Medtronic MiniMed 2007D Implantable Insulin Pump System

Patient Manual

This device is protected under one or more of the following U.S. Patents:

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

U.S., international, and foreign patent applications are pending.

℞ Only

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CHAPTER 1

The Medtronic MiniMed 2007D Implantable Insulin Pump System

Introduction

This manual is a reference guide for both you and your support network of family and friends. It is important that other people in your support network know how to use the Medtronic MiniMed 2007D Implantable Insulin Pump System, so they can be of assistance if the need arises.

Throughout the manual you will see note comments which provide important information about the Medtronic MiniMed 2007D System. If you have a question not covered in the manual, please talk with your doctor. Your doctor knows the most about your medical condition and can give you the best answers to your questions about your diabetes treatment.

> *NOTE: Before you can use the Medtronic MiniMed 2007D System, you will be trained. This training will teach you about implantable insulin pump therapy, and how to operate the Medtronic MiniMed 2007D System. This manual can be used to help, but not replace, your training.*

Medtronic MiniMed help line

Medtronic MiniMed provides a 24-hour help line for assistance. Clinical Services personnel are trained to answer questions you may have about the Medtronic MiniMed 2007D System.

When calling from:	Primary number	Alternate number
Outside the United States	1-818-576-5040	1-818-362-5958
Within the United States	1-800-826-2099	1-818-362-5958

Description of the system

The Medtronic MiniMed 2007D Implantable Insulin Pump System (see Figure 1) is an "open-loop" system, which means you must test your blood glucose in accordance with the method and frequency recommended by your physician. Based on the results of your blood glucose testing, you can program the Pump with desired rates of delivery by using the Personal Pump Communicator (PPC).

The system consists of four components:

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

Implantable Insulin Pump

The Implantable Insulin Pump (Pump) is a round disc, 8.1 cm (3.2 inches) in diameter and 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. The Pump contains an insulin fill port, located at the center of the disc. The fill port is used for rinsing and filling the Pump with insulin, and for diagnostic procedures.

Figure 1: The Implantable Insulin Pump

The Pump has six major components: the medication reservoir, the pumping mechanism, the antenna, the microelectronics, the battery, and the tone transducer. Figure 2 shows the interior of the Pump.

Figure 2: Interior of the Implantable Insulin Pump

Medication reservoir

The medication reservoir holds the insulin and is refilled with a special syringe through the Pump fill port.

Pumping mechanism

The pumping mechanism takes insulin from the medication reservoir and delivers it through a catheter into your body. The pumping mechanism delivers the same amount of insulin every time it pumps. The amount of insulin delivered in each "stroke" of the pump mechanism is called the stroke volume.

Antenna

The Pump antenna receives the radio signals from the PPC and delivers the PPC's programmed message to the microelectronics of the Pump.

Microelectronics

The microelectronics are designed to control the pumping mechanism so that you receive the amount of insulin you have programmed the Pump to deliver. You tell the microelectronics what to do by using your PPC. The

microelectronics also store pump specifications and programming history information in its memory.

Battery

The battery supplies power to the pumping mechanism and microelectronics. It is a lithium carbon mono-fluoride battery specially designed for the Implantable Insulin Pump.

Tone transducer

The tone transducer is a Pump safety feature. It emits audible beeps to confirm your Pump is operating properly. It also alerts you when your Pump needs attention.

Side Port Catheter

The Side Port Catheter (catheter) is a soft plastic tube, made of polyethylene-lined silicone rubber. The Catheter delivers insulin from the Pump into your peritoneal cavity. Intraperitoneal insulin is rapidly absorbed by your body and is used to regulate your blood sugar. Your doctor can use the Catheter's radio-opaque stripe to help locate it on an X-ray.

The Catheter has a subcutaneous part and an intraperitoneal part as shown in Figure 3.
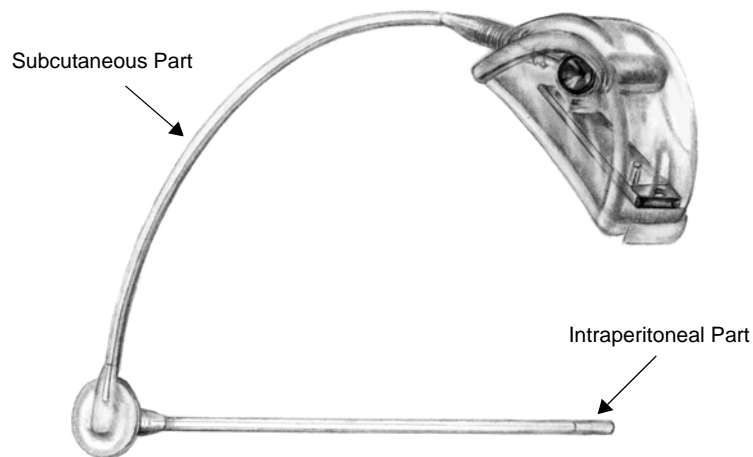
Figure 3: Side Port Catheter

Personal Pump Communicator (PPC)

The Personal Pump Communicator (PPC) is a hand-held device which allows you to send commands to your Pump and receive Pump information using (RF telemetry) radio waves. The PPC is 8.9 cm (3.5 inches) long, 7.0 cm (2.8 inches) wide and 2.0 (0.8 inches) thick and weighs 115 grams (4.06 ounces). The PPC uses one AA (1.5) volt alkaline battery as the main power source. The PPC has an easy-to-read screen. Programming information is entered using a four button keyboard. The four buttons and their functions are described in Chapter 4. See Figure 4.

Figure 4: Personal Pump Communicator (PPC)

To send a command to the Pump, place the PPC near the Pump. With your PPC you can:

- Deliver an immediate, square wave or dual wave insulin bolus to compensate for meals. Boluses can be programmed by reading the screen or listening to beeps (audio bolus)

- Deliver one or many basal rates in a daily pattern

- Preprogram three different daily basal patterns

- Deliver a temporary basal rate

- Suspend the Pump
- Record Personal Events
- Program an Automatic Off

Your PPC also stores important information in its memory (120 days of data). This information includes:

- Current time and date
- Time, date and amount of the last meal bolus
- Current basal rate
- Daily insulin totals (basal and bolus)
- Clinical history
- Insulin amount remaining in the Pump
- Maximum bolus allowed
- Maximum basal rate allowed
- Insulin concentration used

NOTE: The PPC issued to you by your doctor can only be used with your Implantable Insulin Pump. Do not attempt to use any other PPC to program your Pump, unless specifically instructed to do so by your doctor.

Special insulin

The Medtronic MiniMed 2007D Implantable Insulin Pump System uses a special insulin, purified and concentrated exclusively for implantable pump use. The insulin is HOE 21 PH U-400, manufactured by Aventis. Only Aventis HOE 21 PH U-400 may be used in the Medtronic MiniMed 2007D Implantable Insulin Pump System.

Safety features

Pump safety features

Safe telemetry

Your Pump will respond only to telemetry commands from your PPC. Your Pump will not change when exposed to electromagnetic fields, such as microwave ovens, garage door openers, airport security systems, television or video remote controls.

Alarms

The most important safety feature of your Pump is its self-checking circuitry. If your Pump is not working properly, it will signal you with an alarm message on the PPC screen and then automatically turn itself off. This feature ensures that your Pump will always deliver insulin in a controlled, predictable manner.

Negative pressure reservoir

The Pump reservoir has a negative pressure (vacuum) which will draw in fluids. In the event of a Pump malfunction, this vacuum assures your insulin will stay in the reservoir. There are multiple safety features to assure that your body fluids won't enter the Pump. Only the pumping mechanism can overcome this negative pressure and deliver insulin to your body.

PPC safety features

Programming sequence

In order to send a command to your Pump, your PPC must be properly positioned nearby and a series of programming steps must be followed.

Maximum dosage limits

Your doctor will program maximum dose limits into your PPC. The programmed maximum basal rate and bolus amount will protect you from an insulin overdose, in the event of a programming mistake.

Alarms and messages

Your PPC prompts you with many easy-to-read messages on the screen. Also, the PPC emits beeps to notify you of certain conditions, such as battery status, programming errors, and a low or empty pump reservoir. These messages and alarms are discussed further in Chapter 5, entitled, *"Alarms and Messages."*

CHAPTER 3   Implanting the Medtronic MiniMed 2007D Pump System

Hospitalization

You will be admitted to the hospital to have your Medtronic MiniMed 2007D Implantable Insulin Pump surgically implanted and stabilized. Your Pump System will also be programmed and tested prior to your leaving the hospital.

Your hospitalization will consist of three types of procedures:

- Pre-Operative Procedures
- Implantation Procedures
- Post-Operative Procedures

Pre-operative procedures

You will have blood drawn, be given diagnostic procedures, and possibly other tests before your scheduled surgery date. You should ask your doctor what tests will be required before your Pump is implanted. You may also meet with an Anesthesiologist or Surgeon prior to the surgery.

The Pump will be implanted in your abdominal area. Your doctor will discuss the exact location of implantation with you. The choice of a Pump site may depend upon the catheter location and the size and shape of your body or whether or not you have had any previous abdominal surgery, such as an appendectomy.

The Pump may be implanted using either local or general anesthesia. This decision will be made by you, your doctor, the Surgeon, and the Anesthesiologist. If local anesthesia is chosen, you will be awake during the implantation but the pump site will be numbed. Under general anesthesia, you will be kept asleep during the procedure by the anesthesiologist.

Implantation procedures

The Surgeon will make an incision through your skin and create a "pocket" in which to place the Pump. The Pump is then inserted under the fatty tissue just beneath your skin. The Surgeon will then secure the Pump in your tissue to prevent movement. A very small opening will be made in your abdominal muscle wall through which the Surgeon will thread the Side Port Catheter into your peritoneal cavity. After the Catheter is positioned and the Pump is secured, the Surgeon will use sutures to close the incision in your skin. Bandages are used to protect the incision until it heals. Some Surgeons may want you to wear a binder over the implant site for a short time to minimize post-operative swelling.

Post-operative procedures

The length of your hospital stay will be determined by your doctor. Your stay will depend upon how quickly you recover, and how quickly you learn to use the Medtronic MiniMed 2007D Implantable Insulin Pump System.

Before your admission to the hospital, your doctor or a nurse will teach you how to use your PPC to program the Pump. Before leaving the hospital, you must become proficient in understanding and using your PPC to program the Pump. You should:

- Fully understand how to use your PPC.

- Demonstrate appropriate responses to warning messages and alarms from your PPC.

- Be able to identify signs and symptoms your doctor wants you to report.

- Have completed a Patient Emergency Information Card, which indicates you have an implantable pump and provides emergency phone numbers.

- Ask your doctor to complete and return your Device Registration Card to Medtronic MiniMed. This card contains the Pump and Catheter serial numbers, which are needed for device tracking by Medtronic MiniMed.

- Schedule an appointment with your doctor for your first follow-up visit.

- Read Chapter 5, "*Alarms and Messages,*" and ask your doctor to explain anything you don't understand.

Follow-up

Before you leave the hospital, your doctor will schedule an appointment for your first follow-up office visit. Your healthcare team will also keep in close contact with you during the first few weeks following implantation. Frequent adjustments in your insulin delivery are often required for several weeks following implantation.

> *NOTE: ALWAYS keep your PPC with you. During office visits, a member of the healthcare team will check the status of your Pump. Only YOUR PPC can be used to check YOUR Pump.*

Your post-implant recovery will be similar to recovery from other surgical procedures. You will need to obtain adequate rest, eat a nutritious diet, and avoid individuals who are suffering from infections or viruses. Recovery times vary among individuals, but most people recover fully in a few weeks. Your physician will ask you to call if you are not feeling well, particularly if you have an elevated temperature or if you notice any redness or drainage around your incision site.

Pump refills

Insulin used with the Implantable Pump

Aventis, located in Frankfurt, Germany, is the manufacturer of the insulin used in your Implantable Insulin Pump. This insulin, HOE 21 PH U-400, is specifically designed for implanted pumps. **No** other insulin should be put in your Pump.

Pump refill procedure

It is important that the time between your Pump refills should not exceed 90 days. Refilling your Pump is a sterile procedure. Your doctor or a nurse will first disinfect your skin directly over the Pump. All equipment that will touch your skin during the refill procedure is sterile to minimize the risk of infection.

Your doctor or a nurse may now numb the disinfected skin area with a local anesthetic. A short needle will then be inserted through your skin to locate the fill port of the Pump. Then a longer needle will be inserted into the Pump fill

port through the inside of the shorter needle. The doctor or nurse will then empty unused insulin from the Pump and refill it with new Aventis, HOE 21 PH U-400 insulin.

CHAPTER 4   **Programming your Pump**

Introduction

You will program your Implantable Insulin Pump with your PPC. The PPC transmits information by (RF telemetry) radio waves to your Pump. With your PPC you can:

- Deliver an immediate, square wave or dual wave insulin bolus to compensate for meals. Boluses can be programmed by reading the screen or listening to beeps (audio bolus)

- Deliver one or many basal rates in a daily pattern

- Preprogram three different daily basal rate patterns

- Deliver a temporary basal rate

- Suspend the Pump

- Program an Automatic Off

- Adjust the tone frequency of the PPC and the audible alarms of the Pump.

NOTE: Your PPC has been designed for easy use (See Chapter 4 for a list of the PPC commands). You must follow a specific sequence of steps and hold the PPC near the Pump to deliver a command. Therefore, you cannot unintentionally program your Pump.

Your PPC has been specifically pre-programmed for use with your Pump. Do not use another PPC to program your Pump. You must keep your PPC with you at all times because it is the only way to program your Pump.

Remember, you must measure your blood sugar at least four times each day, according to the method recommended by your doctor. You must then use the

results of your blood sugar tests to determine the appropriate dose of insulin to be delivered by your Pump.

PPC screen icons

Your PPC has an easy-to-read dot matrix liquid crystal display (LCD). The main PPC 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:

Icon	Description
	The bell icon is displayed when the PPC receives a RF telemetry message from the Pump. The icon may indicate the Pump or PPC has detected a failure, or the Pump is in a "SUSPEND" mode or "STOPPED."
	The reservoir icon is composed of 4 segments that indicate how full the Pump reservoir is, based on the history of the Pump delivery.
	The PPC shows a "spinning" icon while insulin delivery is in progress. When the Pump delivers a bolus amount, the pattern will show three delivery segments. When the Pump delivers a basal rate, the pattern will show one delivery segment. When the Pump is not delivering, all four segments will be displayed.

PPC buttons

PPC programming information is entered using four buttons:

Buttons	Description
SEL	Means SELECT. The **SEL** button allows you to step through and view each of the option screens.
ACT	Means ACTIVATE. The **ACT** button activates programming changes you wish to make. As a safety check, you must press **ACT** to complete any programming changes. You will always hear a single beep after you have successfully activated a change.
▲ UP ARROW	Allows you to make changes to the screen settings by scrolling to higher values. You must then press the **ACT** button for a change to be activated. This button has a **Sound Icon**. When the "AUDIO BOLUS" feature is turned on, the ▲ button allows you to program an Audio Bolus.
▼ DOWN ARROW	Allows you to make changes to the screen settings by scrolling to lower values. You must then press the **ACT** button for a change to be activated. This button has a **Light Icon** which turns on the backlight. With the display illuminated, you can program your Pump in dark areas. The backlight remains on for 4 seconds after each ▼ press.

Communicating PPC

1. When commands are programmed the PPC will talk to the Pump. When this occurs the following screen will be displayed.

2. The word COMMUNICATING will blink to indicate a communication is taking place.

```
PPC
COMMUNICATING
```

Main programming screen

The Main programming screen is used to program features you will use every day, such as a Meal Bolus or Basal Rate, or putting your Pump in the Suspend mode.

Programming a bolus

Using the PPC, you can program the Pump to deliver a bolus of insulin whenever you need it. The Pump System has several special features which allow you to customize the programming and delivery of a bolus:

- Immediate Bolus (programmed by reading the PPC screen or listening to beeps, using the Audio Bolus)

- Square Wave Bolus

- Dual Wave Bolus

NOTE: To program a Square Wave or Dual Wave Bolus, you must turn on the Variable Bolus programming option (program "ON" in the "SETUP II" menu). Otherwise, only an Immediate Bolus can be given. The Variable Bolus option is programmed by your doctor.

Set an immediate bolus (Variable Bolus option is "off")

1. From the Time/Date screen, press **SEL** until the "BOLUS" screen is displayed. The Time and Date will be flashing, and the last bolus is displayed.

```
08:23          JAN 02
BOLUS
  IMM           EXT
  10 U          _ _ U
  PROG          _ _
```
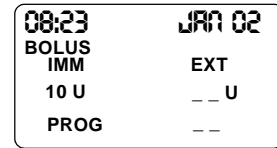
2. Press **ACT** and "SET BOLUS" appears, and the dashes or previous bolus under "IMM" start flashing.

```
SET BOLUS
  IMM
  _ _ U
```
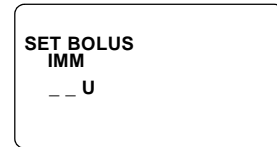
3. Use the ▲ and ▼ buttons to enter an immediate bolus amount.

4. Press **ACT** and the screen shows "CONFIRM IMM." If the number you entered for the immediate bolus is correct, press **ACT** to confirm it. This value will now be programmed into the Pump. If the number was not correct, wait for the screen to return to Time/Date and then repeat this procedure to enter the correct value.

```
CONFIRM
  IMM
  2.6U
```
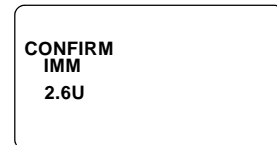
5. Place the PPC near the Pump to complete the programming. The PPC will beep once and display 0.0 units.

```
PPC
COMMUNICATING
```

6. If the Alarm Feedback feature is "ON," the Pump will beep during each of the first five strokes. The PPC will beep when the bolus delivery is complete. Three segments of the insulin delivery icon will be displayed and will spin slowly during the bolus delivery. By pressing **SEL** you can see the amount of insulin being delivered.

```
08:23         JAN 04
BOLUS         0.0U
```

Set an immediate bolus (Variable Bolus option is "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.

```
08:23          JAN 04
BOLUS
  IMM          EXT
 _ _U          _ _U

                _ _
```
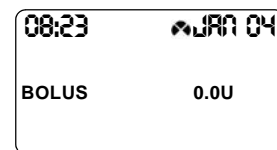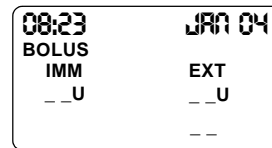
2. Press **ACT** and "SET BOLUS TYPE" appears. Use the ▲ and ▼ buttons to choose "NORMAL."

```
SET
BOLUS TYPE

  NORMAL
```

3. Press **ACT** and "IMM" appears with the dashes underneath flashing.

4. Use the ▲ and ▼ buttons to enter an immediate bolus amount

```
SET BOLUS
  IMM
  _ _U
```

5. Press **ACT** and the screen shows "CONFIRM IMM."

6. If the number was not correct, wait for the screen to return to Time/Date and then repeat this procedure to enter the correct value.

```
CONFIRM
  IMM
  2.6U
```
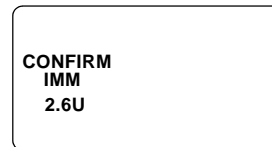
7. If the number you entered for the immediate bolus is correct, press **ACT** to confirm it. Place the PPC near the Pump to complete the programming.

```
PPC
COMMUNICATING
```
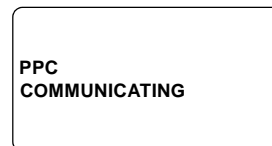
8. The PPC will beep once and display the amount of insulin delivered. If the Alarm Feedback feature is "ON," the Pump will beep during each of the first five strokes.

```
08:23       ≡ ↷JAN 04

BOLUS          0.0U
```
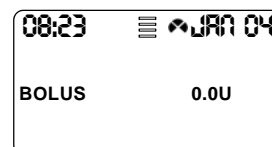
9. The PPC will beep when the bolus delivery is complete. Three segments of the insulin delivery icon will be displayed and spinning slowly during the bolus delivery. By pressing **SEL** you can see the amount of insulin being delivered.

Set a Square Wave bolus

A Square Wave Bolus is delivered evenly over a time period you set, from 30 minutes to 4 hours. A Square Wave Bolus is useful during long meals, high fat meals, or if you have gastroparesis. During a Square Wave Bolus, your Basal Rate insulin continues to be delivered.

To access Square Wave Bolus you must first turn the Variable Bolus feature "ON" in the SET UP II menu.

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.

```
08:23          JAN 04
BOLUS
   IMM           EXT
   10U          _ _U
   PROG          _ _
```

2. Press **ACT** and "SET BOLUS TYPE" appears.

3. Use the ▲ and ▼ buttons to choose "SQUARE".

```
SET
BOLUS TYPE

   SQUARE
```

4. Press **ACT** and the dashes underneath "EXT" will appear flashing.

```
SET BOLUS
   IMM           EXT

   _ _U          _ _U
```

5. Use the ▲ and ▼ buttons to enter an extended bolus amount.

```
SET BOLUS
   IMM           EXT

   _ _U          4.0U
```

6. Press **ACT** and dashes will appear under the bolus amount you just entered.

```
SET BOLUS
IMM              EXT

   _ _U          4.0U
                  --
```

7. Use the ▲ and ▼ buttons to enter a <u>time duration</u> that you would like the Square Wave Bolus to last.

```
SET BOLUS
 IMM        EXT
 _ _U       4.0U
            02:00
```

8. Press **ACT** and the screen shows "CONFIRM EXT" asking you to confirm the <u>extended bolus</u> and <u>time duration</u>.

```
CONFIRM
 IMM        EXT
 _ _U       4.0U
            02:00
```

9. If the numbers you entered are correct, press **ACT** to confirm them. These values will now be programmed into the Pump. If either number is not correct, wait for the screen to return to Time/Date and then repeat this procedure to enter the correct values.

10. Place the PPC near the Pump to complete the programming.

```
PPC
COMMUNICATING
```

11. The PPC will beep once and display the amount of insulin being delivered. If the Alarm Feedback feature is "ON," the Pump will beep during each of the first five strokes.

```
08:23      ≡ ✒JAN 04

BOLUS          0.0U
```

12. The PPC will beep when the bolus delivery is complete. Three segments of the insulin delivery icon will be displayed and will spin slowly during the bolus delivery. By pressing **SEL** you can see the amount of insulin being delivered.
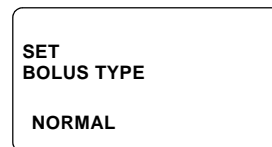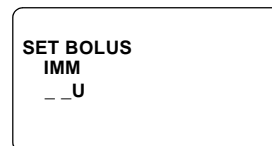
Set a Dual Wave bolus

Variable Bolus Option Must be "ON."

The Dual Wave Bolus allows you to deliver an Immediate Bolus immediately followed by a Square Wave Bolus.

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

```
08:23          JAN 04
BOLUS
  IMM          EXT
  _ _U         _ _U

  PROG         – –
```

2. Press **ACT** and "SET BOLUS TYPE" appears.

3. Use the ▲ and ▼ buttons to choose "DUAL".

```
SET
BOLUS TYPE

  DUAL
```

4. Press **ACT** and "IMM" appears with the dashes underneath flashing.

5. Use the ▲ and ▼ buttons enter an immediate bolus amount.

```
SET BOLUS
  IMM

  2.0U
```

6. Press **ACT** and the dashes underneath "EXT" will appear flashing.

7. Use the ▲ and ▼ buttons enter an extended bolus amount.

```
SET BOLUS
  IMM          EXT

  2.0U         2.0U
```

8. Press **ACT** and dashes will appear under the extended bolus amount you just entered.

```
SET BOLUS
  IMM          EXT

  2.0U         2.0U
```

9. Use the ▲ and ▼ buttons to enter a time duration that you would like the extended bolus to last.

```
SET BOLUS
  IMM          EXT

  2.0U         2.0U

               02:00
```

10. Press **ACT** and the screen shows "CONFIRM" asking you to confirm the immediate bolus, extended bolus, and time duration.

```
CONFIRM
 IMM        EXT
 2.0U       2.0U
            02:00
```
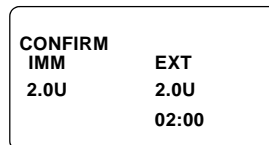
11. If the numbers you entered are correct, press **ACT** to confirm them. These values will now be programmed into the Pump. If any number is not correct, wait for the screen to return to Time/Date and then repeat this procedure to enter the correct values.

```
PPC
COMMUNICATING
```

12. Place the PPC near the Pump to complete the programming. The PPC will beep once and display the amount of insulin being delivered.

```
08:23      ≣✿ JAN 04


BOLUS          0.0U
```
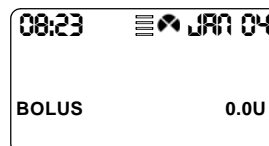
13. If the Alarm Feedback feature is "ON," the Pump will beep during each of the first five strokes.

14. The PPC will beep when the bolus delivery is complete. Three segments of the insulin delivery icon will be displayed and spinning slowly during the bolus delivery. By pressing **SEL** you can see the amount of insulin being delivered.

Review the bolus history

You can review the bolus type, bolus amount, time and day of your last 512 insulin boluses.

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.

```
08:23          JAN 04
BOLUS
 IMM        EXT
 _ _U       _ _U
 PROG       _ _
```

2. Press the ▼ button once to display the previous bolus and the time and date it was delivered. Each additional ▼ press will display the next previous bolus delivery.
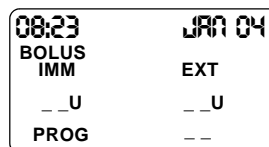
Suspend mode

Suspend Mode allows you to cancel bolus programming. In suspend mode the pump will still deliver a basal rate of approximately 0.2u/hr.

1. From the Time/Date screen press **SEL** until the "SUSPEND PUMP" screen is shown.

2. Press **ACT**.

```
┌─────────────────────┐
│                     │
│  SUSPEND PUMP       │
│                     │
│                     │
└─────────────────────┘
```

3. Place the PPC near the Pump to complete the programming. When communication is finished the Pump will beep 3 times.

```
┌─────────────────────┐
│                     │
│  PPC                │
│  COMMUNICATING      │
│                     │
└─────────────────────┘
```

4. All four segments of the insulin delivery icon will be displayed.

5. To restart the Pump, press **SEL** and **ACT**.

```
┌─────────────────────┐
│ 08:13  ◀≣✪OCT 02    │
│ PUMP SUSPENDED      │
│                     │
│                     │
└─────────────────────┘
```
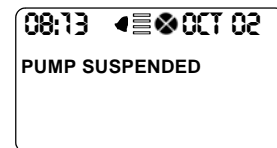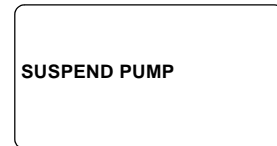
Program basal rates

Your Basal Rate provides you with approximately 50 percent of your daily insulin needs. A Basal Rate is normally delivered all the time, throughout the day and night. Your PPC allows you to tailor your Basal Rates to meet your changing insulin needs throughout the day. If you want to, the PPC can deliver a different Basal Rate every 30 minutes throughout the day. For some people, one Basal Rate will work fine. Other people find that multiple Basal Rates will help them respond better to their insulin needs. You should discuss with your doctor the number and amount of Basal Rates that are best for you.

Set one basal rate

1. From the Time/Date screen press **SEL** until the "BASAL RATE" screen is displayed. Basal Delivery Pattern "A" and the current Basal Rate appear. The word "NOW" also appears and is flashing.

```
┌─────────────────────┐
│                     │
│ BASAL RATE : A  NOW │
│ 00:00        0.2U/H │
│                     │
└─────────────────────┘
```
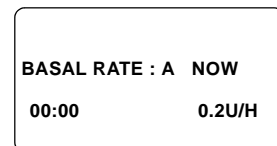
2. Press **ACT** and "1" appears to the right of "A" indicating that you will now program the first Basal Rate "1" in Basal Delivery Pattern "A." The Basal Rate is flashing.

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

3. Use the ▲ and ▼ buttons to enter a new Basal Rate.

4. Press **ACT** and the screen displays "SET RATE," indicating you will now program a start time for Basal Rate "2" The time is flashing.

```
SET RATE
BASAL RATE: A          2
00:30              _ _U/H
```

5. Use the ▲ and ▼ buttons to change time to dashes.

6. To enter one Basal Rate, press **ACT** 2 times.

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

7. Place the PPC near the Pump to complete the programming. The screen will display PPC communicating.

```
PPC
COMMUNICATING
```

8. The screen will calculate and briefly display the total daily Basal insulin from the Basal Rates you have programmed.

```
24 HOUR TOTAL
        4.8U
```

Set multiple basal rates

1. From the Time/Date screen press **SEL** until the "BASAL RATE" screen is displayed. Basal Delivery Pattern "A" and the current Basal Rate appear. The word "NOW" also appears and is flashing.

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

2. Press **ACT** and "1" appears to the right of "A" indicating you will now program Basal Rate "1" in Basal Delivery Pattern "A." The Basal Rate is flashing.

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

3. Use the ▲ and ▼ buttons to enter a new Basal Rate.

4. Press **ACT** and the screen displays "SET RATE", indicating you will now program a start time for Basal Rate "2" The time is flashing.

```
SET RATE
BASAL RATE : A       2
04:30            _ _U/H
```

5. Use the ▲ and ▼ buttons to enter a new start time.

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

6. Press **ACT** and "SET RATE" and "2" appears, indicating you will now program Basal Rate "2" in Basal Delivery Pattern "A." The Basal Rate is flashing.

```
SET RATE
BASAL RATE: A        2
05:00            _ _U/H
```

7. Use the ▲ and ▼ buttons to enter a Basal Rate and start time for Basal Rate #2.

8. Continue this procedure until all desired Basal Rates and start times are programmed. Then press ▼ and **ACT**.

```
PPC
COMMUNICATING
```

9. Place the PPC near the Pump to complete the programming.

10. The screen will calculate and briefly display the total daily Basal insulin from the Basal Rates you have programmed.

```
24 HOUR TOTAL
        4.8U
```

NOTE: To set multiple basal profiles in the other patterns (A, B, C), select the pattern in Setup II menu and follow the above procedure.

Set a temporary basal rate

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

1. From the Time/Date screen press **SEL** until the "TEMP BASAL" screen is displayed.

```
TEMP BASAL
_ _           _ _U/H
```

2. Press **ACT** and "SET DURATION" appears with the Temporary Basal Rate duration flashing.

```
SET DURATION
TEMP BASAL
 00:30           _ _U/H
```

3. Use the ▲ and ▼ buttons to enter a Temporary Basal Rate duration.

4. Press **ACT** and "SET AMOUNT" appears with the Temporary Basal Rate flashing.

```
SET AMOUNT
TEMP BASAL
 00:30           1.5U/H
```

5. Use the ▲ and ▼ buttons to enter the Temporary Basal Rate, then press **ACT** again.
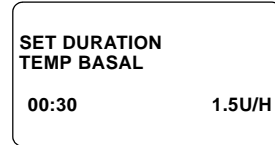
```
PPC
COMMUNICATING
```

6. Place the PPC near the Pump to complete the programming.

NOTE: When your Pump is delivering a Temporary Basal Rate, pressing SEL will display "TEMP BASAL." This will remind you that the Temporary Basal Rate feature is currently active.

Stop a temporary basal rate

1. From for the Time/Date screen press **SEL** until the "TEMP BASAL" screen is displayed.

```
SET DURATION
TEMP BASAL

00:30              1.5U/H
```

2. Press **ACT** and "SET DURATION" will appear with the time flashing.

3. Press the ▼ button until the time is set to dashes, then press **ACT**.

```
PPC
COMMUNICATING
```

4. Place the PPC near the Pump to complete the programming.

5. When the communication is finished, "SET AMOUNT" will appear with the dashes flashing. Allow the PPC to return to the Time/Date screen or press **ACT**. The Temporary Basal Rate is now canceled.

```
SET AMOUNT
TEMP BASAL
– –              _ _U/H
```

Personal events

This feature appears in the Main menu if it has been activated to "ON" in the Pump Setup II menu. The Personal Event menu allows you to enter important "events" during the day.

Preset events

You can enter the following preset codes for these popular events:

- 1 = meal
- 2 = snack
- 3 = sick
- 4 = exercise

Additional events

Codes A, B and C can be used to record other events. Be sure to document the events listed for A, B, and C.

NOTE: Events that happened in the past or present can be entered.

1. From the Time/Date screen, press **SEL** until the "SET PERSONAL EVENTS" screen is displayed.

```
EVENT
– –
```

2. Press **ACT** and the screen will change to "SET EVENT" with "MEAL" flashing.

3. Use the ▲ and ▼ buttons to select the event you want to enter: MEAL, SNACK, SICK, EXERCISE, A, B, C.

```
SET
EVENT
MEAL
```

4. Press **ACT** and the time will appear flashing.

5. Use the ▲ and ▼ buttons to enter the time that the event occurred.

```
08:32 AM
SET TIME
EVENT
MEAL
```

6. Press **ACT** to enter the event in the PPC memory.

History

The History menu allows you to look at important Pump data, such as the amount of insulin remaining in the Pump reservoir or total insulin delivery since the last refill. The History menu contains the following options: Med Remaining, Insulin Total Basal Bolus, Clinical Hist PPC, Clinical History Pump, Est Pump Battery. To read Pump Data perform the following steps.

From the Time/Date screen, press **SEL** until the "HISTORY" screen is displayed.

```
HISTORY
```

1. Press **ACT** and the screen will change to "READ PUMP DATA" with the entire screen flashing.

```
READ PUMP DATA
• • • • • • • • • • • • • • •
• • • • • • • • • • • 10057
```
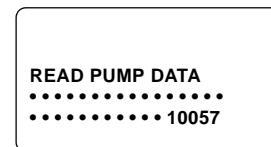
2. Press **ACT**, place the PPC near the Pump. History data will be transferred to the PPC.

```
PPC
COMMUNICATING
```

3. The screen will automatically change to "MED REMAINING." The amount of insulin in the Pump reservoir is reported in units.

```
MED REMAINING
 7263U
```

4. Press **SEL** and the screen will change to "INSULIN TOTAL." The amount of Basal Rate and Bolus insulin delivered is reported for the day indicated.

```
                    JAN 02
INSULIN    TOTAL
BASAL      BOLUS
 9U         22U
```

5. Press the ▼ button to review insulin delivery rates for other days.

6. Press **SEL** and the "CLINICAL HISTORY PPC" screen is shown. Ask your doctor what the numbers mean.

```
6:26            JAN 02
CLINICAL  HISTORY
PPC
 11
```

7. Press the ▼ button to review other days.

8. Press **SEL** to find the "CLINICAL HISTORY PUMP" screen. Ask your doctor what the numbers mean. Press the ▼ button to review other days.

```
6:26            JAN 02
CLINICAL  HISTORY
PUMP
 14
```

9. Press **SEL** and the screen will change to the "EST PUMP BATT" display. This screen indicates the energy left in the Pump battery. Ask your Physician what the numbers mean.

```
                    JAN 02
EST PUMP BATTERY
NO LD           LD
2.9U           2.7U
```

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

```
EXIT HISTORY
```

Pump setup

This screen permits access to other Pump "SETUP" features. These features are normally programmed for you by your doctor or nurse. To reach the "SETUP PUMP" menu, press **SEL** until the "SETUP PUMP" screen is displayed, then **ACT** to access the SETUP screens.

Time and date

The time and date settings must be correct. The PPC uses the time and date to calculate your total daily insulin and display Pump history.
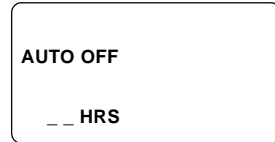
1. From the Time/Date display, press **SEL** until the "SETUP PUMP" screen is displayed.

```
08:32          JAN 02
SET               2004
TIME-DATE
```

2. Press **ACT** two times. The hour digits will begin flashing. Use the ▲ and ▼ buttons to select the current hour.

3. Press **ACT** again, and the minute digits will begin flashing. Use the ▲ and ▼ buttons to select the current minute.

4. Repeat this programming process again to select the current year, month and day.

5. At the conclusion of programming press **ACT**, and then place the PPC near the Pump. When the communication process is complete, the PPC will automatically move to the next screen, "AUTO OFF."

```
PPC
COMMUNICATING
```
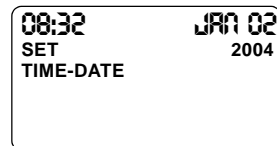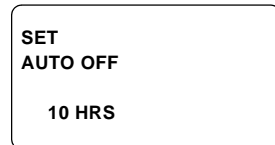
Auto off

"AUTO OFF" sets an alarm on your PPC to remind you if you have not programmed your Pump recently. The "AUTO OFF" alarm can be set between 1 and 16 hours. To turn off the "AUTO OFF" program set the time to dashes.

1. From the "SETUP PUMP" screen, press **ACT** then **SEL**.

   ```
   AUTO OFF

     _ _ HRS
   ```

2. The screen will display "AUTO OFF" with flashing dashes. Press **ACT**.

3. Use the ▲ and ▼ buttons to select the number of hours before an Auto Off alarm occurs.

   ```
   SET
   AUTO OFF

      10 HRS
   ```

4. Press **ACT**. In this example, a time duration of 10 hours was selected. The PPC will alarm if you did not program your Pump during the past 10 hours.

5. Place the PPC near the Pump. The PPC will beep once when the communication is completed.

   ```
   PPC
   COMMUNICATING
   ```

Alarms

There are three PPC Alarm options, two audible tones (Low/High) and a vibrate mode."ALARMS" will alert you if either the PPC or Pump recognizes a problem. The vibrate only alarm provides all programming feedback from PPC with beeps.

1. Press **ACT** on the ALARMS menu to enter the "ALARMS" menu.

   ```
   ALARMS
   ```

2. Press the ▲ and ▼ buttons to select the type of alarm you want, 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 will change to "SELF TEST" and then timeout to the Time / Day screen.

```
PPC
COMMUNICATING
```

Self test

Your doctor may ask you to run a diagnostic test of your Pump System. "SELF TEST" will send messages between your PPC and Pump to check their operation.

NOTE: Notify your doctor if any of these Self Test events do not occur.

If the PPC displays a Medtronic MiniMed logo and software number, the PPC has re-started but has a low battery. Replace the battery immediately.

1. From the "SETUP PUMP" screen, press **SEL** until the "SELF TEST" screen is displayed.

```
SELF TEST
```

2. Press **ACT**.

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

```
PPC
COMMUNICATING
```

4. Verify the following events occur:

The Pump will beep four times.

The PPC backlight will turn on.

The PPC will sound a long changing tone.

The PPC will vibrate.

The PPC will beep once.

The PPC screen displays all possible icons and numbers.

5. If your PPC and Pump "pass" the Self Test, the display will change to "PPC PASSED/ PUMP PASSED." After several seconds, the screen will change back to the Time/Date screen.

```
PPC          PUMP

PASSED       PASSED
```
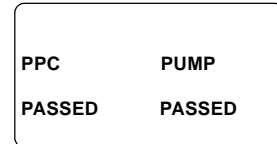
Basal delivery patterns

The PPC allows you to program three different basal delivery patterns (A, B, C). Pattern A is preset at the factory. Patterns B and C can be programmed from the "SETUP PUMP" menus. Each basal rate pattern can accept up to 48 different basal rates, one for each half-hour of the day. These are programmed from the "Basal Rate" screen in the Main Programming menu.

Basal patterns can be used to follow your normal daily routines. For example, separate patterns could be programmed for a typical work day, weekend day, and travel day.

1. From the "SETUP PUMP" screen, press **SEL** until the "DELIVERY PATTERN A" screen is displayed. Press **ACT**.

```
DELIVERY         A
PATTERN
```
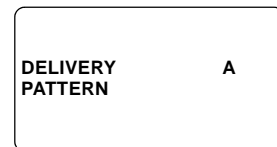
2. Press **SEL** again until the "DELIVERY PATTERN" screen appears. Press **ACT** and the screen will change to "SET DELIVERY PATTERN".

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

3. Press the ▲ and ▼ buttons to select pattern A, B or C.

4. Press **ACT**. Place the PPC near the Pump and allow the communication to complete.

```
PPC
COMMUNICATING
```

NOTE: The PPC will automatically return to the Time/Date screen. Press SEL until the "BASAL RATE" screen is displayed. The pattern you have selected will appear on this screen.

Initialize PPC to pump

This screen initializes your PPC to your Pump. Your doctor will normally perform this programming for you. Contact your doctor if you need to have your PPC replaced.

Pump Setup II

"SETUP II" is another programming menu. "SETUP II" features are used less often than the features in "SETUP." "SETUP II" features are explained in the next section.

Exit Setup Menu

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

Pump Setup II

The "SETUP II" screen allows you to program additional features into your PPC. Your doctor will normally program "SETUP II" features for you.

1. From the "SETUP" screen, press **SEL** until the "SETUP II" screen is displayed.

Turn on the audio bolus feature

The "AUDIO BOLUS" feature allows you to deliver a bolus without looking at the PPC screen. There are two step sizes you can select, 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 key press.

1. From the "SETUP II" screen, press **ACT**. The "AUDIO BOLUS" screen appears.

```
AUDIO BOLUS
                        0.4U
ON
```

2. Press **ACT**, and the screen changes to "SET AUDIO BOLUS" with "ON" flashing.

3. Use the ▲ and ▼ buttons to choose "ON" to turn on the Audio Bolus feature. Choose "OFF" to turn the Audio Bolus off. Press **ACT** again.

```
SET
AUDIO BOLUS
                        0.4U

ON
```
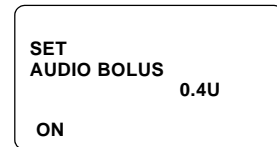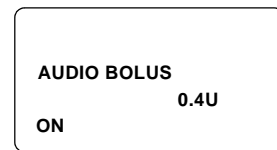
NOTE: If "OFF" is chosen, pressing the ▲ and ▼ buttons will have no effect.

4. If "ON" was chosen, the "SET STEP AUDIO BOLUS" screen appears, with a bolus amount of 0.4U flashing.

```
SET STEP
AUDIO BOLUS
                        0.4U

ON
```

5. Use the ▲ and ▼ buttons to choose a step size of either 0.4U or 0.8U.
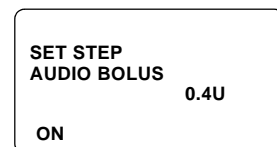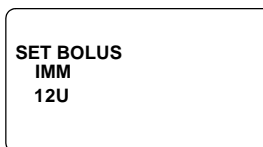
6. Press **ACT** and program the Pump. "AUDIO BOLUS" will now appear on the PPC Main Menu.

Use audio bolus in the Main Menu
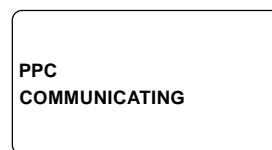
NOTE: When an immediate bolus is being delivered, the ▲ button will be disabled.

From the Time/Date screen press ▲ button. Each time the ▲ button is pressed the PPC will beep one or two times, depending upon the step size set (0.4U or 0.8U).

1. Count the number of beeps to determine how much insulin you want to program. The bolus amount delivered is determined by the step size and the number of times the ▲ button is pressed. For example: If the step size is programmed to 0.4U and the ▲ button is pressed three times, the total bolus delivered will be 1.2U (3 x 0.4U).

```
SET BOLUS
  IMM
  12U
```

2. Press **ACT**, and the beeps repeat to confirm the bolus amount you have entered.

3. Press ACT twice, and the PPC will program the Pump. The PPC will beep once when the communication is completed.
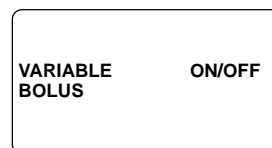
```
PPC
COMMUNICATING
```
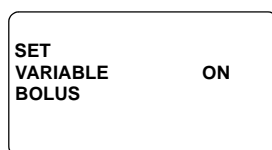
Turn on the Variable Bolus feature

If "OFF" is chosen, the Variable Bolus feature will not be available.

1. From the "SETUP II" menu, press **SEL** until the "VARIABLE BOLUS" screen is displayed.

```
VARIABLE        ON/OFF
BOLUS
```

2. Press **ACT** and the screen changes to "SET VARIABLE BOLUS." The word "ON" is flashing.

```
SET
VARIABLE        ON
BOLUS
```

3. Use the ▲ and ▼ buttons to select "ON" or "OFF."

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

5. If "ON" was chosen, the Variable Bolus option will appear in the Main Menu / Bolus screen.
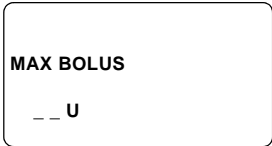
```
PPC
COMMUNICATING
```

Set a maximum bolus
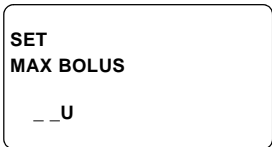
Your doctor will decide if you should use this feature. Setting a maximum bolus amount will minimize the chance of you over-delivering insulin in case you make a programming mistake.

1. From the "SETUP II" menu, press **SEL** until the "MAX BOLUS" screen is displayed.

```
MAX BOLUS

 _ _ U
```

2. Press **ACT** and the screen will change to "SET MAX BOLUS," with the dashes flashing.

```
SET
MAX BOLUS

 _ _U
```

3. Use the ▲ and ▼ buttons to enter a maximum bolus amount (0.0U to 25.0U), then press **ACT**.

```
PPC
COMMUNICATING
```

4. Place the PPC near the Pump and complete the communication. The PPC screen will automatically change to the "MAX BASAL RATE" screen and then times out to the Time/Date screen if no further action is taken.

Set a maximum basal rate

Your doctor will decide if you should use this feature. Setting a maximum basal rate will protect you from over-delivering insulin in case you make a programming mistake.

1. After setting a maximum bolus, the "MAX BASAL" screen appears with the maximum basal rate flashing.

2. Use the ▲ and ▼ buttons to enter a maximum basal rate (0.2U/h to 35.0U/h), then press **ACT**.

```
SET
MAX BASAL RATE

 0.2U/H
```
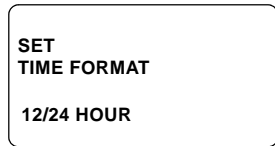
3. Place the PPC near the pump and complete the communication. The PPC screen will automatically change to the "TIME FORMAT" screen.

```
PPC
COMMUNICATING
```

Set time format

1. From the "SETUP II" screen, press **SEL** until the "SET TIME FORMAT" screen is displayed.

```
SET
TIME FORMAT

12/24 HOUR
```

2. Use the ▲ and ▼ buttons to select either a 12 hour (12:00am) or 24 hour (00.00) time format, then press **ACT**.

3. Place the PPC near the pump and complete the communication. The PPC screen will change to the "PERSONAL EVENTS" screen.

```
PPC
COMMUNICATING
```

Personal event

To activate this feature located in the Main Menu it must be "ON."

1. From the "SET UP II" screen, press SEL until the "PERSONAL EVENTS" screen is displayed.

```
PERSONAL        OFF
EVENTS
```
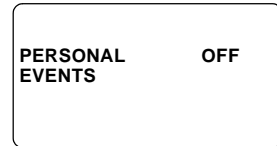
2. Press **ACT** and the "SET PERSONAL EVENTS" screen is displayed and "OFF" is blinking.

```
SET             OFF
PERSONAL
EVENTS
```
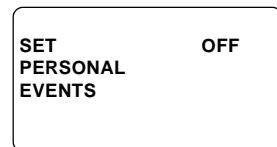
3. Use the ▲ and ▼ buttons to select "ON" or "OFF." Press **ACT**.

4. Place the PPC near the Pump and complete the communications. The PPC screen will change to "PUMP SET UP."

```
PPC
COMMUNICATING
```

Pump setup

This screen allows you to return to the Setup mode by pressing **ACT**. If you press SEL the screen will change to "EXIT SET UP MENU."

Exit Setup Menu

This screen allows you to return to the Main Menu, Time/Date screen by pressing **ACT.**

CHAPTER 5   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 pump alarms

The Implantable Insulin Pump has an alarm system which beeps when an error condition occurs. The beeps are audible through the skin and alert you that the Pump needs attention. The Pump alarm consists of 4 beeps each minute for 10 minutes then, 4 double tones each minute for 10 minutes and will then repeat pattern. Upon hearing the alarm, you need to communicate with your PPC to determine the alarm condition and call your Physician. Use the Read Pump Data option to communicate to the Pump. The alarm can be cleared by pressing **SEL** and **ACT**.

The PPC alarms

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

Some alarms can be cleared by pressing **SEL** then **ACT**. The difference between these alarms will be explained later in this chapter.

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 until the condition is cleared.

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 until the condition is cleared.

Alarm type 2

If the PPC is set to "vibrate", the vibrator will be turned on for 3 seconds every minute while the condition exists.

If the PPC is set to "audible", the PPC will emit 6 beeps, 3 times for every 30 minutes while the condition exists.

Pump alarms

Alarm feedback

The Alarm Feedback function allows you to verify the Pump and the Pump beeper are operating normally. 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.

- 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 seven years during conditions of normal use (see Chapter 9, Technical Specifications). Battery life may vary somewhat depending upon your 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 are 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

You can clear this condition and your Pump will continue to operate normally. However, you should notify your doctor as soon as possible. Your doctor will then schedule a Pump replacement, and may switch you back to conventional insulin therapy.

Depleted pump battery

When there is no longer sufficient battery energy to power the Pump, the Pump Low Battery Alarm will cease. This means that insulin delivery has stopped. You must switch to another type of insulin therapy.

System error

The Implantable Insulin Pump has a sophisticated self-monitoring system that continuously checks for circuit faults. **If the Pump detects a circuit error, it will beep and then automatically shut itself off. When this occurs, you must switch to your alternative insulin therapy established between you and your doctor.** Notify your doctor immediately of the System Error.

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 finds a malfunction. The Pump will stop delivering insulin. Clear the message by pressing **SEL** then **ACT. You must switch to your alternative insulin therapy established between you and your doctor.** Notify your doctor immediately of the Self Test Error.

PPC display	Type of alarm
PUMP SELF TEST FAIL	1

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.

PPC low battery

If the PPC main battery (AA 1.5 volt alkaline) energy is low, the following alarm display will appear:

PPC display	Type of alarm
PPC LOW BATTERY	1

You can clear this message by pressing **SEL** and then **ACT**, and then continue programming. There should be sufficient energy in the battery for at least 24 hours. For instructions on changing the battery, refer to Chapter 8, PPC Care and Maintenance.

NOTE: If while programming the Pump the PPC screen goes blank, the PPC beeps six times and then the "CHECK PUMP STATUS" message appears, the PPC (AA 1.5 volt alkaline) battery needs to be replaced. For instructions, see "Installing/Replacing the Main Battery" in Chapter 8.

Low reservoir

When the Pump calculates that less than 800 units (2 ml) 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

You can clear this message by pressing **SEL** and **ACT**, and then continue programming. You should notify your doctor of the Low Reservoir message, and schedule a Pump refill appointment as soon as possible.

Empty reservoir

When the Pump calculates that less than 400 units (1 ml) 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

You can clear this message by pressing **SEL** and **ACT**, and then continue programming. The PPC Medication Remaining function reads calculated values only, and there may still be some insulin left in the Pump reservoir. You should report this alarm to your doctor 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 a catheter blockage.

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
COMM ERROR RE-ATTEMPT	1

You should reposition the PPC near the pump, press **SEL** and **ACT.** The PPC will attempt to resume communication with the Pump.

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

Place the PPC near the pump, then press **SEL** and **ACT**. Allow the communication to complete.

NOTE: If while programming the Pump, the PPC goes blank, the PPC beeps six times and then the "CHECK PUMP STATUS" message appears, the PPC (AA 1.5V alkaline) battery needs to be replaced. For instructions, see "Installing/Replacing the Main Battery" in Chapter 8.

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, the following message is displayed:

PPC display	Type of alarm
AUTO OFF PUMP PUMP SUSPENDED	1

The Pump will initiate the internal alarm sequence of four beeps every minute for 5 minutes, then double-beep 4 times every minute for 10 minutes, then repeating the pattern. The alarm is cleared by pressing **SEL** and **ACT**, place the PPC near the Pump. The PPC will communicate with the Pump to reset the "Auto Off" duration.

Hourly maximum exceeded

If you attempt to deliver more than 2.5 times the pre-programmed bolus maximum in one hour, the following message will be displayed:

PPC display	Type of alarm
HOURLY MAX EXCEEDED	1

Press **SEL** and **ACT**, place the PPC near the Pump and allow the communication to complete. You may exceed this limit by programming another bolus within 10 minutes.

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.
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.
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.
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.
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 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. Notify your physician immediately.
PUMP SUSPENDED	The Pump is in suspend mode
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, notify your physician immediately.

CHAPTER 6   Warnings and precautions

Warnings

Electrotherapy

The Medtronic MiniMed 2007D Implantable Insulin Pump System has been tested with electrosurgical cutting tools, electrocoagulation, and cardiac defibrillation medical equipment. Typical use of this type of device has not affected the Pump. However, after such procedures you should test the Pump function (e.g., program "SELF TEST") to determine that the Pump and PPC are operating properly. If the system is not performing correctly, contact your doctor.

Diagnostic ultrasound

The Medtronic MiniMed 2007D Implantable Insulin Pump System has been tested with diagnostic ultrasound procedures. These procedures have no effect on the Pump. However, after such procedures you should test the Pump function (e.g., program a "SELF TEST") to determine that the Pump and PPC are operating properly. If the system is not performing correctly, contact your doctor.

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 System.

Diagnostic radiation

The Medtronic MiniMed 2007D Implantable Insulin Pump System has been tested with Computerized Tomography and X-ray. These procedures have no effect on the Pump. However, after such procedures you should test the Pump function (e.g., program a "SELF TEST") to determine that the Pump and PPC

are operating properly. If the system is not performing correctly, contact your doctor.

Therapeutic radiation

The Medtronic MiniMed 2007D Implantable Insulin Pump System has been tested with therapeutic radiation. These procedures have no effect on the Pump. However, it is recommended not to focus therapeutic levels of radiation directly over the pump. After such procedures, you should test the Pump function (e.g., program a "SELF TEST") to determine that the Pump and PPC are operating properly. If the system is not performing correctly, contact your doctor.

Magnetic resonance imaging

You cannot undergo Magnetic Resonance Imaging procedures with the Medtronic MiniMed 2007D Implantable Pump System.

Pump and catheter under-delivery

Under-delivery or "backflow" may occur when insulin deposits collect in the pumping mechanism inside your Pump. These deposits affect the vacuum seal in the pumping mechanism, and can prevent some of the insulin from being delivered. If the pumping mechanism is unable to seal tightly, the pump will under-deliver its insulin.

If your Pump is under-delivering insulin, you may feel symptoms of hyperglycemia. If this occurs, you should contact your doctor immediately. Your doctor will instruct you on how to manage your blood glucose levels until the Pump can be corrected.

Another under-delivery condition can also be caused by body fluids or body tissue collecting at the tip of the Catheter. To correct a Catheter obstruction, your doctor may need to flush your Catheter with a sterile solution.

Pump electronic or alarm malfunction

If the Pump's electronic or alarm systems malfunction, Self Test circuitry will detect the malfunction and may stop the Pump. Notify your doctor immediately if this occurs. If your doctor cannot correct the malfunction, your Pump may need to be replaced and you will need to take alternative insulin therapy.

Reservoir level warnings

Have your Pump refilled before the reservoir is empty. Alarms in the PPC will alert you to low and depleted reservoir levels. For more information on alarms and messages, see Chapter 5. If the low reservoir alarm sounds and you do not have a refill appointment scheduled within two weeks, call your doctor immediately to schedule a refill.

Environmental conditions

> *NOTE: If you are in doubt about whether a condition or situation will affect your Pump, contact your doctor for advice.*

The Implantable Insulin Pump, like all microelectronic devices, should not be exposed to extreme electrical or magnetic fields or temperature extremes which may adversely affect the Pump and its insulin. Do not allow your Implantable Insulin Pump to be exposed to the following environmental conditions:

- Physical damage to the Pump and the Pump pocket

- Altitudes greater than 2500 meters or 8,000 feet (skiing, hiking, sky-diving)

- Depths greater than 4 meters or 15 feet (scuba diving, etc.)

- Elevated temperatures (hot tubs, saunas)

Avoid any sharp blows or pressure on the Pump. A direct blow may damage the Pump or injure the Pump pocket. Extreme pressure on the Pump may cause the sutures and the tissue pocket to be damaged resulting in Pump migration and a possible dislodging of the Catheter. If you suspect that your Pump or Pump pocket have been damaged, you should contact your doctor immediately. You may need to wear a pressure bandage or reduce your level of physical activity until the Pump pocket heals completely.

You may not reside at or travel to an elevation in excess of 8,000 feet, or dive below 15 feet. High altitudes and depths will change the Pump's insulin flow. This warning does not apply to commercial airline travel. Airline cabins are adequately pressurized at any altitude for Pump use. It is still possible to ski, dive or sky-dive with the proper precautions. Consult your doctor.

Exposure to elevated temperatures in excess of 104 degrees Fahrenheit (i.e. hot tubs, saunas) for longer than one hour can effect the potency of the insulin

and the function of your Pump System (see "Pump and Catheter Under-delivery" on the previous pages). If you have any questions about an activity you are planning, you should contact your doctor for advice.

This device may experience communication interruptions when operated at or near some airport facilities. This will not affect the operation of the pump, and it will continue delivery of insulin per previously programmed levels.

Precautions

Blood glucose monitoring

You must check your blood sugar at least four times daily, using a technique recommended by your doctor. Notify your doctor of any increased frequency of serious low or high excursions in your blood sugar. High blood sugar values may indicate under-delivery of insulin. If you experience symptoms of high blood sugar, check the programmed insulin delivery settings in your PPC and contact your doctor immediately.

Conventional insulin supplies

Carry conventional insulin supplies with you at all times, including insulin and a means to inject it, in case your PPC is damaged, lost or inoperative. Periodically review with your doctor your recommended insulin delivery procedure you should utilize in the event your Medtronic
MiniMed 2007D Implantable Pump System becomes inoperative.

Physician's instructions

Follow your doctor's instructions about your insulin delivery. The range of insulin delivery with your PPC is a basal rate between 0.2 and 35 units per hour (U/H), and a maximum meal bolus of 25 units (U). Your doctor may narrow this range by programming maximum limits for your Basal Rate and Bolus. The alarm "Hourly Maximum Exceeded" will be displayed if you try to program more than 2.5 times the maximum bolus in one hour.

PPC

The PPC is an electronic device and can be damaged if dropped. Do not get the PPC wet or take it into very hot or humid environments, such as steam baths or saunas. If the PPC is damaged, check the displays for proper operation by performing a "SELF TEST". If the "SELF TEST" finds a problem,

you will need to replace your PPC. For more information on the "SELF TEST" procedure, see Chapter 6, Warnings and Precautions.

Maximum dosages

Your doctor may program specific limits for your Basal Rate and Meal Bolus. These maximum limits provide a regimen specific to your needs.

Battery change

Carry a fresh AA 1.5-volt alkaline battery with you at all times. The estimated PPC main battery life is approximately 6 weeks, although this can be influenced by how often you program your Pump. If the Low Battery message appears, change the battery as soon as possible, preferably immediately.

Proper PPC positioning

Keep the PPC near to the Pump during a programming sequence. Separation of the PPC and Pump may result in a partial transmission of a command. If this occurs, the PPC will alarm and display "COMM ERROR RE-ATTEMPT" on the screen.

Physical activities to avoid

Physical activities which are not permitted are those involving very HIGH or LOW altitudes and pressure changes. Such activities include skiing, (above 8,000 feet), sky diving, and scuba diving. When you must participate in such activities, discuss them with your physician who will provide treatment requirements, such as the temporary use of another method of insulin delivery, and will refill your Pump with buffer.

Emergency plan

Be fully informed and thoroughly understand what to do in an emergency. Carry your emergency card with you at all times. Additionally, it is important for individuals close to you, such as family, friends, and co-workers, to know what to do if you are unable to treat yourself due to illness or injury.

The following instructions should be used by your family or friends to set the Pump to the lowest basal rate while your doctor is consulted:

1. Press **SEL** until the PPC displays "SUSPEND PUMP".

2. Press **ACT**, the PPC will indicate "PPC COMMUNICATING".

3. Position the PPC near the Pump.

4. When programming is complete, the PPC will beep and the display will automatically return to the Time/Day screen. The message "PUMP SUSPENDED" will be displayed. The Pump will deliver a basal rate of approximately 0.2 U/h.

In addition to the procedure above, review with family members the proper procedure for administering glucagon.

It is important to closely monitor blood sugar levels on refill days. During a refill procedure, a very small amount of insulin may be deposited subcutaneously possibly resulting in hypoglycemia.

Adverse reactions

In clinical studies, adverse reactions associated with the Medtronic MiniMed 2007 Implantable Insulin Pump System included hypoglycemia, diabetic ketoacidosis, hyperglycemia, skin erosion, infection, abnormal healing, elevated anti-insulin antibodies, intestinal obstruction, post-operative discomfort and pain. Malfunctions in the order of frequency and seriousness include insulin aggregation resulting in Pump under-delivery, Catheter occlusion or tissue overgrowth, early Pump battery depletion and electronic Pump failure. Adverse events associated with the use of Aventis HOE 21 PH U-400 insulin are described in the package insert accompanying the insulin medication.

Hyperglycemia

Your Implantable Insulin Pump uses a special regular insulin, so your body will not have any reserve of long-acting insulin. Interruption of insulin delivery (due to Pump malfunction or clogging of the Catheter) or the sudden onset of stress (emotional upset, infection, etc.) may result in a rapid rise of blood sugar levels, and possibly the development of diabetic ketoacidosis (DKA). Check your blood sugar levels, and your urine for ketones, if you suspect a high glucose level. Supplemental insulin delivered by conventional means may be required. Establish a protocol with your doctor for rapidly identifying and treating hyperglycemia to avoid the onset of DKA.

Hypoglycemia

The best method for identifying hypoglycemia is testing your blood sugar levels. Establish a protocol with your doctor for identifying and treating symptoms of hypoglycemia to avoid an insulin reaction.

Pump pocket infection

Pump pocket infection, although rare, occurs around the Pump implantation site. If you notice pain, redness, or swelling in the area of your Pump, contact your doctor immediately. Pump pocket infections may require the removal of your Pump.

Pump pocket seroma

A Pump pocket seroma is generally characterized by swelling around the area of implantation. It may occur after surgery or if a blow is received to the Pump site. If you notice swelling around your Pump, contact your doctor immediately.

CHAPTER 7   # Important Self-Care

Having a Medtronic MiniMed 2007D Implantable Insulin Pump System is only one aspect of an overall management program to treat your diabetes. There are many other requirements for achieving near normal blood glucose levels.

This manual presents general information regarding blood glucose monitoring, meal planning, exercise and other issues concerning your implantable Pump. You will be instructed more specifically on these self-care issues by your doctor, nurse, and dietitian. Be sure to discuss all questions with them as they are your best source of information.

A support person such as a family member or friend should also read this manual and pay particular attention to the section entitled, *"Emergency Plan"* in Chapter 6. Your support person should also be able to program the PPC to stop insulin delivery as described in Chapter 6.

Blood glucose monitoring

> *NOTE: Remember much of the success of implantable pump therapy depends on accurate and frequent blood glucose monitoring.*

Your Pump System does not monitor your blood glucose levels. You must continue to self-monitor your blood glucose at least four times daily, and then use this glucose information to program your Pump System. Blood glucose monitoring is the only way to determine if you are receiving the correct amount of insulin. You should test your blood glucose according to the method recommended by your doctor.

If you begin to have a problem with glycemic control, it is very important to record your blood glucose measurements. A careful record may help determine if the problem is related to your Pump or another cause.

Meal plan

You will always receive some basal insulin from your Implantable Insulin Pump. When you program a meal bolus, this will be **in addition** to your basal rate.

As with any insulin therapy, it is recommended that you keep some form of fast-acting sugar with you at all times to treat hypoglycemia. If you have any questions concerning your meal plan and insulin therapy, discuss them with your healthcare team as they are your best source of information.

Daily activities

There are no restrictions on your normal work, school, social, or sexual activities unless you have a medical condition which does not allow such activities. Because your Pump is implanted, you may bathe and shower without any interruption in insulin therapy. However, your PPC is not waterproof and should be protected from getting damp or wet.

Exercise

You may participate in most physical activities with your Medtronic MiniMed 2007D Implantable Pump Insulin System. Rough contact sports are not recommended as Pump pocket injury may occur. Exercise may reduce your insulin requirements, therefore, you must check your blood glucose frequently during periods of exercise. In addition, it may be necessary to reduce your basal rate during the exercise.

Travel

You may travel with your Medtronic MiniMed 2007D Implantable Insulin Pump System. All extended trips should be discussed with your doctor. It is safe to travel in a pressurized aircraft, which includes all commercial airlines. Security systems at airports will not affect your Pump, but you may be asked to show your Patient Emergency Information Card which explains the Pump and PPC. Remember to always carry conventional insulin supplies with you when you travel (insulin and syringes or an external Pump) in case of a medical emergency.

Medtronic MiniMed information card

Your doctor will give you a Patient Emergency Information Card when you receive your Pump System. It provides information about your Pump, as well as important phone numbers in case of a medical emergency. **Carry Your Information Card With You At All Times.** It is also recommended that you wear a bracelet or necklace indicating that you have an implantable insulin Pump.

PPC Care and Maintenance

Installing/replacing the main battery

PPC Battery life is estimated to be approximately 4 weeks. Only AA 1.5 volt alkaline battery is recommended for use with the PPC. To replace the PPC Main Battery:

1. Locate the battery door on the back of the PPC.

2. Slide the locking bar to the left.

3. Push the middle part of the PPC box (under the battery door) and lift by gently pulling up the battery door to unlatch.

4. Remove the old battery, noting the polarity. The PPC screen will be blank.

5. Position the new battery so the + and - markings on the battery match the polarity diagram in the battery compartment.

6. Close the battery door.

7. Slide the locking bar to the right.

8. The PPC screen reappears after 30 seconds.

9. The PPC will beep six times and display "PPC/PUMP."

```
PPC          8 102 100
PUMP         3 100 348
```

10. After a few seconds, the screen will change to "CHECK PUMP STATUS."

11. Press **SEL** and **ACT**, then place the PPC over the Pump.

```
08:26  ◄ ≡   JAN 02
CHECK
PUMP STATUS
```

12. Allow the communication to complete.

> PPC
> COMMUNICATING

NOTE: When the PPC displays "PPC LOW BATTERY," you can clear the message and continue programming. There should be sufficient energy in the battery to communicate with the Pump. If while programming the PPC goes blank, the PPC beeps six times and then the "CHECK PUMP STATUS" message appears, the PPC (AA 1.5v alkaline) battery needs to be replaced. For instructions, see "Installing/Replacing the Main Battery" in this Chapter.

Physical protection

- Protect the PPC from direct contact with water and moisture. Never take the PPC into a sauna or steam bath. If the PPC comes in contact with moisture where the battery compartment is wet, remove the battery and dry compartment thoroughly. Replace the battery and perform a "SELF TEST."

- Protect the PPC from temperatures greater than 40°C (104°F). Do not leave the PPC in direct sunlight.

- Protect the PPC from cold temperatures less than below freezing 0°C (32°F).

- Do not drop the PPC. Protect the PPC from sharp blows. Either could damage the electrical components of the PPC and affect its ability to program your implantable Pump.

Cleaning the outer surface of your PPC

- If necessary, use a slightly damp cloth and mild soap to clean the outside of the PPC. Do not use a wet cloth or dip the PPC in any liquid. Moisture may harm the PPC's electrical components.

- Never use organic solvents or harsh detergents to clean the PPC.

- Always completely dry the PPC after cleaning.

- Never spray any cleaning solutions directly onto the PPC, especially the keyboard panel.

CHAPTER 9 # Technical specifications

Implantable Insulin Pump (MMT-2007D)

Component	Performance Specification
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	Aventis HOE 21 PH U-400
Stroke Volume	0.42 to 0.58 µl 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 both together. Audio Bolus
Temporary Basal Rate	0.2 to 35.0 units per hour 30 minute increment duration 30 minutes up to 24 hours duration
Diagnostic 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	Titanium Housing, Polyethylene-lined Silicone Rubber Catheter

Personal Pump Communicator (MMT-3160)

Component	Performance Specification
Height	2.0 cm (0.8 inches)
Length	8.9cm (3.5 inches)
Width	7.0 cm (2.8 inches)
Weight	115 gm (4.0 ounces)
Main Power Source	1.5 Volt Alkaline Battery Type AA
Main Battery Life	Approximately 4 weeks, depending upon usage
Operating Temperature	0ºC to 40ºC (32ºF to 104ºF)
Storage Temperature	-0ºC to 30ºC (32ºF to 86ºF)
Messages	Auto Off Pump 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 Communications Error

Side Port Catheter

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

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.