
Medtronic MiniMed 2007D Implantable Insulin Pump System

Physician's Manual

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4,731,051	5,217,442	5,527,307	6,427,088
4,776,842	5,257,971	5,559,828	6,537,268
5,167,633	5,460,618	5,797,733	6,562,001
5,176,644	5,466,218	5,915,929	6,564,105
5,197,322	5,514,103	6,283,943	6,571,128

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Introduction

The Medtronic MiniMed 2007D Implantable Insulin Pump System, shown in Figure 1, brings together sophisticated new technologies to provide continuous intraperitoneal insulin therapy for patients with Insulin Dependent Diabetes Mellitus (IDDM). The development of the Medtronic MiniMed 2007D Implantable Insulin Pump System is the result of years of cooperative research and development between Medtronic MiniMed and:

- The Johns Hopkins University, Applied Physics Laboratory
- U.S. National Aeronautics and Space Administration, Goddard Space Flight Center. U.S. National Institutes of Health



Figure 1: Implantable Insulin Pump and Personal Pump Communicator (PPC)

This manual is intended for use by the physician, surgeon, nurse specialist and all other members of the healthcare team who care for patients with the Medtronic MiniMed 2007D Implantable Insulin Pump System.

The Medtronic MiniMed 2007D Implantable Insulin Pump System can be used with special U-400 insulin formulations specifically labeled for use with the Medtronic MiniMed Implantable Insulin Pump System.

The system consists of three major components:

- Implantable Insulin Pump
- Side Port Catheter
- Personal Pump Communicator (PPC)

Each of these components, as well as system safety features, are discussed in detail in the following sections.

Implantable Insulin Pump

The Implantable Insulin Pump (Pump) is a round disc, 8.1 cm (3.2 inches) in diameter, 2.0 cm (0.8 inches) thick. The Pump weighs 131 grams (4.6 ounces) when empty. The outside case of the Pump is made of titanium. Titanium is a biocompatible metal used in many types of implantable medical devices. A tangential Side Port Catheter is attached to the Pump prior to implant, using a locking connector (see Figure 2).



Figure 2: The Implantable Insulin Pump

The Implantable Insulin Pump is an advanced insulin infusion device with sophisticated microelectronics. It delivers a special insulin medication, using a pulsatile solenoid pumping mechanism that is hermetically sealed inside the biocompatible titanium case. Insulin delivery rates and profiles are programmed using an external device, the Personal Pump Communicator (PPC). Specific information on the Implantable Insulin Pump features is outlined in the following sections.

The Pump has six major components. These components are outlined below:

- medication reservoir
- pumping mechanism
- microelectronics
- antenna
- battery
- tone transducer

Other components of the Pump include the inlet valve, fill port, septum, cyclopentane gas and 20 μ m filter. Figure 3 shows the interior components of the Pump.



Figure 3: Interior of the Implantable Insulin Pump

The Medication Reservoir stores approximately 15 ml or 6,000 units of a special U-400 insulin. Depending on an individual's insulin requirements, the medication reservoir is refilled once in approximately every two to three months. The medication reservoir is maintained at a negative pressure (vacuum) at all times to allow for safe and reliable filling. This vacuum prevents any risk of insulin leakage in the event of a breach in the Pump case or reservoir. The reservoir is refilled with a special needle (Medtronic MiniMed Refill Needle MMT-4102). The fill port has a 20 micron filter to prevent particulate material from entering the Pump and a redundant septum and valve configuration to prevent entry of body fluids.

The Pumping Mechanism is a solenoid-operated, hermetically-welded pulsatile system. The pumping mechanism is designed to seal automatically to prevent leakage both into and out of the reservoir under physiologic temperatures and pressures. The mechanism is designed to provide an insulin delivery accuracy of within 10% from its labeled stroke volume. Individual Pumps are calibrated to one of seventeen different stroke volumes, ranging from 0.42 μL to 0.58 μL per stroke, in increments of 0.01 μL .

The Microelectronics act as the brain of the Pump. The microelectronics contain two microprocessors which monitor and control all pump-stroke activity. All commands delivered from the PPC via RF telemetry to the Pump are then acknowledged back to the PPC. The Pump has a large memory which stores Pump specifications and programming history.

The Antenna receives radiowaves from the PPC and delivers PPC programming commands to the Pump microelectronics.

The Battery is a custom-made lithium carbon mono-fluoride power cell, which supplies energy to the pumping mechanism and microelectronics. It is similar to batteries used in pacemakers and is designed to provide 6 to 10 years of service, depending on the infusion rate (refer to pump specifications).

The Tone Transducer emits beeps to indicate certain alarm conditions. These beeps are designed to be audible through the skin and can be set with the PPC to one of two volumes. The Pump can also be programmed to emit beeps that signal a programmed change in the medication delivery rate.

Radio-Opaque Identification is featured in the Implantable Insulin Pump. In the event of an emergency, the name of the manufacturer and the Pump model number can be identified with an x-ray.

Insulin medication

Only specially formulated U-400 insulins that are specifically labeled for use with the Medtronic MiniMed Implantable Insulin Pump System can be used in the model 2007D Pump.

These special U-400 insulins are supplied in 10mL vials.

Side Port Catheter

The Side Port Catheter (Catheter) transports insulin from the Pump into an individual's peritoneum where it is absorbed. The Catheter is made of polyethylene-lined silicone rubber, which is biocompatible with subcutaneous and intraperitoneal tissues and supports the stability of the special insulin. The Catheter is designed with two perpendicular sections: a proximal subcutaneous section which attaches tangentially to the Pump with a locking connector, and a distal section which is placed in the peritoneum (see Figure 4). To enable post-implant localization, a radioopaque stripe runs the length of the Catheter.

The Catheter Side Port is intended to provide access to the Catheter and Pump outlet, in order to perform the non-surgical interventions and diagnostic procedures described in Appendices E, F and G. The side port allows for the introduction of a needle and small syringe to clear Catheter obstructions using pressures up to 100 psi. It also allows for the introduction of a needle to verify Pump stroke volume.

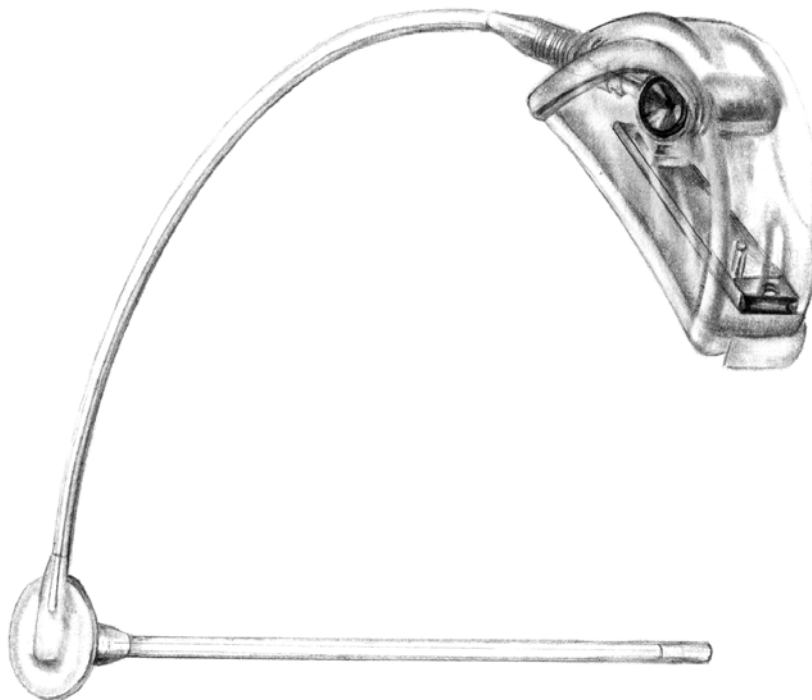


Figure 4: The Intraperitoneal Catheter and Side Port

Personal Pump Communicator (PPC)

The Personal Pump Communicator (PPC) is the hand-held component of the Medtronic MiniMed 2007D Implantable Pump System (see Figure 5).

The PPC allows the physician and patient to communicate with the Pump by transmitting radio frequency messages when the PPC is held within 3" of the Pump. Additionally, the PPC stores important programming information in its memory.



Figure 5: Personal Pump Communicator (PPC)

The PPC has been designed so the physician and patient can:

- Program basal infusion rates (up to 48 basal rates per day, 3 different patterns)
- Deliver or suspend an immediate, Square Wave, or Dual Wave Bolus of insulin
- Deliver or cancel a temporary basal rate
- Review the insulin delivery history
- Enter personal events (meal, snack, exercise)

Independent of the programming function, the PPC is able to receive and record certain programming data from the Pump. The recorded information is accessible and can be displayed on the screen.

Indications and contraindications

Indications for use

The Medtronic MiniMed 2007D Implantable Insulin Pump System is indicated for intraperitoneal administration of exogenous insulin in patients with diabetes mellitus.

The model 2007D Pump can only be used with special U-400 Insulin formulations specifically labeled for use with the Medtronic MiniMed Implantable Insulin Pump Infusion System.

Contraindications for use

The Medtronic MiniMed 2007D Implantable Insulin Pump System is contraindicated in patients who:

- are unwilling or unable to monitor their blood glucose level at least four times per day.
 - are unwilling or unable to make programming modifications to the Pump based on glucose level readings.
 - are unable or unwilling to administer insulin by other means, if necessary.
 - are unable or unwilling to comply with the guidance and advice of their treating physician and other healthcare providers.
 - reside at or travel (other than by pressurized commercial aircraft) at elevations above 8,000 feet.
 - have other medical or mental conditions which may place the patient at risk.
 - are unwilling or unable to return for routine insulin refills according to their dosage requirements (approximately once every 90 days).
 - present or have a history of sensitivity to titanium alloy, polysulfone or silicone materials used in the implanted components of the system.
-

Possible adverse effects

The model 2007D is essentially identical to the model 2007C Pump except for the change in gas needed to maintain negative pressure in the reservoir. Evaluation of components used in the Medtronic MiniMed 2007C system has spanned a period of approximately 4 years and involved approximately 380 patients from both the U.S. and Europe. Although clinically relevant over-delivery of insulin did not occur during the 4 year evaluation period, there is a potential for such an occurrence.

The following are specific adverse effects which should be understood by the physician and explained to the patient. These do not include all adverse effects which can occur with surgery in general or with the use of this device, but are important considerations, particularly in the treatment of diabetic patients. The general surgical risks, as well as operative site cosmetic risks, should be explained to the patient prior to surgery.

- Abdominal Pain
 - Inflammation at Refill Site
 - Infection
 - Necrosis
 - Hypoglycemia
 - Foreign Body Reaction
 - Skin Erosion
 - Pocket Lymph Edema
 - Hyperglycemia
 - Ketoacidosis
-

CHAPTER 3

Personal Pump Communicator (PPC)

Introduction

The Personal Pump Communicator (PPC) has a comprehensive set of programming features to control the Implantable Insulin Pump. The PPC cannot be used by the patient until it has been initialized by the healthcare professional. This chapter of the manual is divided in two parts:

The first part (Part 1) will describe the PPC/PUMP system initialization process that will be performed the day prior to implant.

The second part (Part 2) will describe how to use the additional features that the healthcare professional or patients can activate.

PPC icons

After initialization, the PPC Main Screen displays the time (12hr. or 24hr. format), month, day and a variety of icons. The type and purpose of these icons are as follows:

	Bell Icon: Displayed when the PPC receives a telemetry message from the Pump indicating that the Pump has detected an alarm condition, when a PPC error is detected and when the Pump is Suspended or Stopped.
	Reservoir Level Indicator Icon: The reservoir icon is composed of 4 segments that indicate how full the Pump reservoir is, based on the history of Pump delivery.
	Insulin Delivery Icon: The PPC simulates spinning the delivery icon when insulin delivery is in progress by displaying alternating patterns, the pattern changes every 4 seconds. When the Pump is delivering a bolus, the pattern will show three delivery segments. When the Pump is delivering a basal rate, the pattern will show one delivery segment. When the Pump is not delivering, all four segments will be displayed.

Certain features of the PPC such as programming and dosing limits can be set only by the healthcare professional in a password-protected mode called the Supervisor Mode. Information pertaining to initializing the PPC and entering the PPC Supervisor Mode is not included in the Patient User Manual.

PPC buttons

SEL (Select)	The SEL button steps through each of the displays and menus.
ACT (Activate)	The ACT button activates programming changes in the Pump, new information to be entered into the PPC memory, and alarms to be turned off. As a safety check, ACT must be pressed to complete any programming changes. A single beep is heard after activating a change.
▲ or ▼ (Up or Down Arrows)	The ▲ or ▼ arrows allow changes in the screen settings. Pressing ▲ once will find the next highest setting, and pressing ▼ once will find the next lowest setting. Holding down either button will rapidly scroll through the list of preset values. Desired values can then be programmed by pressing ACT .
Sound Icon (Up Arrow)	When the Audio Bolus feature is turned on, pressing ▲ allows programming an Audio Bolus.
Light Icon (Down Arrow)	From the main operating screen, pressing ▼ once will turn on the backlight. The backlight allows the Pump to be programmed in the dark. The backlight will turn off automatically after four seconds after the last button press.

Communicating with the Pump

Place the PPC near the Pump when the screen displays, “PPC COMMUNICATING.” The word “COMMUNICATING” will blink as indication of successful communication. If a communication link between the PPC and Pump is not established, a “TELEMETRY COMM ERROR 3” message will appear. The PPC will beep six times once every minute until the screen is acknowledged by pressing **SEL** and **ACT**. The screen will then display “PPC COMMUNICATING” again.

After a communication is established between the PPC and Pump and program information is successfully transferred to the Pump, the PPC will beep once and return to the Time/Date screen.

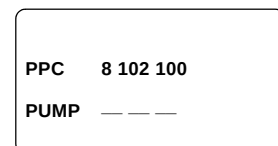
- Always press the PPC buttons slowly and firmly. Wait until the screen changes before pressing the button again.
 - A flashing value on the screen means that the value is activated, and can be changed by pressing the arrow buttons.
-

- The PPC cannot be turned off. Once the battery has been installed, the PPC is on and remains on until the battery is removed.
- Certain types of Radio Frequency (RF) generating equipment could affect PPC communication with the Pump. If you are experiencing communication difficulties, change locations.
- The time and date settings must be correct to ensure appropriate calculation of insulin delivery and display of daily totals and activity history.

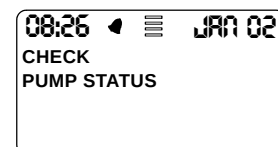
Install/Replace the main battery

The battery used to power the PPC is a 1.5V AA alkaline. The life of the battery is approximately 4 weeks during normal usage conditions.

- Locate the battery door on the back of the PPC.
- Slide the locking bar to the left.
- Push the middle part of the PPC box (under the battery door) and lift by gently pulling up the battery door to unlatch.
- Remove the old battery, noting the polarity. The screen will be blank.
- Position the new battery so the + and - markings on the battery match the polarity diagram in the battery compartment.
- Close the battery door.
- Slide the locking bar to the right.
- The PPC screen will reappear within 30 seconds:



1. The PPC will beep 6 times, and after a few seconds, the screen will display "CHECK PUMP STATUS".



2. Press **SEL** then **ACT**, and place the PPC near the Pump.
3. Wait a few seconds for the communication to complete.



NOTE: When the PPC displays “PPC LOW BATTERY”, the message can be cleared, and programming continued. There should be sufficient energy in the battery to communicate with the Pump a few more times, but the battery should be changed as soon as possible.

NOTE: If while programming the PPC, the screen goes blank, the PPC beeps six times and then the “CHECK PUMP STATUS” message appears, the battery needs to be replaced.

Part 1: PPC/Pump system initialization

The Implantable Insulin Pump arrives from Medtronic MiniMed with preset factory default values. During the initialization process these preset values are downloaded into the PPC memory. The preset values can then be changed by the healthcare professional, allowing the system to be personalized for each patient.

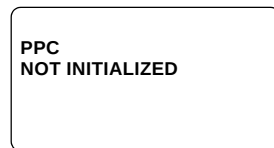
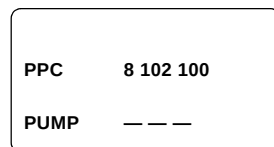
The factory default values are as follows:

Bolus delivery type: Normal	Locked set maximums: Off
Maximum bolus: 25.0 U	Password: YIQ8
Audio bolus: Off	Personal Events status: OFF
Audio feedback: Disabled	Personal ID: 000 (32 characters)
Auto Off duration: Off	PPC alarm type: High
Basal delivery pattern: A	Refill amount: 25 g
Maximum basal rate: 35.0 U/H	Time format: 12 hours
Insulin concentration: 400 U/ml	Variable Bolus status: Off

Initialize the PPC

When the healthcare professional receives a new PPC it must be “married” to the Pump. Following are the basic steps used to initialize a Pump System the day prior to implant:

1. The PPC is delivered without a battery in place. After installing a new battery, the PPC will beep six times and the screen will identify the PPC software used (*see Chapter 3, Install/Replace the Main Battery*).
2. The screen now changes to “PPC NOT INITIALIZED”, and the PPC will beep six times once every minute until the initialization process is started. Press **SEL** and then **ACT**, then quickly place the PPC over the Pump.



3. When a communication link has been established, the screen will read, “PPC COMMUNICATING”, and then will change to the next screen.

PPC
COMMUNICATING

4. “NO” is blinking. Check to make sure the serial number displayed on the screen matches the Pump serial number. Press either ▲ or ▼ once to change “NO” to “YES” and then press **ACT**. Place the PPC over the Pump.

INITIALIZING “NO”
PPC to PUMP
.....
..... 47568

5. The screen again reads “PPC COMMUNICATING”, and the PPC will beep 3 times at the end of the programming sequence. During this process, the PPC receives all of the factory preset values contained in the Pump memory.

PPC
COMMUNICATING

6. The screen will read “PUMP SUSPENDED”. The Pump and PPC are now “married”.

PUMP SUSPENDED

7. Press **SEL**, then **ACT** and place the PPC near the Pump.

PPC
COMMUNICATING

8. The screen now reads “PUMP INITIALIZED”.

PUMP INITIALIZED

9. Press **SEL** and then **ACT** again, and the PPC will display the Time/Date screen.

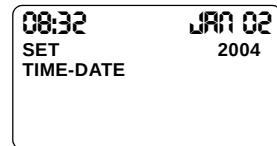
11:16 ☰ JAN 02

NOTE: When the alarm type is set to “VIBRATE” the beeps from the PPC during normal programming will be low volume.

Set the time and date

The time and date settings must be correct to ensure accurate calculation of insulin delivery, daily totals, and the proper display of insulin activity history.

1. Press **SEL** until the “SETUP PUMP” screen is displayed, then press **ACT** two times. The first two digits of the time (hours) will be flashing. Use the ▲ and ▼ buttons to select the correct hour, then press **ACT**. The last two digits of the time (minutes) will be flashing. Use the ▲ and ▼ buttons to select the correct minute, then press **ACT**. Repeat the programming process to enter information for the year, month and day.



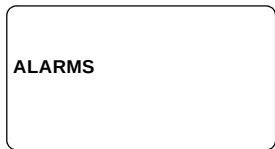
2. After completing the programming process, then place the PPC near the Pump. The PPC will display “PPC COMMUNICATING” while transferring the time and date information to the Pump. The PPC will then move to the next screen, “AUTO-OFF.” Skip the “AUTO-OFF” screen by pressing **SEL** once to reach the next screen, “ALARMS”.



Set alarms

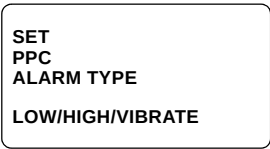
Alarms alert the user in the event the PPC or Pump recognizes an insulin delivery problem. The Alarm Feedback screen must always be in the “ON” position.

1. Press **ACT** to enter the “ALARMS” menu.



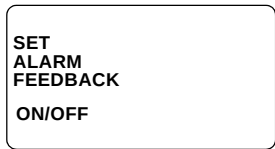
ALARMS

2. The PPC has three alarm options, two audible tones (Low/High) and a vibrate mode. Press the ▲ and ▼ buttons to select the desired alarm, then press **ACT**.



SET
PPC
ALARM TYPE
LOW/HIGH/VIBRATE

3. The screen will now display “SET ALARM FEEDBACK”. This setting should always be “ON”. Press **ACT**.

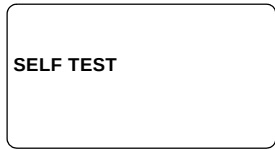


SET
ALARM
FEEDBACK
ON/OFF

4. Place the PPC near the Pump. When the communication is completed, the PPC screen will change to “SELF TEST” and then to the Time/Date screen.



PPC
COMMUNICATING



SELF TEST

NOTE: When the alarm type is set to “vibrate” the beeps from the PPC during normal programming will be low volume.

Set maximum bolus, basal rate and time display format

This programming is performed in the “SETUP II” menus. These screens allow healthcare professionals to limit the maximum amount of insulin a patient can deliver, either when taking a bolus or setting a new basal rate. Access to the “SETUP II” menus is through the “SETUP PUMP” screen.

1. Press **SEL** until the “SETUP PUMP” screen is displayed. Press **ACT** and press **SEL** to reach the “SETUP II” screen. Press **ACT** and then **SEL** to reach the “MAX BOLUS” screen.

MAX BOLUS
-- U

2. Press **ACT** and the maximum bolus amount (units) will start flashing. Press the ▲ and ▼ buttons to change the maximum allowable bolus (0.2 to 25.0 units) and then press **ACT** again.

SET
MAX BOLUS
-- U

3. Place the PPC near the Pump and complete the communication process. The PPC screen will automatically change to the “MAX BASAL” screen.

PPC
COMMUNICATING

4. Press **ACT** and the screen will change to “SET MAX BASAL RATE”. The maximum basal amount will start flashing. Press the ▲ and ▼ buttons to change the maximum allowable basal rate (0.2 to 35.0 units/hour) and then press **ACT** again.

SET
MAX BASAL RATE
0.2U/H

5. Place the PPC near the Pump and complete the communication process. The PPC screen will automatically change to “TIME FORMAT.”

PPC
COMMUNICATING

6. Press **ACT** and the screen will change to “SET TIME FORMAT.” Press the ▲ and ▼ buttons to select either a 12 hour (AM/PM) or 24 hour (military time) format, and then press **ACT**.

SET
TIME FORMAT
12/24 HOUR

- Place the PPC near the Pump and complete the communication process. The PPC screen will return to the “PERSONAL EVENTS” screen. Allow the PPC to time out and return to the Time/Date screen.

PPC
COMMUNICATING

NOTE: Adding screens to the main menu, such as “PERSONAL EVENTS” increases the number of SEL button presses required to reach “SETUP PUMP.”

Lock maximum bolus/basal, enter personal ID and password, stop Pump

To access the Supervisor Mode press **SEL** until the “SETUP PUMP” screen is displayed. Then press and hold down the ▲ and ▼ buttons simultaneously until the “ENTER SUPERVISOR PASSWORD” screen appears.



Patients should not be given the Supervisor Mode password, to avoid the accidental programming of a large priming bolus (99.8 U) or diagnostic insulin rate.

- The first zero will be flashing. Press the ▲ and ▼ buttons to select the first digit, then press **ACT**. The screen advances to the second zero. Press the ▲ and ▼ buttons to select the second digit, then press **ACT**. Repeat for the last two digits. The factory pre-set password is YIQ8.
- Entry into the Supervisor Mode is indicated by the screen “PUMP REFILL.”
- Press **SEL** until the “SET MAXIMUMS” screen is displayed, and then **ACT** to reach “SET MAXIMUMS”. Press the ▲ and ▼ buttons to select “ON” if the patient is not given access to this feature, or “OFF” if the patient is permitted access. Press **ACT** again.

ENTER
SUPERVISOR
PASSWORD

0000

PUMP
REFILL

SET
MAXIMUMS OFF/ON

4. Place the PPC near the Pump and complete the communication process. The PPC screen will automatically advance to the “PERSONAL ID” screen. Press **ACT**.

PPC
COMMUNICATING

5. The first of the 32 possible ID locations is flashing. Enter the patient ID (alpha-numeric) by pressing the ▲ and ▼ buttons and then **ACT** after each entry. Continue to press **ACT**, activating each “0” until the screen changes.

SET PERSONAL ID
.....
..... 20KOLO5

6. Place the PPC near the Pump and complete the communication process.

PPC
COMMUNICATING

7. Press **SEL** until the “SET SUPERVISOR PASSWORD” screen is displayed. Then press **ACT**.

SET
SUPERVISOR
PASSWORD

YIQ8

8. The screen now reads, “SET SUPERVISOR PASSWORD”. Press **ACT**. Use the ▲ and ▼ buttons to enter a new supervisor password (alphanumeric), pressing **ACT** after each entry.

SET
SUPERVISOR
PASSWORD

0000

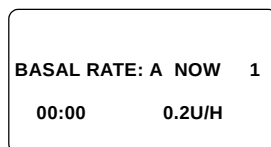
9. Record the password in the patient’s chart and implant form.

Program a basal rate

1. From the Time/Date screen, press **SEL** until the “BASAL RATE” screen is displayed. Preset delivery pattern “A”, a basal rate of 0.2 U/H, and the word “NOW” is flashing. Press **ACT**.

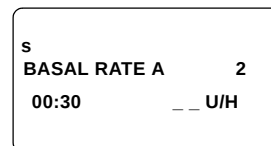


2. A “1” now appears to the right of the “A” indicating that this programming will effect the 1st basal change within the “A” pattern, (there are 3 patterns available [A, B, C] and 48 basal changes possible within each pattern). The flashing 0.2 U/H indicates the value can be changed. Use the ▲ and ▼ buttons to change the value and then press **ACT**.



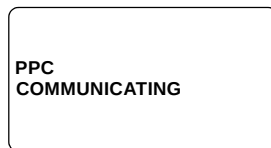
NOTE: 00:00 indicates a start time of MIDNIGHT in 24hr. display mode. In 12hr. display mode, the screen indicates the start time as 12:00am.

3. The screen now displays “SET TIME”, and a time of 00:30 or 12:30 am (24 or 12 hour respectively) and a “2.”



If one basal is all that will be used, press **ACT** two times. If more than one basal rate is to be programmed, enter a start time and amount of the new basal rate for that time period, then press **ACT** and enter the new basal rate. The user can enter a new basal rate at 30 minute intervals, up to 48 basal rates.

4. Place the PPC near the Pump and complete the communication process.



5. The PPC will briefly display the calculated total basal dose for 24 hours, based on the values and times entered in the Basal Rate programming screen. In this example, the total basal dose is 4.8 U/day.



Part 2: Additional PPC programming features

Main menu

This second part will describe how to program the additional features that the patient or the healthcare professional can activate.

Program a bolus

A properly initialized PPC is now ready to program a bolus.

The PPC/Pump allows you to set and deliver a bolus of insulin whenever needed. The PPC has several special features which allow you to customize the programming and delivery of boluses.

- Normal Bolus and Audio Bolus
- Square Wave Bolus
- Dual Wave Bolus

NOTE: To use the Variable Bolus programming options, (e.g. square, dual), this option needs to be programmed “ON” in the SETUP II menu. If it is not “ON” only the default bolus, “Normal bolus”, will be available.

Set a Normal bolus with the Variable Bolus feature turned off

1. From the Time/Date screen, press **SEL**.
The “BOLUS” screen is displayed, with the time and date flashing.

08:13	JAN 02
BOLUS	
IMM	EXT
10U	10U
PROG	--

2. Press **ACT** and the “SET BOLUS” screen appears. The dashes under “IMM” are flashing. Press the ▲ and ▼ buttons to enter an immediate bolus amount.

SET BOLUS
IMM
-- U

3. Press **ACT** and the “CONFIRM” screen is displayed, with the screen flashing. Confirm the bolus amount by pressing **ACT** again.

CONFIRM
IMM
2.6U

4. Place the PPC near the Pump and complete the communication process.

PPC
COMMUNICATING

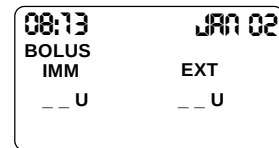
5. When the bolus programming is complete, the PPC will beep once and then briefly display the amount of insulin currently delivered.

08:13	JAN 02
BOLUS	0.0U

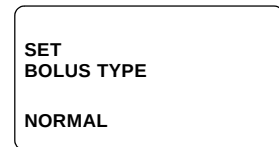
The Pump will beep at each of the first five strokes (if audio feedback is ON). The PPC beeps and at the end of the bolus. Three segments of the insulin delivery icon will be displayed and spinning slowly during the bolus delivery. By pressing **SEL** you can read the amount of insulin delivered.

Set a Normal bolus with the Variable Bolus feature turned on

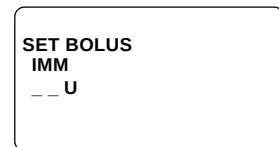
1. From the Time/Date screen press **SEL** until the “BOLUS” screen is displayed. The last bolus value programmed and the Time and Date will be flashing.



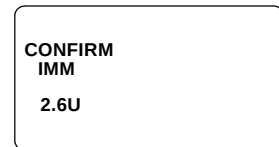
2. Press **ACT** and the “SET BOLUS TYPE” screen appears. If “NORMAL” is not flashing, use the ▲ and ▼ buttons to select “NORMAL.” Press **ACT**.



3. The “SET BOLUS” screen appears, with dashes under “IMM” flashing. Use the ▲ and ▼ buttons to enter an immediate bolus amount.



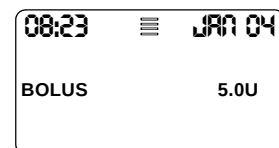
4. Press **ACT** and the “CONFIRM” screen is displayed, with the screen flashing. Confirm the bolus amount by pressing **ACT** again.



5. Place the PPC near the Pump and complete the communication process.



6. When the bolus programming is complete, the PPC will beep once and then briefly display the amount of insulin currently delivered.



The Pump will beep at each of the first five strokes (if audio feedback is ON). The PPC beeps at the end of the bolus. Three segments of the insulin delivery icon will be displayed and spinning slowly during the bolus delivery. By pressing **SEL** you can read the amount of insulin delivered.

Set a Square Wave Bolus

A Square Wave Bolus of insulin is delivered evenly over a preset period of time, from 30 minutes to 4 hours. A Square Wave Bolus may be desirable when eating long meals such as at banquets or receptions, high fat meals, or to compensate for gastroparesis. During a Square Wave Bolus, the programmed basal rate is delivered simultaneously to the bolus.

To access this feature you must first turn the Variable Bolus feature “ON” in the “SETUP II” menu.

1. From the Time/Date screen, press **SEL**. The “BOLUS” screen is displayed, showing the last bolus programmed with the time and date flashing.

08:13	JAN 02
BOLUS	
IMM	EXT
10U	--U
PROG	--

2. Press **ACT** and the “SET BOLUS TYPE” screen appears. Press the ▲ and ▼ buttons to select “SQUARE”. Press **ACT**.

SET BOLUS TYPE
SQUARE

3. The “BOLUS” screen appears, with dashes under “EXT” flashing. Use the ▲ and ▼ buttons to enter an extended bolus amount. Press **ACT**.

SET BOLUS	
IMM	EXT
--U	4.0U

4. Blinking dashes will now appear under the bolus amount entered. Use the ▲ and ▼ buttons to enter a time duration for the Square Wave Bolus, in one-half hour increments from 30 minutes to 4 hours.

SET BOLUS	
IMM	EXT
--U	4.0U
	2:00

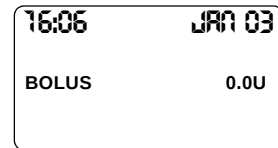
5. Press **ACT** and the “CONFIRM BOLUS” screen is displayed, with the screen flashing. Confirm the Square Wave Bolus by pressing **ACT** again.

CONFIRM BOLUS	
IMM	EXT
--U	4.0U
	2:00

6. Place the PPC near the Pump and complete the communication process.

PPC COMMUNICATING

7. When the bolus programming is complete, the PPC will beep once and then briefly display the amount of insulin currently delivered.



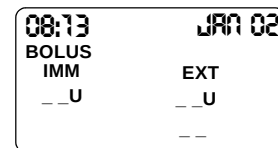
The Pump will beep at each of the first five strokes (if audio feedback is ON). The PPC beeps at the end of the bolus. Three segments of the insulin delivery icon will be displayed and spinning slowly during the bolus delivery. By pressing **SEL** you can read the amount of insulin delivered.

Set a Dual Wave Bolus

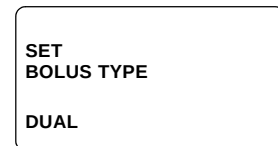
The Dual Wave Bolus programs a Normal Bolus immediately followed by a Square Wave Bolus.

To access this feature you must first turn the Variable Bolus feature ON in the SETUP II menu.

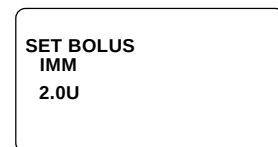
1. From the Time/Date screen, press **SEL**. The “BOLUS” screen is displayed, showing the last bolus programmed with the time and date flashing.



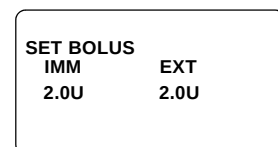
2. Press **ACT** and the “SET BOLUS TYPE” screen appears. Press the ▲ and ▼ buttons to select “DUAL.” Press **ACT**.



3. The “SET BOLUS” screen appears, with dashes under “IMM” flashing. Use the ▲ and ▼ buttons to enter the immediate portion of the Dual Wave Bolus. Press **ACT**.



4. The “SET BOLUS” screen now shows dashes flashing under “EXT.”



Use the ▲ and ▼ buttons to enter the extended portion of the Dual Wave Bolus. Press **ACT**.

5. Blinking dashes will now appear under the bolus amount entered.

Use the ▲ and ▼ buttons to enter a time duration for the Square Wave Bolus, in one-half hour increments from 30 minutes to four hours.

SET BOLUS	
IMM	EXT
2.0U	
2:00	

6. Press **ACT** and the “CONFIRM BOLUS” screen is displayed, with the screen flashing. Confirm the Dual Wave Bolus by pressing **ACT** again.

CONFIRM BOLUS	
IMM	EXT
2.0U	2.0U
2:00	

7. Place the PPC over the pump and complete the communication process.

PPC COMMUNICATING

8. When the bolus programming is complete, the PPC will beep once and then briefly display the amount of insulin currently delivered.

The Pump will beep at each of the first five strokes (if audio feedback is ON). The PPC beeps at the end of the bolus. Three segments of the insulin delivery icon will be displayed and spinning slowly during the bolus delivery. By pressing **SEL**, you can read the amount of insulin delivered.

16:06	JAN 03
BOLUS	2.0U

Review bolus history

To review the type, amount, time and day of your last 512 insulin boluses.

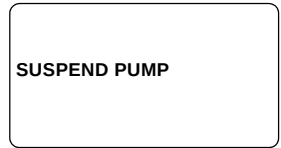
1. From the Time/Date screen, press **SEL**. The “BOLUS” screen is displayed, showing the last bolus programmed.
Use the ▲ and ▼ buttons to display previous boluses, along with the time and day each bolus was delivered.

08:23	JAN 02
BOLUS	
IMM	EXT
--U	--U
PROG	--

Suspend mode

The Suspend Pump mode allows the user to cancel a bolus delivery, while still delivering a basal rate of 0.2 U/hr.

1. From the Time/Date screen, press **SEL** until the “SUSPEND PUMP” screen is displayed. Press **ACT**. The screen will display a flashing “SUSPEND PUMP” message. Press **ACT** again.

A rectangular screen with a black border. The text "SUSPEND PUMP" is centered in the upper half of the screen.

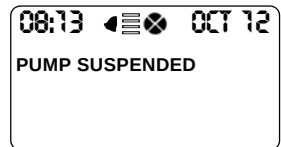
SUSPEND PUMP

2. Place the PPC near the Pump and complete the communication process.

A rectangular screen with a black border. The text "PPC COMMUNICATING" is centered in the upper half of the screen.

PPC
COMMUNICATING

3. When the communication is complete, the Pump will beep 3 times and the PPC screen will change to “PUMP SUSPENDED”. All four segments of the insulin delivery icon are shown. The PPC will beep every half-hour as long as the Pump remains suspended.

A rectangular screen with a black border. At the top, it shows the time "08:13" on the left, a status bar with a signal strength icon, a battery icon, and a cross icon, and the date "OCT 12" on the right. Below this, the text "PUMP SUSPENDED" is centered.

08:13 ◀ █ █ █ █ OCT 12
PUMP SUSPENDED

NOTE: To restart the Pump, press SEL. The “PUMP SUSPENDED” screen will begin flashing. Then press ACT.

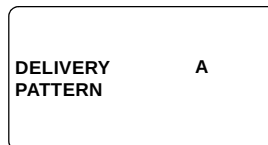
Programming a basal rate

Basic basal rate programming was described earlier in this chapter. This section describes additional basal rate options.

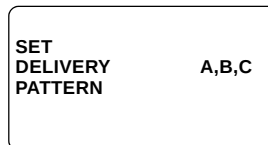
Programming basal delivery pattern

The PPC allows three basal delivery patterns. One such basal pattern could be used for a working day, another for a weekend day, etc. Each of the basal delivery patterns is a set of up to 48 basal rates, one for each half-hour of the day. Pattern A is the factory pre-set. To access profiles B or C you must enter the “SETUP PUMP” screens.

1. Press **SEL** until the “SETUP PUMP” screen is displayed. Press **ACT**. Press **SEL** again to access the basal rate profile screen, “DELIVERY PATTERN”.



2. Press **ACT** and the screen will change to “SET DELIVERY PATTERN”. Use the ▲ and ▼ keys select the pattern preferred; A, B, or C. Each pattern can contain up to 48 different basal rates. Press **ACT** after choosing a pattern.



3. Place the PPC near the Pump and allow the communication to complete.



NOTE: When the PPC times out, press SEL until the “BASAL RATE” screen is displayed. The basal pattern selected in “SETUP PUMP” will now appear to the right of “BASAL RATE” A, B, or C.

Setting basal rate profiles in each delivery pattern

Each of the basal delivery patterns is a set of up to 48 basal rates, one for each half-hour of the day.

1. Press **SEL** until the “BASAL RATE” screen is displayed. A basal pattern is selected (for example Pattern A). Press **ACT**.

BASAL RATE: A NOW
00:00 0.2U/H

2. A “SET RATE” and “1” is now displayed to the right of the “A” indicating this programming will set the 1st basal rate within the “A” profile. The “0.2U/H” is now flashing, indicating the value can be changed. Use the ▲ and ▼ arrow keys to program a new value, for example, “0.4 U/H”, and then press **ACT**.

SET RATE
BASAL RATE: A 1
00:00 0.2U/H

NOTE: 00:00 indicates a start time of MIDNIGHT in 24hr. display mode. 12:00am indicates a start time of MIDNIGHT in 12hr. display mode.

3. The screen now displays “SET TIME”, with a time of “00:30” or “12:30am” flashing (24 or 12 hour respectively) and a “2.” This screen allows the second basal rate to be set. Enter a start time for the 2nd basal rate within the “A” profile, for example “04:30.” Press **ACT**. (Example: a second basal rate of 0.4U/H starting at 04:30.)

SET TIME
BASAL RATE: A 2
04:30 0.4U/H

4. This screen changes to “SET RATE” again, indicating the 2nd basal rate can now be programmed. Use the ▲ and ▼ arrow buttons to enter a new rate, for example “0.2U/H”, and then press **ACT**.

SET RATE
BASAL RATE: 2
04:30 0.4U/H

5. A “3” now appears on the screen with “SET TIME.” Follow the same procedure previously described and program a new profile. If no additional profiles are needed change the flashing time to dashes (by pressing ▼) and press **ACT**.

SET TIME
BASAL RATE: 3
05:00 0.2U/H

- The screen will indicate “PPC COMMUNICATING.” Place the PPC near the Pump and complete the communication process.

PPC
COMMUNICATING

- The screen will briefly display the calculated 24 hour basal dose based on the basal rate programming. In this example a total of “8.4U” will be delivered.

24 HOUR TOTAL
8.4U

To set multiple basal profiles in the other patterns (A,B,C), select the pattern in "SETUP II" menu and follow the same procedure.

Program a temporary basal rate

A Temporary Basal Rate is often used when a brief change in basal delivery is required, for example during exercise.

Set a temporary basal rate

- From the time and date display press **SEL** until the “TEMP BASAL” screen is displayed.

TEMP BASAL
-- -- U/H

- Press **ACT** and the “SET DURATION” screen appears. The time duration of the Temporary Basal Rate is displayed as flashing dashes. Press the ▲ and ▼ buttons to enter a time duration, in 30 minute increments from 30 minutes to 24 hours.

SET DURATION
TEMP BASAL
00:30 -- U/H

- Press **ACT** and “SET AMOUNT” screen appears. The amount of the Temporary Basal Rate is now flashing. Press the ▲ and ▼ buttons to enter a delivery rate. Press **ACT** again.

SET AMOUNT
TEMP BASAL
00:30 1.5U/H

4. Place the PPC near the Pump and complete the communication process.

A rectangular screen with a black border. The text "PPC" is on the top line and "COMMUNICATING" is on the bottom line, both in black, uppercase letters.

5. When the communication is complete, the Pump will beep once. The PPC screen will briefly show the "TEMP BASAL" screen before returning to the Time/Date screen.

A rectangular screen with a black border. The top left shows "08:13" and the top right shows "OCT 02". The center of the screen displays "TEMP BASAL" in black, uppercase letters.

NOTE: When the Pump is delivering a Temporary Basal rate, the first screen displayed when SEL is pressed is "TEMP BASAL." The PPC will also beep every 30 minutes to alert the user that a Temporary Basal rate is currently active.

Stop a temporary basal rate

1. From the Time/Date screen press **SEL** until the "TEMP BASAL" screen is displayed. Press **ACT** and the "SET DURATION" appears, with the time duration flashing. Press ▼ once until it resets to dashes. Then press **ACT**.

A rectangular screen with a black border. The text "SET DURATION" is on the top line and "TEMP BASAL" is on the bottom line. Below "TEMP BASAL", there are two dashes "--" followed by "1.5U/H".

2. Place the PPC near the Pump and complete the communication process.

A rectangular screen with a black border. The text "PPC" is on the top line and "COMMUNICATING" is on the bottom line, both in black, uppercase letters.

3. When the communication is complete, the PPC will briefly return to the "TEMP BASAL" screen with the amount dashes flashing. Allow the PPC to return to the Time/Date screen.

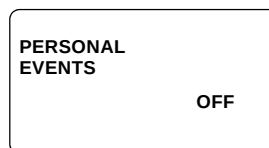
A rectangular screen with a black border. The text "SET AMOUNT" is on the top line and "TEMP BASAL" is on the bottom line. Below "TEMP BASAL", there are two dashes "--" followed by "--U/H".

Personal events

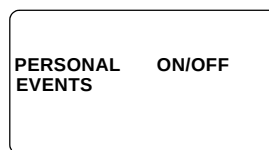
This feature allows the user to enter event codes into the PPC memory, and record the time and date of entry. Preset event codes are: 1 = meal, 2 = snack, 3 = sick and 4 = exercise. In addition, other event codes A, B and C can be entered to record other important events. These other event codes should be documented prior to their use.

To access the “EVENTS” screen in the main menu, “ON” must be activated in the “SETUP II” menu, “PERSONAL EVENTS” screen.

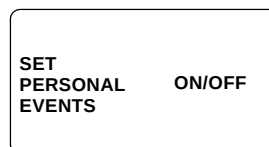
1. From the Time/Date screen, press **SEL** until “SETUP PUMP” is displayed, then press **ACT**. Press **SEL** until “SETUP II” is displayed, then press **ACT**. Press **SEL** until “PERSONAL EVENTS” screen is displayed.



2. Press **ACT** and “ON” or “OFF” begins flashing.



3. Use the ▲ and ▼ buttons to select “ON”, then press **ACT** again. The “PERSONAL EVENTS” screen will now appear on the main menu. Allow the PPC to return to the Time/Date screen.



4. To set an event: From the Time/Date screen press **SEL** until the “EVENT” screen is displayed then press **ACT**. The screen changes to “SET EVENT” with the word “MEAL” flashing. Use the ▲ and ▼ buttons to select the desired event.



5. Press **ACT** and the current time will appear flashing. Use the ▲ and ▼ buttons to enter the time the event occurred. Press **ACT** when the proper time is displayed. Then allow the screen return to Time/Date.



NOTE: Only historic or current event times can be entered.

NOTE: If the Personal Events feature is turned “OFF” in “SETUP II”, events cannot be entered into the PPC.

History

Historical Pump data, such as insulin medication remaining, amount of bolus and basal delivery since the last refill, etc., can be accessed and read on the PPC.

1. From the Time/Date screen press **SEL** until the “HISTORY” screen is displayed. Press **ACT** and the “READ PUMP DATA” screen will appear flashing. Press **ACT** again.

READ PUMP DATA
0000000000000000
0000000000010057

2. Place the PPC near the Pump and complete the communication process. The PPC will acquire data from the Pump.

PPC
COMMUNICATING

3. The screen will change to “MED REMAINING”, indicating the estimated amount of insulin medication remaining in the Pump. Record this number if required.

MED REMAINING
2263U

4. Press **SEL** and the screen will read “INSULIN TOTAL.” Delivered amounts of basal and bolus insulin medication are displayed for the date flashing on the screen. Use the ▲ and ▼ buttons to review other daily totals.

INSULIN TOTAL JAN 02
BASAL BOLUS
9U 22U

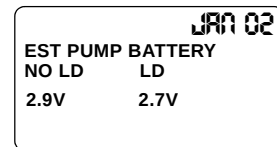
5. Press **SEL** and the screen will change to “CLINICAL HISTORY PPC”. Use the ▲ and ▼ buttons to review other PPC events.

6:16 JAN 02
CLINICAL HISTORY
PPC
11

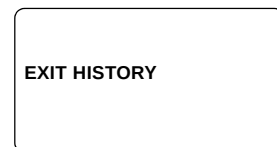
6. Press **SEL** and the screen will change to “CLINICAL HISTORY PUMP”. Use the ▲ and ▼ buttons to review Pump events.

6:26 JAN 02
CLINICAL HISTORY
PUMP
14

7. Press **SEL** and the screen will change to “EST PUMP BATT”. This screen indicates the Pump battery status, during no-load (battery power is not used) and load (extended communication sequence) conditions. The Pump is set to alarm for low battery when the loaded (LD) voltage is at or below 2.5 volts.



8. Press **SEL** and the screen will read “EXIT HISTORY.” Press **ACT**. The PPC will return to the Time/Date screen.



Setup Pump

The “SETUP PUMP” screen permits access to the primary Setup menus for the Pump. Setup features discussed previously in this chapter are referenced here. Other Setup features not previously discussed are presented here. Press **SEL** until the “SETUP PUMP” screen is displayed, then press **ACT** to access the SETUP menus.

Time and Date

This feature is previously described in this Chapter.

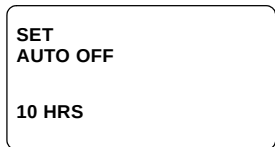
Auto off

Auto Off is a safety feature, reminding the user to update insulin medication delivery programming in the Pump. An alarm can be set after a period of programming inactivity, from one to 16 hours. At the onset of the alarm the Pump will automatically be placed in SUSPEND mode.

1. From the “SETUP PUMP” screen, press **ACT**. Press **SEL** to reach the “AUTO OFF” screen, then press **ACT**. The screen will display “AUTO OFF” with flashing dashes/time. Use the ▲ and ▼ buttons to select the number of hours before an “AUTO OFF” alarm occurs.
2. Press **ACT**. In this example, a time duration of 10 hours was selected. The PPC will alarm if the user did not attempt to program the Pump during the previous 10 hours and be placed in “SUSPEND” mode.
3. Place the PPC near the Pump and complete the communication process. The PPC will beep once and return to the Time/Date screen.



AUTO OFF
-- HRS



SET
AUTO OFF
10 HRS



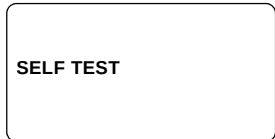
PPC
COMMUNICATING

Alarms

This feature is previously described in this Chapter.

Self test

1. Self Test allows the user to perform a diagnostic test of the Pump and PPC operating system. Messages are relayed between the PPC and Pump. From the “SETUP PUMP” screen, press **ACT**. Press **SEL** until the “SELF TEST” screen is displayed. Press **ACT**.



SELF TEST

2. Place the PPC near the Pump and complete the communication process.



PPC
COMMUNICATING

3. Verify that the following events occur:

- A series of tones will be heard from the Pump (4 beeps).
- An alarm tone will be heard from the PPC.
- The backlight on the PPC will turn on.
- The PPC screen will briefly activate all possible display icons, numbers, etc.
- The PPC will vibrate.

NOTE: If the above test results do not occur or the screen displays irregular characters, please notify Medtronic MiniMed. If the PPC displays the Medtronic MiniMed logo and software version, the PPC has restarted due to a low battery. Replace the battery immediately.

If all electronics “pass” the Self Test, the screen will automatically change to “PPC PASSED/PUMP PASSED.” After several seconds, the screen will return to the Time/Date screen.

Basal delivery pattern

This feature is previously described in this Chapter.

Initialize PPC to Pump

From the "SETUP PUMP" screen press **ACT** until "INITIALIZE PPC TO PUMP" is displayed. This option "marries" the PPC to the Pump, and it is used to initialize a new PPC. For initialization programming follow the steps described in, Part 1: PPC/Pump System initialization of this Chapter.

Setup II

"SETUP II" permits access to an additional group of Setup menus for the Pump. From the "SETUP PUMP" screen, press **ACT** until the "SETUP II" screen is displayed. "SETUP II" features are presented in the next section.

Exit Setup menu

1. From the "SETUP PUMP" screen, press **SEL** until the "EXIT SETUP MENU" screen is displayed. Press **ACT**. The PPC will return to the Time/Date screen.



EXIT SETUP MENU

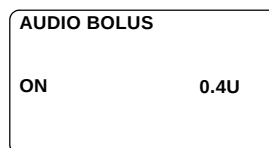
Setup II

Audio Bolus

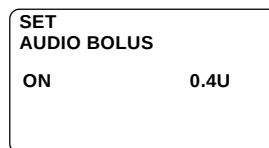
The Audio Bolus feature allows the user to deliver a bolus without looking at the PPC screen. There are two Audio Bolus increments, 0.4U and 0.8U. With each press of the ▲ button, the PPC will beep one time (0.4U setting) or two times (0.8U setting), depending on the delivery amount selected per button press.

Activating the Audio Bolus feature

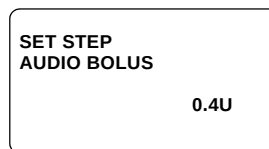
1. From the “SETUP II” screen, press **ACT**. The “AUDIO BOLUS” screen is shown.



2. Press **ACT**, and the screen changes to “SET AUDIO BOLUS” with “OFF/ON” flashing. Use the ▲ and ▼ buttons to choose “ON” to activate the Audio Bolus feature or “OFF” to disable it. Then press **ACT**.



3. If “ON” was chosen, the “SET STEP AUDIO BOLUS” appears with a step value of 0.4U or 0.8U flashing on the screen. Use the ▲ and ▼ buttons to choose between a step rate of 0.4U or 0.8U. Press **ACT**. The Audio Bolus feature is now activated.



NOTE: If “OFF” is chosen, pressing the ▲ button will have no effect.

Set an Audio Bolus from the main menu bolus screen

1. From the Time/Date screen press the ▲ button. The PPC beeps either one or two times, depending upon the audio bolus step amount set. The user counts the number of beeps to determine how much insulin was programmed.

SET BOLUS
IMM
0.8U

2. In this example the PPC was programmed for a 0.8U increment, and the PPC beeps two times for the 0.8U bolus. Press **ACT** and the audio sequence repeats to confirm the bolus amount. Press **ACT** twice and the Pump will be programmed. The PPC beeps once when the programming is completed. Place the PPC on the Pump to complete the communication process.

PPC
COMMUNICATING

NOTE: While an audio bolus is being delivered, the ▲ button will not function.

Variable Bolus

To access the Variable Bolus feature enter “SETUP II” and press **SEL** one time.

1. The screen will display “VARIABLE BOLUS”. Press **ACT**.

VARIABLE
BOLUS

2. The screen will now display “SET VARIABLE BOLUS” and “ON or OFF” will be flashing. Use the ▲ and ▼ buttons to select “ON” or “OFF”, then press **ACT**.

SET
BOLUS ON

3. Place the PPC near the Pump to complete communication. If “ON” was chosen the Variable Bolus option is now available in the Main Menu/Bolus screen.

PPC
COMMUNICATING

NOTE: If “OFF” is chosen, the Variable Bolus option (Square, Dual) will not be available in the (Main Menu) Bolus screen.

Maximum Bolus

This feature is previously described in this Chapter.

Maximum Basal Rate

This feature is previously described in this Chapter.

Time display format

This feature is previously described in this Chapter.

Personal Events

This feature is previously described in this Chapter.

Pump Setup

This screen allows the user to return to the setup mode "TIME/DATE" screen by pressing **ACT**.

Exit Setup Menu

Press **SEL** 7 times in the SETUP II mode. Pressing **ACT** will return the user to the Main Menu "TIME/DATE" screen.

Supervisor mode

To access Supervisor Mode (by a health care professional only) press **SEL** 6 times in the "SETUP PUMP" screen, then press and hold the ▲ and ▼ buttons simultaneously. Hold them down until the screen changes the "ENTER SUPERVISOR PASSWORD" screen.

Refill

The refill procedure will be described in Chapter 5 "Pump Refill Procedure." The following screens are used at the end of this procedure, and allow you to enter the new refill volume and to calculate the refill accuracy.

1. The "PUMP REFILL" screen appears when you access the Supervisor Mode. Press **ACT**.

PUMP REFILL

2. The PPC prompts for the residual amount of insulin removed from the Pump. Use the ▲ and ▼ buttons to enter the weight (grams) of extracted insulin.

SET
EXTRACTED AMOUNT
---- g

3. Press **ACT** and the PPC prompts for the refill insulin amount. Use the ▲ and ▼ buttons to enter the weight (grams) of insulin refilled in the Pump.

SET
REFILL AMOUNT
---- g

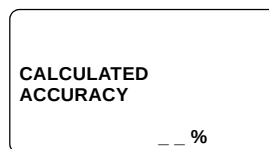
4. Press **ACT**. Confirm that the insulin concentration defaults to U-400. Press **ACT** again.

SET
INSULIN CONCENTRATION U400

5. Place the PPC near the Pump to complete the process.

PPC
COMMUNICATING

6. The calculated accuracy will be displayed briefly. Record this value on the refill form.



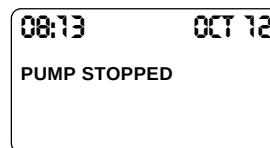
Priming



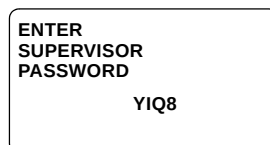
A priming bolus is not intended as a therapeutic bolus. It should only be used when the Pump is not implanted.

The Priming Bolus is used during the preparation of the Pump for implantation. This feature “Primes” the Pump piston chamber, outlet port and Catheter. The Pump will pulse approximately 500 times during this function. To access this feature, the Pump must be in “PUMP STOPPED” mode.

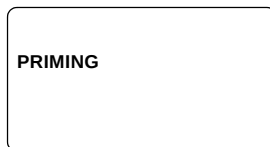
1. From the “PUMP STOPPED” screen, press **SEL**. The screen will begin flashing.



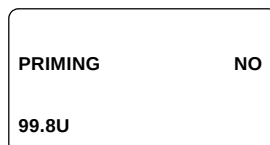
2. Press the ▲ and ▼ buttons at the same time until the “ENTER SUPERVISOR PASSWORD” screen appears.



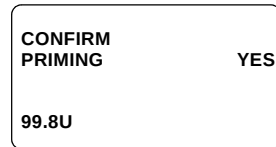
3. Re-enter the supervisor password, pressing **ACT** after each letter or number is entered. The factory preset password is: YIQ8. If the password has been changed, enter the new password. When the Supervisor Password is successfully entered, the screen will change to “PUMP REFILL”. Press **SEL** until the “PRIMING” screen appears.



4. Press **ACT** and “NO” appears flashing. Press the ▲ and ▼ buttons to change to “YES”, then press **ACT**.



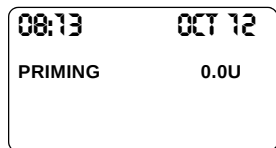
5. The word “CONFIRM” now appears. Press **ACT** to activate the factory preset priming bolus of 99.8U.



6. Place the PPC over the Pump and complete the communication process.



7. The progress of the Priming Bolus can be verified by pressing **SEL**. The Priming Bolus takes approximately 10 minutes to complete.



NOTE: The PPC will alarm every minute during the Priming Bolus. The Priming Bolus can be terminated at any time by using the “SUSPEND PUMP” feature.

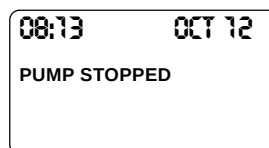
Diagnostic rate



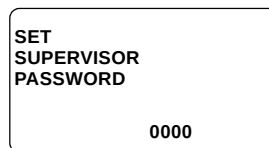
A diagnostic rate is intended for use only when the Pump is filled with rinse buffer.

The Diagnostic Rate feature is used to help “diagnose” Pump delivery problems. Fill the Pump with rinse buffer before using this feature. To access this feature, the Pump must be in the “PUMP STOPPED” mode.

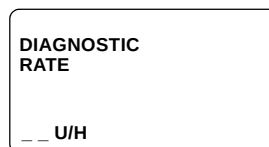
1. From the “PUMP STOPPED” screen, press **SEL**.
The screen will begin flashing.



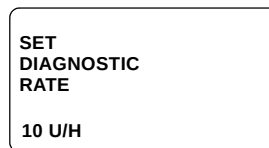
2. Press the ▲ and ▼ buttons at the same time until the “SET SUPERVISOR PASSWORD” screen appears. Re-enter the supervisor password, pressing **ACT** after each letter or number is entered. The factory preset password is: YIQ8.



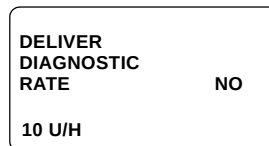
3. When the Supervisor Password is successfully entered, the screen will change to “PUMP REFILL”. Press **SEL** until the “DIAGNOSTIC RATE” screen appears.



4. Press **ACT** and the word “SET” appears flashing. Use the ▲ and ▼ buttons to enter a Diagnostic Rate (units/hour).



5. Press **ACT** and the word “SET” changes to “DELIVER”. “NO” also appears flashing. Use the ▲ and ▼ buttons change “NO” to “YES”, then press **ACT**.



6. The entire screen will be flashing. Press **ACT** again to confirm the Diagnostic Delivery Rate.

CONFIRM
DIAGNOSTIC
RATE

10 U/H

7. Place the PPC near the Pump and complete the communication process.

PPC
COMMUNICATING

8. The words “DIAGNOSTIC RATE” appear briefly on the screen. The PPC then returns to the Time/Date screen.

08:13 OCT 12

DIAGNOSTIC RATE

*NOTE: Press **SEL** and the PPC will indicate “DIAGNOSTIC RATE.”*

NOTE: Diagnostic Rate Delivery can be terminated at any time by using the “SUSPEND PUMP” feature.

Initialize to factory defaults

This feature resets all programmed parameters in the Pump to preset factory default values. To access this feature, the Pump must be in the “PUMP STOPPED” mode.

1. From the “PUMP STOPPED” screen, press **SEL**. The screen will begin flashing.

08:13 OCT 12

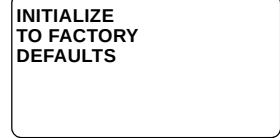
PUMP STOPPED

2. Press the ▲ and ▼ buttons at the same time until the “ENTER SUPERVISOR PASSWORD” screen appears. Re-enter the Supervisor Password, pressing **ACT** after each letter or number is entered. The factory preset password is: YIQ8.

ENTER
SUPERVISOR
PASSWORD

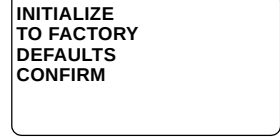
0000

3. When the Supervisor Password is successfully entered, the screen will change to “PUMP REFILL”. Press **SEL** until the “INITIALIZE TO FACTORY DEFAULTS” screen appears.



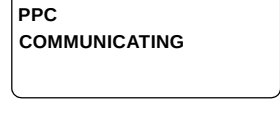
INITIALIZE
TO FACTORY
DEFAULTS

4. Press **ACT** and the word “CONFIRM” will appear. Press **ACT** again to activate.



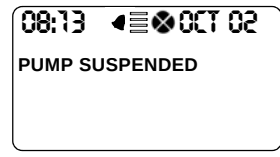
INITIALIZE
TO FACTORY
DEFAULTS
CONFIRM

5. Place the PPC over the Pump and complete the communication process.



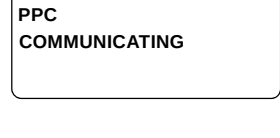
PPC
COMMUNICATING

6. The PPC will now read “PUMP SUSPENDED.” Press **SEL** then **ACT**.



08:13 0CT 02
PUMP SUSPENDED

7. Place the PPC over the Pump and complete the communication process.



PPC
COMMUNICATING

8. The PPC now displays the “PUMP RESET” screen, and beeps six times every minute until the Pump is restarted. Press **SEL** then **ACT**. The PPC returns to the Time/Date screen. The Pump may now be reprogrammed.

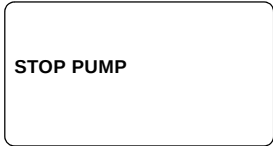


08:13 0CT 02
PUMP
RESET

Stop Pump

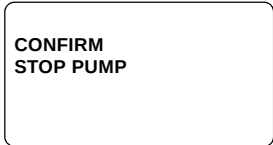
This screen allows the Physician to stop the operation of the Pump.

1. From the “PUMP REFILL” screen in the Supervisor Menu, press **SEL** until the “STOP PUMP” screen appears.

A rectangular screen with a black border. The text "STOP PUMP" is centered in a bold, black, sans-serif font.

STOP PUMP

2. Press **ACT** and the word “CONFIRM” appears highlighted with the entire screen flashing. Press **ACT** again to confirm.

A rectangular screen with a black border. The text "CONFIRM" is centered in a bold, black, sans-serif font, and "STOP PUMP" is centered below it in a smaller, black, sans-serif font.

CONFIRM
STOP PUMP

3. Place the PPC near the Pump and allow the communication to complete.

A rectangular screen with a black border. The text "PPC" is centered in a bold, black, sans-serif font, and "COMMUNICATING" is centered below it in a smaller, black, sans-serif font.

PPC
COMMUNICATING

4. The PPC will beep four times to confirm the “STOP PUMP” command. To restart the Pump, press **SEL** and “PUMP STOPPED” will start to flash. Press **ACT**. Place the PPC near the Pump. When the communication is complete, the PPC returns to the Time/Date screen.

A rectangular screen with a black border. At the top, the time "08:13" is on the left, and "OCT 02" is on the right, separated by a small icon. Below this, the text "PUMP STOPPED" is centered in a bold, black, sans-serif font.

08:13 ◀ ☰ ⊗ OCT 02
PUMP STOPPED

Supervisor password

If the password is lost, access the Supervisor Menu as follows:

- Program the time to midnight (12:00 am or 00:00) and the date to January 01.
- Enter the password 0000 within one minute. If the password is not entered within one minute the time will be reset to midnight again.
- Record the new password in the patient’s chart.

Exit supervisor

To exit the Supervisor Programming Menu, press **SEL** until the “EXIT SUPERVISOR” screen appears, then press **ACT**.

Personal Pump Communicator messages

Display Screen Message	Message Meaning or Action Required
AUTO OFF PUMP SUSPENDED	Auto Off time interval has elapsed. Pump operation is suspended.
BOLUS 0.0U	A bolus has been programmed and is being delivered.
CHECK PUMP STATUS	The PPC battery has been replaced. The PPC needs to check the Pump status.
LOW RESERVOIR	The PPC has recognized the Pump has 800 units (2 ml) or less insulin remaining in its reservoir. Schedule a Pump refill as soon as possible. Allowing the reservoir to completely empty may damage the Pump.
EMPTY RESERVOIR	The PPC has recognized the Pump has 400 units (1 ml) or less insulin remaining in its reservoir. Schedule a Pump refill as soon as possible. Allowing the reservoir to completely empty may damage the Pump.
HOURLY MAX EXCEEDED	You attempt to deliver more than 2.5 times the bolus maximum in one hour. To clear the message, press SEL and ACT . You may exceed this limit by programming another bolus within 10 minutes.
PPC LOW BATTERY	The PPC battery is low. The PPC can be used for at least 24 hours. Replace the AA battery immediately
PPC NOT INITIALIZED	The PPC has not been initialized to a Pump.
PUMP LOW BATTERY	The Pump battery energy is low but still functioning. Schedule a replacement as soon as possible.
PUMP INITIALIZED	The PPC has been “married” to a Pump. Press SEL and ACT .
PRIMING XX U	A Priming Bolus has been programmed and is being delivered.
PUMP RESET	The Pump was reprogrammed to the preset factory values.
PUMP SELF TEST FAIL	A Pump malfunction was detected during a Self Test.
PUMP STOPPED	The Pump is in stop mode.
PUMP STOPPED 1 or 2 or 3 or 4 or 5 or 6	When the Pump recognizes a system malfunction, it automatically stops and insulin delivery ceases.
PUMP SUSPENDED	The Pump is in suspend mode
PUMP ERROR 0 or 1	User attempts to initialize the PPC to a Pump that is not compatible with it. Clear by pressing SEL and ACT . Verify the personal ID of the Pump responding corresponds to the personal ID entered into the PPC.
PUMP ERROR 40 or 41	The Pump has invalid data. The PPC will not initialize to Pump.

Display Screen Message	Message Meaning or Action Required
TELEMETRY COMM ERROR 3	The PPC and Pump are not communicating. Reposition the PPC over the Pump, then press SEL and ACT. If the error message persists, contact Medtronic MiniMed.
TELEMETRY COMM ERROR 20	Move the PPC away from any other Pump and perform the request again.

Technical history codes

In the “HISTORY” menu, the user can access clinical history from the PPC and the Pump. Each number code corresponds to a particular event. The following table lists each of the number codes with their corresponding events.

Technical history PPC codes

Clinical Event	Code	Clinical Event	Code
Version Error	1	Time Out	2
No Response	3	Retry Packet	4
No Synchronization	5	Bad CRC	6
Invalid transmission	7	RX Overflow	8
Invalid Op code	9	TX Underflow	10
		Unknown IRQ Vector	12
Bolus Total Error	13	NMI Occurred	14
Bad Duplicates	15	Suspend Alarm	16
Stop Pump Alarm	17	Diagnostic Rate Alarm	18
Prime Pump Alarm	19	Exclusion List Full	20
Max Clock Stealer	21	Min Clock Stealer	22
Non Initialized PPC	23	Pump Self Test Error	24
Pump Initialized	25	Pump Reset to Defaults	26
		Hourly Maximum	28

Clinical Event	Code	Clinical Event	Code
Refill Divide Error	29	Refill Invalid Calculation	30
Divide by 0	31	EEPROM Error	32
Bad EEPROM	33	Main Battery Low	34
Temporary Basal Rate	37	Check Pump Status	38
		Invalid Concentration	40
Invalid Stroke Volume	41	Battery Removed	42

Clinical history Pump codes

Clinical Event	Code	Clinical Event	Code
IP Communication Error	1	Charge Time Too Long	2
Post-Fire Voltage Reading too High	3	Over-Delivery Error	4
Under-Delivery Error	5	Dead Battery	6
Auto Off Interval Exceeded	7	Low Reservoir	8
Empty Reservoir	9	Low Battery	10
Normal Delivery Mode	11	Stop Delivery Mode	12
Suspend Delivery Mode	13	Diagnostic Rate delivery mode	14
Priming Bolus Delivery Mode	15	Insulin Concentration Change	16

Preprogramming and pre-testing the Pump

Every Implantable Insulin Pump is fully tested before shipment and is accompanied by a package insert indicating the measured stroke volume and Pump type. Prior to shipping, each Pump is filled with sterile rinse buffer to assure sterility.

Programming of the Pump may be performed a day before Pump implantation. The Implantable Insulin Pump may be programmed through the outer tray of the sterile package. First, the PPC needs to be “married” to the Pump, then the Pump function is verified by performing the initialization procedure described in Chapter 3, *PPC/Pump System Initialization*.

Registration card

To ensure proper patient identification and device serial number tracking, the Registration Card that accompanies each Pump must be completed and promptly returned to Medtronic MiniMed.

Supplies and solutions

Before preparing the Pump, be sure to read Appendix D, *Precautions and General Procedures*. Assemble the necessary materials prior to starting the procedure:

Supplies

- One (1) 100 μ L sterile pipette
(available non sterile from Medtronic MiniMed) MMT-4104
 - One (1) sterile scalpel blade
 - One (1) scale (0.01g resolution)
 - One (1) sterile beaker (or sterile barrier towel) for weighing
 - One (1) sterile bag for PPC
-

- One (1) Pump System: PPC, Pump and Side Port Catheter
- Sterile markers and Steri-Strips®
- Three (3) refill Kits - MMT-4105:
 - 1 kit to remove shipping fluid from Pump
 - 1 kit to fill the Pump with U-400 INSULIN (to rinse the pump)
 - 1 kit to fill the Pump with U-400 INSULIN (final insulin fill)
- One (1) 3 mL syringe (fluid barrier)
- Three (3) Medtronic MiniMed refill needles, MMT-4102
- Three (3) 18 gauge needles
- One (1) Implant Worksheet
- One (1) Back-up Pump System: PPC, Pump, Port Catheter

Solutions

- One (1) bottle of sterile water, room temperature
- One (1) vial 10 mL Rinse Buffer (RB), MMT-2008
- Four (4) vials 10 mL U-400 INSULIN, stored at room temperature for a minimum of ten hours prior to surgery.

Emptying and filling the Pump

To prepare the Pump for implantation, the Pump must be emptied and then filled twice and tested with insulin. These procedures are performed in the operating room prior to surgery. As this is a surgery, all supplies and required equipment should be prepared in accordance with the institution's approved sterile procedures.



When you remove the Pump from the sterile box, do not remove the plastic tubing placed at the Pump outlet. Trim the distal part with a scalpel blade. This tubing will be used for the “Stroke Volume Measurement” procedure.

A sterile field is established in the operating room to prepare the RINSE BUFFER (RB) syringe and remove the shipping fluid from the Pump. Document the Pump, Catheter and PPC serial numbers on the Implant Worksheet.

Remove shipping fluid from the Pump

1. Using aseptic technique, open the Pump sterile package. Do not remove the plastic tubing from the Pump outlet. Trim the distal part of the tubing with the scalpel blade.
2. Remove the refill syringe from the refill kit package.
3. Firmly attach the two-way stopcock to the refill syringe and attach an 18 gauge needle to the stopcock.
4. Draw approximately 4 mL of RINSE BUFFER into the refill syringe.
5. Fill the hub of the refill needle with RINSE BUFFER and firmly attach it to the stopcock, prime the needle and close the stopcock. (See Figure 6.)
6. Retract the plunger until it locks into place. This should be no further than 55 mL. Do not go beyond the vent hole. Press the lock into the plunger groove to be sure it is firmly secured.
7. Fill one 3 mL syringe with RINSE BUFFER (RB) and attach a needle.
8. Fill the Pump fill port using the 3 mL syringe. Any time a refill needle is to be inserted into the Pump fill port, a fluid barrier must be present to prevent air from entering the Pump reservoir.
9. With the stopcock still closed, insert the RB syringe into the Pump fill port.
10. Open the stopcock and allow the syringe vacuum to empty the Pump of shipping fluid. Allow 30 seconds after the fluid level appears to have stopped rising in the refill syringe, to assure the Pump is completely emptied. Close the stopcock and remove the syringe.

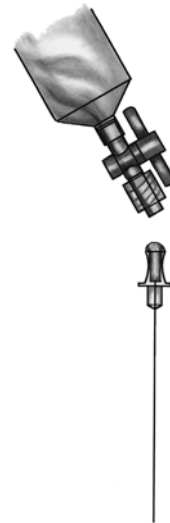


Figure 6: Filling the hub of the refill needle

Rinse the Pump with insulin (IN1)

1. Remove the second refill syringe from the refill kit package.
2. Firmly attach the two-way stopcock to the refill syringe and attach an 18 gauge needle to the stopcock. Use the sterile marker to label the syringe, “IN1”.
3. Draw 20 mL of INSULIN (two vials) into the refill syringe.
4. Remove the 18 gauge needle and expel all air bubbles in the syringe.
5. Close the stopcock.
6. Retract the plunger until it locks into place. This should be no further than 55 mL. Do not go beyond the vent hole. Press the lock into the plunger groove to be sure it is firmly secured.
7. Shake vigorously for a minimum of 30 seconds to degas the INSULIN.
8. Point the syringe tip upward and slowly open the stopcock to vent the syringe.
9. Release the locking ring on the refill syringe.
10. Expel air in the syringe and carefully observe to ensure no air bubbles remain in the syringe. If air bubbles are noted, repeat steps 5-10.
11. Fill the hub of the refill needle with INSULIN and attach it to the stopcock.
12. Prime the needle and close the stopcock.
13. Refill the fill port with the 3 mL RINSE BUFFER syringe, as needed, to maintain the fluid barrier.
14. Use the “IN1” syringe containing the degassed INSULIN to fill the Pump.

OPTIONAL

Use these steps only if the plunger is not moving forward while filling the reservoir.

1. With the refill needle pointing down, vent the syringe head space by pulling back firmly on the plunger until the second sealing ring on the black rubber cap passes beyond the vent hole (see Figure 7).
-

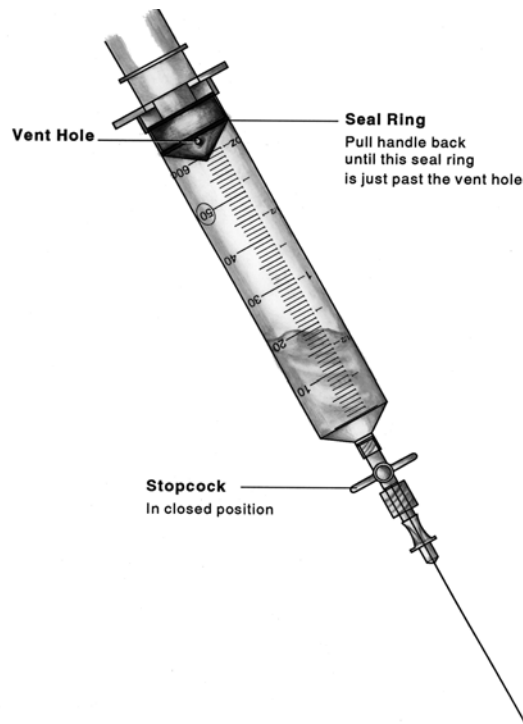


Figure 7: Venting the syringe head space

2. With the stopcock closed, insert the refill needle into the Pump fill port.
3. Open the stopcock. Maintain downward pressure on the barrel of the syringe to ensure the inlet valve of the Pump remains open.



Never push on the refill syringe plunger to fill the Pump. When the refill needle is properly seated in the fill port of the Pump, the vacuum in the reservoir will draw the insulin from the syringe.

4. Allow the Pump vacuum to draw the INSULIN into the reservoir. When the INSULIN stops moving, the Pump is filled. Close the stopcock and remove the syringe.
5. Prepare the IN1 syringe for aspiration. Remove any air from the syringe, prime the needle, close the stopcock and obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured. A fluid barrier of at least 2 mL should remain in the syringe.

6. Insert the refill needle back into the Pump fill port with the stopcock closed.
7. Open the stopcock and empty the Pump. Allow 30 seconds after the INSULIN level appears to have stopped rising in the refill syringe to assure the Pump is completely emptied.
8. Close the stopcock and remove the syringe.

Fill the Pump with insulin

1. Remove another refill syringe (IN2) from a refill kit package.
 2. Firmly attach the two-way stopcock to the refill syringe and attach an 18 gauge needle to the stopcock. Label the syringe IN2.
 3. Draw 20 mL of INSULIN (two vials) into the IN2 syringe.
 4. Remove the 18 gauge needle and expel all air bubbles in the syringe.
 5. Close the stopcock.
 6. Retract the plunger until it locks into place. This should be no further than 55 mL. Do not go beyond the vent hole. Press the lock into the plunger groove to be sure it is firmly secured.
 7. Shake vigorously for a minimum of 30 seconds to degas the INSULIN.
 8. Point the syringe tip upward and slowly open the stopcock to vent the syringe.
 9. Release the locking ring on the refill syringe.
 10. Expel the air in the syringe and carefully observe it to ensure no air bubbles remain in the syringe. If air bubbles are noted, repeat steps 5 - 10.
 11. Fill the hub of the refill needle with INSULIN and attach it to the stopcock.
 12. Prime the needle and close the stopcock.
 13. Place a sterile beaker or sterile barrier towel on the scale and tare it (position balance at 0.)
 14. Weigh the refill syringe and record the weight on the Implant Worksheet.
 15. Insert the refill syringe into the Pump fill port, open the stopcock and allow the Pump vacuum to draw INSULIN into the reservoir until the fluid level stops moving. Close the stopcock.
-

16. Remove the IN2 syringe and prepare for aspiration without expelling any fluid. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
17. Reenter the Pump fill port with the stopcock closed.
18. Open the stopcock and withdraw 2 mL in order to activate the negative pressure safety feature of the Pump. Close the stopcock and remove the syringe.
19. Weigh the IN2 syringe to calculate the Pump refill amount. Subtract the weight after the fill and 2 mL withdrawal from the weight before the fill and record the difference on the Implant Worksheet.

Measure stroke volume

1. Place the PPC in the sterile bag. Enter the Supervisor Mode. The screen displays “PUMP REFILL”. Press **ACT** until the “SET REFILL AMOUNT” screen appears. When filling the Pump for the first time, set the “EXTRACTED AMOUNT” to zero. Otherwise, enter the amount of insulin extracted. Then use the ▲ and ▼ buttons to enter the refill amount from the Implant Worksheet. Program the Pump.
 2. Again, enter the Supervisor Mode and program “STOP PUMP”. From the screen “PUMP STOPPED”, press **SEL**. “PUMP STOPPED” will begin flashing. Press both the ▲ and ▼ buttons at the same time, until the screen changes to the password screen. Reenter the password and the screen will change to “PUMP REFILL.” Press **SEL** to reach the “PRIMING” screen. “NO” will be flashing. Use the ▲ and ▼ buttons to select “YES,” then press **ACT**. When the word “CONFIRM” is highlighted, press **ACT** again. Place the PPC near the Pump to complete the communication process. Record the time the priming bolus was initiated on the implant worksheet.
 3. Listen for five beeps and observe that fluid is being pumped from tubing attached to the Pump outlet.
 4. Attach the 18 gauge needle (from the 3 ml syringe filled with RINSE BUFFER) to the plastic tubing from the Pump outlet.
 5. Remove the 3 ml syringe and fill the needle hub.
-

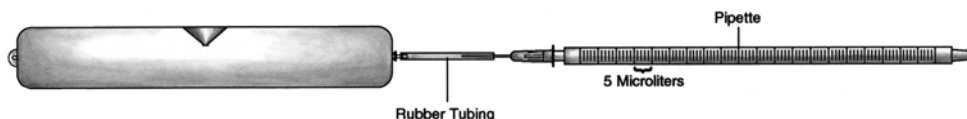


Figure 8: Testing Pump stroke volume with a pipette

6. Insert the pipette into the hub. A meniscus of fluid will be present in the pipette. This should be done on a flat surface with the pipette/tubing assembly horizontal (see Figure 8).
7. Note the exact location of the fluid meniscus in the pipette.
8. Measure the stroke volume by noting the volume displaced by a minimum of 10 pulses. Record the total volume delivered and the number of pulses on the Implant Worksheet. Divide the total volume delivered by the total number of pulses used to deliver that volume. The volume per stroke must be between 0.40 and 0.60 μL . Record this value on the Implant Worksheet.

Prepare the Side Port Catheter

The Side Port Catheter (“Catheter”) is attached to the Pump before implantation; however, it must be primed with INSULIN and inspected before being attached to the Pump.



Never insert a needle into the connector end of the Catheter for priming or for testing. There is a precision sealing surface in the connector that may be damaged by the insertion of any needle.

1. Keep the Catheter in its package until the Pump is prepared and stroke volume has been verified. Remove the Catheter from its sterile package and document the serial number on the Implant Worksheet.
 2. Using the last insulin syringe (IN2) from the Pump preparation procedure, enter the Catheter port cone and push a small volume of insulin out of the connector end of the Catheter. This primes the proximal portion of the Catheter and cleans any debris from the connector outlet. Remove the syringe.
-

3. (See Figure 9.) Remove the plastic tubing and tubing retainer from the Pump outlet. Remove the tubing retainer by rotating it one-quarter turn clockwise to disengage it from the connector flange. Then lift and remove the tubing and retainer together from the Pump outlet. Dispose of the tubing and retainer.

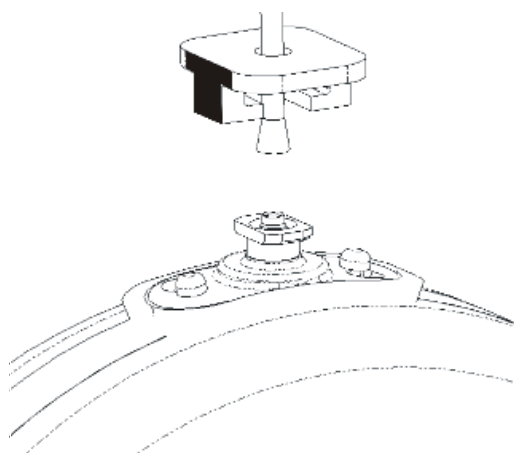
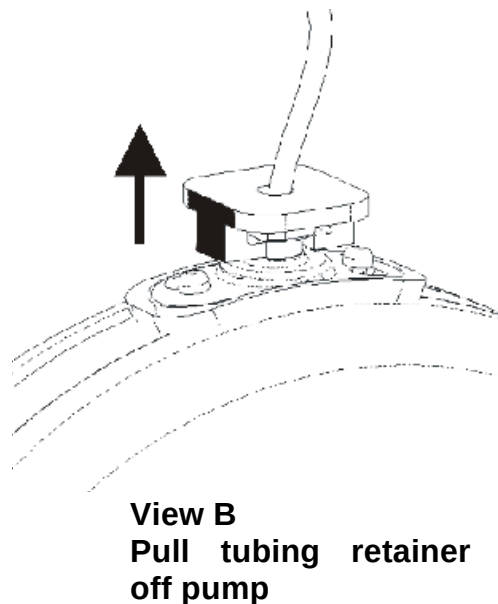
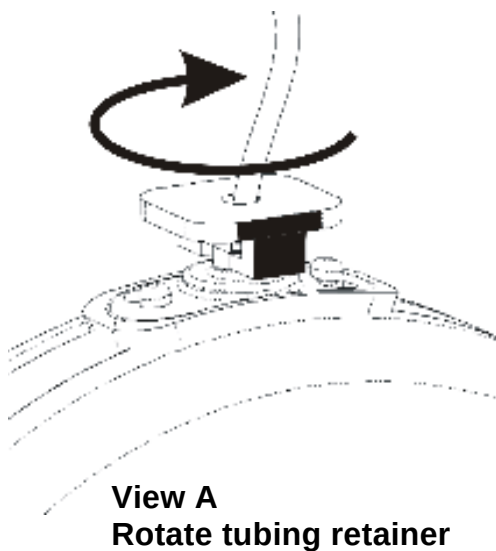


Figure 9: Tubing and retainer removal

4. Inspect the outlet of the Pump for debris. Debris, especially fibers, left in the fluid path will compromise the function of the Catheter check valve. Rinse the outlet tube of the Pump with water from a syringe, if necessary. Avoid wiping the Pump with gauze or drapes that will leave fibrous debris.
5. Pull the locking bar out and gently push the Catheter straight down onto the Pump outlet. Never twist the connector.
6. Only after the Catheter is seated, squeeze the connector (see Figure 10, item 1), firmly against the Pump between the thumb and forefinger of one hand. Then push the locking bar (item 2) into place with the thumb of the other hand.

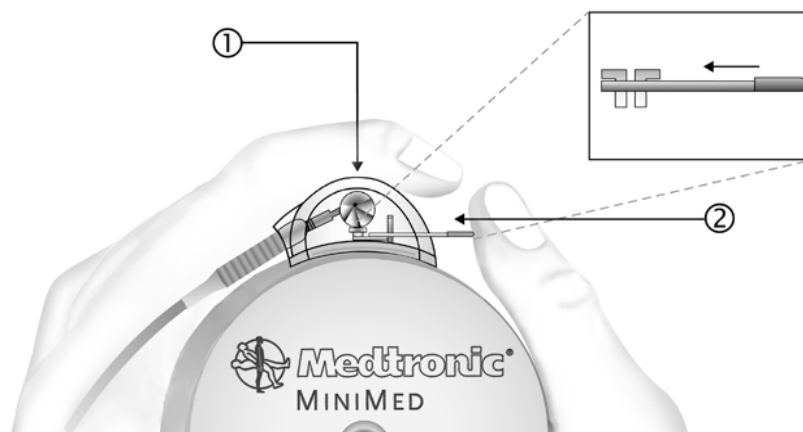


Figure 10: Proper attachment of the Side Port Catheter to Pump

7. Verify the Catheter is securely attached to the Pump. Look into the connector and observe the position of the locking bar with respect to the Pump connector outlet. Check the side port connector hub for abnormalities (e.g., cracks, misalignment.)
 8. Using the IN2 refill syringe, enter the Catheter side port cone and push a small amount of INSULIN out the Catheter tip. Verify that no insulin flow is observed at the Pump/Catheter interface. Remove and reseat the Catheter if flow is noted. Remove the syringe.
 9. Confirm insulin delivery from the tip of the Catheter and note it on the Implant Worksheet. The INSULIN will form a dome on the tip of the Catheter. Pulsatile delivery will not be obvious. If the priming bolus has already ended, program an immediate bolus (about 20 units) to confirm delivery. (This bolus may be canceled after delivery is verified.)
-

10. At the end of the bolus, rinse the outside of the Pump thoroughly with sterile water to remove traces of INSULIN. The Catheter tip should not be placed in the water. Protect the Pump with sterile drapes until the surgeon is ready to implant it. Verify that the priming bolus is finished or canceled prior to the implantation.

The Pump and Catheter are now ready for implantation.

Performing the surgical procedure

Pre-operative evaluation

The Pump implant depth should not exceed 5 cm (2 inches) beneath the surface of the skin. If the Pump is implanted too deeply in the subcutaneous tissue it may be difficult to access the refill port.

Formation of the pump pocket

Pump implantation can be performed either under local or general anesthesia. After satisfactory anesthesia, a pre-selected abdominal site is prepped and draped in the customary surgical method.

A transverse or longitudinal incision is made and deepened through the skin and subcutaneous tissue. Care should be taken in choosing the location of the incision so the suture line is next to but not over the Pump inlet fill port or the Catheter side port. A subcutaneous blunt dissection is performed to create a pocket large enough to accommodate the Pump. Meticulous hemostasis should be established with electrocautery.

The Pump is secured to the fascia of the abdominal musculature using the three suture tabs provided. Securing the Pump with all three suture tabs is recommended, as it will prevent migration, rotation or inversion in the pocket and possible dislodgment of the Catheter.

Figure 11 indicates a possible Pump placement and corresponding incision sites.

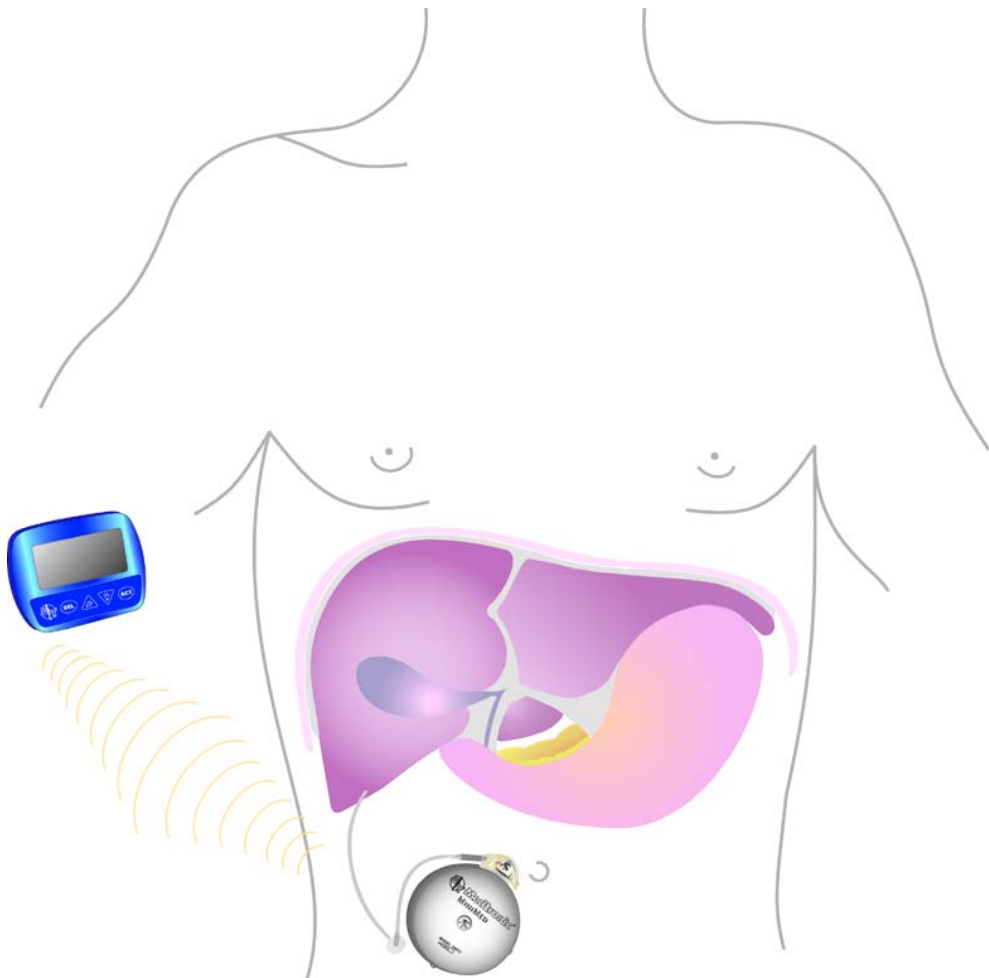


Figure 11: Example of Pump placement

Catheter placement

The Catheter is not designed to be tunneled subcutaneously. The Catheter insertion should be at the extreme edges of the Pump pocket.

At a site not directly beneath the Pump, the layers of abdominal musculature are divided to expose the peritoneum. Concentric purse string sutures are placed and the peritoneum is exposed with a 1 cm incision. The distal tip of the Catheter is placed in the peritoneal space. The flange of the Catheter is sutured firmly to the fascia of the abdominal musculature. Sutures should only be placed on the reinforced flange of the Catheter. Sutures must not be placed directly on the Catheter itself.



Never trim or cut the tip of the Catheter.

The implant site should be irrigated with an *antibiotic* solution. Interrupted absorbable sutures should be used to approximate the subcutaneous tissues and the skin closed with a running subcuticular absorbable suture. The wound is dressed using standard surgical technique. At the end of the surgery, place an abdominal binder over the implant site. This binder must be worn until the capsule has formed (about 1 month.) The binder is recommended because it will obtain a better cosmetic result and minimize the post operative swelling.

Post-operative management

Post-operative hospitalization

After implantation, the surgical incision should be inspected for any signs of unusual swelling, tenderness, pain, or drainage. Potential post-operative complications include Pump pocket seroma, wound dehiscence, wound infection, and catheter dislodgment.

Length of post-operative hospitalization depends upon how rapidly the patient adjusts to the Pump and how quickly blood glucose levels stabilize. During post-operative hospitalization, the Pump can be reprogrammed to accommodate the needs of the patient. As post-operative stress decreases, insulin requirements may decline. It may be necessary to make several changes in insulin delivery rates during the first few days following implantation.

Patients must be thoroughly educated in all aspects of follow-up care with the Pump. The Medtronic MiniMed Patient Manual should be used to supplement patient education. Prior to discharge, patients should:

- Fully understand how to use their PPC;
- Know what to do in the event of Pump or PPC difficulties;
- Have scheduled their first refill appointment;
- Have set an appointment for their first follow-up visit;

Post-operative x-rays

The Catheter has been designed with a radio-opaque stripe for identification after implantation. A lateral and anterior X-ray is recommended after implantation to locate and document the position of the Catheter. This radiograph should be kept with the patient's records for future reference.

Introduction

Initial appointments for Pump Refills should be made with patients at the time of implantation. Subsequent appointments should be made in advance, normally during each refill procedure. The Pump stores approximately 6,000 units of insulin medication and typically requires a refill every two to three months. In order to maintain the physical stability of the insulin, the Pump must be refilled at a maximum interval of no more than 90 days. The PPC will display warning messages to alert the patient of calculated low or emptied reservoir volumes.

The low reservoir message will appear when the PPC calculates that 800 (2 ml) or fewer units of insulin medication remain in the Pump. The empty reservoir message will appear when the PPC calculates that 400 or fewer units (1 ml) of insulin remain. The time to medication depletion depends upon the insulin delivery rate of the Pump.



The Pump refill procedure should always be scheduled in advance of PPC “low reservoir” or “empty reservoir” messages.

Supplies and solutions

The refill kit (MMT-4105) is intended exclusively for use with the Medtronic MiniMed 2007D Implantable Insulin Pump System. The refill kit consists of a specially designed syringe and stopcock for removing fluids from and placing fluids into the Pump. Use only refill needles (MMT-4102) available from Medtronic MiniMed to perform all Pump refill procedures. This 22 gauge needle, featuring a rounded, lubricated tip and a beveled side hole, has been specially developed to mate with the Pump fill port.



Use of other needles may result in damage to the Pump septum in the fill port, and may allow body fluids to enter the Pump.

Below is a list of the supplies and solutions necessary to perform the refill procedure:

Supplies:

- Steri-Strips® and Markers
- The Patient's PPC, Glucose Monitoring Equipment, Drapes
- One (1) Scale (0.01 gram resolution)
- One (1) 250 ml Sterile Beaker
- One (1) Port Locating Template - MMT-4106
- Two (2) Refill Kits - MMT-4105 - Three (3) Medtronic MiniMed MMT-4102 Refill Needles (Extra needles should be available for use.)
- Four (4) 18 Gauge Regular Bevel Needles

Solutions:

- One (1) 10 ml Vial, Rinse Buffer Solution, MMT-2008
 - Two (2) 10 ml Vials, U-400 Insulin, stored at room temperature for a minimum of 10 hours prior to surgery.
-

Prepare for pump refill

NOTE: Before beginning any refill, rinse, flush, or pressure measurement procedure, carefully read Appendix D, Precautions and General Procedures.



Never push on the refill syringe plunger to fill the Pump. When the refill needle is properly seated in the Pump fill port, the vacuum in the Pump reservoir will draw the insulin from the syringe into the reservoir.

To prepare for emptying and refilling the Pump, perform the following steps:

- Use the “HISTORY” feature of the PPC to determine the amount of insulin medication remaining in the Pump. Make sure that **ACT** is pressed on the “READ PUMP DATA” screen to update PPC history from the Pump. Record this value on the refill worksheet (Appendix C).
 - Prepare a sterile field. The physician should scrub, mask and glove for the refill procedure. Refilling the Pump is an aseptic procedure.
 - (See Appendix D, *Precautions and General Procedures*.)
 - Aseptic skin preparation of the patient’s Pump refill site should be performed using your institution’s standard operating procedures.
-

Perform the refill procedure

Fill out the refill form

Fill out the top part of the Refill Form (Appendix C) with the patient's I.D., refill date, insulin lot number, previous refill volumes, insulin medication remaining, and the name of the person performing the refill procedure. This information can be helpful for diagnostic purposes.

Label syringes

Use a sterile marker and Steri-Strips® to label one refill syringe “RB” (rinse buffer syringe) and the other “IN” (insulin syringe).

Prepare the refill syringe for emptying the Pump

1. Firmly attach a stopcock to the RB syringe and attach the 18 gauge needle to the stopcock. Check connections to ensure they are secure. Draw 5 ml of Rinse Buffer into the RB refill syringe.
2. Expel all air bubbles from the refill syringe. Remove the 18 gauge needle from the stopcock.
3. Fill the hub of the refill needle with Rinse Buffer from the RB refill syringe and attach it to the stopcock. (See Figure 12) Prime the refill needle completely. Close the stopcock.
4. Obtain the weight and record it on the Refill Form. Set the syringe aside.

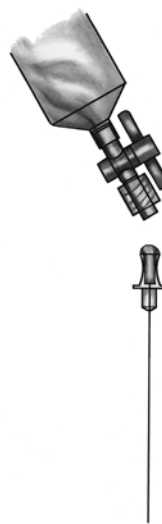


Figure 12: Filling the hub of the refill needle

Prepare the refill syringe for filling the Pump

1. Firmly attach a stopcock to the IN refill syringe and attach an 18 gauge needle to the stopcock. Draw 20 ml of U-400 insulin into the syringe.
2. Expel all air from the refill syringe. Close the stopcock and remove the 18 gauge needle.
3. Retract the plunger until it locks into place. This should be no further than 55 ml - do not go beyond the vent hole. Press the lock into the plunger groove to be sure it is firmly secured.
4. Shake vigorously for a minimum of 30 seconds.
5. Point the syringe tip upward and slowly open the stopcock to allow air to enter the syringe.
6. Release the locking ring on the refill syringe. With the syringe pointed upward, push on the plunger to expel the air and prime the stopcock.
7. Open the stopcock and prime the refill needle. Attach the refill needle to the stopcock. Close the stopcock.
8. Inspect the syringe to ensure there are no air bubbles. If air bubbles are noted, remove the refill needle and repeat steps 2 - 8.
9. Weigh the IN syringe and record on the refill form.
10. Set the syringe aside.

Empty the Pump

1. Obtain a vacuum in the RB syringe by pulling back on the plunger until it locks. Press the lock into the plunger groove and be sure it is firmly secured.
 2. Locate the fill port by centering the template over the Pump. The center hole in the template should be directly over the Pump fill port. Insert the 18 gauge guide needle into the Pump fill port. Local anesthesia may be used prior to insertion of the 18 gauge needle.
 3. Press the primed refill needle (attached to the RB syringe) into the Pump fill port, by sliding it through the 18 gauge guide needle. Pull back slightly (approximately 2 mm) on the guide needle to allow the refill needle to enter the Pump fill port and actuate the inlet valve.(See Figure 13)
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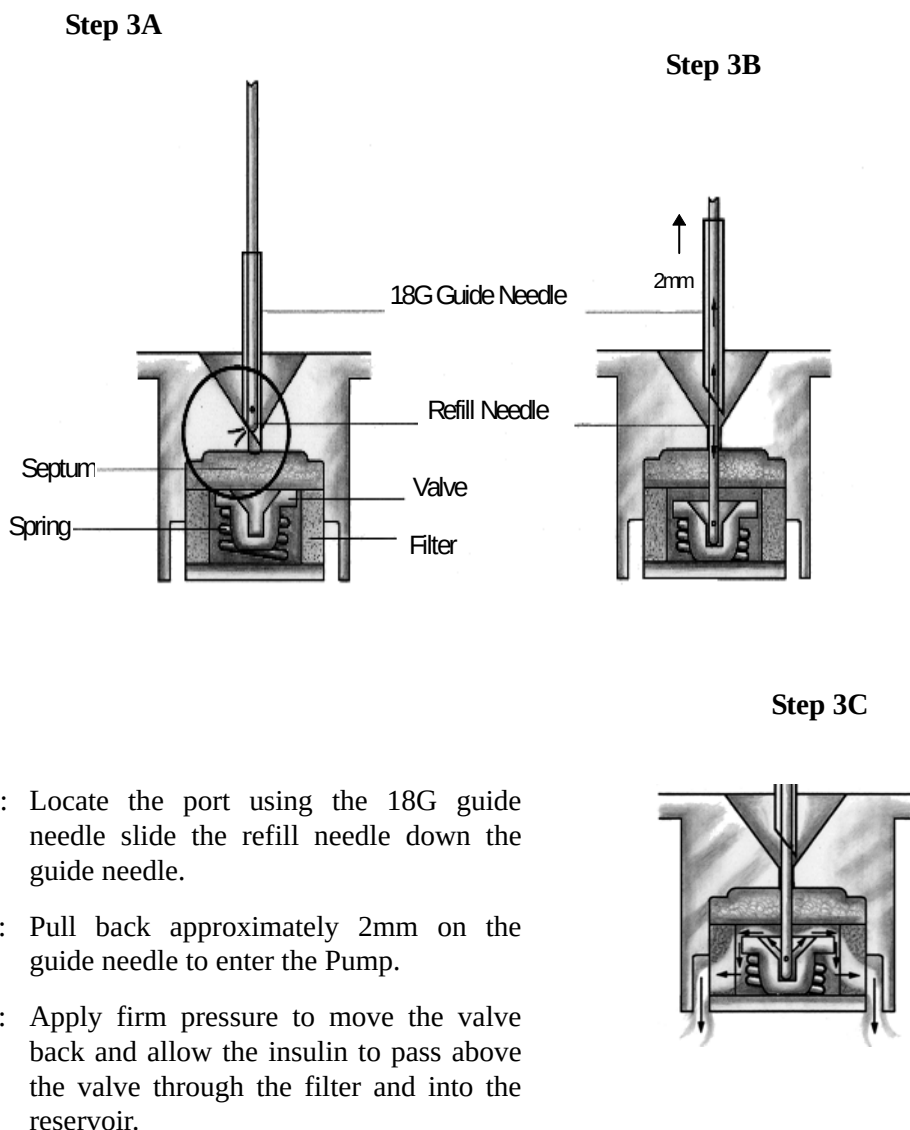


Figure 13: Operation of the Pump inlet valve

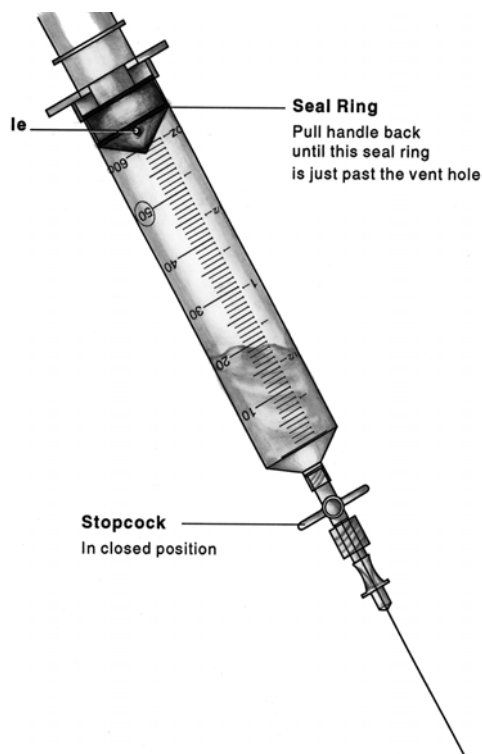
4. Actuate the valve by applying a gentle downward force on the refill needle. This depresses the valve approximately 0.5 mm.
5. Open the stopcock and allow residual insulin from the Pump to be drawn into the RB refill syringe. Maintain a downward pressure on the syringe to ensure that the inlet valve in the Pump remains open. Wait 30 additional seconds after the insulin level appears to have stopped rising in the RB refill syringe to ensure the Pump is completely emptied.
6. When all residual insulin is withdrawn from the Pump, close the stopcock. Remove the RB refill syringe.

NOTE: Do not remove the 18 gauge guide needle.

7. Weigh the RB syringe and record on the refill form.
-

Refill the Pump

1. Use the IN refill syringe containing 20 ml of degassed insulin, at room temperature.
2. Enter the Pump by passing the refill needle with the attached IN refill syringe through the 18 gauge guide needle. Pull back slightly (approximately 2 mm) on the 18 gauge needle to allow the refill needle to enter the Pump and actuate the inlet valve (see Figure 13).
3. Open the stopcock. Maintain downward pressure on the IN refill syringe to ensure the inlet valve in the Pump remains open. Allow the Pump to draw in insulin until the fluid level stops moving. Close the stopcock.
4. Remove the IN syringe and prepare for aspiration without expelling any fluid by pulling back on the plunger until it locks. Re-enter the Pump, open the stopcock and withdraw 2 ml in order to activate the negative pressure safety feature of the Pump.



OPTIONAL

Use this step only if the plunger is not moving during the fill of the reservoir.

With the refill needle pointing down, vent the syringe head space by pulling back firmly on the plunger until the second sealing ring on the black rubber cap passes beyond the vent hole (see Figure 14).

Figure 14: Venting the Medtronic MiniMed refill syringe

5. Remove the IN syringe. Remove the 18 gauge needle and apply pressure to the insertion site.
6. Weigh the IN syringe and record on the Refill Form.

Calculate extracted and refill amounts

1. Calculate the extracted amount by using the calculation section of the refill form.
2. Calculate the refill amount by using the calculation section of the refill form.
3. Enter the extracted amount (amount withdrawn as calculated on the refill worksheet at line E) and the refill amount (as calculated on the refill worksheet at line G) into the PPC.

Calculate refill accuracy

The PPC automatically calculates the refill accuracy following the PPC refill programming. You can also follow the calculation section of the refill form to calculate the refill accuracy.

Enter the refill accuracy value (in %) on the line provided on the refill form. It is important to record this value to evaluate system function.

CHAPTER 6

Explanting the Pump System

Explant considerations

When the battery in the Pump is depleted or if acceptable glycemic control cannot be achieved, it may become necessary to explant the Pump system.

Prior to explantation, it may be possible to perform interventions that could correct certain conditions. These procedures are described in Appendices E and F.

If all appropriate interventions have been exhausted without an acceptable outcome, please contact Medtronic MiniMed prior to scheduling a Pump explantation.

Returning devices/components to Medtronic MiniMed

Explanted Pumps and Catheters or other components should be returned to Medtronic MiniMed for evaluation. Please call Medtronic MiniMed and obtain a *Returned Sales Order* (RSO) number prior to each return.

Explanted devices must be sealed in an appropriate biohazard container and packed with a gauze pad soaked with sterile saline. The shipping container should be water tight. Chemical and reliability analysis require that the device not dry out during transportation.

Be certain to include required patient information as well as the RSO number, date, and reason for the explant and place all pertinent documentation in a water tight document package. Put the RSO number on the shipping label.

Please take the necessary precautions when shipping the Pump System via commercial carrier to avoid damage to the Pump. Please return explanted Pump Systems to:

United States:
Medtronic MiniMed
18000 Devonshire Street
Northridge, CA 91325
Telephone: 1-818-576-5555

or

Europe:
Medtronic EOC
Earl Bakkenstraat 10
6422 PJ Heerlen
Netherlands
Tel 3 145 56 68 000

Warnings

The Physician should be completely familiar with the function of the Pump, Catheter, and PPC prior to use. Patients should be provided a complete copy of the Patient Manual and have demonstrated the ability to program the PPC, recognize and respond to safety alarms, and take care of the device prior to discharge.

Only special U-400 insulins specifically labeled for use with the Medtronic MiniMed Insulin Infusion Systems may be used in the Medtronic MiniMed 2007D Implantable Insulin Pump. Use of other insulin types may cause damage to the Pump mechanism resulting in impaired insulin delivery or Pump failure.

Any unauthorized changes or modifications made to any component of the Medtronic MiniMed 2007D Implantable Insulin Pump System may prevent effective use of that and other components.

Electrotherapy

The Medtronic MiniMed 2007D Implantable Insulin Pump System has been tested in close proximity with electrosurgical, electrocoagulation, and cardiac defibrillation medical equipment. Typical use of this type of device has not affected the Pump. However, patients should be instructed to test Pump function (e.g., self test) after such procedures to determine that the Pump and PPC are operating properly. If the system is not performing correctly, contact Medtronic MiniMed.

Diagnostic ultrasound

The Medtronic MiniMed 2007D Implantable Insulin Pump System has been tested during diagnostic ultrasound procedures. These procedures have no effect on Pump performance. However, patients should be instructed to test the Pump function (e.g., self test) after such procedures to determine that the Pump and PPC are operating properly. If the system is not performing correctly, contact Medtronic MiniMed.

Ultrasound therapy

The Medtronic MiniMed 2007D Implantable Insulin Pump System should not be exposed to therapeutic ultrasound procedures such as lithotripsy. Exposure to ultrasound therapy may damage the Pump, and not be immediately apparent.

Diagnostic radiation

The Medtronic MiniMed 2007D Implantable Insulin Pump System has been tested during diagnostic radiation procedures, such as Computed Tomography and X-ray. These procedures have no effect on Pump performance. However, patients should be instructed to test the Pump function (e.g., self test) after such procedures to determine that the Pump and PPC are operating properly. If the system is not performing correctly, contact Medtronic MiniMed.

Elevated anti-insulin antibodies

The results of clinical investigations suggest a small population of patients may develop anti-insulin antibodies when using the Medtronic MiniMed 2007D Implantable Pump System and U-400 insulin. Patients with multiple autoimmune disorders may be more susceptible to developing high titers of anti-insulin antibodies, which in turn may cause symptoms. There was no correlation between length of exposure to the study drug and the resultant titer of anti-insulin antibodies. Elevated levels of anti-insulin antibodies alone have been proven not to interfere with diabetes management using continuous intraperitoneal insulin infusion with this system.

Environmental conditions

The Medtronic MiniMed 2007D Implantable Insulin Pump System should not be exposed to extreme electrical or magnetic fields. Although it is not possible to include every environmental condition that may affect the Pump, most are listed below. Please contact Medtronic MiniMed when in doubt if certain environmental exposure will affect the pump.



DO NOT EXPOSE THE MEDTRONIC MINIMED 2007D IMPLANTABLE INSULIN PUMP SYSTEM TO ANY OF THE FOLLOWING CONDITIONS:

- Magnetic Resonance Imaging (MRI) Procedures.
- Lithotripsy Treatment.
- Large Rotating Magnetic Fields - Refers to large industrial rotating magnetic fields, such as those found in Industrial Power Plants.
- Magnets Held Directly Over the Pump.
- High Power Radio or Satellite Transmitting Towers.
- Altitudes Above 2,400 meters (8,000 feet).
- Therapeutic Ultrasound
- Therapeutic Radiation

The Medtronic MiniMed 2007D Implantable Insulin Pump System is not designed for use at elevations above 2,400 meters (8,000 feet). Use of the Pump System at higher elevations may result in insulin over delivery, which may cause personal injury or death. Therefore, patients who live at elevations above 2,400 meters (8,000 feet) should not use the Pump. Patients who use the Pump and who plan to travel to an elevation above 2,400 meters (8,000 feet) should first have their Pump reservoir emptied of insulin, and they must self-administer insulin by other means for the duration of the trip and until their Pump reservoir is refilled again.

(This warning does not apply to travel on commercial aircraft because normal cabin pressurization is adequate to ensure proper operation of the Pump.)

- Diving Below 7.6 Meters (25 Feet).
- Physical Damage to the Pump or Pump Pocket.

Physicians should instruct patients to avoid any sharp blows or pressure directly at the Pump location. A direct hit by an object such as a baseball may damage the Pump and/or injure the Pump pocket. Extreme pressure on the Pump may cause the sutures and the tissue pocket to be damaged. As a result, the Pump may move from its pocket and possibly dislodge from the Catheter.

If the Pump has been damaged by such a blow, the patient should be instructed to contact their physician. Physicians may order a pressure bandage or a reduction in the patient's physical activity until the pump pocket reheels completely.

- Exposure to Extreme Body Temperatures

Exposure to elevated body temperatures in excess of 104°F (40°C) will compromise the negative pressure reservoir safety feature of the Medtronic MiniMed 2007D Implantable Pump. Glucose levels should be monitored closely if this occurs.

Sterilization

The Pump, Catheter and the refill kit are sterilized with ethylene oxide (EtO).

The Pump System is NOT Reusable.

If the sterile package has been opened, damaged or tampered with DO NOT USE the packaged device.

NOTE: Do Not Re-Sterilize the Implantable Insulin Pump

NOTE: Do Not Re-Sterilize the Side Port Catheter

NOTE: Do Not Re-Sterilize Components of the Refill Kit.

The Pipette (MMT-4104), may be resterilized using autoclave, EtO or according to hospital procedures.

The Template (MMT-4106) may be resterilized using steam autoclave or EtO per hospital procedure. This template is made from polycarbonate plastic and will have a limited life in steam autoclave cycle. The template will not withstand dry heat autoclave cycles.

Precautions

Emergencies and the use of conventional insulin supplies

Physicians should advise patients who are implanted with the Medtronic MiniMed 2007D Implantable Insulin Pump System how to deal with emergency conditions such as hyperglycemia and hypoglycemia. Patients should always carry conventional insulin supplies with them, including insulin and a means to inject it, in the event of impaired insulin delivery by the Pump System. Delivery of insulin can become impaired due to a failure of a Pump and/or PPC, or a Catheter occlusion. Replacement of the Pump, PPC or Catheter may be required. Physicians should review the Pump replacement and Catheter clearing procedures in this Physicians Manual

PPC reliability requirements

The PPC is a sensitive electronic device, and can incur physical damage. If the PPC is dropped or receives an impact patients should be instructed to immediately perform a SELF TEST to check the displays for proper operation. If the PPC does not display correctly, a replacement PPC is required. Patients should initiate alternative diabetes management until a replacement PPC is received.

The PPC housing is not watertight and it may malfunction if immersed in water. “Condensing humidity” conditions such as steam rooms should also be avoided, because condensation can also damage the PPC’s microelectronics. If either situation occurs, contact Medtronic MiniMed immediately and arrange for the repair or replacement of the PPC. If the PPC is accidentally splashed, sprayed or immersed, remove excess moisture with a soft towel and then place the PPC in a warm place to thoroughly dry. When dry, perform a “SELF TEST.” If the PPC does not display correctly, call Medtronic MiniMed to replace the device.

Maximum dosages

The physician can program specific limitations to insulin Basal Rates and Bolus amounts, as well as total daily insulin usage. These limitations provide some control of patients’ ability to program their insulin regimens, and to avoid overdosing.

Electrical and magnetic fields

Common electrical and magnetic fields that do not affect the Pump include microwave ovens, satellite receiving dishes, common household appliances, security devices found in department stores and airports, standard medical X-rays, cellular phone, and radiowaves.

Adverse reactions

In clinical studies, adverse reactions associated with the Medtronic MiniMed 2007D Implantable Pump included hypoglycemia, diabetic ketoacidosis, hyperglycemia, skin erosion, infection, abnormal healing, elevated anti-insulin antibodies, intestinal obstruction, post-operative discomfort and pain. Pump System malfunctions in order of frequency and seriousness include, insulin aggregation resulting in insulin under-delivery, Catheter occlusion or tissue overgrowth, premature depletion of the Pump battery, and failure of Pump electronics. Adverse events associated with the use of U-400 insulin are described in the package insert accompanying the insulin medication.

Prevention

The majority of adverse reactions in patients using the Medtronic MiniMed 2007D Implantable Pump System can be prevented by teaching patients dependable blood glucose monitoring. The patient plays a significant role in diagnosing and correcting Pump System performance problems. Should Pump performance change, the patient would be able to detect a change in blood glucose levels.



Patients should be instructed to contact their physician's office, if they experience unresolvable difficulties with the Pump System. Patient visits and diagnostic procedures may be necessary to correct these conditions.

System alarms and messages

The Medtronic MiniMed 2007D Implantable Insulin Pump System is equipped with various alarms and messages that ensure the correct function of the system.

The Implantable Insulin Pump alarm system will “beep” when certain conditions occur. The beeps are designed to be audible through the skin and alert the patient that the Pump needs attention. For severe alarm conditions the Pump will alarm 4 tones each minute for 10 minutes then, 4 double tones each minute for 10 minutes and repeat the pattern. Upon hearing the alarm, the patient must communicate with the PPC, to determine the alarm condition. The alarm can be cleared by pressing **SEL** then **ACT**. The following descriptions explain the alarm conditions the system may encounter.

The PPC has three types of alarms: audible, vibrate and visual alarms. The chapter will describe for each alarm condition, which screen message appears and the vibrate or audible alarm associated with it.

Two audible or vibrate alarm types are used:

Alarm Type 1:

If the PPC is set to “vibrate”, the vibrator will be turned on for 3 seconds every minute for 30 minutes.

If the PPC is set to “audible”, the PPC will beep 6 times every minute for 30 minutes. If the alarm is not cleared in 30 minutes, the PPC will beep 6 alternating tones. The PPC will continue to do so every minute.

Alarm Type 2:

If the PPC is set to “vibrate”, the vibrator will be turned on for 3 seconds every 30 minutes while the condition exists.

If the PPC is set to “audible”, the PPC will beep 3 times every 30 minutes while the condition exists.

Some alarms can be cleared by pressing **SEL** then **ACT**.

Pump alarms

Alarm feedback

The Alarm Feedback function allows the user to verify the Pump and Pump alarm are operating normally. Physicians can also use Alarm Feedback to measure the time intervals between Pump strokes to verify accurate insulin delivery. When Alarm Feedback is programmed “YES”, the Pump will beep on each of the first five Pump strokes:

- Following a change in the delivery regimen, for example when completing a meal Bolus and then changing to a Basal Rate, or at the start of a bolus.
- After the Alarm Feedback function is programmed “YES.” Alarm Feedback will stay on until programmed back to “NO.”

Pump low battery

The Implantable Insulin Pump battery is designed to last approximately ten years during conditions of normal use (see Chapter 11 for Technical Specifications). Battery life may vary somewhat depending upon a user’s insulin delivery requirements. When battery energy becomes low, a voltage sensor in the Pump will trigger the Pump Low Battery Alarm. A Pump Low Battery Alarm indicates there is approximately eight weeks of battery energy remaining.

PPC Display	Type of Alarm	Pump Alarm
PUMP LOW BATTERY	1	In 24 hours if no PPC communication

The Pump Low Battery alarm can be cleared and the Pump will continue to operate normally. However, users should be instructed to report the alarm immediately to their physician. A Pump replacement or resumption of conventional insulin therapy should then be scheduled.

Depleted pump battery

When there is no longer sufficient battery energy to power the Pump, the Pump Low Battery Alarm will cease and insulin delivery will stop. Alternate insulin therapy must be initiated.

System error

The Implantable Insulin Pump has a sophisticated self-monitoring system that periodically checks for circuit faults. If a fault should occur in the Pump electronics, insulin delivery will stop. Conventional insulin therapy must be initiated immediately. Notify Medtronic MiniMed immediately.

PPC Display	Type of Alarm	Pump Alarm
PUMP STOPPED 1 or 2 or 3 or 4 or 5 or 6	1	In 5 minutes if no PPC communication

Pump self test fail

If during a “SELF TEST” the Pump presents a malfunction, the insulin delivery will stop. Clear the message by pressing **SEL** then **ACT**. Notify Medtronic MiniMed immediately.

PPC Display	Type of Alarm
PUMP SELF TEST FAIL	1

PPC low battery

If the PPC main battery (AA 1.5 volt alkaline) energy is low, the following alarm display appears each time a new function is programmed:

PPC Display	Type of Alarm
PPC LOW BATTERY	1

Clear this message by pressing **SEL** and then **ACT**. While the battery should have sufficient energy for a few additional programming commands, the battery should be changed as soon as possible. For instructions on changing the battery, (see Chapter 3, *Personal Pump Communicator*).

NOTE: If while programming the PPC, the screen goes blank, the PPC beeps six times and then the “CHECK PUMP STATUS” message appears, the battery needs to be replaced. (See Chapter 3 for instructions, Install/Replace the Main Battery).

PPC alarms

The PPC offers a choice of two alarms, audible and vibrate. In addition, a screen message appears indicating the type of alarm condition that occurred.

Low reservoir

When the Pump calculates that less than 800 units (2ml) of insulin remains in its reservoir, the following display will appear:

PPC Display	Type of Alarm	Pump Alarm
LOW RESERVOIR	1	In 24 hours if no PPC communication

Clear this message by pressing **SEL** and **ACT**. Users should be instructed to report this alarm to their physician as soon as possible and schedule an appointment for a Pump refill.

Empty reservoir

When the Pump calculates that less than 400 units (1ml) of insulin remain in its reservoir, the following display will appear:

PPC Display	Type of Alarm	Pump Alarm
EMPTY RESERVOIR	1	In 24 hours if no PPC communication

Clear this message by pressing **SEL** and **ACT**, and then continue programming. Users should be instructed to report this alarm to their physician as soon as possible and schedule an appointment for a Pump refill. It is important not to allow the Pump to deplete its insulin supply as this may result in catheter blockage.

Telemetry communication error

If programming is interrupted after partial transmission of a command, the PPC will display the following message on the display screen:

PPC Display	Type of Alarm
TELEMETRY COMM ERROR3	1

Reposition the PPC near the Pump, and then press **SEL** and **ACT**. The PPC will attempt to resume communication with the Pump.

Initialize alarm

Attempting to initialize a PPC to a Pump that is not compatible with it, results in one of the following messages. The physician should press **SEL** and **ACT** to clear the alarm, then verify the personal ID of the Pump is correct.

PPC Display	Type of Alarm
PUMP ERROR 0 or 1	1

Attempting to initialize a PPC to a Pump that contains invalid stroke volume or insulin concentration information, results in one of the following messages to be displayed. Contact Medtronic MiniMed for instructions.

PPC Display	Type of Alarm
PUMP ERROR 40 or 41	1

Responding “NO” to the “INITIALIZE PPC TO PUMP” 8 consecutive times will result in the following message being displayed. Step away from any other Pump in the area and perform the request again.

PPC Display	Type of Alarm
TELEMETRY ERROR 20	1

PPC not initialized

If the PPC is not initialized to a Pump, the following message is displayed:

PPC Display	Type of Alarm
PPC NOT INITIALIZED	1

When successfully completing a PPC initialization, the following message is displayed:

PPC Display	Type of Alarm
PUMP INITIALIZED	1

Battery replacement

If the PPC main battery (AA 1.5V alkaline) has been replaced or the PPC recognizes the “PUMP STATUS” needs to be checked, the following message is displayed:

PPC Display	Type of Alarm
CHECK PUMP STATUS	1

The user should reposition the PPC near the Pump, and then press **SEL** and **ACT**. The PPC will communicate with the Pump.

NOTE: If while programming the PPC, the screen goes blank, the PPC beeps six times and then the “CHECK PUMP STATUS” message appears, the battery needs to be replaced. (See Chapter 3 for instructions, Install/Replace the Main Battery.)

Initialize to factory defaults

When the Pump is reinitialized to its factory default settings, the following message is displayed:

PPC Display	Type of Alarm
PUMP RESET	1

Pump stopped

If the Pump is intentionally stopped, the following message is displayed:

PPC Display	Type of Alarm
PUMP STOPPED	2

To restart the Pump, press **SEL** and **ACT**, and then place the PPC near the Pump and allow the communication to complete. The Pump can only be stopped in the Supervisor Mode.

Pump suspended

If the Pump operation has been suspended, the following message is displayed:

PPC Display	Type of Alarm
PUMP SUSPENDED	2

During “SUSPEND PUMP”, the Pump will deliver a basal rate of 0.2 U/h. To restart insulin delivery programming, press **SEL** and **ACT**, then place the PPC near the Pump and allow the communication to complete.

Auto off

If the “AUTO OFF” time interval elapses in the Pump and the PPC recognizes this condition, the following message is displayed:

PPC Display	Type of Alarm
AUTO OFF PUMP PUMP SUSPENDED	1

Press **SEL** and **ACT**, and then place the PPC near the Pump and allow the communication to complete. The PPC then communicates with the Pump to reset the “AUTO OFF” duration.

If five more minutes elapse, the Pump will initiate the internal alarm sequence of a beep every 15 seconds for 10 minutes, then double-beeps every 15 seconds for 10 minutes, then repeating the pattern. The alarm is cleared by pressing **SEL** and **ACT**.

Hourly maximum exceeded

Attempting to deliver more than 2.5 times the pre-programmed bolus maximum in one hour causes the following message to be displayed:

PPC Display	Type of Alarm
HOURLY MAX EXCEEDED	1

Press **SEL** and **ACT**, and then place the PPC near the Pump and allow the communication to complete. The patient may exceed the pre-programmed bolus limit by programming another bolus within 10 minutes.

Pump alarm table

Alarm Condition	Type of Alarm	Pump Communications
AUTO OFF	1	YES
CHECK PUMP STATUS	1	YES
EMPTY RESERVOIR	1	YES
HOURLY MAX EXCEEDED	1	NO
LOW RESERVOIR	1	YES
PPC LOW BATTERY	1	NO
PPC NOT INITIALIZED	1	YES
PUMP INITIALIZED	1	NO
PUMP LOW BATTERY	1	YES
PUMP RESET	1	NO
PUMP SELF TEST FAIL	1	NO
PUMP ERROR 0 or 1	1	NO
PUMP ERROR 40 or 41	1	NO
PUMP STOPPED 1 or 2 or 3 or 4 or 5 or 6	1	YES
PUMP SUSPENDED	2	YES
PUMP STOPPED	2	YES
TELEMETRY COMM ERROR	1	YES
TELEMETRY COMM ERROR 20	1	NO

Troubleshooting Pump System under-delivery

Potential under-delivery of insulin by the Medtronic MiniMed 2007D Implantable Insulin Pump System may result in an increase in daily programmed insulin usage, difficulty maintaining euglycemia, occasional hyperglycemia, and problems calculating refill accuracy. This chapter describes how to diagnose potential Pump System problems that may cause insulin under-delivery, and offers potential Pump and Catheter solutions to correct for under-delivery.

Diagnostic procedures

When refill procedures reveal the possibility of a Pump System under-delivery problem, diagnostic procedures must be performed to verify if there is a problem with either the Pump or Catheter. The Stroke Volume Measurement Procedure tests Pump function, while the Pressure Measurement Procedure tests Catheter patency. These diagnostic procedures should be performed according to the steps outlined in Appendix G.

Under-delivery caused by backflow

Backflow results in the inverted flow of insulin through the Pump System. Backflow is caused by insulin deposits that compromise valve integrity, and allow the negative reservoir pressure (vacuum) to pull insulin back into the reservoir. To compensate for this under-delivery, the user can program appropriate increases in their basal rates and bolus amounts.

Backflow conditions are characterized by increases in daily programmed insulin usage, difficulty in maintaining euglycemia, increasingly negative refill accuracy and sometimes hyperglycemia. Confirm a backflow condition by performing the Stroke Volume Measurement Procedure. Then rinse the Pump System with NaOH solution to dissolve insulin deposits, following the Pump Rinse Procedure outlined in Appendix E.

Under-delivery caused by catheter occlusion

Under-delivery caused by Catheter occlusion can occur either abruptly or gradually. The insulin usage and clinical symptoms are identical to those of Pump under-delivery. Confirm a Catheter occlusion condition by performing a Pressure Measurement Procedure. Then perform the following procedures to clear the occlusion:

- First, flush the Catheter by using the Side Port Catheter Flush Procedure outlined in Appendix F.
- If the Flush Procedure is unsuccessful, replace the Catheter.

Catheter replacement surgery should be performed in a manner similar to the initial Pump System implantation. PPC initialization will not be necessary. However, after the Catheter replacement, Pump function and delivery verifications must be performed.

Implantable Insulin Pump MMT-2007D

Diameter	8.1 cm (3.2 inches)
Thickness	2.0 cm (0.8 inches)
Reservoir Volume	13 ml to 15 ml
Weight - Empty	131 gm (4.6 ounces)
Insulin - Concentration	U-400
Stroke Volume	0.42 to 0.58 ul per stroke 0.17 to 0.23 units per stroke
Basal Rate	0.2 to 35.0 units per hour (U/h)
Basal Patterns	3 patterns of up to 48 basal rates each.
Meal Bolus	0.2 to 25.0 units
Bolus Duration	Immediate, Square Wave (30 minutes to 4 hours), or Dual Wave. Audio Bolus
Temporary Basal Rate	0.2 to 35.0 units per hour 30 minute increment duration 30 minutes up to 24 hours delay
Diagnostic Delivery Rate	10 to 150 U/h
Power Supply	Lithium - Carbon Monofluoride Battery
Audio Alarms	Low Battery System Error
Safety Features	Negative Pressure Reservoir with Passive Filling Pump Shutdown and Alarm with System Error (unique code sequences)
Materials in contact with tissue	Titanium, Silicone Rubber

Personal Pump Communicator (PPC) model MMT-3160

Height	8.9 cm (3.5 inches)
Length	7.0 cm (2.8 inches)
Width	2.0 cm (0.8 inches)
Weight	115 gm (4.0 ounces)
Main Power Source	1.5 Volt Alkaline Battery Type AA
Main Battery Life	4 weeks
Operating Temperature	0°C to 40°C (32°F to 104°F)
Storage Temperature	0°C to 30°C (32°F to 86°F)
Messages	Suspended Check Pump Status Communication Error Empty Reservoir Hourly Maximum Exceeded Low Reservoir PPC Not initialized PPC Low Battery Pump Self Test Fail Pump Reset Pump Stopped Pump Version Error Telemetry Communication Error

Side Port Catheter

MMT- 4027 Length Proximal: Distal:	 11.8 ± 1.3 cm (4.7 ± 0.5 inches) 17.8 ± 0.7 cm (7.0 ± 0.3 inches)
MMT- 4024 Length Proximal: Distal:	 11.8 ± 1.3 cm (4.7 ± 0.5 inches) 10.2 ± 0.4 cm (4.0 ± 0.2 inches)
Material	Polyethylene-lined Silicone Rubber
Sideport	Polysulfone, Silicone Septum

The Implantable Pump System complies with European RF Regulations. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes or modifications to the system not expressly approved by Medtronic MiniMed could void the user's authority to operate the system.

FCC compliance

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

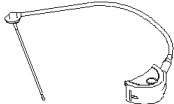
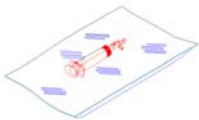
APPENDIX A

Label information symbol dictionary

	Do Not Reuse This Device
	Please Read “Important Information”
	Sterilized by Ethylene Oxide
	Manufacture Date (Year-Month)
	Lot Number
	Expiration Date (Use By Date) (Year-Month)
REF MMT-XXXX	Reference / Record Number (reorder number)
SN	Device Serial Number
	IEC Icon indicating equipment providing a particular degree of protection against electric shock (Type B)
	CE Marking
	CE Marking
	Radio Frequency (RF) is not harmonized

Packaging

The icon on each label indicates the contents of the package. The number with the icon is the quantity. Descriptions of the icons are in the table below.

Icon	Description
	Medtronic MiniMed 2007D Implantable Insulin Pump
	Medtronic MiniMed 3160 Personal Pump Communicator (PPC)
	Medtronic MiniMed Side Port Catheter - MMT 4024 and MMT 4027
	Medtronic MiniMed 4105 Refill Kit
	Medtronic MiniMed 4102 Refill Needles

Other information

Manufactured by:	Medtronic MiniMed
Distributed in the United States by:	Medtronic MiniMed
Distributed in Europe by:	Medtronic EOC, Netherlands
CE Marking:	
Notified Body:	GMED - France
Notified Body Authorizations:	0459, 0976
Year of Initial CE Authorization:	2000

APPENDIX B**Implant worksheet**

Implant worksheet form

Please refer to “Implant Worksheet” attached.

Medtronic MiniMed Implant Worksheet Form

Prep Date:_____ Center:_____ Patient Code:___

Patient name:_____

Pump Label:

Catheter Label:

PPC Label:

Insulin Lot Number:_____

Communicator-settings:

Patient Communicator ID:_____ Supervisor Code:___

Max meal bolus:___ U Max basal rate:_____U/h

Maximums (locked/unlocked):__ Alarm feedback "ON":__

Basal rate programmed with PPC:_____U/h

Weight of full "IN 2" syringe before filling the reservoir:_____g (1)

Weight of full "IN 2" syringe after filling the reservoir and removing 2ml from the pump:_____g (2)

Total amount placed in the reservoir (1-2):_____g

Verification of alarm feedback: **yes / no**

Time delivery started, priming bolus:_____

Calculated stroke volume:_____

a) number of strokes delivered:_____

b) total volume delivered:_____

c) calculated stroke volume (b/a):_____ul

Verification of the delivery from the catheter tip: **yes / no**

Implant date:_____

Surgeon name:_____

Anesthesia:_____

Pocket depth:_____cm

Catheter fixation:_____

Pump fixation:_____

Catheter type:_____

Pump type:_____

Pump orientation:

Complications:

APPENDIX C**Refill form**

Pump refill data

Please refer to “Refill Data Form” attached.

Medtronic MiniMed Refill Worksheet

Before the refill: U/384.6=_____ g (F)*

Insulin remaining from PPC:_____ (F)

Data:

Weight of primed "RB" syringe:_____ g (A)

Weight of "RB" syringe after
insulin withdrawn:_____ g (B)

Weight of filled "IN" syringe:_____ g (C)

Weight of "IN" after pump filled and 2ml
withdrawn:_____ g (D)

Amount withdrawn

Refill Amount

(B)_____ g (C)_____ g

(A)_____ g - (D)_____ g

= _____ g (E) = _____ g (G)

*Corrected for density of insulin

Patient name:_____

Patient code:_____

Center:_____

Physician name:_____

Insulin "IN" _____ Rinse Buffer "RB" _____

Previous refill amount:_____ g (1)

Residual amount withdrawn (E):_____ g (2)

Actual amount used (line 1 - line 2):_____ g (3)

Theoretical amount used:_____ g (4)

(line 1 - remaining dose from PPC (F))

Difference between actual and theoretical
amount used (line 4 - line 3):_____ g (5)

Refill accuracy (line 5 / line 4, then x 100):_____ %

Usable units of insulin (gx384.6): _____ U

Average daily insulin use:_____ U/d

Estimated refill period:_____ Days

Schedule next refill visit:_____

D / M / Y

APPENDIX D **Precautions and general procedures**

Special note and precautions

Before beginning the implant, refill, stroke volume measurement, rinse/flush, or pressure measurement procedure, carefully read this Appendix and keep the information in mind as you perform each procedure.

1. All procedures should be performed using ASEPTIC TECHNIQUE.
 2. Air in the Pump System has been shown to be a significant contributing factor to aggregation of insulin. Proper degassing of all solutions that enter the Pump is essential. Read the insert in the refill kit packaging about the degassing procedure.
 3. When using the refill kit, never release the syringe-locking ring while there is a vacuum within the refill syringe. The plunger of the syringe will snap back forcefully and may rupture the syringe and eject the contents.
 4. It is important that the syringe needle is perpendicular to the fill port to prevent binding when entering or exiting.
 5. The Side Port Catheter attachment site contains up to 20 units of INSULIN. The distal portion of the Catheter and the tubing can contain up to 13 units of INSULIN. However, the INSULIN in the Pump fluid pathway and the side port receptacle can be cleared by following the procedure to pull RINSE BUFFER through the side port. During a flush procedure to push out a catheter tip blockage, the 13 units in the distal catheter will be delivered to the patient. The 13 units can be managed by programming continuous bolus amounts prior to the procedure, or with the use of oral or IV glucose as needed during the procedure. Individual patient response to INSULIN bolus amounts must be considered.
 6. Patient blood glucose monitoring must be performed during, and up to one hour after the procedure. Oral and intravenous glucose should be available for glycemic management.
-

7. After the flush procedure, at least 13 units of RINSE BUFFER will remain in the distal portion of the catheter. Programmed bolus amounts to remove the RINSE BUFFER may be completed before the patient leaves the clinic. A prescribed INSULIN basal rate should be programmed when the system is clear of RINSE BUFFER.
8. Never push down on the plunger to fill the Pump. When the Medtronic MiniMed refill needle is properly seated in the fill port, the vacuum in the reservoir will draw the fluid from the syringe.
9. Each step of the procedure will list the syringes and appropriate fluids needed for that step. It is suggested that the syringes be prepared and labeled prior to the start of the procedure.
10. The Side Port Catheter is intended to be accessed only during the implant procedure, the combined rinse/flush procedure, the catheter flush procedure, and for diagnostic procedures. The catheter is not intended to provide access to the peritoneum for bolus injections of fluids or for withdrawal of body fluids.

General procedures

Before beginning any of the procedures, be sure you are familiar with the general techniques for locating the Pump fill port and the Side Port Catheter, accessing the Pump inlet, venting the refill syringe, and preparing the syringes.

Locating the pump fill port and the side port

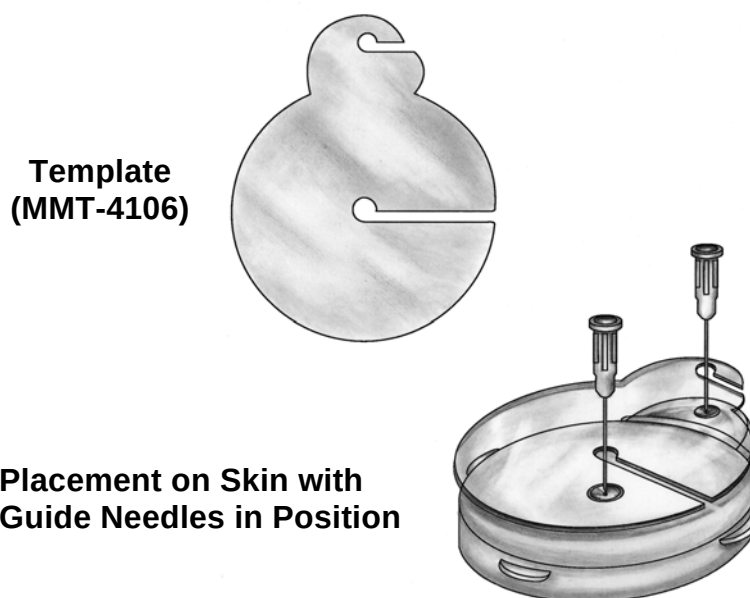


Figure 15: Template and placement

1. Locate the Pump, then aseptically prep and drape the Pump area. Use topical or local anesthetic if desired.
2. To locate the Pump fill port, located in the center of the Pump, align the sterile template (MMT-4106) over the Pump by palpating the Pump circumference. Then insert an 18 gauge needle into the central Pump fill port as shown in Figure 15 above.
3. To locate the side port, palpate around the circumference of the Pump. It is helpful to grasp the side port between the thumb and index finger when aligning the template.
4. Using the template as a guide, insert the second 18 gauge needle into the side port as shown. The side port can be accessed by inserting the guide needle just inside the outer edge of the side port connection. This outer edge is raised around the outer aspect of the side port, in order to help guide the needle into the port.

Accessing the pump inlet

(See Figure 16.) To enter the Pump fill port or the side port, make sure the refill syringe stopcock is closed, then pass the Medtronic MiniMed refill needle (MMT- 4102) through the 18 gauge guide needle. Pull back slightly (approximately 2 mm) on the guide needle to allow the Medtronic MiniMed refill needle to enter the Pump fill port or the side port. The refill needle entry opens the inlet valve of the Pump fill port.

After passing through the septum and seating in the valve, you can feel the increased force, about 0.5 pounds, required to move the valve 0.5 millimeter to open. Maintain this downward pressure in the pump fill port to ensure that the inlet valve remains open. In the case of the side port, a downward pressure is not required after the needle is completely inserted.

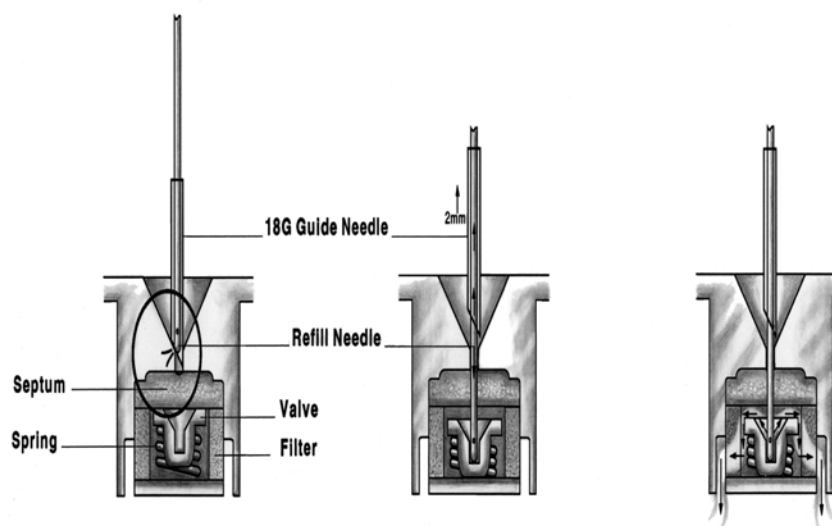
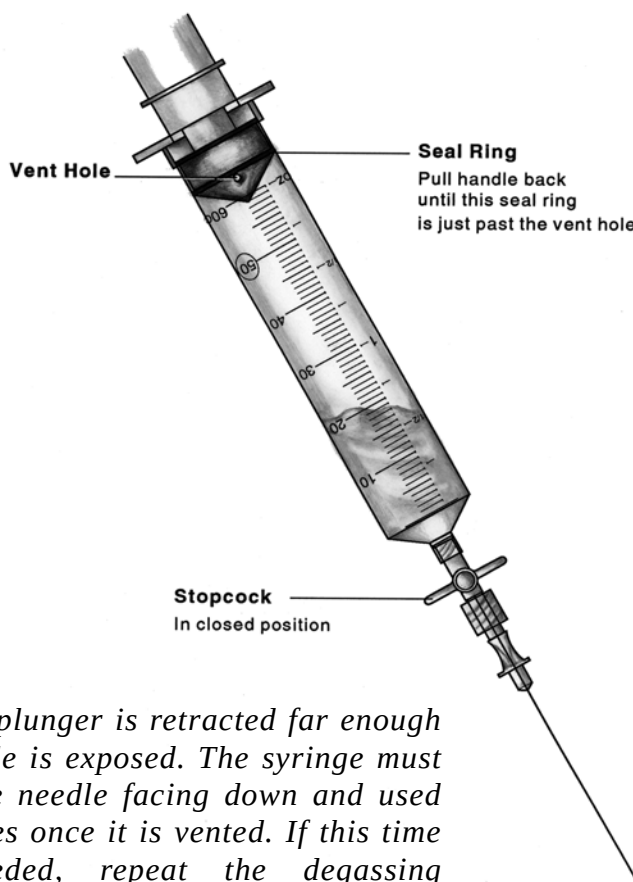


Figure 16: Inlet valve

Venting the Medtronic MiniMed refill syringe (optional)

In order to fill the Pump, it may be necessary to vent the headspace in the Medtronic MiniMed refill syringe. Refill syringes do not have lubricant on the syringe housing or on the plunger tip. Some syringes may be “sticky” and require the venting procedure described below to assist the vacuum in the Pump to overcome this condition.

To vent, hold the syringe with the refill needle pointing down. Vent the syringe headspace by pulling back firmly on the plunger until the second sealing ring on the rubber cap passes beyond the vent hole as shown in Figure 17.



NOTE: Be sure that the plunger is retracted far enough that the vent hole is exposed. The syringe must be held with the needle facing down and used within 10 minutes once it is vented. If this time limit is exceeded, repeat the degassing procedure and re-vent.

Figure 17: Venting the refill syringe

APPENDIX E **Pump rinse procedure**

The purpose of this procedure is to dissolve insulin deposits within the Pump reservoir, pumping mechanism, and the Side Port Catheter “port.”

Supplies and solutions

Prior to performing this procedure, assemble the necessary supplies and solutions as outlined below:

Supplies

- Steri-Strips[®] and markers
 - Local anesthesia (if necessary)
 - Sharps container
 - Safety glasses
 - PPC
 - Oral or IV glucose
 - Glucose monitoring equipment
 - Drapes
 - One (1) scale - 0.01 gram resolution
 - One (1) sterile bag for PPC (intestinal or cassette bags work well)
 - One (1) Side port locating template, MMT-4106
 - Seven (7) Refill kits, MMT-4105
 - Seven (7) Medtronic MiniMed MMT-4102 refill needles. (Extra needles should be available to use as needed)
 - Eight (8) sharp 18 gauge regular bevel needles
-

Solutions

- 50 ml. sterile 0.1M NaOH (0.4 grams NaOH per 100 ml of Sterile water for injection) MMT-9005
- Seven (7) 10 ml vials, rinse buffer solution, MMT-2008
- Five (5) 10 ml vials, U-400 Insulin



The 0.1M of NaOH used in this procedure can cause permanent eye damage. Safety glasses must be worn during this procedure.

Preparing for the procedure

NOTE: Before beginning any refill, flush, stroke volume measurement, carefully read Appendix D, Precautions and General Procedures, and keep this in mind as you perform each procedure.

In order to prepare for the Side Port Catheter rinse and flush procedure, a total of seven syringes will need to be labeled and then prepared with different solutions. Table 1 defines the syringe numbers and corresponding solutions:

Table 1:

Syringe #	Syringe type	Solution
1	Refill	5 ml RINSE BUFFER
2	Refill	20 ml NaOH
3	Refill	30 ml NaOH
4	Refill	20 ml RINSE BUFFER
5	Refill	30 ml RINSE BUFFER
6	Refill	20 ml INSULIN
7	Refill	30 ml INSULIN

Prepare syringes for emptying the Pump

Syringe 1 is used for emptying the Pump. Label and prepare syringe 1 per Table 1.

Prepare syringes for filling the Pump

During the Catheter rinse/flush procedure, syringes 2, 3, 4, 5, 6, and 7 are used for filling the Pump. Each of these syringes needs to be labeled with its solution and syringe number, per Table 1, and then filled and degassed.

Program minimal basal rate

Place the PPC in a sterile bag and program the Pump to “SUSPEND” mode, the basal rate will be 0.2 U/h.

Remove insulin from the Pump and fill with NaOH

INSULIN is removed from the Pump and then the Pump is filled with NaOH. The following volumes are used:

- Syringe 1 - 5 ml RINSE BUFFER
- Syringe 2 - 20 ml NaOH
- Syringe 3 - 30 ml NaOH

Follow the steps below to perform this procedure:

Syringe 1: Rinse Buffer - Degassed

1. Prime the needle. Weigh the syringe and record the weight on the refill form (Line A).
2. Close the stopcock. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
3. Enter the Pump with the refill needle.
4. Open the stopcock; withdraw the INSULIN. After the INSULIN appears to have stopped rising in the syringe, wait an additional 30 seconds to make sure all of the INSULIN and air are removed.

NOTE: Air in the Pump System has been shown to be a significant contributing factor to aggregation of INSULIN. Proper degassing of all solutions that enter the Pump is essential.

5. When 30 seconds have elapsed, close the stopcock, remove the syringe. Weigh the syringe and record the weight on the refill form. Discard the INSULIN in the syringe except for a 5 ml barrier. This syringe will be used to pull NaOH through the side port. Attach and prime a new refill needle.
-



The 0.1M NaOH used in this procedure can cause permanent eye damage. Safety glasses must be worn during this procedure.

Syringe 2: NaOH - Degassed

1. Prime the needle. Close the stopcock
2. Enter the Pump with the refill needle.
3. Open the stopcock and allow the Pump to fill completely with NaOH. When the fluid level stops moving, the Pump is filled.
4. Close the stopcock. Remove the syringe.
5. Prepare syringe 2 for aspiration. Remove the air from the syringe. Close stopcock and obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
6. Re-enter the Pump.
7. Open the stopcock and remove the NaOH. After the fluid level stops moving, wait an additional 30 seconds for all the NaOH to be removed.
8. When the time has elapsed, close the stopcock and remove the syringe. Discard syringe 2.

Syringe 3: NaOH - Degassed

1. Prime the needle. Close the stopcock.
 2. Enter the Pump fill port with the refill needle.
 3. Open the stopcock and allow the Pump to fill completely with NaOH. When the Pump is filled, approximately 10 ml will remain in the syringe. Leave this NaOH in the syringe, and **leave this syringe in place for the next step.**
-

Equilibrate and pull NaOH through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and NaOH is pulled through the pumping mechanism. This procedure uses the following volumes in syringes 3 and 1:

- Syringe 3 with residual NaOH from the previous section.
- Syringe 1 with 5 ml insulin/buffer mixture from previous section.

Syringe 3: NaOH - Residual

1. Verify that the stopcock on syringe 3 is open.

Syringe 1: Insulin - Residual

1. Prime the needle. Close the stopcock.
2. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
3. Enter the side port with the stopcock closed.
4. Open the stopcock.
5. Program and deliver a 4 unit bolus to open the valve in the Pump mechanism.
6. Observe syringe 3. When the level of the NaOH approaches 2 ml, close the stopcock to prevent air from entering the Pump. Observe syringe 1. At least 1 ml of NaOH must pass into syringe 1 in order to thoroughly clean the Pump mechanism. If less than 1 ml enters, repeat the bolus from Step 5, some pumps may require 3 successive boluses to obtain 1 ml.

NOTE: In order to completely dissolve deposits in the Pump mechanism, it is important to maintain a vacuum with syringe 1 and deliver the entire bolus.

7. After the bolus, close the stopcock on syringe 1. Remove both syringes. Set aside syringe 3 for use in removing the NaOH from the Pump fill port in the next step. Discard syringe 1.
-

Remove NaOH and fill with rinse buffer

The NaOH is removed from the Pump and the system is filled with RINSE BUFFER. This procedure uses the following volumes in syringes 3, 4, and 5:

- Syringe 3 with residual of at least 5 ml NaOH from previous step
- Syringe 4 with 20 ml RINSE BUFFER
- Syringe 5 with 30 ml RINSE BUFFER

Syringe 3: NaOH - Residual

1. Prepare syringe for aspiration.
2. Close the stopcock and obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured. Enter the Pump with the refill needle.
3. Open the stopcock and withdraw all the NaOH. After the NaOH appears to have stopped rising in the syringe, wait an additional 30 seconds to make sure all the NaOH and air is removed.
4. When the time has elapsed, close the stopcock, remove the syringe, and discard.

Syringe 4: Rinse Buffer - Degassed

1. Prime the needle. Close the stopcock.
 2. Enter the Pump with the refill needle and syringe.
 3. Open the stopcock and allow the Pump to fill completely with RINSE BUFFER. When the fluid level stops moving, the Pump is filled.
 4. Close the stopcock. Remove the syringe.
 5. Prepare syringe 4 for aspiration. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
 6. Re-enter the Pump.
 7. Open the stopcock and remove the RINSE BUFFER. After the fluid level stops moving, wait an additional 30 seconds for all the RINSE BUFFER and air to be removed.
-

8. When the time has elapsed, close the stopcock and remove the syringe and set aside.

Syringe 5: Rinse Buffer - Degassed

1. Prime the needle. Close the stopcock.
2. Enter the Pump fill port with the refill needle.
3. Open the stopcock and allow the Pump to fill completely with RINSE BUFFER. When the fluid level stops moving, the Pump is filled. When the pump is filled, approximately 10 ml of RINSE BUFFER will remain in the syringe. Leave the RINSE BUFFER in the syringe and **leave the syringe in place for the next step.**

Equilibrate and pull rinse buffer through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and RINSE BUFFER is pulled through the fluid system. This procedure uses the following volumes in syringes 4 and 5:

- Syringe 4 with RINSE BUFFER. Expel all RINSE BUFFER except 5 ml. Change refill needle if desired.
- Syringe 5 with residual RINSE BUFFER from previous step.

Syringe 5: Rinse Buffer

1. Verify that the stopcock on syringe 5 is open.

Syringe 4: Rinse Buffer - Residual

1. Prime the needle of syringe 4. Close the stopcock.
 2. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
 3. Enter the side port with the stopcock closed.
 4. Open the stopcock.
 5. To open the valve in the Pump mechanism, program and deliver a 4 unit bolus using the PPC.
 6. Observe syringe 4. When at least 1 ml of RINSE BUFFER has entered syringe 4, close both stopcocks and remove the syringes. If less than 1 ml enters, repeat the bolus from Step 6. Some Pumps may require 3 successive
-

boluses to obtain 1 ml. Discard syringe 4 and set aside syringe 5 to be used later to remove RINSE BUFFER.

Remove rinse buffer and fill with insulin

The RINSE BUFFER is removed from the Pump fluid system and the system is filled with INSULIN. This procedure uses the following volumes in syringes 5, 6, and 7:

- Syringe 5 with residual RINSE BUFFER from the previous steps
- Syringe 6 with 20 ml INSULIN
- Syringe 7 with 30 ml INSULIN

Syringe 5: Rinse Buffer - Residual

1. Prime the needle. Close the stopcock.
2. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
3. Enter the Pump with the refill needle and syringe.
4. Open the stopcock and remove the RINSE BUFFER. After the fluid level stops moving, wait an additional 30 seconds to make sure all the RINSE BUFFER and air are removed.
5. When the time has elapsed, close the stopcock, remove the syringe, and discard.

Syringe 6: Insulin - Degassed

1. Prime the needle. Close the stopcock.
 2. Enter the Pump fill port with the refill needle and syringe.
 3. Open the stopcock and allow the Pump to fill completely with INSULIN. When the fluid level stops moving, the Pump is filled.
 4. Close the stopcock and remove the syringe.
 5. Prepare syringe 6 for aspiration. Prime needle and close stopcock. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
 6. Re-enter the Pump.
-

7. Open the stopcock, remove the INSULIN. After the fluid level stops moving, wait an additional 30 seconds for all the INSULIN and air to be removed.
8. When the time has elapsed, close the stopcock and remove the syringe. Discard all but 5 ml of solution. Remove any air, prime needle and close stopcock. Set aside the syringe.

Syringe 7: Insulin - Degassed

1. Prime the needle on syringe 7. Weigh and record the combined weight of syringes 6 and 7 on the Refill Form.
 2. Close the stopcock. Enter the Pump fill port with the refill needle.
 3. Open the stopcock and allow the Pump to fill completely with INSULIN. When the fluid level stops moving, the pump is filled. When the Pump is filled, approximately 10 ml of INSULIN will remain in the syringe. **Leave the syringe in place for the next step.**
-

Equilibrate and pull insulin through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and INSULIN is pulled through the fluid system. This procedure uses the following volumes in syringes 6 and 7:

- Syringe 7 with residual INSULIN from previous step.
- Syringe 6 with 5 ml solution. To perform this procedure with syringes 6 and 7, follow the steps below:

Syringe 7: Insulin - Residual

1. Maintain syringe 7 with approximately 10 ml of residual INSULIN in the Pump fill port. Verify that the stopcock on syringe 7 is open.

Syringe 6: Insulin - Residual

1. Prime the syringe 6 needle. Close the stopcock.
 2. Obtain a vacuum in syringe 6 by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
 3. Enter the side port with syringe 6 - stopcock closed.
 4. Open the stopcock on syringe 6.
 5. Using the PPC, program and deliver a 4 unit bolus.
 6. Observe syringe 7. If the level of INSULIN approaches 2 ml, close the stopcock to prevent air from entering the Pump. Observe syringe 6. At least 1 ml of INSULIN must pass into syringe 6 to assure removal of all the RINSE BUFFER from the side port. If less than 1 ml enters, repeat the bolus from Step 6, some Pumps may require 3 successive boluses to obtain 1 ml.
 7. Close both stopcocks. Remove syringe 7 from the Pump. Set aside the syringe to be weighed.
 8. With the stopcock closed, remove syringe 6 from the side port. Syringe 6 will have a vacuum from the previous step. Enter the Pump fill port with syringe 6 and open the stopcock to remove 2 ml. This will restore the negative pressure safety feature of the Pump.
 9. Close the stopcock, remove syringe 6 from the Pump, and set it aside to be weighed.
-

Remove guide needles and record fill amount

At this point, the 18 gauge guide needles should be removed and the refill amount should be calculated and recorded. Follow the steps below:

1. Remove the 18 gauge guide needles. Apply pressure to the needle insertion sites.
2. Weigh syringes 6 and 7 and record on the refill form. Subtract the combined weight from the weights obtained in step 14 of the section, "Remove RINSE BUFFER and Fill with Insulin." The result is the new refill amount.
3. Record the extracted and new refill amounts in the PPC.

Program new basal rate

Using the patient's PPC, cancel the SUSPEND mode, to return to the normal patient's basal rate and modify if needed.

APPENDIX F

Side Port Catheter flush procedure

When delivery of insulin is impaired due to catheter tip obstruction, the Catheter may be flushed using 5 - 10 ml of RINSE BUFFER, MMT-2008.

Supplies and solutions

Prior to performing this procedure, assemble the necessary supplies and solutions as outlined below:

Supplies

- Steri-Strips[®] and markers
 - Local anesthesia
 - Sharps container
 - PPC
 - Oral or IV glucose
 - Glucose monitoring equipment
 - Drapes
 - One (1) scale - 0.01 gram resolution
 - One (1) sterile bag for PPC (intestinal or cassette bags work well)
 - One (1) Side port locating template, MMT-4106
 - Five (5) Refill kits, MMT-4105
 - Six (6) Medtronic MiniMed MMT-4102 refill needles. (Extra needles should be available to use as needed)
 - Eight (8) 18 gauge regular bevel needles
 - One (1) 10 or 20 ml Luer Lock[®] syringe
 - One (1) stopcock - 2 way
-

Solutions

- Seven (7) 10 ml vials, Rinse Buffer Solution, MMT-2008
- Five (5) 10 ml vials, U-400 Insulin

NOTE: One-handed flush with a 10-20 mL syringe only.

Preparing for the procedure

NOTE: Before beginning any refill, flush, stroke volume measurement, carefully read Appendix D, Precautions and General Procedures, and keep this in mind as you perform each procedure.

In order to prepare for the Side Port Catheter rinse and flush procedure, a total of five different refill syringes and one 10 or 20 ml syringe will need to be labeled and prepared with different solutions. Table 2 defines the syringe numbers and corresponding solutions.

Table 2: Preparation and labeling of syringes

Syringe #	Syringe type	Solution
#1	Refill	5 ml RINSE BUFFER
#2	Refill	20 ml RINSE BUFFER
#3	Refill	30 ml RINSE BUFFER
#4	10 ml	5-10 ml RINSE BUFFER
#5	Refill	20 ml INSULIN
#6	Refill	30 ml INSULIN

Record patient's blood glucose

Record the patient's blood glucose value at the start of the procedure. Monitor blood glucose every 30 minutes, or as needed.

Prepare syringes for emptying the Pump

Syringe 1 is used for emptying the Pump. Prepare syringe 1 as described in the "Precautions and General Procedures" section in Appendix D of this manual. Label the syringe per table 2.

After the syringe is prepared, weigh the syringe and enter the weight on the Refill Form.

Prepare syringes for filling the Pump

During the Catheter flush procedure, syringes 2, 3, 5, and 6 are used for filling the Pump. Each syringe should be labeled per Table 2, then filled and degassed following the General Procedures section in Appendix D of this manual.

Prepare syringe for flushing the Side Port Catheter

During the Catheter flush procedure, syringe 4 is used for flushing the Side Port Catheter. This syringe needs to be labeled and then prepared by following the steps below:

1. Firmly attach a stopcock to the 10 or 20 ml Luer Lock connector of a 10 or 20 ml syringe. Then attach an 18 gauge needle to the stopcock.

NOTE: Use only a 10-20 ml Luer Lock syringe for this procedure. Smaller syringes may damage the Catheter and/or Pump, by allowing too much high pressure.

2. Draw 5-10 mL of RINSE BUFFER into the syringe.
 3. Expel all air from the syringe.
 4. Close the stopcock and remove the 18 gauge needle from the syringe.
 5. Fill the hub of the Medtronic MiniMed refill needle with RINSE BUFFER from the syringe and attach it to the syringe.
 6. Prime the Medtronic MiniMed refill needle completely.
 7. Close the stopcock.
 8. Set the syringe aside.
-

Flushing the Side Port Catheter

Program minimal basal rate

Place the PPC in a sterile bag and program the pump to “SUSPEND” mode, the basal rate will be 0.2 U/h.

Remove insulin and fill with rinse buffer

The INSULIN is removed from the Pump and the system is filled with RINSE BUFFER. This procedure uses the following volumes in syringes 1, 2, and 3:

- Syringe 1 with 5 ml RINSE BUFFER
- Syringe 2 with 20 ml RINSE BUFFER
- Syringe 3 with 30 ml RINSE BUFFER

Syringe 1: Rinse Buffer

1. Prime the needle and close the stopcock. Weigh the syringe.
2. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove and be sure it is firmly secured.
3. Enter the Pump with the refill needle.
4. Open the stopcock and withdraw the INSULIN. After the INSULIN appears to have stopped rising in the syringe, wait an additional 30 seconds to make sure all of the INSULIN and air are removed.

NOTE: Air in the Pump System has been shown to be a significant agonist to aggregation of INSULIN. Proper degassing of all solutions that enter the Pump is essential.

5. When the time has elapsed, close the stopcock, remove the syringe. Weigh the syringe and record the weight on the Refill Worksheet.

Syringe 2: Rinse Buffer - Degassed

1. Prime the needle and close the stopcock.
 2. Enter the Pump with the refill needle.
-

3. Open the stopcock and allow the Pump to fill completely with RINSE BUFFER. When the fluid level stops moving, the Pump is filled.
4. Close the stopcock and remove the syringe.
5. Prepare syringe 2 for aspiration. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove and be sure it is firmly secured.
6. Re-enter the Pump.
7. Open the stopcock and remove the RINSE BUFFER. After the fluid level stops moving, wait an additional 30 seconds for all the RINSE BUFFER and air to be removed.
8. When the time has elapsed, close the stopcock and remove the syringe.
9. Prime the needle and close the stopcock.

Syringe 3: Rinse Buffer - Degassed

1. Enter the Pump fill port with the refill needle.
2. Open the stopcock and allow the Pump to fill completely with RINSE BUFFER. When the fluid level stops moving, the Pump is filled. When the Pump is filled, approximately 10 mL of RINSE BUFFER will remain in the syringe. Leave the RINSE BUFFER in the syringe, and **leave the syringe in place for the next step.**

Equilibrate and pull rinse buffer through system

The reservoir pressure in the Pump is equilibrated with ambient pressure and RINSE BUFFER is pulled through the fluid system. This procedure uses syringes 2 and 3:

- Syringe 2 with RINSE BUFFER. Expel all RINSE BUFFER except 5 mL. Change the refill needle if desired.
- Syringe 3 with residual RINSE BUFFER from the previous section.

Syringe 3: Rinse Buffer - Residual

1. Maintain syringe 3 with approximately 10 mL of RINSE BUFFER in the Pump fill port. Verify that the stopcock on syringe 3 is open.

Syringe 2: Rinse Buffer - Residual

1. Prime the needle. Close the stopcock.
2. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
3. Enter the side port with the stopcock closed.
4. Open the stopcock.
5. Program and deliver a 4 unit bolus to open the valve in the Pump mechanism.
6. Observe syringe 3. When the level of the RINSE BUFFER approaches 2 mL, close the stopcock to prevent air from entering the Pump. Observe syringe 2. When at least 1 mL of RINSE BUFFER has entered syringe 2 close both stopcocks and remove the syringes. If less than 1 ml enters, repeat the bolus from Step 6. Some Pumps may require 3 successive boluses to obtain 1 ml. Discard syringe 2 and set aside syringe 3 to be used later to remove the RINSE BUFFER.

Flush side port catheter

The Side Port Catheter is flushed using syringe 4 which is completely filled with RINSE BUFFER.



Approximately 13 units of INSULIN remain in the distal Side Port Catheter. This INSULIN will be delivered to the patient rapidly in the next three steps. Alternatively, the INSULIN may be removed prior to flushing by programming continuous bolus amounts. Closely monitor blood glucose during INSULIN delivery, and administer intravenous glucose or glucogen as needed.

Syringe 4: Rinse Buffer

1. Prime the needle. Close the stopcock.
 2. Enter the side port with the needle.
 3. When the needle is firmly positioned in the side port, open the stopcock and quickly push the plunger all the way down. This should take no longer than one to two minutes.
 4. After flushing, close the stopcock, remove and discard the syringe.
-

NOTE: This is the only time a plunger should be manually pushed down.

Remove rinse buffer and fill with insulin

The RINSE BUFFER is removed from the Pump fluid system and the system is filled with insulin. This procedure uses the following volumes in syringes 3, 5, and 6:

- Syringe 3 with residual RINSE BUFFER from the previous step
- Syringe 5 with 20 ml INSULIN
- Syringe 6 with 30 ml INSULIN

Syringe 3: Rinse Buffer - Residual

1. Prime the needle. Close the stopcock.
2. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove and be sure it is firmly secured.
3. Enter the Pump with the refill needle and syringe.
4. Open the stopcock and remove the rinse buffer. After the fluid level stops moving, wait an additional 30 seconds to make sure all of the RINSE BUFFER and air is removed.
5. When the time has elapsed, close the stopcock, remove the syringe, and discard it.

Syringe 5: Insulin - Degassed

1. Prime the needle and close the stopcock.
 2. Enter the Pump fill port with the refill needle.
 3. Open the stopcock and allow the Pump to fill completely with INSULIN. When the fluid level stops moving, the Pump is filled.
 4. Close the stopcock and remove the syringe.
 5. Prepare syringe 6 for aspiration. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
 6. Re-enter the Pump.
-

7. Open the stopcock and remove the INSULIN. After the fluid level stops moving, wait an additional 30 seconds for all INSULIN and air to be removed.
8. When the time has elapsed, close the stopcock and remove the syringe. Discard all but 5 mL of the solution. Remove the air and **set aside the syringe**.

Syringe 6: Insulin - Degassed

1. Weigh and record the combined weight of syringes 5 and 6 on the Refill Worksheet. Prime the needles.
2. Close the stopcocks. Enter the Pump fill port with the refill needle.
3. Open the stopcock and allow the Pump to fill completely with INSULIN. When the fluid level stops moving, the Pump is filled. Approximately 10 mL of INSULIN will remain in the syringe. **Leave the syringe in place for the next step.**

Equilibrate and pull insulin through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and INSULIN is pulled through the fluid system. This procedure uses the following volumes in syringes 5 and 6:

- Syringe 6 with residual INSULIN from the previous step
- Syringe 5 with 5 mL solution of Rinse Buffer.

Syringe 6: Insulin - Residual

1. Maintain syringe 6 with approximately 10 mL of residual insulin in the Pump fill port. Verify that the stopcock on syringe 6 is open.

Syringe 5: Rinse Buffer -Residual

1. Prime the syringe 5 needle and close the stopcock.
 2. Obtain a vacuum in syringe 5 by pulling back on the plunger until it locks. Press the lock into the plunger groove and be sure it is firmly secured.
 3. Enter the side port with syringe 5 - stopcock closed.
 4. Open the stopcock on syringe 5.
-

5. Press **SEL**. When the PPC screen is flashing “PUMP SUSPEND” press **ACT**. The system is now in normal mode.
6. Using the PPC, program and deliver a 4 unit bolus.
7. Observe syringe 6. If the level of INSULIN approaches 2 mL, close the stopcock to prevent air from entering the Pump. Observe syringe 5. At least 1 mL of INSULIN must pass into syringe 5 to be sure that all of the RINSE BUFFER is removed from the side port. If less than 1 ml enters, repeat the bolus from Step 7, some Pumps may require 3 successive boluses to obtain 1 ml.
8. Close both stopcocks. Remove syringe 6 from the Pump. Set the syringe aside to be weighed.
9. With the stopcock closed, remove syringe 5 from the side port. It will have a vacuum inside from the previous step. Enter the Pump fill port with syringe 5 and open the stopcock and remove 2 ml. This will restore the negative pressure safety feature of the Pump.
10. Close the stopcock, remove syringe 5 from the Pump, and set it aside to be weighed.
11. Press **SEL** until the “SUSPEND PUMP” screen is displayed. Then Press **ACT**.

Remove guide needles and record refill amount

At this point, the 18 gauge guide needles should be removed, and the refill amount should be calculated and recorded.

1. Remove the 18 gauge guide needles and discard them. Apply pressure to the insertion sites.
2. Weigh syringes 5 and 6 and record the combined weight on the Refill Form. Subtract the combined weight from the weight obtained in step 14. Remove Rinse Buffer and Fill with Insulin. The result is the new refill amount.
3. Record the new and extracted refill amount in the PPC refill worksheet.

Program new basal rate

Using the patient’s PPC, cancel the “SUSPEND” mode and allow the Pump to return to the patient’s original basal rate.

Remove rinse buffer from catheter

Approximately 13 units of RINSE BUFFER remain in the distal Side Port Catheter. Depending on blood glucose values, program the appropriate bolus amount to remove the RINSE BUFFER from the Catheter. Release the patient when blood glucose levels are stable.

APPENDIX G

Stroke volume measurement

If under-delivery of insulin is noted during a refill procedure or suspected due to blood glucose control, it may be useful to verify the proper stroke volume of the Pump by accessing the side port.

In this procedure, a pipette is attached to a stopcock and refill needle. This system is inserted into the side port. The insulin pulses in the pipette are measured to calculate the pump stroke volume.

Supplies and solutions

Prior to performing this procedure, assemble the necessary supplies and solutions as outlined below:

Supplies

- Local anesthesia
 - Sharps container
 - PPC
 - Oral or IV glucose
 - Glucose monitoring equipment
 - Drapes
 - 5 ml or 3 ml syringe
 - One (1) sterile bag for PPC (intestinal or cassette bags work well)
 - One (1) Side port locating template, MMT-4106
 - One (1) sterile 100 microliter pipette, MMT-4104
 - Two (2) 18 gauge needles
 - One (1) MiniMed MMT-4102 refill needle. (Extra needles should be available to use as needed)
-

- One (1) sterile stopcock - 3 way

Solutions

- One (1) 10 mL vial, Rinse Buffer Solution, MMT-2008

Preparing for the procedure

NOTE: Before beginning any refill, flush, stroke volume measurement, carefully read Appendix D, Precautions and General Procedures, and keep this in mind as you perform each procedure.

Record patient's blood glucose

Record the patient's blood glucose value at the start of the procedure. Monitor blood glucose every 30 minutes, or as needed.

Measuring stroke volume

1. In a sterile field before the procedure; prepare the apparatus. Prime the stopcock, pipette, and needle.
2. Turn the stopcock as shown in Figure 18. Press on the syringe to obtain a liquid meniscus in the pipette.

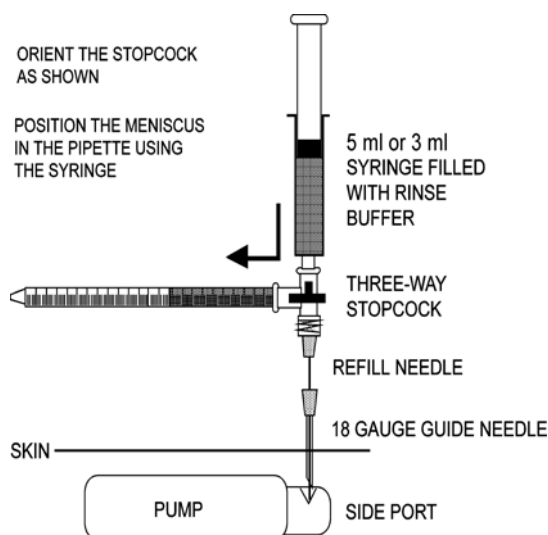


Figure 18: Stroke volume measurement setup

3. Insert the needle into the side port.
4. Turn the stopcock as shown in Figure 19.
5. Program a high rate bolus (approximately 20 units) and measure the stroke volume over 20 pulses in the pipette.
6. Cancel the bolus at the end of the measurement.
7. Turn the stopcock back to the position shown in Figure 19 to close. Remove the apparatus.

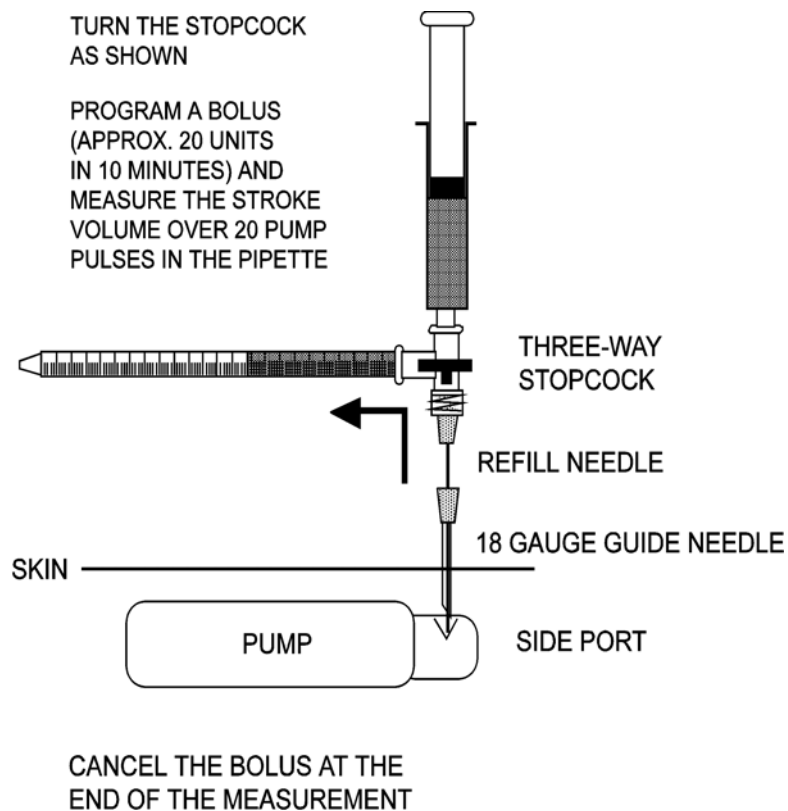


Figure 19: Stroke volume measurement

Record patient's blood glucose

It is likely that some insulin is pumped out of the Catheter and into the patient in this procedure. Monitor the patient's blood glucose and release the patient only after blood glucose values are stable.