MySentry™ User Guide

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6025332-011 061108

REF MMT-9100

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Introduction 1

Thank for choosing Medtronic Diabetes (legally known as Medtronic MiniMed, Inc.) as your partner in diabetes management. We believe that the combination of state-of-the-art technology and the simple, menu-driven programming of the MySentry™ system will provide many benefits for you.

Your MySentry system is designed to provide a simple and reliable way to remotely monitor a sensorenabled insulin pump that is worn by a person in your care. This device is ideally suited for nighttime use, when you worry most about glucose variations.

This user guide is designed to help you understand the operation of your MySentry system. Please read this guide in its entirety before you begin using the system.

MySentry Monitor

Assistance

Medtronic Diabetes provides a 24-hour HelpLine for assistance. The HelpLine is staffed with representatives who are trained in the setup and operation of the MySentry system, and who are able to answer any system-related questions. When calling the HelpLine or your local Medtronic Diabetes office, please have the MySentry device and its serial number available.

The phone number for the 24 Hour HelpLine, as well as your MySentry serial number, is also listed on the back of the MySentry Monitor.

Department	Telephone number
24 Hour HelpLine (within the United States)	800.646.4633
24 Hour HelpLine (outside the United States)	818.576.5555
Web site	www.medtronicdiabetes.com

How to use this guide

The terms and symbols used in this guide are in the following table.

Convention	Description
Press	Push and release the button.
Select	Press ∧ or ∨ to select an item, then press > to perform the action (such as choosing a menu item or displaying a particular screen.)
Monitor buttons	Indicated by images; for example, press < to return to the Utilities menu.

Convention	Description
Menu paths	Displayed in bold text; for example: Main Menu > Go to Utilities menu > Link to Pump
	 The previous instruction directs you to do the following: 1 From the monitor, go to Main menu, then select Go to Utilities menu. 2 In the Utilities menu, choose Link to Pump.
NOTE	Provides additional information.
CAUTION	Warns of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.
WARNING	Notifies you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.
Go to thescreen.	When a step instructs you to go to a screen, the path to that screen is included in the step. For example: Go to the LINK TO PUMP screen. Main menu > Go to Utilities menu > Link to Pump
MySentry Monitor	Referred to within procedures as Monitor.
MySentry Outpost	Referred to within procedures as Outpost.

NOTE: This user guide shows sample screens only. Your monitor screens may look slightly different.

User safety

This section describes all user safety information that you need to know regarding the use of your MySentry system.

Indications

The MySentry system is indicated for the remote monitoring, within your home, of a single Medtronic MiniMed Paradigm 523/723 sensor-enabled insulin pump.

The real-time glucose values provided by the Monitor, as received from the Paradigm 523/723 insulin pump, are not intended to be used directly for making therapy adjustments. Rather, they provide an indication that may require a confirmation fingerstick measurement. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not based on the value displayed by the Monitor or Paradigm 523/723 insulin pump.

Contraindications

None known.

Warnings

MySentry is intended to act as a personal sentry for your loved ones, but it is not a substitute for personal visual monitoring. Although MySentry has been designed and tested to meet or exceed the latest industry standards as required by EN, FDA and Underwriters Laboratories, MySentry can be susceptible to RF or electrical interference. Transmission of all data or alarms cannot be guaranteed with MySentry. This product does not provide any medical advice and should not be relied upon for such purpose.

Power supply

- MySentry notifies you if its power source (household current) fails. If this occurs, check pump data directly from the insulin pump.
- Using an unqualified power supply may affect the operation of MySentry. Use only the Medtronic MiniMed power supply, part number MMT-9103.

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Required distance

MySentry only displays real-time glucose values and alarms/alerts that are transmitted by a Paradigm 523/723 insulin pump. The required distance between the pump and the Outpost is six feet (1.8 meters) or less. The distance between the Outpost and the Monitor can be up to 100 feet (30.5 meters). If a pump is not within the required distance from the MySentry Monitor or MySentry Outpost, then real-time glucose values and any associated alarms or alerts from the Paradigm 523/723 insulin pump might not be received and displayed on the MySentry Monitor. Refer to your Paradigm 523/723 insulin pump for real-time glucose values and alarms or alerts.

Additional safety instructions

- Please refer to the Paradigm 523/723 user guide for pump warnings.
- Read, follow, and keep all instructions identified within this guide.
- Heed all warnings identified on the product, and within this guide.
- Protect the power cord from being walked on or pinched, particularly at plugs, convenience receptacles, and the point where it exits from the device.
- To reduce the risk of fire or electric shock, MySentry should not be exposed to water or moisture of any kind, including, but not limited to, dripping or splashing. Do place the Monitor or Outpost near objects filled with water, such as vases, sinks or bathtubs.
- Do not block any ventilation openings.
- Install MySentry in accordance with the manufacturer's instructions.
- Refer all servicing to qualified service personnel. Servicing is required when MySentry operates
 abnormally or has been damaged in any way, to include: dropping, crushing, exposure to rain, water or
 other liquids, or power supply cord or plug damage. If the MySentry is damaged in any way, refer to the
 Paradigm 523/723 pump for all operational and glycemic information.

Precautions

Review the following precautions before operating your device.

Monitor

- The Monitor does not control or affect the Paradigm 523/723 insulin pump in any way. It only displays operational and glycemic data received from the pump.
- The Monitor displays only the most essential alarms received from the Paradigm 523/723 insulin pump.
- The Monitor also displays certain alarms only one time.

Notice

CAUTION: Any changes or modifications to the devices not expressly approved by Medtronic Diabetes could interfere with your ability to operate the equipment and void your warranty.

RF communication

These devices comply with the United States Federal Communications Commission and international standards for electromagnetic compatibility.

These devices comply with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) These devices may not cause harmful interference, and (2) these devices must accept any interference received, including interference that may cause undesirable operation. It does not interfere with any RF signals transmitted from outside sources.

These standards are designed to provide reasonable protection against excessive radio frequency interference, and prevent undesirable operation of the devices from unwanted electromagnetic interference. Operation is subject to the following two conditions:

1 These devices have been tested and found to comply with the regulations governing such devices in your area. For the specific regulation and test results for your area, please contact your local representative.

Introduction

- 2 These devices generate, use, and can radiate radio frequency energy and, if installed and used in accordance with the instructions, may cause harmful interference to radio communications. If the devices do cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:
 - Reorient or relocate the MySentry components.
 - Decrease the distance between the MySentry Monitor and MySentry Outpost to 100 feet or less.
 - Decrease the distance between the MySentry Outpost and Paradigm Revel insulin pump to six feet or less.
 - Decrease the distance between the MySentry Monitor and Paradigm Revel insulin pump to six feet or less.
 - Increase the separation between MySentry devices and the device that is receiving/emitting interference.

If other devices that employ radio frequencies are in use, such as cell phones, cordless phones and wireless networks, they may prevent communication between the MySentry system and the Paradigm Revel insulin pump. This interference does not cause any incorrect data to be sent and does not cause any harm to your devices. Moving away from, or turning off, these other devices may enable communication. If you continue to experience RF interference, please contact your local Medtronic MiniMed representative, or call the 24 Hour HelpLine (see the *Assistance* section in this chapter).

RF power

The MySentry and Outpost system operate at a frequency of 2.4 GHz and a power of 100 milliwatts. It must be used at distances greater than 7.9 inches (20 cm) from the human body, except for hands and wrists.

WARNING: The MySentry Monitor and Outpost have been approved for use where the Monitor and Outpost are used at distances greater than 20 cm from the human body (with the exception of hands and feet). Operation at distances of less than 20 cm is strictly prohibited.

Basics 2

The MySentry system

MySentry is an integrated system consisting of a monitor, a radio-frequency-operated repeater, and a power supply. The Monitor provides remote viewing of Paradigm 523/723insulin infusion pump status, glucose data, trends and alarms. The Outpost repeater relays the insulin pump data to the Monitor. The power supply connects the Monitor to a standard electrical wall socket.

The Monitor

The Monitor (MMT-9100) receives data directly from the Paradigm 523/723 sensor-enabled pump (if within range), or remotely through the Outpost. The Monitor powers on when you plug the power supply into both the Monitor and a wall socket. It does not use batteries, and has no On or Off button. After the Monitor is properly linked to an insulin pump, it does not display data from other MySentry systems or insulin pumps, even if they are in the vicinity. The Monitor can, with minimum user interaction, receive data transmitted by the insulin pump, including glucose sensor values, historical graphs, pump status, alarms, remaining insulin in the reservoir, and the amount of time remaining until a glucose sensor calibration is required.



CAUTION: Never use sharp objects to press the buttons on your MySentry device as this can damage the buttons or compromise the seal of the device. Some examples of sharp objects that may damage the keypad are fingernail files, pens or pencils, paper clips, knives, scissors, and keys.

The Outpost

The Outpost (MMT-9102) receives data produced by the Paradigm 523/723 sensor-enabled insulin pump and transmits this data to the Monitor. It plugs into a regular wall socket and communicates with the pump and Monitor while maintaining data integrity. The required distance between the Outpost and the pump is six feet (1.8 meters) or less. The distance between the Outpost and the Monitor can be up to 100 feet (30.5 meters).



The power supply

The 5V DC power supply (MMT-9103) plugs into the back of the Monitor and a regular wall socket and provides electrical power to the Monitor.



Monitor screens

This section describes the general types of Monitor screens. It does not include all screens.

Glucose screens

Access the Glucose screens by pressing \odot . See the *Monitoring glucose levels* section in the *Everyday use* chapter for more information.

Alarm screens

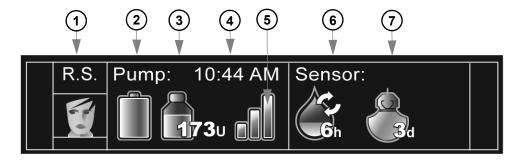
The Alarm screens are displayed when the Monitor receives an alarm or glucose alert from the pump, or when the Monitor has a communication problem. See the *Alarms* section in the *Everyday use* chapter for more information.

Utilities screens

The Utilities menu screens allow you to set up communication with the pump and Outpost, enter user information, and adjust preferences such as alarm volume. See the Setting up communication and Adjusting Monitor settings sections in the Getting started chapter, for more information.

Quick status view

MySentry allows you to quickly view pump and sensor status. The following information icons are displayed along the top of each glucose-related screen, as well as the confidential screen.



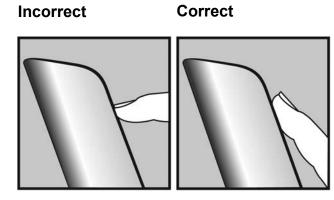
- 1. User: Displays the initials and image of the monitored pump user.
- 2. Battery: Indicates how much power remains in the monitored pump battery.
- 3. Reservoir: Indicates how many insulin units remain in the monitored pump reservoir.
- 4. Time: Displays the time currently shown on the monitored pump.
- 5. Communication status: Shows the signal strength between the pump and Monitor. More bars means stronger signal.
- 6. Next sensor recalibration: Indicates how many hours remain before the monitored pump must be recalibrated.
- 7. Next sensor change: Indicates how much time remains before the sensor must be replaced on the monitored pump user.

MySentry buttons

The Monitor screen display important information such as alarm messages, insulin pump status, and glucose trends. The buttons on the Monitor face are used to navigate through the MySentry system options and screens.

The Monitor buttons work by creating an electrical connection between your finger and an embedded sensor. Unlike regular buttons, they require a certain amount of surface contact between your finger and the button in order to work properly. The illustration to the right shows the correct and incorrect way to activate the Monitor buttons.

The buttons are also lighted when they are active for a given screen; they are not lighted when they are not active for a given screen. The following table shows you the functions and properties of each button.



Button	Uses
VIEW	 Accesses the Main Menu Cycles through the Glucose screens Updates the display with another view of data
BACK	 Cancels the current operation Cycles backwards through the sensor graph Displays the previous screen in a sequence

Button	Uses
NIGHTLIGHT	Switches the nightlight on and off
SILENCE	Silences alarms and disables the audio so that alarms display only on screen, such as when the pump that is being monitored has gone out of range.
UP	 Selects the previous menu option Increases the glucose graph display range
NEXT	 Selects the highlighted option Moves forward in time on the graph screen
DOWN	 Selects the next menu option Decreases the glucose graph display range

MySentry Monitor

Setting up communication

Before you can use the MySentry system, you must set up communication from the pump to the Monitor, and the Monitor to the Outpost (if used). The following linking procedures only need to be performed once, unless the Monitor or Outpost is unplugged or an alarm has cleared the pump settings. If so, then you must re-link the Monitor to the pump.

NOTE: It is recommended that you place the pump, Monitor, and Outpost in one location during the setup process, and you not move any component until they are linked. After the components are successfully linked, you can move them to their permanent locations. The Monitor and Outpost work best if they stay in one location in your home.

Linking the Monitor to the pump

Do not move the pump or Monitor during this process.

- 1 Remove the pump from the user and place it within six feet (183 cm) of the Monitor.
- 2 Use the power supply provided with the MySentry system to plug the Monitor into a standard electrical wall outlet.
- **3** If the Monitor is not linked to a pump, the **Link to Pump** screen displays.

If the **Link to Pump** screen does not display, follow these steps:

- a. Press ountil the main menu displays.
- b. Go to the Link to Pump screen.

Main Menu > Go to Utilities Menu > Link to Pump

- 4 Follow the onscreen instructions on your Monitor to set up the pump. A rotating circle indicates that the linking step is in process, while the Monitor locates the pump.
 - It takes up to approximately two minutes to complete the linking process.

If the linking process fails, reposition the Monitor and pump and repeat steps 1 through 4.

If the Monitor is still unable to link to the pump, call the 24 Hour Helpline (1-800-646-4633).

Linking the Monitor to the Outpost

Do not move the Monitor or Outpost during this process.

- 1 Place the Outpost within six feet of the Monitor. Do not plug in the Outpost until directed to do so.
- 2 From the Main Menu, go to the Link to Outpost screen.
 - Main menu > Go to Utilities menu > Link to Outpost
- **3** Follow the onscreen instructions.

It takes approximately two minutes to complete the linking process, and during this time the Outpost flashes slowly. Once the linking process is complete, the Outpost stays lit. If the linking process fails, reposition the components and repeat steps 1 through 4.

If the Monitor is unable to link to the Outpost, call the 24 Hour Helpline. The phone number for the 24 Hour HelpLine and the Outpost serial number are listed on the back of the Outpost.

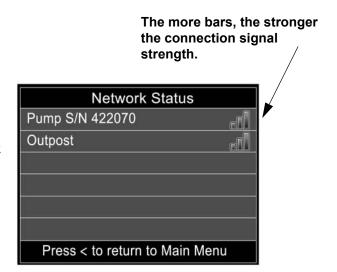
Checking the communication status

To verify that the Monitor is successfully communicating with the pump and the Outpost, go to the Network Status screen.

Main Menu > View Network Status

Communication status is shown for the link between the Monitor and the pump, and the link between the Monitor and the Outpost. Solid bars indicate successful communication. Empty, flashing bars indicate a communication problem.

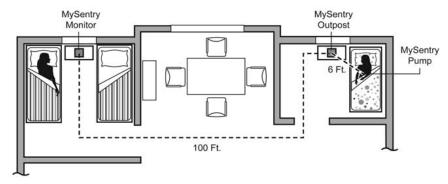
If communication is lost, a Monitor alarm displays that indicates whether the issue is with the pump or the Outpost. Communication issues are typically resolved by moving the devices closer to one another.



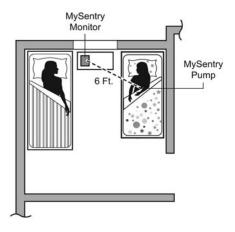
Home configuration

Once MySentry is linked to the pump, use the following examples as guidelines for positioning the system within your home.

Monitor with Outpost



Monitor without Outpost



Adjusting Monitor settings

Follow the procedures in this section to adjust your monitor settings. You can change these settings at any time.

NOTE: In the procedures below, use the \land and \lor buttons to scroll through each list of options.

Adjusting user information

The Enter User Info screen enables you to adjust the initials of the person wearing the pump, and the pump user image. It also displays the pump serial number, which is obtained when the pump is linked to a Monitor.

To adjust this information, perform the following procedure.

- 1 From the Main Menu, go to the Enter User Info screen.
 Main Menu > Go to Utilities Menu > Edit User Info
- 2 Scroll to locate each user initial, pressing **>>** to confirm your selection. After you select the second initial, the user image displays.
- Scroll to choose your desired image, then press >> . A confirmation screen displays.



Adjusting the nightlight brightness

There is a nightlight on the back of the Monitor to help you find it in the dark. You can adjust the nightlight to your desired level of brightness.

- 1 From the Main Menu, go to the Adjust Nightlight screen.
 - Main Menu > Go to Utilities Menu > Adjust Nightlight Brightness
- 2 Follow the instructions on screen to adjust the brightness to your desired level.

NOTE: To switch off the nightlight, press 🔆 .

Adjusting the display light

The display light is used during waking hours. You can adjust the display light to your desired level of brightness.

- 1 From the Main Menu, go to the Adjust Screen Brightness screen.
 - Main Menu > Go to Utilities Menu > Adjust Screen Brightness
- 2 Follow the onscreen instructions to adjust the brightness to your desired level.

Adjusting the alarm volume

This setting allows you to adjust the alarm volume.

- 1 From the Main Menu, go to the Adjust Alarm Volume screen.
 Main Menu > Go to Utilities Menu > Adjust Alarm Volume
- 2 Follow the instructions on screen to adjust the volume to your desired level.

NOTE: If the Alarm Silence option is on, then the alarm is silent. See the Alarm settings section in the Everyday use chapter for information about the Alarm Silence feature.

MySentry Monitor

This chapter contains information about MySentry features that you are likely to use on a daily basis. This includes responding to alarms, checking current glucose levels, and viewing the glucose graphs.

Monitoring glucose levels

MySentry gives you the ability to quickly view the pump user's most recent glucose reading at any time, or view a more detailed graph that shows glucose readings over a number of hours. If the glucose readings exceed the values defined in the pump, or if there is a problem with the sensor or transmitter, a glucose alarm displays. See the *Responding to an alarm* section in the *Everyday use* chapter for more information about alarms.

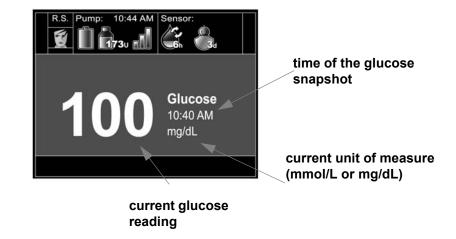
Viewing a glucose snapshot

The Glucose Snapshot screen displays the current glucose reading recorded in the pump, and the time at which the reading was made.

To view the current glucose snapshot, press •.

NOTE: If the glucose level is less than 40 mg/dL (2.2 mmol/L) or greater than 400 mg/dL (19.4 mmol/L), then the Monitor indicates that the glucose level is out of range.

The snapshot shows all of the pump's current settings and measurements. The glucose trend indicates whether glucose levels are stable, rising, rising rapidly,

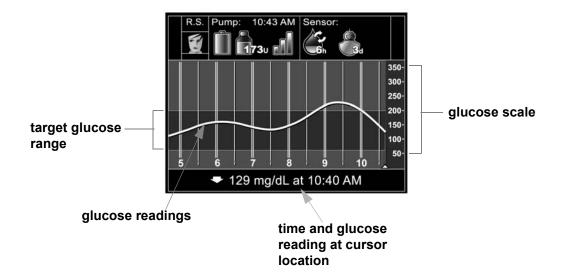


dropping, or dropping rapidly, and correspond to the rapid change arrows on the pump.

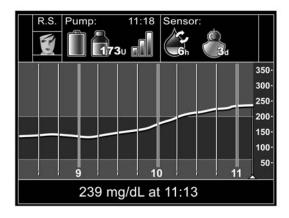
Viewing the glucose graph

The glucose graph displays glucose data in a range of 3 hours, 6 hours, 12 hours, or 24 hours. To view the glucose graph, press \odot from the Glucose Snapshot screen. Press \supset and < to navigate forward and backward in time across the graph. Press \land and \lor to increase or decrease the amount of time represented on the graph.

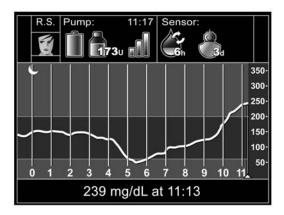
6-hour view



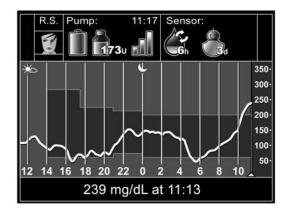
3-hour view



12-hour view

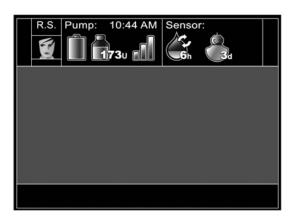


24-hour view



Viewing the Privacy screen

The Privacy screen allows you to see an overview of the system data without displaying any specific glucose details. To activate this screen, press from the glucose graphs screen.



Alarms

MySentry displays three types of alarms:

- Monitor alarms display when there are communication issues encountered by the Monitor. They
 indicate whether the communication issue is with the pump or the Outpost, and include the time that
 communication was lost. If this type of alarm occurs, do the following:
 - Move the pump closer to the Outpost.
 - Move the Outpost closer to the Monitor.

You can check the communication status by going to the View Network Status screen.

Main Menu > View Network Status

- Pump alarms display when your pump generates an alarm or alert. The Monitor displays most alarms and alerts generated by the pump, such as **Weak Battery** or **Empty Reservoir**. An explanation of each pump alarm or alert can be found in the pump user guide.
- Glucose alarms display when a glucose reading causes a sensor alert on the pump (for example, Rise Rate), or when there is an issue with the sensor or the transmitter (for example, Change Sensor). An explanation of each glucose alarm can be found in the pump user guide.

Alarm settings

You can adjust the alarms as follows:

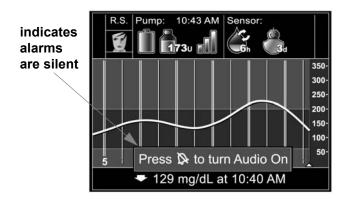
- Setting the volume Go to the Adjust Alarm Volume screen.
 - Main Menu > Go to Utilities Menu > Adjust Alarm Volume

For more information, see the *Adjusting the alarm volume* section in the *Getting started* chapter.

 Alarm Silence feature — To switch the Alarm Silence feature on or off, make sure there are no alarms currently displayed on the monitor, then press .

Responding to an alarm

The Monitor displays alarms sent from the pump. However, clearing an alarm on the Monitor does not clear it on the pump. When an alarm is received, one of the following happens, depending on the alarm mode:



- Standard mode the alarm tone sounds and the alarm text is displayed. The alarm text remains on the screen. Press > once to silence the alarm, and twice to clear it.
- Silent Alarm mode the alarm text is displayed. Press 🄉 to clear the alarm.

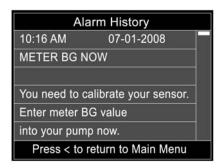
If the pump is out of range of either the Monitor or Outpost, the Monitor does not display alarms sent from the pump. See the *Alarms* section in the *Everyday use* chapter for examples and descriptions of the each type of alarm screen.

Alarm history

You can view up to the 12 most recent alarms the Monitor has received. From the Monitor, go to the **Alarm History** screen.

Main menu > View Alarm History

Press \wedge and \vee to scroll through the available alarms.



Daily alarm reset

To account for planned periods of time when the pump is out of the range of the Monitor or Outpost, perform the following daily procedure.

Morning

- 1 Before the pump goes out of range, silence your Monitor.
- 2 If the pump has already gone out of range and the Monitor alarms, clear the alarm.
- 3 Silence the Monitor to avoid future lost connection alarms while the pump is out of range.

Evening

- 1 Press x to clear the alarm.
- 2 Press 🌣 to un-silence the Monitor.

MySentry Monitor

This section provides information on how to clean your Monitor. Make sure you have the following items before you begin cleaning your Monitor:

- Clean cloths
- Clean water
- Mixture of clean water and mild liquid soap

Cleaning the Monitor

The following procedure describes how to clean your Monitor.

CAUTION: • Never place the Monitor directly in water.

- Never try to clean the inside of the Monitor.
- Use only a damp cloth and mild liquid soap to clean the Monitor.
- Never use organic solvents such as lighter fluid, nail polish remover, or paint thinner to clean the Monitor.
- Never use lubricants of any kind to clean the Monitor.

To clean the Monitor:

- 1 Make sure the Monitor is unplugged from the power supply.
- 2 Dampen a clean cloth with mild liquid soap and warm water, and wipe the outside of the Monitor.
- **3** Dry the Monitor by wiping it with the dry part of the cloth.

MySentry Monitor

MySentry Monitor specifications

Monitor size

- Height: approximately 5.7 inches (14.4 cm)
- Width: approximately 7.0 inches (18.0 cm)
- Depth: (thickness) approximately 3.7 inches (9.4 cm)

Monitor weight

Approximately 1.5 lbs (680.4 grams)

Alarm types

- Audible tone The alarm tone increases from a beep to a siren when no action is taken for that alarm.
- Visual The alarm name displays and the ightharpoonup key flashes.

Alarm messages and codes

- Alarm information appears on the monitor screen.
- Types of alarm information:
 - alarm source (Monitor, pump, glucose sensor)
 - alarm name
 - alarm message (what to do when you receive the alarm)

Alarm/alert history

Maximum number of recent alarms or alerts recorded: 12

Display

Type: LCD (Liquid Crystal Display)

Default settings

Feature	Options	Default Setting	Limits, Range of Values
Alarm Silence	– On – Off	Off	Possible values - On - Off
Alarm Type	Sound and visualVisual only	Sound and visual	Possible values Beep values - Volume settings from 1 to 6 Visual only - Flashing indicator

Alarm table

Every pump alarm that stops insulin delivery is sent to MySentry to notify you of the condition. However, it is possible that the cause of the alarm may prevent further communication until the condition is fixed.

Power

Medtronic MiniMed AC power supply, part number MMT-9103.

Operating Conditions

• Temperature: $+41^{\circ} F (+5^{\circ} C)$ to $+104^{\circ} F (+40^{\circ} C)$.

34 Specifications

- Humidity: 5% to 85% relative humidity.
- Transportation: $+41^{\circ}$ F ($+5^{\circ}$ C) to $+104^{\circ}$ F ($+40^{\circ}$ C).

Storage conditions

- Temperature: +23° F (-5°C) and +113° F (+45°C).
- Humidity: Up to 95% relative humidity.
- Transportation: 5% to 85% relative humidity.

MySentry Outpost specifications

Outpost size

- Height: approximately 4.0 inches (10.2 cm)
- Width: approximately 2.6 inches (6.60 cm)
- Depth: (thickness) approximately 2.0 inches (5.0 cm)

Outpost weight

Approximately 0.3 lbs (131.0 grams)

Power

- Standard AC power, 5VDC 3A
- Part Number MMT-9102
- Protection against electric shock: Class II

Operating conditions

- Temperature: +41° F (+5°C) to +104° F (+40°C).
- Humidity: 5% to 85% relative humidity.
- Transportation: +41° F (+5°C) to +104° F (+40°C).

Storage conditions

- Temperature: +23° F (-5°C) and +113° F (+45°C).
- Humidity: Up to 95% relative humidity.
- Transportation: 5% to 85% relative humidity.

MySentry power supply specifications

Power supply

- Standard AC power supply: 5VDC
- Part Number MMT-9103
- Protection against electric shock: Class II

Recycling

Recycle all parts and packaging materials per your local regulations.

Icon table

Attention: See Instructions for Use	\triangle
Date of manufacture (year - month)	M
Catalogue number	REF
Device serial number	S/N
Quantity per package (1)	(1X)
Radio communication	0
Polarity of d.c. power connector	\bigcirc \oplus

Guidance and manufacturers declaration

Guidance and Manufacturers Declaration - Electromagnetic Emissions

The MySentry system is intended for use in the electromagnetic environment specified below. The customer or the user of the MySentry system should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions		MySentry system must emit electromagnetic energy
Test: CISPR 11	Group 2	in order to perform its intended function. Nearby electronic equipment may be affected.

Guidance and Manufacturers Declaration - Electromagnetic Emissions

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Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions		
	Class B	
CISPR 11		The MySentry system is suitable for use in all
Harmonic emissions		establishments, including domestic and those
	Class B	directly connected to the public low-voltage power
IEC 61000-3-2		supply network that supplies buildings used for
Voltage fluctuations/flicker		domestic purposes.
emissions	TBD	
IEC 61000-3-3		

Guidance and Manufacturers Declaration - Electromagnetic Immunity

The MySentry system is intended for use in the electromagnetic environment specified below. The customer or the user of the MySentry system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD)	±6 kV contact	±30 kV air	TBD
IEC 61000-4-2	±8 kV air	(<5% relative humidity)	
Electrical fast transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	TBD
IEC 61000-4-4	±1 kV for input/output lines	±1 kV for input/ output lines	TBD
Surge	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	TBD
IEC 61000-4-5	±2 kV line(s) to earth	±2 kV line(s) to earth	TBD

Guidance and Manufacturers Declaration - Electromagnetic Immunity

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Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Voltage dips, short interruptions and voltage variations on power supply lines	<5% U _T (>95% dip in U _T) for 0.5 cycle	<5% UT (>95% dip in UT) for 0.5 cycle	TBD
IEC 61000-4-11	$40\% \ U_T$ (60% dip in U_T) for 5 cycles	40% UT (60% dip in UT) for 5 cycles	TBD
	$70\%~\rm U_T$ (30% dip in $\rm U_T$) for 25 cycle	70% UT (30% dip in UT) for 25 cycle	TBD
	<5% U _T (>95% dip in U _T) for 5 seconds	<5% UT (>95% dip in UT) for 5 seconds	TBD
Power frequency (50/60 Hz) magnetic field	3 A/m	3 A/m	TBD
IEC 61000-4-8			

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturers Declaration - Electromagnetic Immunity

The MySentry system is intended for use in the electromagnetic environment specified below. The customer or user of the MySentry system should assure that it is used in such an electromagnetic environment.

Immunity Test	IEC 60601 Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	10Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	10Vrms 150kHz to 80MHz 3V/m	TBD

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption, and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasts and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MySentry System is used exceeds the applicable RF compliance level above, the MySentry System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MySentry System.

Recommended separation distances between portable and mobile RF communications equipment and the MySentry System

The MySentry system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the MySentry users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MySentry system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of	Separation distance according to the frequency of transmitter (m)		
transmitter (W)	80MHz to 800MHz	800MHz to 2,5GHz	
	$d = 0.35\sqrt{P}$	$d = 0.70\sqrt{P}$	
0.01	0.035	0.07	
0.1	0.11	0.11	
1	0.35	0.7	
10	1.1	2.2	
100	3.5	7	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Warranty

Medtronic Diabetes warrants the Medtronic MySentry Monitor and MySentry Outpost against defects in materials and workmanship for a period of three months from the date of purchase. During the warranty period, Medtronic Diabetes will, at its discretion, either repair or replace (with a new or recertified Monitor or Outpost, at Medtronic Diabetes' discretion) any defective Monitor or Outpost, subject to the conditions and exclusions stated herein. In the event that the Monitor or Outpost is repaired or replaced, the warranty period will not be extended.

This warranty is valid only if the MySentry Monitor or MySentry Outpost is used in accordance with the manufacturer's instructions. This warranty will not apply:

- If damage results from changes or modifications made to the Monitor or Outpost by the user or third persons after the date of manufacture.
- If damage results from service or repairs performed by any person or entity other than the manufacturer.

If damage results from a Force Majeure or other event beyond the control of the manufacturer.

• If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water or physical abuse, such as dropping or otherwise.

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate. This warranty does not apply to any accessories.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic Diabetes nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

All other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

MySentry Monitor

This chapter answers and provides further information for the most frequently asked questions about the MySentry system.

How do I turn the monitor on/off?

Turn the Monitor on/off by plugging it into, and out of, the power supply. There is no power switch.

How many pumps does MySentry monitor?

MySentry is designed to monitor a single pump.

How often does the pump send a transmission?

The pump sends a transmission every minute.

What is the RF frequency that the MySentry transmitter uses?

The MySentry operates at ultra high frequency, similar to a mobile phone.

What situations will cause RF interference?

Most cellular (mobile) phones and 900 MHz cordless phones, when transmitting or receiving, may cause significant interruption of transmitter-receiver communication. It is likely that other devices operating in similar frequency ranges will have a similar effect. This interference, however, does not cause any incorrect data to be sent and will not cause any harm to your transmitter.

The pump includes a programmable WEAK SIGNAL alert that notifies you when one or more expected transmissions were not received as expected by the pump. (The pump will also issue a LOST SENSOR alert if communication is interrupted for an extended period of time.)

How do I resolve RF interference issues?

When you experience an RF communication issue, the MySentry Monitor identifies which device is having the problem by issuing an alarm. Communication problems can usually be resolved by:

- ensuring that there is less than six feet (1.8 meters) between the pump and Monitor, or the pump and Outpost;
- turning off or moving away from other RF transmitting devices;
- reorienting or relocating the transmitter or receiving device, or both.

Communication problems may also occur due to cellular telephone interference. Testing conducted with several different cellular telephones indicates that, while a glucose value is being transmitted, using a cell phone within 12 inches (31 cm) of receiving devices, transmitters, or RF glucose meters can interfere with the reception of transmitted values. In the event of such interference, normal communication can be re-established by:

- turning the cell phone off;
- keeping the cell phone at least 12 inches (31 cm) away from the receiving device, transmitter or glucose meter when a glucose measurement is being transmitted.

What is the recommended distance to keep the pump/transmitter away from other RF devices?

There is no need to separate the pump from other RF devices unless you are receiving interference. If you are receiving interference, reposition the devices until the interference stops.

How often do I need to re-link the pump to MySentry?

Unless you are experiencing RF interference that you cannot resolve, or there has been a system failure that has cleared the settings on the pump, you only need to link the pump to MySentry once. After initial linking, even if the power supply is unplugged, MySentry will automatically resynchronize upon power-up.

If you do need to re-link, it may take up to seven minutes.

What if I cannot resolve RF interference issues?

Re-link MySentry with the pump by performing the procedures in the *Getting started* chapter.

What is the RF power used by our devices?

Conducted RF:150KHz to 80MHz; Radiated radio frequency: 80 MHz to 2.5GHz

- Paradigm 523/723 insulin pump:
- MySentry Monitor:
- Outpost:

If I lose RF communication, what do I need to do to recover communication?

If you lose RF communication, do the following:

- Reorient or relocate the MySentry devices.
- Decrease the distance between the MySentry Monitor and MySentry Outpost to 100 feet or less.
- Decrease the distance between the MySentry Outpost and Paradigm 523/723 insulin pump to six feet or less.

What if MySentry experiences a power failure?

If a power failure occurs, the Monitor alarms for 15 seconds before turning itself off.

Why are the buttons on the MySentry Monitor sometimes lighted and sometimes not lighted?

To help you with navigate the system, only the active buttons are illuminated.

What do the bars on the Outpost indicate?

The bars are for cosmetic purposes only. The Outpost stays illuminated when there is a connection between it and the pump.

My Outpost is flashing very quickly. Does this indicate a problem?

Yes. This indicates that the Outpost needs to be reset. To reset the Outpost, unplug it from the power outlet and then plug it back in.

If unplugged, how long does it take for the pump and monitor to reconnect?

It might take up to seven minutes.

How long will it take for the pump and monitor to link during setup?

It typically takes between five and 30 seconds for the pump to link to the Monitor.

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Warranty

Medtronic Diabetes warrants the Medtronic MySentry Monitor and MySentry Outpost against defects in materials and workmanship for a period of six months from the date of purchase. During the warranty period, Medtronic Diabetes will replace (with a new Monitor or Outpost) any defective Monitor or Outpost, subject to the conditions and exclusions stated herein. In the event that the Monitor or Outpost is replaced, the warranty period will not be extended.

This warranty is valid only if the MySentry Monitor or MySentry Outpost is used in accordance with the manufacturer's instructions. This warranty will not apply:

- If damage results from changes or modifications made to the Monitor or Outpost by the user or third persons after the date of manufacture.
- If damage results from service or repairs performed by any person or entity other than the manufacturer.
- If damage results from a *Force Majeure* or other event beyond the control of the manufacturer.
- If damage results from negligence or improper use, including but not limited to: improper storage, submersion in water or physical abuse, such as dropping or otherwise.
- If changes or modifications not expressly approved by the party responsible for compliance are made. Such changes could void the user's authority to operate the equipment.

This warranty shall be personal to the original user. Any sale, rental or other transfer or use of the product covered by this warranty to or by a user other than the original user shall cause this warranty to immediately terminate. This warranty does not apply to any accessories.

The remedies provided for in this warranty are the exclusive remedies available for any breach hereof. Neither Medtronic Diabetes nor its suppliers or distributors shall be liable for any incidental, consequential, or special damage of any nature or kind caused by or arising out of a defect in the product.

All other warranties, expressed or implied, are excluded, including the warranties of merchantability and fitness for a particular purpose.

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