CHAPTER 9

System Alarms and Messages

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

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

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

Two audible or vibrate alarm types are used:

Alarm Type 1:

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

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

Alarm Type 2:

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

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

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

Pump alarms

Alarm feedback

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

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

Pump low battery

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

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

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

Depleted pump battery

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

System error

The Implantable Insulin Pump has a sophisticated self-monitoring system that periodically checks for circuit faults. If a fault should occur in the Pump electronics, insulin delivery will stop. Conventional insulin therapy must be initiated immediately. Using the PPC Supervisor Mode, the physician should use the "DOWNLOAD SOFTWARE" feature to reprogram the Pump from software in the PPC memory. Notify MiniMed immediately.

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

Pump self test fail

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

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 appears each time a new function is programmed:

PPC Display	Type of Alarm
PPC LOW BATTERY	1

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

If "VIBRATOR" is selected, the PPC battery should last about six weeks during normal use conditions. If the PPC determines that the vibrator is causing a low battery condition, it will automatically change the Alarm Mode to "LOW VOLUME" in order to extend battery life.

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

PPC depleted battery

When the PPC main battery (AA 1.5 volt alkaline) no longer has sufficient power to program the Pump, the following message will appear on the display:

PPC Display	Type of Alarm
PPC DEPLETED BATTERY	**1**

This message can only be cleared by replacing the PPC battery. For instructions on changing the battery, (refer to Chapter 3, *Personal Pump Communicator).*

PPC needs servicing

When the PPC internal battery (lithium) energy becomes low, the following message will be displayed:

PPC Display	Type of Alarm
PPC NEEDS SERVICING	1

Clear this message by pressing **SEL** and **ACT**. Users should be instructed to report this alarm to their physician as soon as possible and have their PPC replaced. If the PPC loses all power, it may also lose information stored in memory.

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

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

Empty reservoir

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

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

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

Telemetry communication error

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

PPC Display	Type of Alarm
TELEMETRY COMM ERROR3	1

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

Initialize alarm

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

PPC Display	Type of Alarm
PUMP ERROR 0 or 1	1

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

PPC Display	Type of Alarm
PUMP ERROR 40 or 41	1

Responding "NO" to the "INITIALIZE PPC TO PUMP" screen eight consecutive times, results in the following message to be displayed. Step away from any other Pump in the area and perform the request again.

PPC Display	Type of Alarm
TELEMETRY ERROR 20	1

PPC not initialized

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

PPC Display	Type of Alarm
PPC NOT INITIALIZED	1

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

PPC Display	Type of Alarm
PUMP INITIALIZED	1

Battery replacement

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

PPC Display	Type of Alarm
CHECK PUMP STATUS	1

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

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

Initialize to factory defaults

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

PPC Display	Type of Alarm
PUMP RESET	1

Pump stopped

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

PPC Display	Type of Alarm
PUMP STOPPED	2

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

Pump suspended

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

PPC Display	Type of Alarm
PUMP SUSPENDED	2

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

Auto off

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

PPC Display	Type of Alarm
AUTO OFF PUMP PUMP SUSPENDED	1

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

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

Hourly maximum exceeded

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

PPC Display	Type of Alarm
HOURLY MAX EXCEEDED	1

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

Pump alarm table

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

PUMP SUSPENDED	**2**	**YES**
PUMP STOPPED	**2**	**YES**
TELEMETRY COMM ERROR	**1**	**YES**
TELEMETRY COMM ERROR 20	**1**	**NO**

CHAPTER 10

Troubleshooting Pump System Under-delivery

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

Diagnostic procedures

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

Under-delivery caused by backflow

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

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

Under-delivery caused by catheter occlusion

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

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

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

CHAPTER 11

Medtronic MiniMed 2007C Implantable Insulin Pump System

Implantable Insulin Pump MMT-2007C

Diameter **Thickness** **Reservoir Volume**	**8.1 cm (3.2 inches)** **2.0 cm (0.8 inches)** **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 ml 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 delay**
Diagnostic Rate	**10 to 150 U/h**
Power Supply	**Lithium - Carbon Monofluoride Battery**
Battery life	**See Figure 1**

Audio Alarms	**Low Battery** **Nearly Depleted Battery** **System Error**
Safety Features	**Negative Pressure Reservoir with Passive Filling** **Pump Shutdown and Alarm with System Error (unique code sequences)**
Materials in contact with tissue	**Titanium, Silicone Rubber**

Personal pump communicator (PPC) model MMT-3150

Height **Length** **Width**	**8.9 cm (3.5 inches)** **7.0 cm (2.8 inches)** **2.0 cm (0.8 inches)**
Weight	**115 gm (4.0 ounces)**
Main Power Source	**1.5 Volt Alkaline Battery Type AA**
Main Battery Life	**6-8 weeks**
Backup Battery	**Lithium Battery**
Backup Battery Life	**3 years minimum with no AA battery installed**
Operating Temperature	**0ºC to 40ºC (32ºF to 104ºF)**

Storage Temperature	**0ºC to 30ºC (32ºF to 86ºF)**
Messages	**Auto Off in 5 min / Auto Off Pump Suspended** **Check Pump Status** **Communication Error** **Download Complete** **Empty Reservoir** **Hourly Maximum Exceeded** **Low Reservoir** **PPC Not initialized** **PPC Needs Servicing** **PPC Low Battery** **PPC Depleted Battery** **Pump Self Test Fail** **Pump Reset** **Pump Stopped** **Pump Version Error** **Telemetry Communication Error**

Side Port Catheter

MMT- 4027A **Length**	**Proximal: 11.8 ± 1.3 cm (4.7 ± 0.5 inches)** **Distal:17.8 ± 0.7 cm (7.0 ± 0.3 inches)**
MMT- 4028A **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**

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.

Operation of this device is authorized by the FCC under the FCC ID OH22007C (Implantable Pump) and OH23150 (PPC).

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

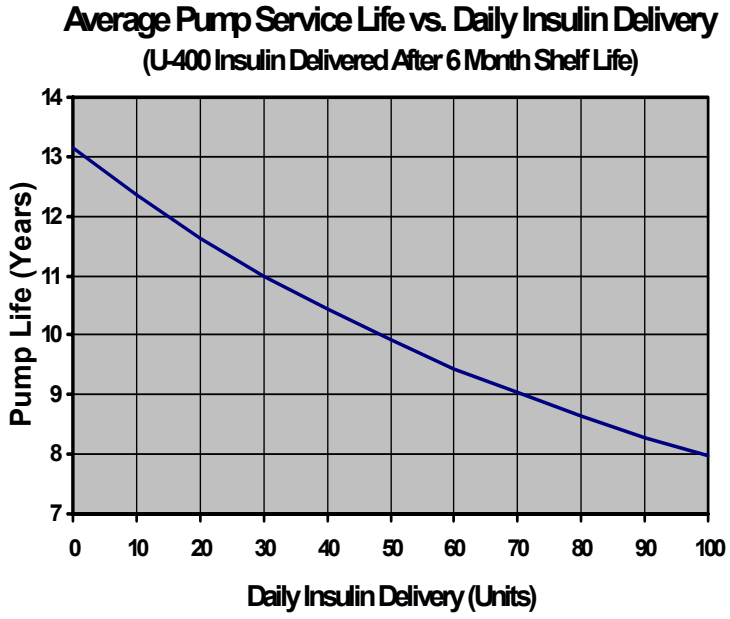


Figure 15: Average Pump Battery Life

APPENDIX A Label Information

Symbol dictionary

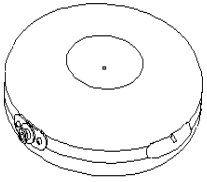
	**Do Not Reuse This Device**
	**Please Read "Important Information"**
STERILE EO	**Sterilized by Ethylene Oxide**
 1994-12	**Manufacture Date (Year-Month)**
LOT 123456	**Lot Number**
 1996-12	**Expiration Date (Use By Date) (Year-Month)**
REF MMT-XXXX	**Reference / Record Number (reorder number)**
SN	**Device Serial Number**

	**IEC Icon indicating equipment providing a particular degree of protection against electric shock (Type B)**
0459 0168 	**CE Marking/Notified Body Authorization**

Packaging

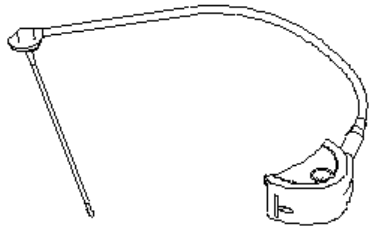
The icon on each label indicates the contents of the package.
The number with the icon is the quantity.

MiniMed 2007C Implantable Insulin Pump

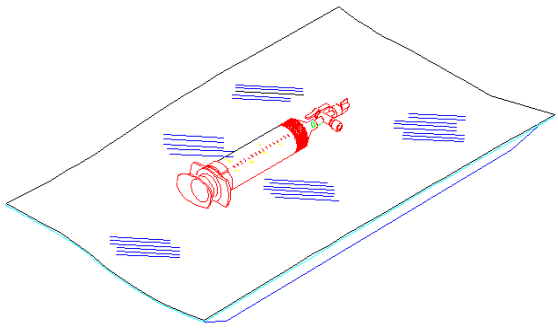


MiniMed 3150 Personal Pump Communicator

MiniMed 4024A and 4027A Side Port Catheter



MiniMed 4105 Refill Kit



MiniMed 4102 Refill Needles

Other Information

Manufactured by:Medtronic MiniMed

Distributed in the United States by:Medtronic MiniMed Inc.

Distributed in Europe by:Medtronic MiniMed S.A. - Paris, France

CE Marking:

Notified Body:GMED - France

Notified Body Authorizations:0459, 0168

Year of Initial CE Authorization:2000

APPENDIX B Implant Worksheet

Implant worksheet form

Please refer to “Implant Worksheet” attached.

MiniMed Implant Worksheet

Date:_____ Center:_____ Patient Code:_____

Patient name:_____

Pump Label:

Catheter Label:

PPC Label:

Insulin Lot Number:_____

Communicator-settings:

Patient Communicator ID:_____ Supervisor Code:_____

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

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

Basal rate programmed with PPC:_____U/h

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

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

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

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

Time delivery started, priming bolus:_____

Calculated stroke volume:

a) number of strokes delivered:_____

b) total volume delivered:_____

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

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

Date:_____ Surgeon name:_____

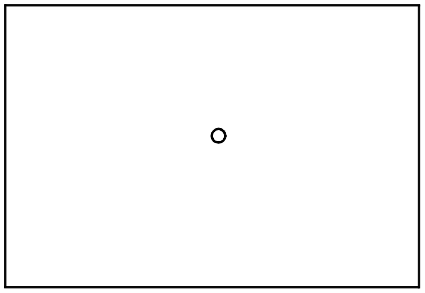
Anesthesia:_____ Pocket depth:_____cm

Catheter fixation:_____ Pump fixation:_____

Catheter type:_____ Pump type:_____

Pump orientation:

Complications:



APPENDIX C Refill Form

Pump refill data

Please refer to “Refill Data Form” attached.

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

Insulin remaining from PPC:_____ (F)

Data:

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

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

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

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

Amount withdrawn	**Refill Amount**
(B)_____ g	(C)_____ g
- (A)_____ g	- (D)_____ g
=_____ g (E)	= _____ g

*Corrected for density of insulin

Date:_____

Patient name:_____ Patient code:_____

Center:_____ Physician name:_____

Insulin "IN" _____ ☐

Rinse Buffer "RB" _____ ☐

Previous refill amount:_____ g (1)

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

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

Theoretical amount used:_____ g (4)

(line 1 - remaining dose from PPC (F)

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

Percentage difference:

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

Usable units of insulin (Gx384.6): _____ U

Average daily insulin use:_____ U/d

Estimated refill period:_____ Days

Schedule next refill visit:_____
D / M / Y