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CHAPTER 1   Description of the Medtronic MiniMed 2007C Implantable Insulin Pump System

Introduction

The Medtronic MiniMed 2007C Implantable Insulin Pump System 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 2007C Implantable Insulin Pump System is the result of years of cooperative research and development between 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.

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 2007C Implantable Insulin Pump System.

The Medtronic MiniMed 2007C Implantable Insulin Pump System uses only special insulin formulations. The only insulin available today for use in the Pump is HOE 21 PH U-400, manufactured by Aventis.

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.

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

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 Cather 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, Freon gas and 20µm 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 (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 $\pm10\%$ 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 at 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 the Implantable Insulin Pump features radio-opaque identification. 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 Aventis HOE 21 PH U-400 insulin can be used with the Medtronic MiniMed 2007C Implantable Insulin Pump System.

HOE 21 PH U-400 is a highly purified, semi-synthetic human insulin with 0.2% phenol as a preserving agent, glycerol as an isotonic component, TRIS as a buffer, plus zinc and Genapol$^®$ as stabilizing agents.

HOE 21 PH U-400 is equivalent in mode of action to normal (soluble) insulin. A special U-400 insulin concentration has been developed for use in the Implantable Insulin Pump and is supplied in 10mL vials (400U/mL) from Aventis.

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.
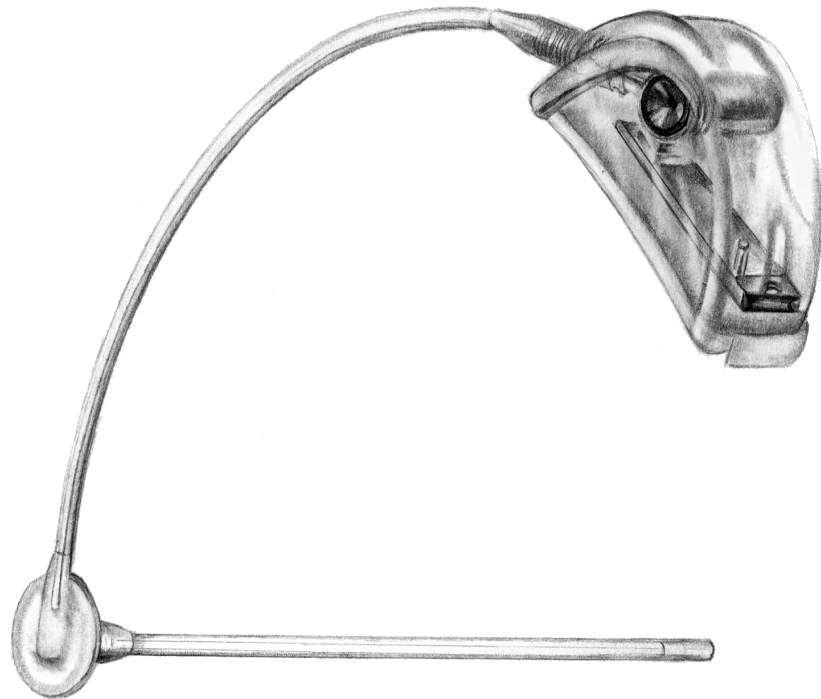
Figure 4: The Intraperitoneal Catheter and Side Port

The Catheter side port is intended to provide access to the Catheter and
Pump outlet, in order to perform the non-surgical interventions and diag-
nostic 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 introduc-
tion of a needle to verify Pump stroke volume and permit non-surgical
diagnoses of Catheter blockages by direct pressure measurement.

Personal Pump Communicator (PPC)

The Personal Pump Communicator (PPC) is the hand-held component of the MiniMed 2007C 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 (48 basal rates, 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 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.

CHAPTER 2 Indications and Contraindications

Indications for use

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

Only Aventis HOE 21 PH U-400 insulin is indicated for use in the Medtronic MiniMed 2007C Implantable Insulin Pump System.

Contraindications for use

The Medtronic MiniMed 2007C 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 2-3 months).

- 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 MiniMed 2001 Implantable Insulin Pump System has undergone an extensive clinical evaluation. The model 2007C is essentially identical to the model 2001 Pump except for the use of updated electronics and battery. Evaluation of components used in the MiniMed 2001 System spanned a period of ten years and involved approximately 650 patients from both the U.S. and Europe. Although clinically relevant over-delivery of insulin did not occur during the ten 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	Foreign Body Reaction
Abnormal Healing	Skin Disorder
Infection	Urinary Disorder
Necrosis	Psychiatric Decompensation
Retinal Disorder	Skin Erosion
Abnormal Liver Function	Kidney Disorder
Ileus	Pocket Lymph Edema
Inflammation at Refill Site	Pump Failure
Hyperglycemia	Catheter Occlusion/Encapsulation
Hypoglycemia	Battery Depletion
Ketoacidosis	PPC Failure

Personal Pump Communicator (PPC)

Introduction

The Personal Pump Communicator (PPC) has a comprehensive set of programming features to control the Implantable Insulin Pump in the treatment of IDDM. 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

Select:**SEL** Activate:	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.
Up and Down Arrows: ▲ or ▼	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 the Up Arrow	When the Audio Bolus feature is turned on, pressing ▲ allows programming an Audio Bolus.
Light Icon the 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.

Communicating with the pump

Place the PPC near the Pump when the screen displays, "PPC COMMU-NICATING." The word "COMMUNICATING" will blink as indication of succesfull 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 8 weeks during normal usage conditions. If the vibrator mode is selected, the battery life is approximately 6 weeks.

- 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".

```
PPC    4 102 100

PUMP   _ _ _
```

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

```
08:26 ◄ ☰   JAN 02
CHECK
PUMP  STATUS
```
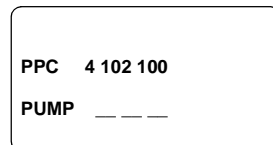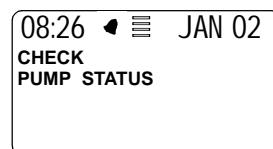
3. Wait a few seconds for the communication to complete.

```
PPC
COMMUNICATING
```

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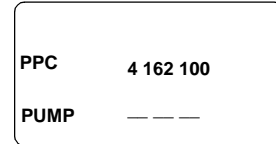
The Implantable Insulin Pump arrives from MiniMed with preset factory default values. During the initialization process these preset values are downloaded into the PPC memory. The preset values can then be changed by the healthcare professional, allowing the system to be personalized for each patient.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

Bolus Delivery Type	Normal	Off Locked Maximum status	Off
Maximum Bolus	25 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 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 1, Install/Replace the Main Battery).*

```
PPC       4 162 100

PUMP      — — —
```

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.

```
PPC
NOT INITIALIZED
```
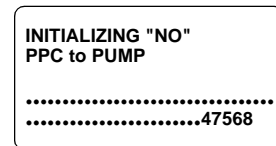
3. When a communication link has been established, the screen will read, "PPC COMMUNICATING", and then will change to the next screen.

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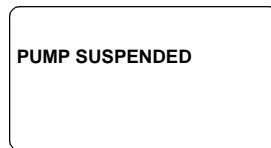
5. The screen again reads "PPC COMMUNICATING", and the PPC will beep 3 times at the end of the programming sequence. During this process, the PPC receives all of the factory preset values contained in the Pump memory.

```
PPC
COMMUNICATING
```

6. The screen will read "PUMP SUS-PENDED". The Pump and PPC are now "married".
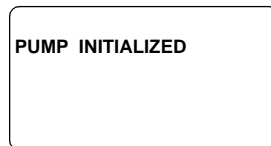
> PUMP SUSPENDED

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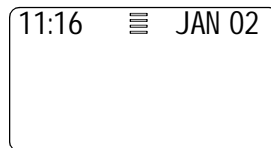
> PPC
> COMMUNICATING

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

```
08:32          Jan 02
SET              2000
TIME-DATE
```

(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.
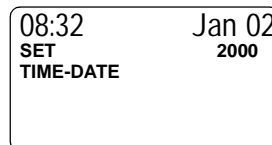
2. After completing the programming process, quickly place the PPC near the Pump. The PPC will display "PPC COMMUNICATING" while transferring the time and date information to the Pump. The PPC will then move to the

```
PPC
COMMUNICATING
```

next screen, "AUTO-OFF." Skip the "AUTO-OFF" screen by pressing **SEL** once to reach the next screen, "ALARMS".
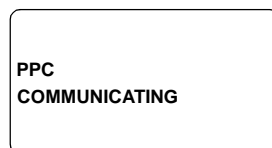
Set alarms

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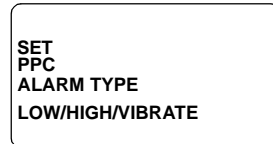
3. The screen will now display "SET ALARM FEEDBACK". This setting should always be "ON". Press **ACT**.

SET
ALARM
FEEDBACK
 ON/OFF
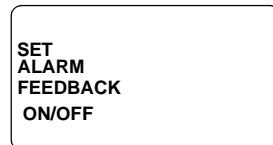
4. Place the PPC near the Pump. When the communication is completed, the PPC screen will change to "SELF TEST" and then to the Time/Date screen.
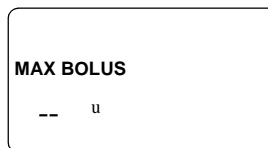
PPC
COMMUNICATING

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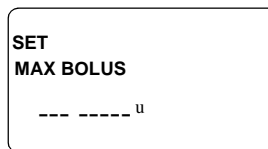
This programming is performed in the "SETUP II" menus. These screens allow healthcare professionals to limit the maximum amount of insulin a patient can deliver, either when taking a bolus or setting a new basal rate. Access to the "SETUP II" menus is through the "SETUP PUMP" screen.

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 (0.0 to 25.0 units) and then press **ACT** again.
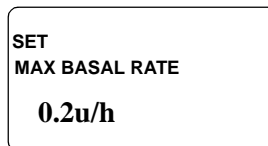
   | SET MAX BOLUS |
   | --- ----- ^{u} |

3. Place the PPC near the Pump and complete the communication process. The PPC screen will automatically change to the "MAX BASAL" screen.
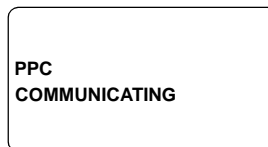
   | PPC COMMUNICATING |

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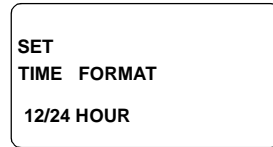
7. Place the PPC near the Pump and complete the communication process. The PPC screen will return to the "PERSONAL EVENTS" screen. Allow the PPC to time out and return to the Time/Date screen.

> 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.

> **WARNING**
>
> ⚠️
>
> **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.**

1. 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.

```
ENTER
SUPERVISOR
PASSWORD
     0000
```

2. Entry into the Supervisor Mode is indicated by the screen "PUMP REFILL."

```
PUMP
REFILL
```

3. 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 <u>not</u> given access to this feature, or "OFF" if the patient <u>is</u> permitted access. Press **ACT** again.
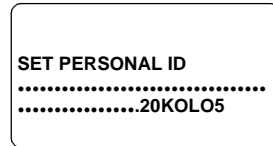
```
SET
MAXIMUMS OFF/ON
```

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 (alphanumeric) 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 "SUPERVISOR PASSWORD" screen is displayed. Then press **ACT**.

> SET
> SUPERVISOR
> PASSWORD
> 　　　　　Y1Q8

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.
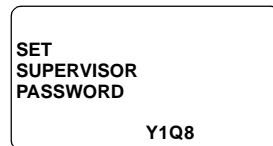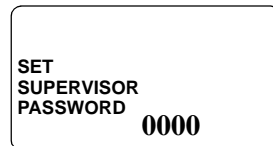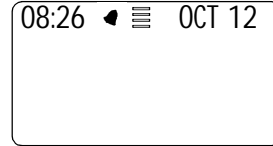
> SET
> SUPERVISOR
> PASSWORD　0000

NOTE: Record the password in the patient's chart.
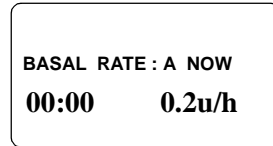
Program a basal rate

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**.

```
08:26 ◄ ≣   OCT 12
```

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
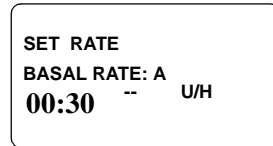
```
BASAL RATE : A NOW
00:00       0.2u/h
```

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
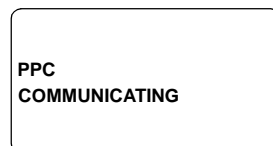
```
SET RATE
BASAL RATE: A
00:30    --    U/H
```

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.

```
PPC
COMMUNICATING
```

5. The PPC will briefly display the calcu-
   lated 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.

24 HOUR TOTAL

4.8U

Part 2: Additional PPC programming features

Main menu

This second part will develop 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.
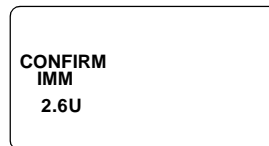
Set a normal bolus with the variable bolus feature turned off

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
  10  U    --  U
PROG          --
```

2. Press **ACT** and the "SET BOLUS" screen appears.The dashes under "IMM" are flashing. Press the ▲ and ▼ buttons to enter an underline 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
                0.0U
BOLUS
```

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.

```
08:13              Jan 02
BOLUS
  IMM            EXT
  -- U    -- U
```

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

```
SET
BOLUS TYPE

  NORMAL
```

3. The "SET BOLUS" screen appears, with dashes under "IMM" flashing. Use the ▲ and ▼ buttons to enter an <u>immediate</u> bolus amount.

```
SET BOLUS
  IMM
  --- ---  U
```

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

```
CONFIRM
IMM
  2.6u
```

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

```
PPC
COMMUNICATING
```

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

```
08:23      ≣ ■ JAN 04

BOLUS         0.0U
```

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 banquets or receptions, high fat meals, or to compensate for gastroparesis. During a Square Wave Bolus, the programmed basal rate is also delivered.

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
 10  U    --  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 <u>extended</u> 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 <u>time duration</u> for the Square Wave Bolus, in one-half hour increments from 30 minutes to four 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
```
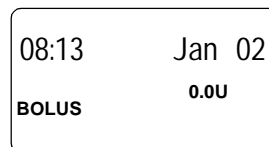
6. Place the PPC near the Pump and complete the communication process.

```
PPC
COMMUNICATING
```

7. When the bolus programming is complete, the PPC will beep once and then briefly display the amount of insulin currently delivered.
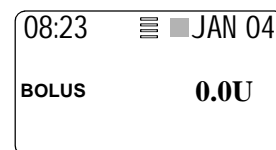
```
16:06          JAN 03

BOLUS         0.0U
```

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.

```
08:13          Jan 02
BOLUS
  IMM          EXT
--- --- U  ---- ---- U
               --- ---
```

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

```
SET
BOLUS TYPE

   DUAL
```

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

```
SET  BOLUS
  IMM

  2.0u
```

4. The "BOLUS" screen now shows dashes flashing under "EXT."
Use the ▲ and ▼ buttons to enter the extended portion of the Dual Wave Bolus. Press **ACT**.

```
SET  BOLUS
  IMM       EXT

  2.0u     2.0u
```

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     2.0u
        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
```
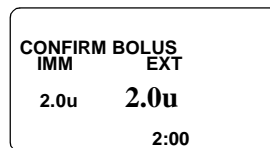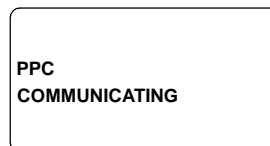
8. When the bolus programming is complete, the PPC will beep once and then briefly display the amount of insulin currently delivered.
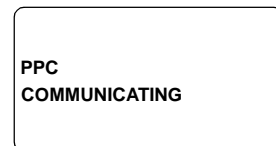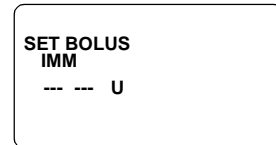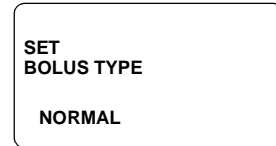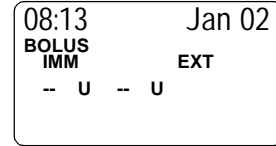
```
16:06          JAN 03


BOLUS          0.0u
```
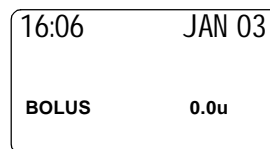
The pump will beep at each of the first five strokes (if audio feedback is ON). The PPC beeps at the end of the bolus. Three segments of the insulin delivery icon will be displayed and spinning slowly during the bolus delivery. By pressing **SEL**, you can visualize the amount of insulin delivered.

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         --- ---
```
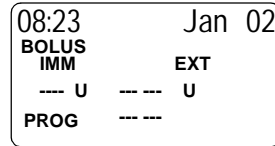
Suspend mode

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.

```
SUSPEND PUMP
```

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

```
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.

```
08:13   ◀≣✿OCT 12
PUMP SUSPENDED
```
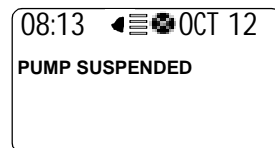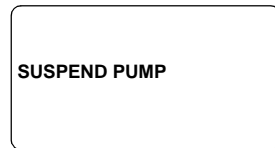
NOTE: To restart the pump, press SEL. The "PUMP SUSPENDED" screen will begin flashing. Then press ACT.

Programming a basal rate

Basic basal rate programming was described in 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 I" screens.

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

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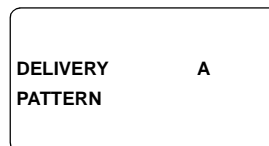
2. Press **ACT** and the screen will change to "SET DELIVERY PATTERN". Use the ▲ and ▼ keys select the pattern preferred; A, B, or C. Each pattern can contain up to 48 different basal rates. Press **ACT** after choosing a pattern.

```
SET
DELIVERY       A,B,C
PATTERN
```

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

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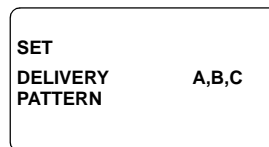
NOTE: When the PPC times out, press SEL until the "BASAL RATE" screen is displayed. The basal pattern selected in SETUP II will now appear to the right of "BASAL RATE" A, B, or C.

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
                0.2U/H
00:00
```

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
                0.2U/H
00:00
```

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  TIME
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
```

6. The screen will indicate "PPC COMMU-NICATING." Place the PPC near the Pump and complete the communication process.

```
PPC
COMMUNICATING
```

7. 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

1. From the time and date display press **SEL** until the "TEMPORARY BASAL" screen is displayed.

```
TEMP BASAL
--- --- --- ---     u/h
```

2. 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
          --- ---  u/h
00:30
```
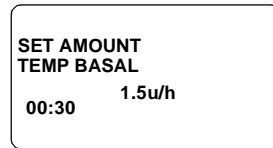
3. Press **ACT** and "SET AMOUNT" screen appears. The amount of the Temporary Basal Rate is now flashing.
Press the ▲ and ▼ buttons to enter a delivery <u>amount</u>. Press **ACT** again.
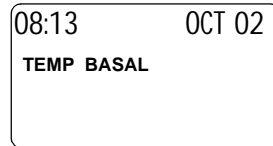
```
SET AMOUNT
TEMP BASAL
            1.5u/h
 00:30
```

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

```
PPC
COMMUNICATING
```

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.

```
08:13          OCT 02
 TEMP  BASAL
```

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**.

```
SET DURATION
TEMP BASAL
--- ---           1.5u/h
```

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

```
PPC
COMMUNICATING
```

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.

```
SET AMOUNT
TEMP BASAL
--- ---  --- ---  u/h
```
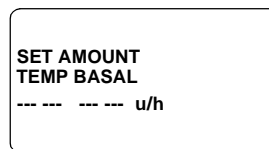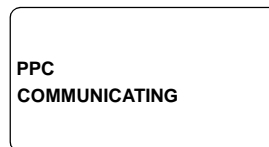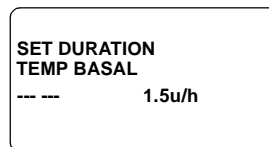
Personal events

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" is screen is displayed.

```
PERSONAL
EVENTS
              OFF
```
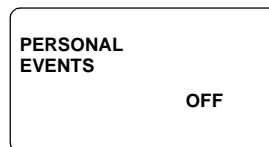
2. Press **ACT** and "ON" or "OFF" begins flashing.

PERSONAL ON/OFF
EVENTS

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.

SET
PERSONAL ON/OFF
EVENTS

4. <u>To set an event:</u> 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.

SET
EVENT
MEAL

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.

07:32ᴀᴍ
SET TIME
EVENT
MEAL

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**
> **00000000000000000000000**
> **00000000000000000010057**

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**
> **2263 u**

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.
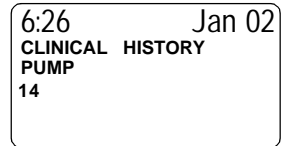
> Jan 02
> **INSULIN TOTAL**
> **BASAL   BOLUS**
> **9u   22u**

5. Press **SEL** and the screen will change to "CLINICAL HISTORY PPC". Use the ▲ and ▼ buttons to review other PPC events.
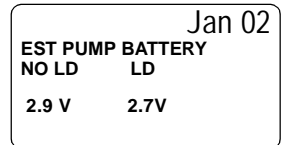
> 6:16   Jan 02
> **CLINICAL HISTORY**
> **PPC**
> **11**

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.

```
                  Jan 02
EST PUMP BATTERY
NO LD      LD

 2.9 V     2.7V
```

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

```
EXIT HISTORY
```

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.

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.

   ```
   AUTO OFF
   --- --- HRS
   ```
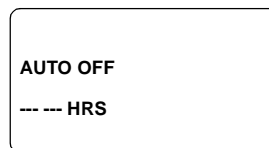
2. Press **ACT**. In this example, a time duration of 10 hours was selected. The PPC will alarm if the user did not attempt to program the Pump during the previous 10 hours and be placed in SUSPEND mode.

   ```
   SET
   AUTO OFF

   10 HRS
   ```
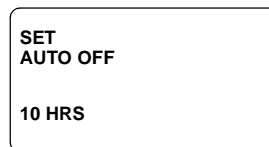
3. Place the PPC near the Pump and complete the communication process.The PPC will beep once and return to the Time/Date screen.

   ```
   PPC
   COMMUNICATING
   ```

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
```

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 MiniMed. If the PPC displays the 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.

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 sytem initialization.

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.

```
AUDIO BOLUS

ON            0.4u

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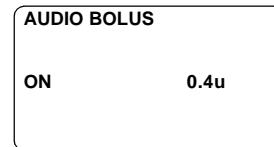
2. Press **ACT**, and the screen changes to "SET AUDIO BOLUS" with "OFF/ON" flashing. Use the ▲ and ▼ buttons to choose "ON" to activate the Audio Bolus feature or "OFF" to disable it. Then press **ACT**.

```
SET
AUDIO BOLUS

              0.4u
ON

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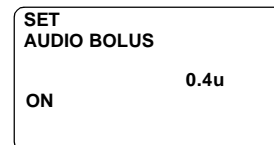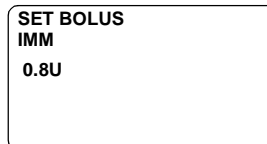
3. If "ON" was chosen, the "SET STEP AUDIO BOLUS" appears with a step value of 0.4U or 0.8U flashing on the screen. Use the ▲ and ▼ buttons to choose between a step rate of 0.4U or 0.8U. Press **ACT**. The Audio Bolus feature is now activated.

```
SET STEP
AUDIO BOLUS

              0.4u

```
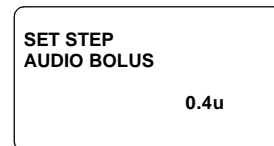
NOTE: If "OFF" is chosen, pressing the ▲ button will have no effect.
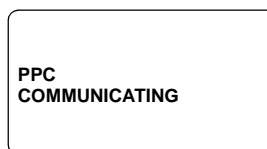
Set an audio bolus from the main menu bolus screen

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

```
PPC
COMMUNICATING
```

programmed. The PPC beeps once when the programming is completed. Place the PPC on the Pump to complete the communication process.
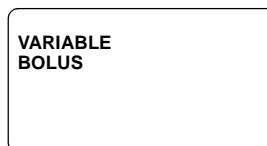
NOTE: While an audio bolus is being delivered, the ▲ button will not function.

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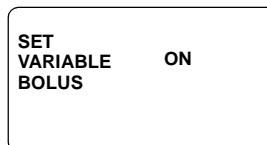
To access the Variable Bolus feature enter "SETUP II" and press **SEL** one time.

The screen will display "VARIABLE BOLUS". Press **ACT**.

```
VARIABLE
BOLUS
```

The screen will now display "SET VARI-ABLE BOLUS" and "ON or OFF" will be flashing. Use the ▲ and ▼ buttons to select "ON" or "OFF", then Press **ACT**.

```
SET
VARIABLE        ON
BOLUS
```

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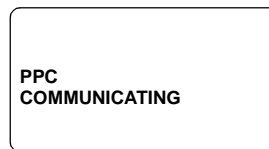
NOTE: If "OFF" is chosen, the-
Variable Bolus option (Square, Dual) will not be
available in the (Main Menu) Bolus screen.

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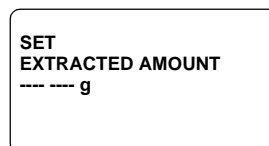
The refill procedure will be described in Chapter 5 "Pump Refill Procedure." The following screens are used at the end of this procedure, and allow you to enter the new refill volume and to calculate the refill accuracy.

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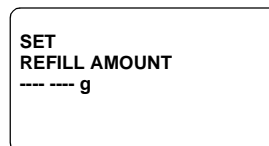
> **PUMP REFILL**

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.
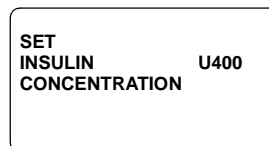
> **SET**
> **EXTRACTED AMOUNT**
> **---- ---- g**

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**

Press **ACT**. Confirm that the insulin concentration defaults to U-400. Press **ACT** again.
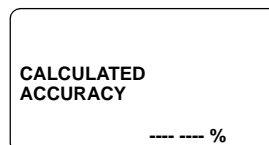
> **SET**
> **INSULIN   U400**
> **CONCENTRATION**

Place the PPC near the Pump to complete the process.

> **PPC**
> **COMMUNICATING**

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

> **CALCULATED**
> **ACCURACY**
>
> **---- ---- %**

Priming

A priming bolus is not intended as a therapeutic bolus. It should be only 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.

```
08:13        Oct 12

PUMP STOPPED
```

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

```
ENTER
SUPERVISOR
PASSWORD
              YIQ8
```

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.

```
PRIMING
```

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

```
PRIMING        NO

99.8u
```

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

```
CONFIRM
PRIMING              YES

99.8u
```

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

```
PPC
COMMUNICATING
```

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

```
08:13              OCT 12
PRIMING            0.0u
```

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

WARNING ⚠	**A diagnostic rate is intended for use only when the Pump is filled with 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.

```
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.

```
SET
SUPERVISOR
PASSWORD

          0000
```

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

```
DIAGNOSTIC
RATE


--- --- u/h
```

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

```
SET
DIAGNOSTIC
RATE

10 u/h
```

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**.

```
DELIVER
DIAGNOSTIC
RATE

10 u/h
```

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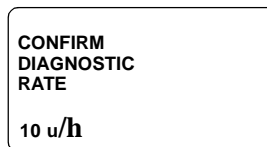
8. The words "DIAGNOSTIC RATE" appear briefly on the screen.The PPC then returns to the Time/Date screen.

```
08:13        OCT 12

DIAGNOSTIC RATE
```
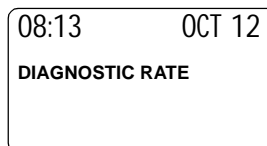
NOTE: Press SEL and the PPC will indicate "DIAGNOS-TIC RATE."

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. Reenter 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   ◀≡✪OCT 02

PUMP SUSPENDED
```

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

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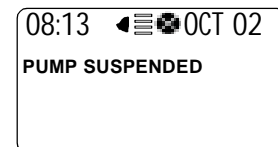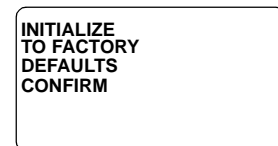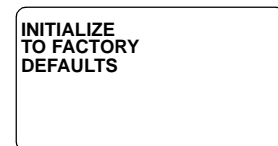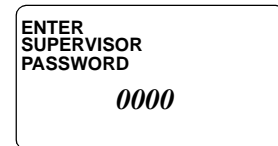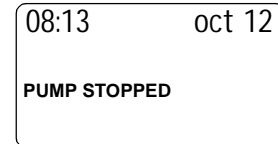
8. The PPC now displays the "PUMP RESET" screen, and beeps six times every minute until the Pump is restarted. Press **SEL** then **ACT**. The PPC returns to the Time/Date screen. The Pump may now be reprogrammed.

```
08:13   ◄≡✪ OCT 02
PUMP
RESET
```

Download software

This feature has been disabled at the factory.

1. From the "PUMP REFILL" screen in the Supervisor menu, press **SEL** until the "DOWNLOAD SOFTWARE" screen appears.

```
DOWNLOAD
SOFTWARE
```

Stop Pump

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

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

```
STOP PUMP
```
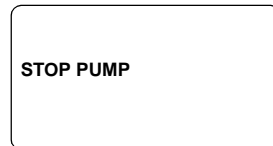
Press **ACT** and the word "CONFIRM" appears highlighted with the entire screen flashing. Press **ACT** again to confirm.

```
CONFIRM
STOP PUMP
```

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

```
┌─────────────────────┐
│                     │
│ PPC                 │
│ COMMUNICATING       │
│                     │
└─────────────────────┘
```
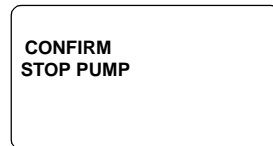
The PPC will beep four times to confirm the "STOP PUMP" command. To restart the Pump, press **SEL** and "PUMP STOPPED" will start to flash. Press **ACT**. Place the PPC near the Pump. When the communication is complete, the PPC returns to the Time/Date screen.

```
┌─────────────────────┐
│ 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 PUMP SUSPENDED	Auto Off time interval has elapsed. Pump operation is suspended.
BOLUS 0.0 u	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 NEEDS SERVICING	The internal PPC backup battery is depleted. The PPC can be programmed. Replace the PPC as soon as possible.
PPC LOW BATTERY	The internal PPC backup battery is low. The PPC can be programmed. Replace the PPC as soon as possible.
PPC DEPLETED BATTERY	The PPC cannot be programmed. Replace the PPC AA 1.5 volt alkaline battery.
PPC NOT INITIALIZED	The PPC has not been initialized to a Pump.
PPC LOW BATTERY	The PPC can be programmed. Replace the PPC AA 1.5 volt alkaline battery.
PUMP LOW BATTERY	The Pump battery energy is low but still functioning. Schedule a replacement as soon as possible.

Display Screen Message	Message Meaning or Action Required
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. Notify your physician immediately.
PUMP STOPPED	The Pump is in stop mode.
PUMP STOPPED 1 or 2 or 3 or 4or 5 or 6	When the Pump recognizes a system malfunction, it automatically stops and insulin delivery ceases. Notify your physician immediately.
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.
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 MiniMed.
TELEMETRY COMM ERROR 20	If the response is "NO" to the "INITIALIZE PPC TO PUMP" until this screen appears. Move the PPC away from any other Pump and perform the request again.

Clinical 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.

Clinical history PPC/Pump 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
Bolus Total Error	13	Unknown IRQ Vector	12
Bad Duplicates	15	NMI Occurred	14
Stop Pump Alarm	17	Suspend Alarm	16
Prime Pump Alarm	19	Diagnostic Rate Alarm	18
Max Clock Stealer	21	Exclusion List Full	20
Non Initialized PPC	23	Min Clock Stealer	22
Pump Initialized	25	Pump Self Test Error	24
		Pump Reset to Defaults	26

Clinical Event	Code	Clinical Event	Code
Download Failure	27	Hourly Maximum	28
Refill Divide Error	29	Refill Invalid Calculation	30
Divide by 0	31	EEPROM Error	32
Bad EEPROM	33	Main Battery Low	34
Main Battery Depleted	35	Back-up Battery Low	36
Temporary Basal Rate	37	Check Pump Status	38
Download Complete	39	Invalid Concentration	40
Invalid Stroke Volume	41	Battery Removed	42
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

Pump Implantation

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 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 µL sterile pipette (available non sterile from 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) MiniMed refill needles, MMT-4102
- Three (3) 18 gauge needles
- One (1) Implant Worksheet
- One (1) Back-up Pump System: PPC, Pump and Side Port Catheter

Solutions

- One (1) bottle of sterile water, room temperature
- One (1) vial 10 mL rinse buffer (RB)
- Four (4) vials 10 mL Aventis HOE 21 PH U-400 INSULIN

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 implanting the patient. As this is a surgery, all supplies and required equipment should be prepared in accordance with the institution's approved sterile procedures.

> **WARNING**
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> **When you remove the Pump from the sterile box, <u>do not remove</u> 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. <u>DO NOT TRY TO REPLACE THE TUBING BACK ON THE PUMP OUTLET,</u> or you can displace or damage the "O" ring placed around the outlet.**

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.

Figure 6: Filling the Hub of the Refill Needle

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. Press down with at least one-half pound of force to open the inlet valve. As the needle passes through the septum and seats in the valve, you can feel approximately 0.5mm of movement as the valve is opened.

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.

Rinse the Pump with insulin (IN1)

11. Remove the second refill syringe from the refill kit package.

12. 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".

13. Draw 20 mL of INSULIN (two vials) into the refill syringe.

14. Remove the 18 gauge needle and expel all air bubbles in the syringe.

15. Close the stopcock.

16. 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.

17. Shake vigorously for a minimum of 30 seconds to degas the INSULIN.

18. Point the syringe tip upward and slowly open the stopcock to vent the syringe.

19. Release the locking ring on the refill syringe.

20. Expel air in the syringe and carefully observe to ensure no air bubbles remain in the syringe. If air bubbles are noted, repeat steps 15 - 20.

21. Fill the hub of the refill needle with INSULIN and attach it to the stopcock.

22. Prime the needle and close the stopcock.

23. Refill the fill port with the 3 mL RINSE BUFFER syringe, as needed, to maintain the fluid barrier.

24. Use the "IN1" syringe containing the degassed INSULIN to fill the Pump.

OPTIONAL

25. Use this step only if the plunger is not moving forward while filling the reservoir.

26. 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).
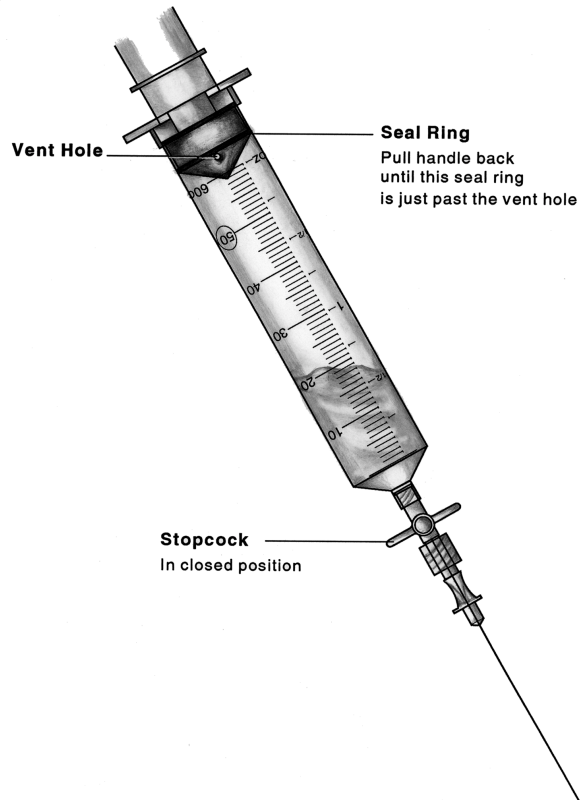

Figure 7: Venting the Syringe Head Space

27. With the stopcock closed, press the refill needle into the Pump fill port.

28. Open the stopcock. Maintain downward pressure on the barrel of the syringe to ensure the inlet valve of the Pump remains open.

> **WARNING**
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>
> **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.**

29. 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.

30. 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.

31. Press the refill needle back into the Pump fill port with the stopcock closed.

32. 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.

33. Close the stopcock and remove the syringe.