is whether controller 24 is clearly linked to the function of "automatically controlling" the pump. See *B. Braun Medical v. Abbott Lab.*, 124 F.3d 1419, 1424 (Fed.Cir.1997) (structures are only corresponding "if the specification or prosecution history clearly links or associates that structure to the function recited in the claim"). The specification does not use the phrase "automatically controlling" when describing how controller 24 operates the pump. The specification does, however, state that "control means are normally provided for operating the pump drive motor continuously, or at periodic intervals, to obtain a closely controlled and accurate delivery of medication over an extended time period." ('065 patent, col.

1:21-24.) This excerpt clearly implies that the "controller means" described in the specification is controlling the pump in an automatic fashion. Further, the only controller means in the specification that uses a pump to control the delivery means is controller 24. (*Id.*, col. 4:11-49.) Therefore, controller 24 is clearly linked to the function of "automatically controlling" the pump. Consequently, the corresponding structure for the "controller means" limitation is controller 24 and it is not restricted to the algorithm depicted in Figure 3 that uses block 32.

d. "means for inputting blood data to said controller means"

i. The Parties' Proposed Constructions

The parties agree that this claim element is a means-plus-function limitation. (D.I. 165 at 4.) Further, the parties essentially agree that the function claimed is "inputting blood data to said controller means." (*Id.*) The dispute between the parties focuses on what structures in the patent specification correspond to the claimed function. (*Id.*) Smiths argues that the only corresponding structure is the "glucose sensor 16." (*Id.*) MiniMed argues that switches or buttons, an RF telemetry receiver, an infrared receiver, and an integrated wire connection are all corresponding structures. (*Id.*)

ii. The Court's Construction

I agree that this limitation is in means-plus-function format and that the claimed function is "inputting blood data to said controller means." Thus, it is necessary to identify the structure corresponding to the function. Structure is deemed "corresponding" when the "specification or prosecution history clearly links or associates that structure to the function recited in the claim." *B. Braun Med.*, 124 F.3d at 1424.

The specification identifies a "glucose sensor or meter" used subcutaneously or adapted to receive and read a glucose test strip as being used to input blood data to said controller 24 ('065 patent, col. 4:11-30), which has already been defined as a corresponding structure for "controller means," *see supra*, Part IV.B.1.c. A receiver using radio telemetry or infrared is also identified as a structure used for "inputting blood data to said controller means." (*Id.*, col. 5:51-60.) The switches and buttons that MiniMed argues are structures, however, are not clearly linked to the claimed function. FN11 "Buttons" are mentioned in the same sentence that describes a "glucose sensor or meter" being used to input blood data. ('065, col.4:11-14.) "Buttons," however, are described as being used to enter instructions, not blood data. (*Id.*) Nowhere else in the specification are "switches or buttons" linked to the "inputting of blood data." Consequently, the only corresponding structures are a "glucose sensor or meter," used either subcutaneously or adapted to receive and read a glucose test strip, and a radio telemetry or infrared receiver.

FN11. Although MiniMed argues in the Joint Claim Construction Chart that an "integrated wire connection" is a corresponding structure, it abandoned that position in its briefs. (D.I. 165 at 4; D.I. 169 at 13-14; D.I. 214 at 26-29.) Rightly so, since the specification does not support MiniMed's earlier position.

e. "current patient condition parameter"

MiniMed argues that the term "current patient condition parameter" means "a recent patient condition parameter, such as a patient's recently measured glucose level using a test strip in a glucose meter." (D.I. 214 at 29.) Smiths argues that during the prosecution of the '065 patent, the patentee made clear that the "current patient condition parameter" was a real time glucose reading because the patentee used such

language to distinguish prior art. (D.I. 190 at 25-26.) The office action that Smiths cites to support this argument, however, does not require that conclusion.

In that office action, the patentee wrote that the reference "does not contemplate automatic or substantially continuous blood glucose readings, for example, by means of an implanted sensor. Instead ... the blood glucose readings are taken manually by enzyme test strips or the like." (D.I. 192, Ex. 24 at 6.) A further examination of that paragraph reveals, however, that the patentee was distinguishing the reference because the reference contemplated "a recommendation with regard to timing for taking the next blood glucose reading," not with respect to recommending a modified dispensing protocol. (*Id.* at 6-7.) Thus the reference to "manually" taking a blood glucose reading was to highlight the fact that the prior art reference alerted the user to take such a reading. It was not to highlight that the invention used real time glucose monitoring. Read in context, the office action cited by Smiths provides no reason to limit "current patient condition parameter" to a real time reading. Consequently, I hold that the meaning of the term is "a recent patient condition parameter."

f. "means responsive to said data for recommending a second medication dispensing protocol that is responsive to said data"

i. The Parties' Proposed Constructions

The parties agree that this claim element is a means-plus-function limitation. (D.I. 165 at 5.) The parties disagree as to the function of the limitation. MiniMed believes that the function is "recommending a second medication dispensing protocol that is responsive to said data," while Smiths believes that the function is merely "recommending a second medication dispensing protocol." (*Id.*) There is no discussion by either party as to why one or the other construction is correct. The parties do agree that the corresponding structure is a controller. (*Id.* at 5-6.) Smiths believes, however, that this structure should be further limited to controllers that "automatically respond to blood data to select and recommend a second from a plurality of dosage rates preprogrammed into the medication infusion device." (*Id.*)

The parties also disagree as to the proper construction of the terms "recommending" and "responsive to said data" contained in the claim limitation. FN12 (*Id.*) Smiths believes that the proper construction for the term "responsive to said data" is "to select from any one of a plurality of pre-programmed dosage rates based on blood data," and that "recommending" means "automatically recommending." (*Id.*) MiniMed, however, believes both of these terms should carry their plain meaning. (*Id.*)

FN12. The parties also dispute the term "second medication dispensing protocol." (D.I. 165 at 5.) I have already construed this term, however, and it retains that meaning here. *See supra*, Part IV.B.1.a.

To support its argument that "recommending" means "automatically recommending," Smiths cites an alternative embodiment in the specification where the recommended medication dispensing protocol is automatically implemented. (D.I. 190 at 20 (citing '065 patent, col. 4:43-54).) Smiths further cites to the prosecution history of the '065 patent to show that the "applicant clearly limited the recommendation function to an 'automatic recommendation' rather than one that was user initiated." (*Id.*) Specifically, Smiths cites an office action where the patentee stated that "[t]his concept of *automatically recommending* but not automatically implementing an alternative dispensing protocol, i .e., one that is different form the originally set dispensing protocol, is still not disclosed or suggested in the references of record." (*Id.* (citing D.I. 192, Ex 26 at 5) (emphasis added by Smiths).) Lastly, Smiths argues that the notion of automatically

recommending "makes sense only in the context of ... real-time continuous glucose sensing...." (*Id.* at 20-21.)

MiniMed replies that it is legal error to limit the claim to an alternative embodiment contained in the specification. (D.I. 214 at 20-21.) MiniMed further contends that Smiths cites the prosecution history out of context and that the quoted language is not a clear disavowal of the claim language. (*Id.*)

As to the claim term "responsive to said data," Smiths argues that "one of ordinary skill [in] the art would have been at a loss as to exactly how the '065 controller algorithm responds to the inputted blood glucose data." (D.I. 190 at 21.) Therefore, Smiths argues it is proper to look to the prosecution history where it contends the "applicants made clear that the method by which recommendations are made involve something akin to a simple lookup table programmed into the controller...." (*Id.* (citing D.I. 192 at 21, Ex. 24 at 4-5).) MiniMed argues that there is sufficient structure contained in the specification to accomplish this function and, therefore, it is improper to look to the prosecution history. (D.I. 214 at 21-23.)

ii. The Court's Construction

I agree that this limitation is in means-plus-function format and thus it is necessary to identify the function recited by the claim. *Sage Prods.*, 126 F.3d at 1428. When identifying the function, it is improper to broaden it "by ignoring the clear limitations contained in the claim language." *Lockheed Martin*, 249 F.3d at 1324. As the "responsive to said data" limitation acts as a marker for when the "means" recommends a second medication dispensing protocol, it limits the function. Consequently, I agree with MiniMed that the function is "recommending a second medication dispensing protocol that is responsive to said data."

With respect to the construction of the term "recommend" contained in the function, I find that it carries its plain meaning. It is improper to limit a claim term to one of the embodiments in the specification, as Smiths attempts here. *Comark Communs. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed.Cir.1998) (stating that "limitations from the specification are not to be read into the claims"). Further, Smiths' citation of the prosecution history shows nothing but one potentially inconsistent use of the word "automatically" in an office action. (D.I. 192, Ex. 26 at 5.) In the sentence prior to the one cited by Smiths, the patentee describes his invention as one that responds to a "blood glucose level to *recommend* a different dispensing protocol...." (*Id.* (emphasis original).) The word "automatically" is not used. The passing use of the word "automatically" in the later sentence is not the type of "clear and unmistakable" disavowal required to limit the claim term. *See Omega*, 334 F.3d at 1325-26.

Smiths' final argument is that in the "context of ... real-time continuous glucose sensing," "recommend" only makes sense if understood to mean "automatically recommend." (D.I. 190 at 20-21.) I have already determined, however, that this invention is not limited to real-time continuous glucose sensing. *See supra*, Part IV.B.1.e. Consequently, I hold that "recommend" has its plain meaning.

As to the limitation "responsive to said data," I also find that it has its plain meaning. Smiths argues that because the specification does not explain how the structure should respond to the data, I should look to the prosecution history to determine how it responds. (*Id.* at 21-22.) That argument is not about the construction of the term "responsive to said data," however. Rather, Smiths argues to add a limitation to the function of the corresponding structure, which is impermissible. *See Micro Chem.*, 194 F.3d at 1258 ("incorporating unrecited functional limitations into the claims" is impermissible).

After the function is identified and construed, the court must identify the structure(s) in the specification of the patent necessary to perform the recited function. Sage Prods., 126 F.3d at 1428. I agree with the parties that the corresponding structure is controller 24, as the specification "clearly links" that structure to the function. ('065 patent, col. 4:1-14.)

Smith also states that there is "[v]ery little, if anything, ... disclosed in the '065 patent regarding the methods used by the '065 controller software to select the recommended dosage rate." (D.I. 190 at 21.) Consequently, it argues, "one of ordinary skill [in] the art would have been at a loss as to exactly how the '065 controller algorithm responds to the inputted blood data." (*Id.*) "Whether or not the specification adequately sets forth structure corresponding to the claimed function necessitates consideration of that disclosure from the viewpoint of one skilled in the art." *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1376 (Fed.Cir.2001). Smiths does not, however, address what one of ordinary skill in the art would have known at that time.

Although extrinsic evidence should not be used "for the purpose of varying or contradicting the terms of the claims," it is proper to use extrinsic evidence to assist "the court's understanding of the patent." *Markman*, 52 F.3d at 981. MiniMed has cited its expert report to show that "[o]ne of ordinary skill in the art would know that such algorithms are readily available in a variety of public documents." (D.I. 170, Ex. E at 14-15.) In that report, its expert lists many sources that contain suitable algorithms that could have been used by the controller in the specification. (*Id.*) Finally, its expert stated that "I do not find it the least bit unusual that specific algorithms are not disclosed in the '065 patent." (*Id.*) In light of the specification and the expert report, it seems clear to me that one of ordinary skill in the art could have easily supplied through general knowledge or from a third party sources the algorithm needed to use the controller. Consequently, I hold that the controller structure is not limited to any specific algorithm.

g. "patient accessible manual set means for enabling said controller means to deliver the medication to the patient according to a selected one of said first and second medication dispensing protocols"

i. The Parties' Proposed Constructions

The parties agree that this is a means-plus-function limitation governed by 35 U.S.C. 112 para. 6. (D.I. 165 at 6.) They also agree that the function of the limitation is "enabling said controller means to deliver the medication to the patient according to a selected one of said first and second medication dispensing protocols." (*Id.*)

The parties disagree as to which structure(s) in the specification correspond to the function. (*Id.*) Smiths argues that buttons 22 are the only structures that correspond to the function. (D.I. 190 at 24-25.) Smiths further argues that buttons 22 "must be operated to enable the controller means to reset for purposes of implementing the 'second medication dispensing protocol.'" (*Id.*) To support this argument, Smiths cites to the prosecution history, where the patentee described the switch to the second protocol from the first as one in which the second protocol is "implemented in substitution for the 'first' protocol" (*Id.* (citing D.I. 192, Ex. 24 at 4).)

MiniMed argues that the corresponding structures include not only the buttons 22, but also the controller buttons, manually adjustable dials or plungers, and externally exposed key switches. (D.I. 169 at 16.) MiniMed further argues that "Smiths' construction improperly adds additional functions for the manual set means not recited in the claim...." (*Id.*)

ii. The Court's Construction

Again this limitation is in means-plus-function format and it is necessary to identify the function recited by the claim. I agree with the parties that the function is "enabling said controller means to deliver the medication to the patient according to a selected one of said first and second medication dispensing protocols."

Looking to the specification for the corresponding structures, control buttons ('065 patent, col. 2:58-64), buttons 22 (id., col. 4:55-57), and a dial 42 and plunger 44 (id., col. 5:34-36) are explicitly described as being used to select one of the recommended protocols. As these structures are clearly linked to the function, they are corresponding structures. FN13 B. Braun Med., 124 F.3d at 1424.

FN13. Again, Smiths seizes on one word or sentence in the prosecution history and argues that the patentee disavowed certain subject matter. (D.I. 190 at 24-25 (citing D.I. 192, Ex. 24 at 4).) The language cited by Smiths, however, is not a "clear and unmistakable" disavowal of subject matter and thus does not limit the claim. *Omega*, 334 F.3d at 1325-26.

C. '798 Patent

1. Claim 1 FN14

FN14. The term "codes" in dependant Claim 7 is also in dispute. (D . I. 165 at 33.) Smiths has not addressed it in its briefing, however. Consequently, I adopt MiniMed's position, which is that it has its plain meaning.

Claim 1 of the '798 patent reads as follows:

An external infusion device for infusion of a liquid into a body from a reservoir, the external infusion device comprising:

a drive mechanism to operatively couple with a reservoir to infuse a liquid into a body;

a housing adapted for use on an exterior of the body, wherein the housing is sized to contain at least a portion of a reservoir, wherein the drive mechanism is contained within the housing, wherein the drive mechanism operatively couples with the at least a portion of a reservoir within the housing, and wherein the housing is sized to fit in a clothing pocket;

a processor coupled to the housing;

a bolus estimator used in conjunction with the processor and externally supplied values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body; and

an indication device, providing at least one of a visual indication, an audible indication or a tactile indication, to indicate when an amount of fluid to be infused has been calculated.

('798 patent, col. 30:25-46.)

a. "liquid"

i. The Parties' Proposed Constructions

MiniMed proposes that I construe "liquid" to have its plain meaning. (D.I. 169 at 22.) MiniMed argues that although the specification teaches that "liquid" can be a medication, it is improper to limit it to a specific embodiment. (*Id.* at 22-23 (citing *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed.Cir.2001)).)

Smiths argues that liquid should be construed to mean "a dose of medication, such as insulin, measured in units." (D.I. 190 at 27.) Smiths argues that the terms "liquid" and "fluid," both used in Claim 1, should be construed differently. (*Id.*) Moreover, it argues that "[c]onsidering the claim language in context and definition of 'liquid' as used throughout the specification, one of ordinary skill in the art would understand that the applicants acted as their own lexicographer and redefined the term 'liquid'...." (*Id.*) Specifically, Claims 4 and 5 also state that the "liquid to be infused is insulin." (*Id.* (citing '798 patent, col. 30:55-60).) As to the construction of the phrase "measured in units," Smiths points out that one of the preferred embodiments states that the insulin is delivered in units ('798 patent, col. 6:14-18) and that the amount delivered is usually delivered in terms on "units" (D.I. 192, Ex. 34 at 11).

ii. The Court's Construction

"Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history." *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996).

I agree with Smiths that the patentee has acted as his own lexicographer with respect to the term "liquid," but I do not agree that the term has the meaning Smiths suggests. In the specification, the patentee describes possible liquids as things such as "medication, chemicals, enzymes, antigens, hormones, vitamins or the like." ('798 patent, col. 6:13-17.) While some of these substances may be liquid in nature, others are not liquids but are rather dissolved in a liquid. Moreover, all of these substances have or can have an effect on the human body. The idea that the liquid is active in the human body is reinforced by dependent Claim 3, wherein the bolus estimator uses the patient sensitivity to the "liquid" to determine the proper amount of liquid to be infused. (*Id.*, col. 30:51-54.) Further, Claim 9 states that the "liquid will remain active in the body." (*Id.*, col. 31:4-7.) If "liquid" was not defined by the patentee to be a substance that is active in the human body, then the idea that a person would have a sensitivity to it or that it would remain active in the body is illogical. Consequently, I construe "liquid" to mean "a substance, such as insulin, that is active within the human body." FN15

FN15. I find no support in the specification or prosecution history for the assertion that "liquid" be limited to a medication measured in units. The fact that a substance is ordinarily measured in a certain way or is disclosed in the specification as being measured in a certain way does not limit the claim limitation. *See Rexnord Corp. v. Laitram Corp.*, 274 F.3d at 1344 (holding that a court should not limit a claim term to a preferred embodiment).

b. "an amount of fluid to be infused"

i. The Parties' Proposed Constructions

Smiths proposes that I construe this limitation to mean "a volume of solution to be expelled from the

reservoir." (D.I. 190 at 29.) Smiths argues that because "liquid" means a "dose of medication (e.g., insulin) measured in units, one of ordinary skill in the art would understand the claims to require 'fluid' to mean a 'volume of solution.'" (*Id.*) Specifically, Smiths cites the specification which makes clear that in certain preferred embodiments the concentration of the insulin will affect how much is pumped into the body with every pump stroke. (*Id.* (citing '798 patent, col. 28:60-63, 29:12-14, 29:17-20).) Smiths argues that one of ordinary skill in the art would understand that the amount of insulin must be converted to a volumetric amount before infusion. (*Id.*) Smiths also points out that if the terms "fluid" and "liquid" were construed to have the same meaning, the construction would violate the general rule that different words in a claim should be given different meanings. (D.I. 190 at 28 (citing CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co. KG, 224 F.3d 1308, 1317 (Fed.Cir.2000)).)

MiniMed argues that the terms "liquid" and "fluid" are used interchangeably throughout the specification and prosecution history. (*Id.* at 29-31.) Specifically, MiniMed points to numerous instances in the specification where it claims the two are used interchangeably. (*Id.* at 30 (citing 2:47-54, 3:37-43, 3:53-55, 3:56-57, 3:61-4:5, 4:6-7, 4:12-15, 4:19-20, 4:27-28, 4:41-42, 6:5-54, 6:63-65, 7:3, 11:7-11, 13:24-28, 16:56-60, 23:42-45, 23:64-24:8, 24:13-14, 29:25).) MiniMed asserts that, comparing all of these uses, it is clear that the two words were intended to mean the same thing. Additionally, MiniMed cites to the prosecution history to support its argument that the two terms were used interchangeably. (*Id.* at 30.) For example, it cites an office action response where the patentee stated that "[b]olus generally refers to an amount of *liquid* provided ... [and] may be provided as the sole source of *fluid*." (*Id.* at 30 (citing D.I. 207 at 19 (emphasis added by MiniMed)).) Finally, MiniMed argues that "an amount of fluid to be infused" should not include a volumetric requirement.

ii. The Court's Construction

It is important to remember that "the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed.Cir.1998) (internal citations omitted). Additionally, "[a] patent claim should be construed to encompass at least one disclosed embodiment in the written description portion of the patent specification." *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1355 (Fed.Cir.1998). "A claim construction that does not encompass a disclosed embodiment is thus rarely, if ever, correct and would require highly persuasive evidentiary support." *Id.* (internal citation and quotations omitted).

At the *Markman* hearing, both parties agreed that patients do not care about the volume of solution that is pumped into their body; rather, it is the amount of insulin that the patient wants to know about. (D.I. 269 at 31-32.) Smiths concedes that the preferred embodiment of claim 1 would calculate units of insulin to be delivered and indicate that amount to the patient. (*Id.* at 21-22 .) It also argues, however, that the invention calls for another indication, when "the number of units ... has been converted into the solution that needs to be pumped." (*Id.* at 22.) To understand how Smiths' construction impacts the functioning of Claim 1 it is helpful to examine how the invention would operate under Smiths' construction. If the patient was entering a meal bolus, he would enter his current blood glucose and the "number of carbohydrates to be consumed." ('798 patent, col. 19:24-34.) The bolus estimator would then calculate the number of units of insulin that should be infused into the patient and display that suggestion to the patient. (*Id.*, col. 19:42-45.) The user could then accept the suggestion or change the number of units. (*Id.*, col. 19:39-41.) Smiths argues that the invention would then indicate to the patient that it had converted units of insulin into volume of fluid. (D.I.

269 at 21-22.) Smiths states that this second indication is "important to the user ... because one of the primary objectives of this patent is to be able to program and operate the pump while it's concealed." (*Id.* at 22.) Presumably, this means that the user would instruct the machine to inject the fluid after receiving the second indication that informed him that the conversion from units to volume had been completed.

The operation of the pump, according to Smiths' claim construction, does not comport with common sense. Smiths seems to concede that the user does not care to know the volumetric amount of fluid that is pumped into him. (*See* D.I. 269 at 31-32.) If this is so, why would the user want to know when the computer has made a simple arithmetic computation, if not to check its validity? This construction does not "naturally align[] with the patent's description of the invention" and therefore is unpersuasive. *See* *Renishaw*, 158 F.3d at 1250.

More importantly, however, Claim 1, under Smiths' construction of this term, does not encompass any of the preferred embodiments of the invention. None of the embodiments that are directed to a bolus estimator indicate that there is a "second indication." FN16 In fact, the preferred embodiments appear to suggest just the opposite. The preferred embodiments directed to a "bolus estimator" state that once the user selects the units to be infused, he presses the "ACT key" which "starts the bolus." ('798 patent, col. 19:42-45.) The preferred embodiment does not contemplate the argument that a "second indication" occurs after pressing the "ACT key" and before the infusing of the liquid. Consequently, under Smiths' construction of this term, Claim 1 would not "encompass a disclosed embodiment." *See* *Johns Hopkins Univ.*, 152 F.3d at 1355.

FN16. During oral argument, counsel for Smiths argued that two portions of the specification support the argument that there is a "second indication." First, he cited to the preferred embodiments, wherein the patentee stated that "[t]he amount of insulin delivered per pump stroke depends upon the concentration. If the concentration is changed, the constant factors which convert pump strokes into units of insulin are changed accordingly." (D.I. 269 at 26 (citing '798 patent, col. 29:18-21).) This cite, however, does not reference a second indication, only that units must be converted to volume before being infused. Second, counsel for Smiths cited to the summary of the invention, which states that "[t]he indication device indicates when a command has been received and indicates when the command is being utilized to control the external infusion device." (*Id.* at 29 (citing '798 patent, col. 2:66-69).) This section does not refer to a second indication of a completed calculation either. Rather, this indication is used to tell the user when "the command is being utilized to control the external infusion device." Consequently, neither of the sections of the '798 patent specification cited by Smiths' counsel appears to stand for the proposition asserted.

An alternative construction of this term that is both logical and in accordance with the disclosures in the specification is one that does not limit the term "an amount of fluid to be infused" to a volumetric amount. Because "an amount of fluid to be infused" can be measured in units, Claim 1 comports with the written description of the specification because no second indication is necessary. The visual indication of the "an amount of fluid to be infused" would simply be the number of units of insulin to be infused. Moreover, although fluid is not normally measured in units, the invention contemplates that the concentration of the insulin is a "constant factor[]." Therefore, a specific number of units of insulin corresponds to a volumetric measurement of the fluid.FN17 In short, read in light of the specification, the claim language "amount of fluid to be infused" embraces amounts quantifiable in terms which can include measurements other than strictly volumetric measurements. Consequently, the term "an amount of fluid to be infused" means "a quantity of fluid to be infused in the patient." FN18

FN17. An appropriate analogy is that of converting a particular number of moles of a substance to grams, which occurs through a simple mathematical calculation using a known constant (*i.e.*, the number of moles per gram of a substance). Thus, in such a situation, the number of moles of a substance is appropriately described as an "amount" of that substance, just as here, with a known concentration, the number of units of insulin can be described as "an amount of fluid."

FN18. I have already construed "liquid" to mean, in the context of this case, "a substance, such as insulin, that is active within the human body." *See supra*, Part IV.C.1.a. Consequently, to give "fluid" its plain meaning would not raise any of the problems associated with different words in the same claim having the same meanings, as argued by Smiths.

c. "bolus estimator"

Smiths argues that "bolus estimator" is "a device separate from the processor that estimates the amount of medication to be infused" (D.I. 190 at 32), while MiniMed argues that the term should have its ordinary meaning (D.I. 214 at 33). I reject Smiths' argument. The claim itself reads as follows: "bolus estimator used in conjunction with the processor ... to estimate an amount of liquid " ('798 patent, col. 30:39-41.) Consequently, I construe the term to mean "a device that estimates the amount of liquid to be infused."

d. "indication device"

i. The Parties' Proposed Construction

Smiths argues that the meaning of "indication device" is "a device located in a remote commander, providing at least one of a visual indication, an audible indication or a tactile indication." (D.I. 165 at 28.) Smiths argues that the claim language, specification, and prosecution history support this construction. (D .I. 190 at 33-36.) It argues that the term "indication device" has "no stated physical relationship to any other elements in the claim ." (*Id.* at 33.) Smiths also argues that the purpose of this invention is to conceal the pump, specifically noting that the specification states that "one of the objectives of this invention is to provide an external pump 'capable of being concealed from view when being remotely commanded.'" (*Id.* (citing '798 patent, Abstract).) Further, Smiths argues that the specification lists multiple uses of an RF (radio frequency) programmer or indicator. (*Id.* at 34 (citing '798 patent, col. 5:38-40, 6:54-58, 8:18-21).) Smiths also argues that, during the prosecution of the patent, the patentee "disclaimed coverage of embodiments in which the indication device is located in or on the infusion pump." (*Id.*)

MiniMed argues in response that nothing in the claims requires a remote "indication device." (D.I. 214 at 34.) In addition, it argues that the specification lists many preferred embodiments that do not use a remote "indication device." (*Id.* at 35.) Lastly, MiniMed argues that the portions of the prosecution history cited by Smiths were either cited out of context or do not apply to the claims at issue. (*Id.* at 35-38.)

ii. The Court's Construction

The plain meaning of "indication device" in this case is "a device providing at least one of a visual indication, an audible indication or a tactile indication." FN19 Looking to the rest of Claim 1, I see nothing that warrants the inclusion of Smiths' proposed additional limitation. Other elements of the claim are required to be located on the housing, such as "a processor coupled to the housing." ('798 patent, col.

30:38.) There is nothing in the claim, however, that prevents the indicator from being connected to the housing. (*Id.*, col. 30:38-47.) Contrary to what Smiths argues, all this proves is that the processor must be attached to the housing and the indicator may or may not be attached to the housing.

FN19. Smiths' proposed meaning strays from the plain meaning of "indication device." This is supported by their repeated attempts to show how the patentee redefined the term in the specification or disclaimed certain subject matter during the prosecution of the patent. (*See* D.I. 190 at 33-36.)

With respect to the specification, it is important to remember that although "examples disclosed in the preferred embodiment may aid in the proper interpretation of a claim term, the scope of a claim is not necessarily limited by such examples." *Ekchian v. Home Depot*, 104 F.3d 1299, 1303 (Fed.Cir.1997) (internal citation omitted). In the '798 patent specification, in addition to numerous examples of the invention using a remote indication device, there are also numerous instances of the indication device being attached to the housing of the pump. ('798 patent, col. 4:6-18, 6:25-58, 11:52-12:4, 13:1-34, 15:1-3, 15:53-58, 28:11-12.) Smiths itself states that it is only "one of the objectives" of the invention to use a remote "indication device;" it is not the sole objective. (D.I. 190 at 33.)

Additionally, the prosecution history does not show "both [a] clear and unmistakable" disavowal of claim scope. *Omega*, 334 F.3d at 1325-26. Two of the sections cited by Smiths discuss how the invention uses a remote programmer, while the prior art does not. (D.I. 190 at 34-35 (citing D.I. 193, Ex. 41 at 4-5).) These two cited sections point to the invention as a whole, however, and not the specific claims at issue. (*See* D.I. 193 at 5 (beginning the discussion of specific claims at the bottom of page 5).) It is true that, the cited document, the patentee discusses a claim that is not at issue in this case that explicitly requires "remotely generated commands." FN20 But it is reasonable to understand that the mention of a remote programmer related to the specific claim in connection with which it was discussed, and not a later claim that made no reference to such a capability.

FN20. Both parties agree that during prosecution Claims 1, 10, and 12 were labeled as 35, 52, and 54, respectively. (D.I. 190 at 34; D.I. 214 at 35.)

Lastly, Smiths cites an office action where the patentee stated that the pump can be concealed from view "when being remotely commanded." (D.I. 190 at 35-36 (citing D.I. 193, Ex. 37 at 26-27).) This passage, however, is aimed directly at overcoming the rejection of claims not at issue in this case. (*See* D.I. 193, Ex. 37 at 26-27.) FN21 These cites provided by Smiths do not show both a "clear and unmistakable" action on the part of the patentee to limit the definition of the term "indication device." *See Omega*, 334 F.3d at 1325-26. Consequently, I hold that "indication device" means "a device connected to the infusion device or in a remote, providing at least one of a visual indication, an audible indication or a tactile indication." FN22

FN21. That passage refers to Claim 1. Smiths, however, made it clear that Claims 1, 10, and 12 were labeled as 35, 52, and 54 during prosecution. (D.I. 190 at 34.) Consequently, Claim 1 in that document refers to a claim not at issue in this litigation.

FN22. The term "externally supplied values" is listed in the Joint Claim Construction Chart as disputed. (D.I. 165 at 27.) In the parties' briefing, however, there is no discussion of this term. Therefore, I presume

that the parties no longer have a dispute as to the meaning of this term.

2. Claim 12 FN23

FN23. Smiths has argued that the disputed claim terms in Claims 10 and 12 should be construed differently to avoid the two claims having the same meaning. *See Comark Communs. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed.Cir.1998) (stating that "[t]here is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant"). For convenience, I have chosen to construe the term "basal rate profile" in Claim 12 before construing the term "personal delivery pattern" in Claim 10.

Claim 12 of the '798 patent reads as follows:

An external infusion device for infusion of a liquid into a body from a reservoir, the external infusion device comprising:

a drive mechanism to operatively couple with a reservoir to infuse a liquid into a body;

a housing adapted for use on an exterior of the body, wherein the housing is sized to contain at least a portion of a reservoir, wherein the drive mechanism is contained within the housing, wherein the drive mechanism operatively couples with the at least a portion of a reservoir within the housing, and wherein the housing is sized to fit in a clothing pocket;

a processor coupled to the housing;

a memory coupled to and used in conjunction with the processor to store at least two basal rate profiles;

a keypad coupled to the housing and used in conjunction with the processor to program the at least two basal rate profiles; and

an indication device to indicate the basal rate profiles during programming,

wherein the processor controls the external infusion device in accordance with the programmed at least two basal rate profiles.

('798 patent, col. 31:65-32:21.)

a. "basal rate profile"

i. The Parties' Proposed Construction

In the Joint Claim Construction Chart, Smiths asserts that I should construe "basal rate profile" to mean "an infusion rate with a start and stop time." (D.I. 165 at 39.) At oral argument, Smiths amended its position somewhat, stating that "basal rate profile" is a "basal rate with a start and stop time." (D.I. 269 at 42.) MiniMed argues that I should construe "basal rate profile" to mean "a series of variable liquid infusion

rates." (Id.)

Smiths argues that the specification supports its construction of the term "basal rate profile." Specifically, Smiths points to a paragraph in the specification where the term "profile segment," which is described as being programmed with a "start time and a basal rate," and the term "profile" are, says Smiths, used interchangeably. ('798 patent, col. 27:1-6.) Smiths also notes that the two terms are used interchangeably throughout the '798 patent. (D.I. 218 at 39, n. 22.) This, Smiths argues, supports the construction of the term "profile" as a single rate. (Id. at 39.) Lastly, Smiths argues that MiniMed's product literature uses the term "profile" to mean a "basal rate with a start and a stop time." (D.I. 193, Ex. 35 at 136.)

MiniMed argues that, in the part of the specification cited by Smiths, the patentee merely left out the word "segment" after the word "profile." (D.I. 169 at 37, n. 3.) MiniMed further argues that, in the prosecution history, the patentee clearly indicated that the meaning of "basal rate profile" does not mean a constant basal rate. (D.I. 214 at 38-39.) Lastly, MiniMed argues that it is improper for the court to look at MiniMed's product literature in order to construe the claims. (Id.)

ii. The Court's Construction

The definition of "profile" is "a set of data ... portraying the significant features of something...." Merriam-Webster Dictionary, 928 (10th ed.2001). The word "set" in this definition supports the construction that "basal rate profile" means multiple rates.

The prosecution history of the patent also supports this construction. In attempting to overcome the examiner's objection to Claim 12, labeled as Claim 54 in the application, the patentee stated that:

the [prior art] references only describe and disclose storing *basal and bolus rates* in the memory of the pump. Thus ... [the] references do not disclose, teach or suggest an external infusion device including a memory to store at least two *basal rate profiles*, as recited in Claim 54.

(D.I. 207, Ex. J at 35 (emphasis added).) In this excerpt, the patentee distinguished storing "basal and bolus rates" from storing "at least two basal rate profiles." (Id.) This supports the argument that a "basal rate profile" is more than a simple "basal rate."

The section of the patent cited by Smiths is unconvincing. In that paragraph, the patentee continually uses the term "profile segments" to refer to a single basal rate. ('798 patent, col. 27:1-16.) In the last sentence, however, the patentee uses the term "profile" instead of the term "profile segment." (Id. at 27:13-16.) The fact that the patentee chose the term "profile segment" leads me to believe that, the patentee intended that the term "profile" encompasses multiple segments and that the single use of the term "profile" as opposed to "profile segment" was merely an inadvertent dropping of the word "segment." FN24

FN24. Smiths' statement that the terms "profile" and "profile segment" are used interchangeably throughout the specification is incorrect, as this appears to be the only instance of the two terms being used in such a manner.

Lastly, it is improper for Smiths to argue that literature from MiniMed's commercial embodiment of the invention should be used to construe the terms. *See Vitronics, Inc.*, 90 F.3d at 1584 (stating that "[o]nly if

there were still some genuine ambiguity in the claims, after consideration of all available intrinsic evidence, should the trial court have resorted to extrinsic evidence").

With respect to the construction of the term "basal rate," I hold that it has a plain meaning that does not include a bolus rate. Neither side has cited, nor have I have found anything in the specification or prosecution history that would lead me to expand the definition to include a bolus rate. The term "basal rate profile" means "a series of variable basal rates."

b. "processor controls"

Smiths argues that "processor controls" means "the processor causes the infusion device to sequentially infuse the at least two basal rate profiles." (D.I. 165 at 41.) MiniMed argues that "processor controls" means "the processor causes the infusion device to deliver the liquid in accordance with one of the at least two basal rate profiles." (*Id.*) There is nothing to support Smiths' argument that the term should be restricted to "sequentially" infusing the "basal rate profiles." Additionally, common sense says that two profiles cannot be implemented at the same time. Consequently, I hold "processor controls" to mean "the processor causes the infusion device to deliver the liquid in accordance with one of the at least two basal rate profiles."

3. Claim 10

Claim 10 of the '798 patent reads as follows:

An external infusion device for infusion of a liquid into a body from a reservoir, the external infusion device comprising:

a drive mechanism to operatively couple with a reservoir to infuse a liquid into a body;

a housing adapted for use on an exterior of the body, wherein the housing is sized to contain at least a portion of a reservoir, wherein the drive mechanism is contained within the housing, wherein the drive mechanism operatively couples with the at least a portion of a reservoir within the housing, and wherein the housing is sized to fit in a clothing pocket;

a processor coupled to the housing;

a memory coupled to and used in conjunction with the processor to store at least two personal delivery patterns;

a keypad coupled to the housing and used in conjunction with the processor to select one of the at least two personal delivery patterns; and

an indication device to indicate the selected personal delivery pattern,

wherein the processor controls the external infusion device in accordance with the selected one of the at least two personal delivery patterns.

('798 patent, col. 31:8-32.)

a. "personal delivery pattern"

i. The Parties' Proposed Construction

Smiths argues that I should construe the term "personal delivery pattern" to mean "an individual pattern of multiple infusion rates ." (D.I. 165 at 36.) MiniMed argues that I should construe the term to mean an "individual pattern of multiple basal rates to be infused into a user over a 24 hour period." (Id.)

Smiths argues that MiniMed's construction imports limitations, specifically the "24 hour" and "basal rate" requirements, found nowhere in Claim 10 and unsupported by the specification. (D.I. 218 at 38.) MiniMed argues that the specification and prosecution history support this construction. Specifically, one of the preferred embodiments describes a "delivery pattern" as being programed to operate over 24 hours. ('798 patent, col. 27:1-16.) To support its argument that the term be construed to cover only basal rates, MiniMed cites to a response to an office action. (D.I. 169 at 35.) In that response, the patentee overcame the prior art by pointing out that "the ability to switch between bolus and basal rates is not the same as the at least two personal delivery patterns ... [and that] there is no pattern since one merely switches between two rates." (D.I. 207, Ex. J at 35.) MiniMed argues that the patentee "overcame prior art rejections specifically by distinguishing between basal delivery and bolus delivery." (D.I. 169 at 36.)

ii. The Court's Construction

"Personal delivery pattern" means "an individual pattern of multiple infusion rates." "Personal delivery pattern" contains no durational limitation nor is it restricted to only basal rates, as opposed to bolus rates. With respect to limiting "personal delivery pattern" to just basal rates, MiniMed's arguments are unconvincing. In the cited text, there is nothing singling out basal rates as being connected to "personal delivery pattern." (D.I. 207, Ex. J at 35.) The patentee merely states that "the ability to switch between bolus and basal rates is not the same as the at least two personal delivery patterns...." (Id.) Moreover, the specification describes a bolus that is programmed ahead of time with a variable delivery pattern. ('798 patent, col. 10:48-62.) In describing such a bolus, the specification states that "the user may program a profiled bolus that uniquely matches the needs of the individual user (for instance it may contain square, ramp, pulse or curved portions that make up the profile to be delivered over a period of time)." (Id. at 10:53-57.) This supports the argument that a "personal delivery pattern" could be used to supply a bolus as well as a basal rate.FN25

FN25. Because I have construed "personal delivery pattern" to include both basal and bolus rates and I have construed "basal rate profile" to be limited to basal rates, *see supra*, Part IV.C.2.a, I am not confronted with a problem under the doctrine of claim differentiation. *See Comark Communs. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed.Cir.1998) (stating that "[t]here is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims"). The doctrine of claim differentiation supports this construction of "personal delivery pattern."

The intrinsic evidence does not support adding the "24 hour" limitation. The part of the specification cited by MiniMed to support adding this limitation represents only one of the preferred embodiments of the invention. ('798 patent, col. 6:10-12, 27:1-16.) It is improper to limit the claim to one of its preferred embodiments. Thus, I construe "personal delivery pattern" to mean "an individual pattern of multiple infusion rates."

4. Claim 16

Claim 16 of the '798 patent is as follows:

An external infusion device according to claim 10, wherein the selected one of the at least two personal delivery patterns repeats daily.

('798 patent, col. 32:51-53.)

I do find that dependant Claim 16 adds a durational limitation to the "personal delivery pattern" limitation. It does not, however, limit the "personal delivery pattern" to a series of infusion rates over a 24 hour period. In dependent Claim 16, at least one of the "personal delivery patterns repeats daily." ('798 patent, col. 32:51-53.) Therefore, at least one of the "personal delivery patterns" contained in dependant Claim 16 must be limited in duration to no more than 24 hours. This limitation is not inherent in the term "personal delivery pattern," but rather, is added to dependant Claim 16 through the addition of the term "repeats daily." Consequently, this durational limitation is included in dependant Claim 16 but is not included in independent Claim 10.FN26

FN26. The terms "characteristic values," "current characteristic value," and "target characteristic values" are in dispute. (D.I. 165 at 29-30.) MiniMed addresses these terms briefly in its briefing, while Smiths does not address them at all in its briefing. MiniMed argues that "characteristic value" means "a physiological characteristic value that is particular to the user." (D.I. 169 at 31.) In the Joint Claim Construction Chart, Smiths states that this term means "physiological attributes that are known to influence the well being of a diabetic such as body weight, body fat index, metabolic rate, level of exercise, and growth rate." (D.I. 165 at 29-30.) Smiths supplies no reason to limit the term in the manner it advocates. Therefore, I agree with MiniMed that "characteristic values" means "a physiological characteristic value that is particular to the user." The remaining words, "current" and "target" have their plain meaning.

V. CONCLUSION

For the reasons stated, the terms in dispute are construed as follows:

CLAIM TERM/PHRASE	THE COURT'S CONSTRUCTION
The '704 Patent	
Claim 6	
"A pump apparatus for pumping fluid to a patient"	This preamble is limiting and has its plain meaning.
"processor means electronically connected to said memory for retrieving said operational data to control the operation of said pump mechanism"	The claim term is a means-plus-function limitation, the claimed function being "retrieving said operations data to control the operation of said pump mechanism" and the corresponding

and the corresponding structure is

microprocessor 182.

"at least one port means operable as either a communications port for effecting communication with a device external of said pump mechanism or as an input port for receiving input from the patient or a user for specifying the amount of fluid to be pumped by said pump mechanism."

The claim term is a means-plus-function limitation with two separate functions.

The first function is "operable as a communications port for effecting communication with a device external of said pump mechanism" and the

corresponding structure is

communications port 132.

The second function is "operable as an input for receiving input from the patient or a user for specifying the amount of fluid to be pumped by said pump mechanism" and the corresponding structure is remote

does port 234.

Claim 11

"controller means utilizing said operations program for controlling the operation of said pump"

The claim term is a means-plus-function limitation, the claimed function being "controlling the operation of said pump" and the corresponding structure to be microprocessor 182 used in conjunction

with memory 184.

"access code"

The claim term means "a sequence of characters used as a password

which an authorized user must enter to gain

	access to the controller means."
"locked state"	The claim term has its plain meaning.
"unlocked state"	The claim term has its plain meaning.

"wherein said access code required for altering the operations of said operations

program is entered via said keyboard"	
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"wherein said access code program places said controller means in the locked state after the operations controlled by said operations program

has been altered"	
The '065 Patent	
Claim 1	

"dispensing protocol" The claim term means "a plan or regimen

	for the delivery of medication."
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"first medication dispensing protocol," "second medication dispensing protocol," and "third manually inputted medication

dispensing protocol."	
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"automatically control" The claim term has its plain meaning.

"controller means for automatically controlling said delivery means to deliver the selected medication dosage to the

The claim term is a means-plus-function limitation, the claimed function being "automatically controlling said delivery

patient according to a first medication dispensing protocol"	means to deliver the selected medication dosage to the patient according to a first medication dispensing protocol" and the
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	corresponding structure is controller 24.
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"means for inputting blood data to said controller means"	The claim term is a means-plus-function limitation, the claimed function being "inputting blood data to said controller means" and the corresponding structures are a "glucose sensor or meter" used either subcutaneously or adapted to receive and read a glucose test strip and
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	a radio telemetry or infrared receiver.
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"current patient condition parameter"	The claim term means "a recent patient
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	condition parameter."
--	-----------------------

"means responsive to said data for recommending a second medication dispensing protocol that is responsive to said data"	The claim term is a means-plus-function limitation, the claimed function being "recommending a second medication dispensing protocol that is responsive to said data" and the corresponding
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	structure is a controller.
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"patient accessible manual set means for enabling said controller means to deliver the medication to the patient according to a selected one of said first and	The claim term is a means-plus-function limitation, the claimed function being "enabling said controller means to deliver the medication to the patient
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second medication dispensing protocols"

according to a selected one of said first and second medication dispensing protocols" and the corresponding structures are control buttons, buttons 22, and a dial 42 and

	plunger 44.
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Claim 10	
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"automatically operate"	The claim term has its plain meaning.
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The '798 Patent	
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Claim 1	
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"characteristic values," "current characteristic value," and "target characteristic values"	"Characteristic value" means "a physiological characteristic value that is particular to the user." The remaining words, "current" and "target," have their
---	---

	plain meaning.
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"liquid"	The claim term means "a substance, such as insulin, that is active within the
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	human body."
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"an amount of fluid to be infused"	The claim term embraces amounts quantifiable in terms which can include measurements other than strictly volumetric measurements, and means "a quantity of fluid to be infused in the
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	patient."
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"bolus estimator"	The claim term means "a device that estimates the amount of liquid to be
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	infused."
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"indication device"	The claim term means "a device connected to the infusion device or in a remote, providing at least one of a visual indication, an audible indication or a tactile indication."
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"externally supplied values"	The claim term has its plain meaning.
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Claim 7	
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"codes"	The claim term has its plain meaning.
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Claim 12	
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"basal rate profile"	The claim term means "a series of
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	variable basal rates."
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"processor controls"	The claim term means "the processor causes the infusion device to deliver the liquid in accordance with one of the at
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	least two basal rate profiles."
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Claim 10	
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"personal delivery pattern"	The claim term means "an individual
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	pattern of multiple infusion rates."
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Claim 16	
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"An external infusion device according to claim 10, wherein the selected one of the at least two personal delivery patterns	The claim requires that at least one of the "personal delivery patterns" is limited in duration to no more than 24 hours.
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repeats daily."	
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An appropriate order will issue.

ORDER

For the reasons set forth in the Memorandum Opinion issued today in this matter,

IT IS HEREBY ORDERED that the disputed claim terms in U.S. Patent No. 6,241,704, U.S. Patent No. 6,554,065, and U.S. Patent No. 6,241,798 are construed as follows:

CLAIM TERM/PHRASE	THE COURT'S CONSTRUCTION
The '704 Patent	
Claim 6	
"A pump apparatus for pumping fluid to a	This preamble is limiting and has its plain
patient"	meaning.
"processor means electronically connected to said memory for retrieving said operational data to control the operation of said pump mechanism"	The claim term is a means-plus-function limitation, the claimed function being "retrieving said operations data to control the operation of said pump mechanism" and the corresponding structure is
	microprocessor 182.
"at least one port means operable as either a communications port for effecting communication with a device external of said pump mechanism or as an input port for receiving input from the patient or a user for specifying the amount of fluid to be pumped by said pump mechanism."	The claim term is a means-plus-function limitation with two separate functions. The first function is "operable as a communications port for effecting communication with a device external of said pump mechanism" and the corresponding structure is communications port 132. The second function is "operable as an input for receiving input from the patient or a user for specifying the amount of fluid to be pumped by said pump mechanism" and

the corresponding structure is remote

dose port 234.

Claim 11

"controller means utilizing said operations program for controlling the operation of said pump"

The claim term is a means-plus-function limitation, the claimed function being "controlling the operation of said pump" and the corresponding structure to be microprocessor 182 used in conjunction

with memory 184.

"access code"

The claim term means "a sequence of characters used as a password which an authorized user must enter to gain

access to the controller means."

"locked state"

The claim term has its plain meaning.

"unlocked state"

The claim term has its plain meaning.

"wherein said access code required for altering the operations of said operations

The claim term has its plain meaning.

program is entered via said keyboard"

"wherein said access code program places said controller means in the locked state after the operations controlled by said operations program

The claim term has its plain meaning.

has been altered"

The '065 Patent

Claim 1

"dispensing protocol"

The claim term means "a plan

or regimen

for the delivery of medication."

"first medication dispensing protocol,"

"second medication dispensing protocol," and "third manually inputted medication

dispensing protocol."

These claim terms are consistent with the meaning of "dispensing protocol."

"automatically control"

The claim term has its plain meaning.

"controller means for automatically controlling said delivery means to deliver the selected medication dosage to the patient according to a first medication dispensing protocol"

The claim term is a means-plus-function limitation, the claimed function being "automatically controlling said delivery means to deliver the selected medication dosage to the patient according to a first medication dispensing protocol" and the

corresponding structure is controller 24.

"means for inputting blood data to said controller means"

The claim term is a means-plus-function limitation, the claimed function being "inputting blood data to said controller means" and the corresponding structures are a "glucose sensor or meter" used either subcutaneously or adapted to receive and read a glucose test strip and

a radio telemetry or infrared receiver.

"current patient condition parameter"

The claim term means "a recent patient

condition parameter."

<p>"means responsive to said data for recommending a second medication dispensing protocol that is responsive to said data"</p>	<p>The claim term is a means-plus-function limitation, the claimed function being "recommending a second medication dispensing protocol that is responsive to said data" and the corresponding</p>
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	structure is a controller.
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<p>"patient accessible manual set means for enabling said controller means to deliver the medication to the patient according to a selected one of said first and second medication dispensing protocols"</p>	<p>The claim term is a means-plus-function limitation, the claimed function being "enabling said controller means to deliver the medication to the patient according to a selected one of said first and second medication dispensing protocols" and the corresponding structures are control buttons, buttons 22, and a dial 42 and</p>
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	plunger 44.
--	-------------

Claim 10	
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"automatically operate"	The claim term has its plain meaning.
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The '798 Patent	
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Claim 1	
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<p>"characteristic values," "current characteristic value," and "target characteristic values"</p>	<p>"Characteristic value" means "a physiological characteristic value that is particular to the user." The remaining words, "current" and "target," have their</p>
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	plain meaning.
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<p>"liquid"</p>	<p>The claim term means "a substance, such as insulin, that is active</p>
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such as insulin, that is active within the

human body."

"an amount of fluid to be infused"

The claim term embraces amounts quantifiable in terms which can include measurements other than strictly volumetric measurements, and means "a quantity of fluid to be infused in the

patient."

"bolus estimator"

The claim term means "a device that estimates the amount of liquid to be

infused."

"indication device"

The claim term means "a device connected to the infusion device or in a remote, providing at least one of a visual indication, an audible indication or a

tactile indication."

"externally supplied values"

The claim term has its plain meaning.

Claim 7

"codes"

The claim term has its plain meaning.

Claim 12

"basal rate profile"

The claim term means "a series of

variable basal rates."

"processor controls"

The claim term means "the processor causes the infusion device to deliver the liquid in accordance with one of the at

least two basal rate profiles."

Claim 10

"personal delivery pattern"	The claim term means "an individual
	pattern of multiple infusion rates."
Claim 16	
"An external infusion device according to claim 10, wherein the selected one of the at least two personal delivery patterns repeats daily."	The claim requires that at least one of the "personal delivery patterns" is limited in duration to no more than 24 hours.

Produced by Sans Paper, LLC.