

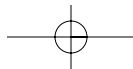
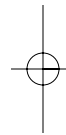
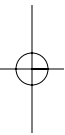
FCC ID: LF58832



You and Your SynchroMed® II Personal Therapy Manager
Model 8832 Personal Therapy Manager for Your SynchroMed® II
Implantable Drug Pump



Patient Manual
Rx Only



A Company Dedicated to Patients

Medtronic was founded in 1949 by Earl Bakken, a graduate student in electrical engineering, and his brother-in-law, Palmer J. Hermundslie. Today Medtronic is the world leader in medical technology, pioneering therapies that restore health, extend life and alleviate pain.

From its modest beginnings in a 55-square-meter Minneapolis garage, we have transformed Medtronic into a worldwide company that serves customers in more than 120 countries. Each year, millions of patients are treated with Medtronic products and therapies. We invest almost \$500 million each year in research and development, working closely with the world's leading physicians and scientists to enhance our current products and therapies, and to develop new ones. Although we are a large company, individual patients and their needs are still the driving force behind what we do and how we do it.

Our goal is to improve the quality of your life. This booklet, which provides information about your SynchroMed Personal Therapy Manager, is one small way we try to help.

Welcome to the Medtronic family. We wish you well.

Explanation of Symbols on Product and Packaging



IEC 60601-1, Type BF Equipment



Storage Temperature



Attention: See accompanying documents



Relative Humidity



Serial Number



Atmospheric Pressure



Radio frequency device (IEC-60601-1)

Medtronic® and SynchroMed® are registered trademarks of Medtronic, Inc.

This equipment has been tested and complies with the limits for medical devices as outlined in IEC 60601-1-2:1997. The device provides reasonable protection against harmful interference in a typical medical setting. However, there is no guarantee that interference will not occur. Refer to the troubleshooting section of this manual for instructions on what to do if the Personal Therapy Manager does not communicate completely with your pump and you suspect interference may be the cause.

FCC ID: LF5 8832

This device complies with Part 15 Rules. Operation is subject to the following 2 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.

IMPORTANT: Changes or modifications to this product not authorized by Medtronic, Inc., could void the FCC Certification and negate your authority to operate this product.

CONTENTS

GLOSSARY 1

INTRODUCTION4

 Identification of Buttons and Icons5

DESCRIPTIVE INFORMATION7

 Purpose of the Device (Indications)8

 List of Personal Therapy Manager Materials..... 9

 When the Device Should Not be Used
 (Contraindications)10

 Risks and Benefits10

 General Warnings and Precautions12

 Warnings12

 Precautions12

 Electromagnetic Interference (EMI).....13

 Care Regimen14

OPERATING INFORMATION15

- Setup Instructions15
 - Assembly15
 - Install the Batteries16
 - Turning on Your Personal Therapy Manager ..16
 - Patient Option Screen18
 - Synchronization21
- Activating a Dose22
 - Position Your Personal Therapy
Manager (Interrogation)23
 - Determining the Status of Your
Activation Request26
- Toolkit Screen.....30
 - Therapy Information Screen31
 - Refill Information Screen.....33
 - Pump Alarm Status Screen34
 - Volume Setting Screen34

Caring for Your Personal Therapy Manager35

 How to Determine if Batteries Need
 to be Replaced35

 Removing the PDA Batteries38

 Replacing the PDA Batteries.....39

 Removing the Telemetry Module Batteries41

 Replacing the Telemetry Module Batteries.....42

Cleaning and Care43

Storage45

Disposal47

TROUBLESHOOTING48

 When to Call Your Doctor’s Office.....48

 Call your doctor’s office if48

 How to Get Help55

ADDITIONAL INFORMATION	56
Specifications	56
Special Notice	57
Travel or International Use	57
SPECIAL PROCEDURES	58
Interrogation	58
Patient Diary Use	60
Setting the Volume	62
Calibration.....	64
Touchscreen Backlight Use	67
Resetting Your Personal Therapy Manager	68

GLOSSARY

Button—A picture on the screen of your Personal Therapy Manager that, when pressed, causes a specific action or function. On-screen buttons are presented as dark backgrounds that have lighter-colored pictures inside.

Calibration—The process that sets up your Personal Therapy Manager the first time batteries are installed or after the device has been without power for several minutes.

Dose Activation—The initiation of a command from your Personal Therapy Manager to your SynchroMed II Pump that tells the pump to activate a prescribed dose of medication.

Electromagnetic Interference (EMI)—A field of energy made by equipment found in the home, work, medical, or public environments that is strong enough to interfere with the operation of your Personal Therapy Manager.

Icon—A picture on your Personal Therapy Manager that gives you information or represents a function or action.

Incomplete Communication—The failure of your Personal Therapy Manager to complete delivery of a message to your pump.

Interrogate—The act of using your Personal Therapy Manager to get information from your pump.

Interference—Anything that reduces the effectiveness of or interferes with the communication between your Personal Therapy Manager and pump.

Lockout Interval—A period of time during which you cannot activate a dose using your Personal Therapy Manager. This time period is determined by your physician.

PDA (Personal Digital Assistant)—The hand-held component of the Personal Therapy Manager that contains the screen.

Search Tone—The continuous beeping sound you will hear while your Personal Therapy Manager is looking for your pump.

Synchronization—The process that updates your Personal Therapy Manager with information from the pump (such as therapy information).

Telemetry—A radio frequency signal that allows the Personal Therapy Manager to communicate with your implantable pump.





















Telemetry Module—The component of the Personal Therapy Manager that communicates with your pump.

INTRODUCTION

You have been supplied with a SynchroMed II Model 8832 Personal Therapy Manager that enables you to activate a programmed dose of medication prescribed by your doctor from your SynchroMed II Implantable Drug Pump.

Identification of Buttons and Icons

A laminated card provided with your Personal Therapy Manager defines the icons you may see on the screen. Those icons are also defined below:

	Dose Activation Request		Toolkit		Therapy Information
	Searching for Pump		Pump Alarm—Status		Patient Dose Information
	Successful Activation		Interrogate Pump		Dose Lockout Interval
	Request Denied		Refill Date		Pump Infusion — Continuous
	Time Remaining		Write to Diary		Patient-Activated Infusion
	Communication Failed		Speaker On		Return to Patient Option Screen
			Speaker Off		Attention

This manual will describe how to:

- calibrate your Personal Therapy Manager (page 64);
- interrogate your pump (page 58);

- activate a dose of medication from your pump (page 22);
- determine the status of your dose activation request (page 26);
and
- access additional information about your pump therapy (page 31).

If you have questions unanswered by this manual, or if any unusual situations or problems arise, consult your doctor. He or she knows your personal medical history and can give you the detailed information you may need. In particular, you should ask about the potential complications, risks, and benefits of this therapy.

Important terms appear in **bold** text and are listed in the glossary at the front of this manual.

DESCRIPTIVE INFORMATION

The Personal Therapy Manager is a hand-held device (Figure 1) that communicates with your implanted pump. The Personal Therapy Manager has two parts, a personal digital assistant (PDA) and a **telemetry module**.

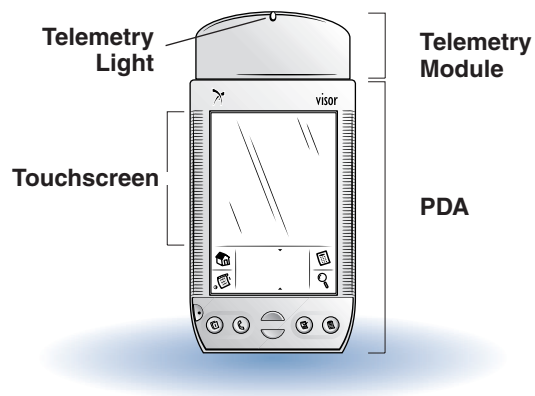


Figure 1. Personal Therapy Manager components.

The **PDA** part of your Personal Therapy Manager has a touchscreen with buttons and icons on the screen that are used to direct your interaction with the device. Buttons are activated when you press them with your finger.

The Personal Therapy Manager uses **telemetry** (radio waves) to communicate with your pump.

Purpose of the Device (Indications)

The Personal Therapy Manager enables you to activate from your pump a programmed dose of medication prescribed by your doctor. The dose of medication activated by your Personal Therapy Manager is a supplement to the continuous infusion of medication supplied by your implantable pump.

Your doctor will program your pump to accept commands from your Personal Therapy Manager. You can activate a dose as soon as the **lockout interval** time ends, if needed. A clock in the pump

keeps track of your **lockout interval** periods. You cannot activate more doses than your doctor prescribes in one day.

Be sure to talk with your doctor about the number of doses he has prescribed for you and the **lockout interval** period between doses so you understand how the Personal Therapy Manager is intended to work. Your doctor may have to adjust your prescription periodically until a dose schedule is found that is best for your needs.

List of Personal Therapy Manager Materials

Case material: Injection-molded acrylonitrile butadiene/
polycarbonate blend plastic resin

Label: Polycarbonate

When the Device Should Not be Used (Contraindications)

The Personal Therapy Manager should not be used when the pump is implanted more than 1 inch (2.5 cm) from the surface of the skin, because the Personal Therapy Manager may not be able to communicate with the implanted pump.

Risks and Benefits

The possible risks of using the Personal Therapy Manager include:

- The Personal Therapy Manager features of your pump might be programmed incorrectly, which could cause your pump to deliver too little or too much medicine. Delivering too much medicine could result in a serious overdose.
- The radio signals sent by your Personal Therapy Manager could interfere with other medical devices. Tell your doctor if you use any other devices (such as a pacemaker, insulin pump, or pain-relief device.)

- The Personal Therapy Manager might not work or might be unable to communicate with your pump, and you would be unable to activate a supplemental dose of medication.

The possible benefits of using the Personal Therapy Manager include:

- The Personal Therapy Manager allows you to activate a physician-prescribed supplemental dose of medication when you need it.

General Warnings and Precautions

Warnings

Do not attempt to use the Personal Therapy Manager on another device, for example, a pump other than the SynchroMed II Implantable Pump or a cardiac pacemaker. The Personal Therapy Manager will not work on devices other than the SynchroMed II Implantable Pump. Also, the radio signals (**telemetry**) from the Personal Therapy Manager might adversely affect the performance of other implantable devices.

Precautions

- Do not use mercury or zinc-air batteries.
- Do not use rechargeable batteries.
- Do not immerse the Personal Therapy Manager in liquid, or clean it with aromatic or chlorinated hydrocarbons or acetone (for example, bleach or nail polish remover).

Electromagnetic Interference (EMI)

Electromagnetic Interference is a field of energy (electrical, magnetic, or both) made by equipment found in the home, work, medical or public environments that is strong enough to interfere with the operation of your Personal Therapy Manager.

Electromagnetic interference could prevent your Personal Therapy Manager from communicating with the implantable pump.

If you think that equipment is interfering with your Personal Therapy Manager function, you should do the following:

1. Move away from the equipment or object.
2. If possible, turn off the equipment or object.
3. Inform the equipment owner/operator of what happened.

If the above actions do not correct the effects of the interference, or if you think that your therapy is not effective after exposure to EMI, you should contact your doctor.

Care Regimen

Following are some important guidelines for using your Personal Therapy Manager.

- Use your Personal Therapy Manager only as your doctor has explained to you.
- Handle your Personal Therapy Manager with care. Do not drop, throw, or toss your Personal Therapy Manager, or immerse it in water.
- Keep fresh AAA batteries on hand so that you can replace the Personal Therapy Manager batteries when needed.

OPERATING INFORMATION

Setup Instructions

Assembly

The Personal Therapy Manager is shipped unassembled. You must place the **telemetry module** on the **PDA** before use. Slide the module into the accessory slot of the PDA (Figure 2).

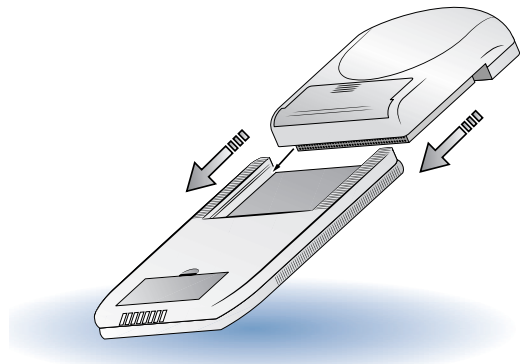


Figure 2. Slide telemetry module onto the PDA.

Your doctor can install the batteries in your Personal Therapy Manager and calibrate it when you receive the device. You will need to replace the batteries and calibrate the Personal Therapy Manager occasionally. Refer to the Special Procedures section (page 58) of this manual for calibration instructions.

Install the Batteries

Your SynchroMed II Personal Therapy Manager runs on four AAA batteries. If batteries are not installed when you receive your Personal Therapy Manager, follow the instructions (page 38) to install the batteries.

Turning on Your Personal Therapy Manager

To turn on your Personal Therapy Manager, use your fingertip to depress the half-moon ON/OFF button on the bottom left of your Personal Therapy Manager (Figure 3).

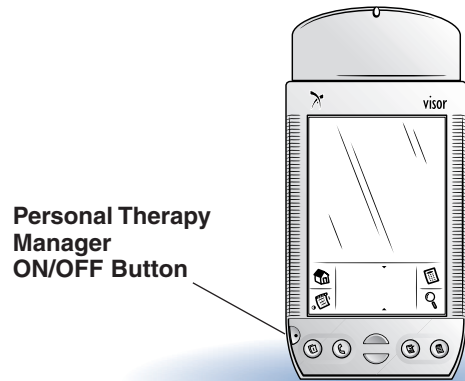


Figure 3. Personal Therapy Manager ON/OFF button.

Note: DO NOT press any of the buttons below the PDA screen. These buttons are for physician use only.

If you do not touch the screen for at least 25 seconds, the Personal Therapy Manager goes into standby mode, and the screen turns off. To reactivate the screen, press the ON/OFF button again.

Patient Option Screen

After you turn on your Personal Therapy Manager, you will see the Patient Option Screen (Figure 4).

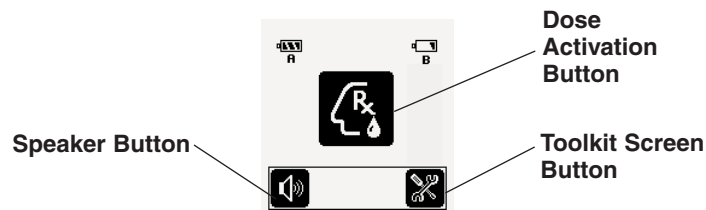


Figure 4. Patient Option Screen.

The Patient Option Screen displays your name, the Personal Therapy Manager battery status, and three buttons:



Dose activation request button (press this to activate a dose; refer to page 22).



Toolkit button (press this for information on your therapy and on additional features of the Personal Therapy Manager; refer to page 30).

Speaker ON  or OFF  button. Pressing this button turns the sound on or off.

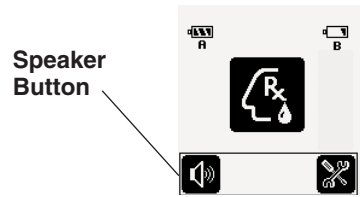



Figure 5. Turning the volume ON and OFF.

When the speaker ON button  is on the screen, the sound is ON.

When the speaker OFF button  is on the screen, the sound is OFF.

Synchronization

You should **synchronize** your Personal Therapy Manager with your pump as soon as possible after your doctor programs or refills your pump. You **synchronize** the two devices by interrogation. When you interrogate your pump, the information in your Personal Therapy Manager is updated to match the information in your pump. Refer to page 58 for interrogation instructions.

Activating a Dose

To activate a dose, press the dose activation request button on the Patient Option Screen.

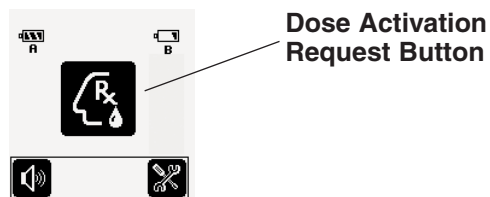


Figure 7. Location of the dose activation request button.

Your doctor might have programmed your Personal Therapy Manager with a Patient Diary feature. This feature lets you record how you are feeling. If the Patient diary screen appears, (Figure 8), make an entry into your Patient Diary (refer to page 60), then press the dose activation request button at the bottom of the screen.

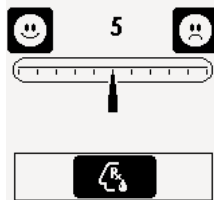


Figure 8. Patient Diary Screen.

Position Your Personal Therapy Manager (Interrogation)

The Personal Therapy Manager has a pump search function to help you to position it properly over your pump to ensure successful communication. After you press the patient-activated dose button, a graphic on the screen (Figure 9) will direct you to place the Personal Therapy Manager over your pump.



Figure 9. Pump Search Screen.

If the speaker is ON, you will hear a search tone (continuous beeping) while the Personal Therapy Manager is looking for your pump. The light at the top of the telemetry module will also blink.

The Personal Therapy Manager must be positioned closely over your pump for communication to occur. Place the Personal Therapy Manager over your implant site, and move it around slowly in the area of your pump (Figure 10). When the Personal Therapy Manager finds your pump, the search tone will stop,

and the telemetry light will quit blinking and remain on. Hold the Personal Therapy Manager still while it communicates with the pump. When communication is complete, you will hear a short series of beeps, and the telemetry light at the top of the Personal Therapy Manager (refer to Figure 1) will turn off.

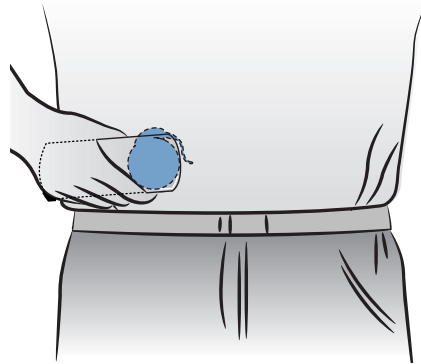


Figure 10. Position your Personal Therapy Manager over your pump.

Note: If your Personal Therapy Manager has found your pump, but loses it (for example, you move it away from the pump), the **search tone** will start again and the telemetry light will start blinking again. Move the Personal Therapy Manager back over the pump until the beeping stops and the light remains on.

Determining the Status of Your Activation Request

During and after an activation request, your Personal Therapy Manager makes sounds that indicate the status of the activation request (Table 1).

Table 1. Personal Therapy Manager Sounds

Sound	Meaning
Continuous Beeping	Your Personal Therapy Manager is looking for your pump.
Ascending Tones	Your Personal Therapy Manager has successfully communicated with your pump, and a dose has been activated.
Descending Tones	Your Personal Therapy Manager did not communicate with your pump or an activation was not allowed.

After you have completed an activation request, look at the screen on your therapy manager. One of the following screens will appear, indicating the status of the activation attempt:



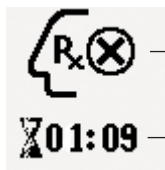
Successful Dose Activation

The screen that displays a successful dose activation icon means that you have successfully activated a dose.



Communication Failed

The screen with an incomplete telemetry icon means that your Personal Therapy Manager and pump did not successfully communicate. Press the patient-activated dose button in the lower left corner of the screen and reposition your Personal Therapy Manager over your pump (refer to instructions beginning on page 22).



Request Denied

Request Denied

Time Remaining

The screen with request denied and time remaining icons means that you cannot activate a dose at this time.


The time remaining (hh:mm), if shown, is the amount of time you must wait before you can successfully activate a dose.

Note: The time remaining function might not be available on your Personal Therapy Manager.

If you cannot activate a dose

There are several reasons why you may not be able to activate a dose of medication:

- You might have tried to activate a dose too soon after your last activation
- You might have tried to exceed the total number of activations prescribed by your doctor.

Press the home button  to return to the Patient Option Screen, or press the ON/OFF button to turn off your Personal Therapy Manager.

Toolkit Screen

To find information about your pump and its therapy, you can access the Toolkit Screen via the toolkit button on the Patient Option Screen. The Toolkit Screen contains four buttons (Figure 11).

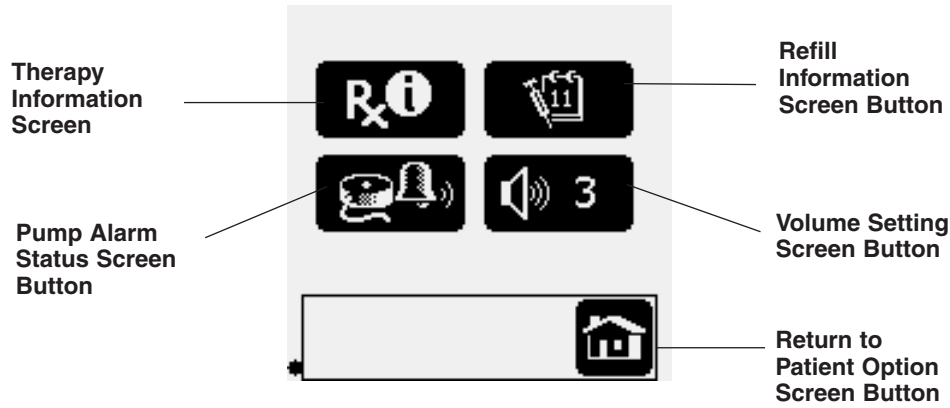


Figure 11. Toolkit Screen.

Therapy Information Screen

When you select the therapy information button, your Personal Therapy Manager screen will change, and three types of therapy information become available for you to review.

You can access the different types of information by selecting one of the three tabs at the top of the screen (Figure 12).

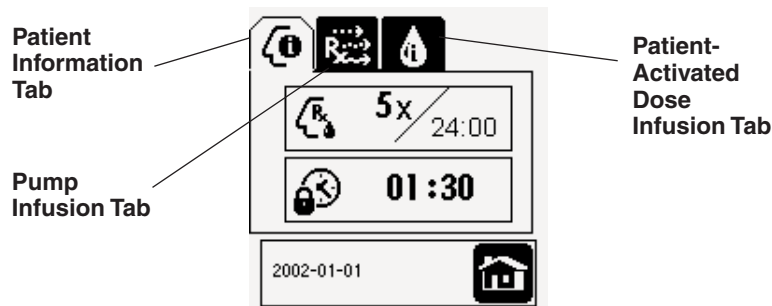


Figure 12. Therapy Information Screen.

- The patient information tab tells you how many doses you can activate in one day and how long your **lockout interval** period lasts.
- The pump infusion tab tells you what prescription drug is contained in your pump and how much of the prescription your pump is programmed to deliver.
- The patient-activated dose infusion tab tells you how much prescription drug will be delivered during a dose activation.

The date your pump was last programmed is displayed at the bottom of the Therapy Information Screen. Press the home button to return to the Patient Option Screen.

Refill Information Screen

The refill information button on the Toolkit Screen shows your doctor information about your refill date. Your doctor will use the information on this screen to tell you when you should get your pump refilled (Figure 13). Press the home button to return to the Patient Option Screen.

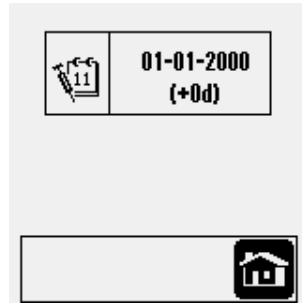


Figure 13. Refill Information Screen.

Pump Alarm Status Screen

If your pump alarm sounds, press the pump alarm button, then press the interrogate button and place your Personal Therapy Manager over your pump. Your Personal Therapy Manager will interrogate your pump. If the communication is successful, you will see a screen telling you a code for the pump alarm (Figure 14). Call your doctor with this information as soon as possible. Press the home button to return to the Patient Option Screen.

34

Figure 14. Pump Alarm Status Screen.

Volume Setting Screen

The volume setting button allows you to set the volume to low (1), medium (2), or high (3) (refer to page 62).

Caring for Your Personal Therapy Manager

How to Determine if Batteries Need to be Replaced

Your Personal Therapy Manager is powered by four AAA batteries—two batteries power the **PDA** and two batteries power the **telemetry module**.

Battery icons on your Personal Therapy Manager are located on the Patient Option Screen (Figure 15). These icons show the status of the batteries in the **PDA** and in the **telemetry module**.

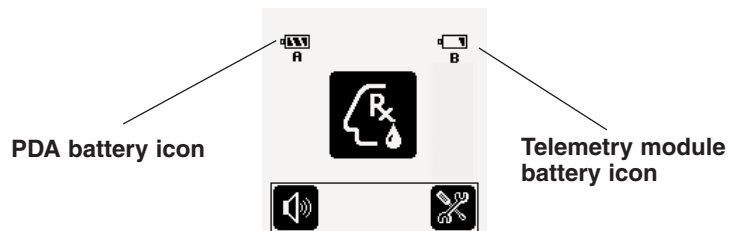




Figure 15. Location and identification of the battery icons on the Patient Option Screen.

To check the status, access the Patient Option Screen, and look at the battery icons.

-  Batteries are fully charged or near fully charged.
-  Batteries are okay.

 Batteries are low.

 Batteries are depleted. Change batteries.

Notes:

- Alkaline batteries are recommended for use in your Personal Therapy Manager.
- When not using your therapy manager for more than 4 weeks, remove the AAA batteries from both the **PDA** and the **telemetry module** to prevent damage.
- Make sure that you always have fresh AAA batteries on hand.

Removing the PDA Batteries

1. Remove the battery cover labeled with the A (Figure 16).

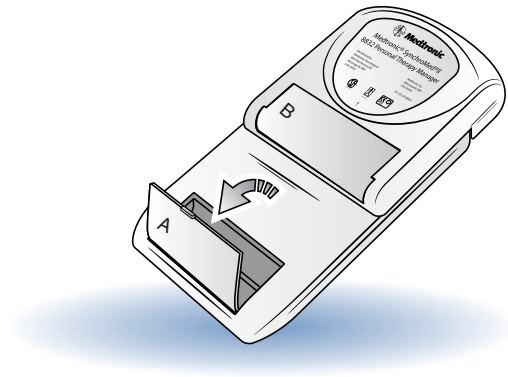


Figure 16. Removing the battery cover.

2. Lift the batteries out of the battery wells.

Replacing the PDA Batteries

1. Check the battery labels for positive [+] and negative [-] contacts. Match them with the [+] and [-] symbols in the battery wells.
2. Press the batteries down (spring end first) into the battery wells (Figure 17).

Note: The spring end is the negative contact.

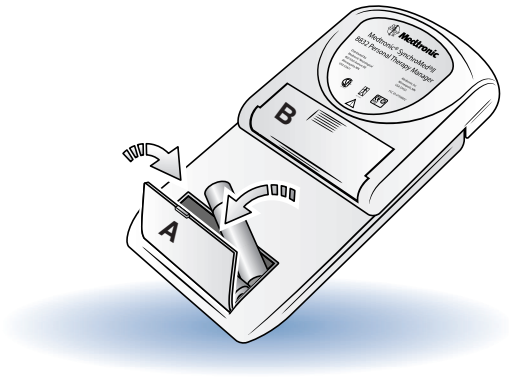


Figure 17. Inserting the batteries.

3. Replace the battery cover.

Removing the Telemetry Module Batteries

1. Remove the battery cover labeled with the B (Figure 18).

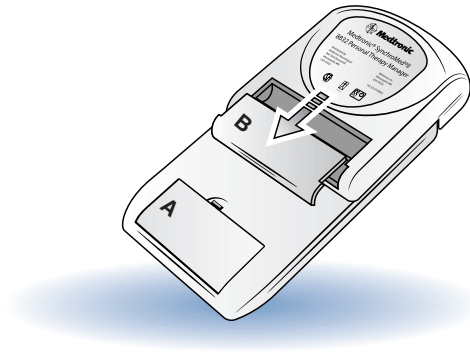


Figure 18. Removing the battery cover.

2. Lift the batteries out of the battery wells.

Replacing the Telemetry Module Batteries

1. Check the battery labels for positive [+] and negative [-] contacts. Match them with the [+] and [-] symbols in the battery wells.
2. Press the batteries down (spring end first) into the battery wells (Figure 19).

Note: The spring end is the negative contact.

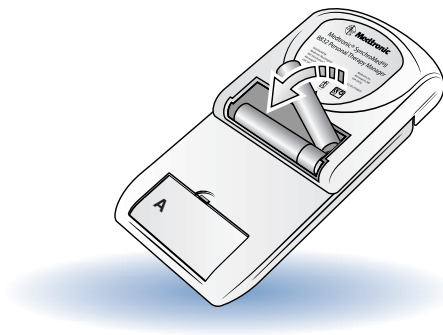


Figure 19. Inserting the batteries.

3. Replace the battery cover.

Dispose of depleted batteries according to local regulations.

Cleaning and Care

- Your Personal Therapy Manager is a precision device; handle it with care.
- Do not take apart or tamper with the Personal Therapy Manager; this could affect how it works.
- Protect the Personal Therapy Manager from sharp blows or physical shocks.
- Clean the outside of the Personal Therapy Manager with a slightly damp cloth. Mild household cleaners will not damage the case or labels.
- Your Personal Therapy Manager is not waterproof. Do not allow moisture to get into the device.

⚠ Caution

Do not immerse the Personal Therapy Manager in liquid. Do not clean it with bleach, nail polish, or other similar substances.

- Clean the battery contacts periodically with a cotton swab dampened with alcohol. Do not use a pencil eraser or sandpaper.
- Replace low or depleted batteries to ensure proper operation and to prevent corrosion of the Personal Therapy Manager.
- When not using the Personal Therapy Manager for more than 4 weeks, remove the batteries to prevent corrosion of the device.
- To conserve battery power, always turn off your Personal Therapy Manager when you are done using it.

Storage

You do not need to remove your Personal Therapy Manager from its pouch to use it. The pouch helps to protect the Personal Therapy Manager (Figure 20).

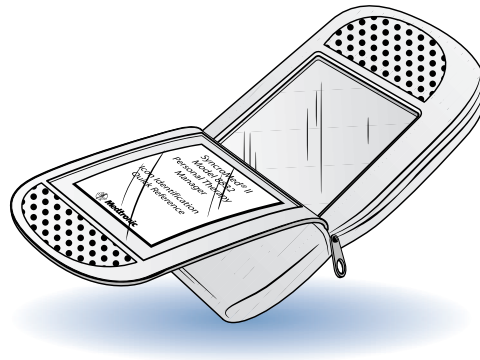


Figure 20. Personal Therapy Manager pouch.

Place the Personal Therapy Manager in the pouch so that the screen is against the fold-down flap (Figure 21).

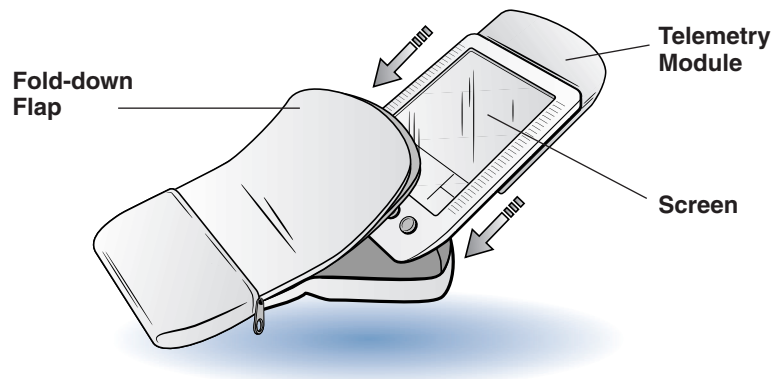


Figure 21. Storing your Personal Therapy Manager in its pouch.

Disposal

Return devices for disposal to the manufacturer. Medtronic office addresses are listed at the back of this manual.

TROUBLESHOOTING

When to Call Your Doctor's Office

Call your doctor's office if:

- you experience anything unusual, such as new or unexplained symptoms;
- you notice that you begin to feel differently or worse;
- your symptoms do not decrease with activation of a dose;
- you are not getting adequate relief from your symptoms; or
- your symptoms have dramatically changed.

This section will help you solve problems or identify when to call your doctor. Problems are described in the left column. The text in the middle and right columns lists possible causes of the problems and describes how to correct the problem.

Note: If your problem is not described here, contact your doctor.

Table 2. Troubleshooting

Problem	Potential Cause	Correction
Your Personal Therapy Manager is stuck on one screen.	Your Personal Therapy Manager has a hardware or software problem.	Reset your Personal Therapy Manager (refer to the Special Procedures section of this manual). Call your doctor.
Your Personal Therapy Manager does not respond to fingertip touch.	No battery, depleted battery, battery is in backward.	Replace the batteries with fresh batteries.
	Software/hardware failure	Reset your Personal Therapy Manager (refer to the Special Procedures section of this manual).
Your symptom relief is not adequate.		Call your doctor.

Problem	Potential Cause	Correction
Your Personal Therapy Manager does not turn on.	Personal Therapy Manager failure.	Reset your Personal Therapy Manager (refer to the Special Procedures section of this manual).
You cannot activate a dose.	Depleted battery.	Replace batteries
	You have tried to activate too many doses in one day period, or you have tried to activate a dose too soon since the last activation.	Wait until activation is allowed.
The beeper does not sound.	Your Personal Therapy Manager did not communicate correctly with your pump.	Reposition the Personal Therapy Manager over your pump and try again to activate a dose.
	You have turned the volume down too low to be able to hear it, or you have turned it off.	Turn the volume up (refer to page 62) or on (refer to pages 19-20).

Problem	Potential Cause	Correction
Your Personal Therapy Manager is non-functional.	You have spilled fluid on your Personal Therapy Manager.	Dry it with a towel, and turn the Personal Therapy Manager on to ensure it is working correctly.
	Your Personal Therapy Manager falls into water.	<ol style="list-style-type: none">1. Remove the Personal Therapy Manager from the water.2. Wipe it with a towel dampened with clean tap water.3. Open the battery covers and remove the batteries. Shake to remove as much water as possible.4. Dry battery compartments with a towel.5. Allow battery compartments to dry at room temperature for as long as possible.6. Shake the Personal Therapy Manager. If you see or hear water inside, repeat steps 4 and 5.

Problem	Potential Cause	Correction
	<p>Your Personal Therapy Manager falls or is dropped. NOTE: The Personal Therapy Manager is designed to withstand falls of short distances.</p>	<ol style="list-style-type: none"> 7. When the Personal Therapy Manager is dry, replace the batteries and battery covers. 8. Turn on the Personal Therapy Manager to ensure it is working correctly. 9. If the Personal Therapy Manager does not work properly, call your doctor. <p>Turn on the Personal Therapy Manager to see if the device is working. If you think the Personal Therapy Manager is not working correctly, call your doctor.</p>

Problem	Potential Cause	Correction
The telemetry light does not appear to be functioning.	Sunlight may be obscuring your view.	Shade the light with your hand or move into a darker area.
	The batteries on the PDA are depleted or are very low.	Check the appropriate battery status icon on the Patient Option Screen (refer to page 37). Change the batteries in the PDA (refer to pages 38-40).
The incomplete telemetry icon is displayed.	Battery placement is incorrect.	Check to see that the batteries are inserted properly.
	The Personal Therapy Manager was not close enough to the pump during the activation attempt.	Realign the Personal Therapy Manager and try again.

Problem	Potential Cause	Correction
After communication with the pump, the Personal Therapy Manager screen contains an alert icon with a number.	<p>The Personal Therapy Manager was moved away from the pump too quickly.</p> <p>Excessive electromagnetic interference (EMI). Interference caused by computer monitors or other electronic equipment.</p>	<p>Realign the Personal Therapy Manager with the pump and try again.</p> <p>Move away from possible EMI sources such as TVs or computer monitors.</p>
A generic PDA screen appears instead of the Patient Option Screen.	<p>A pump alarm is occurring.</p> <p>The telemetry module was not inserted correctly.</p>	<p>Call your doctor.</p> <p>Remove and replace the telemetry module, ensuring that none of the buttons on the bottom of the PDA are pressed during this time.</p>

How to Get Help

You can contact Medtronic Patient Services for help at the address and phone number listed on the back cover of this manual. Record other important contacts and phone numbers below, in the spaces provided:

Contact:

Phone:

ADDITIONAL INFORMATION

Specifications

Model 8832 SynchroMed II Personal Therapy Manager

Power Source: Four commercially available AAA batteries (LR 03)

Operating Temperature: 10 °C—40 °C (50 °F—104 °F)

Operating Time: Short

Storage Temperature: -20 °C—60 °C (-4 °F—140 °F)

Relative Humidity: 90% maximum

Atmospheric Pressure: 700 hPa to 1060 hPa (20.7 in. Hg to 31.3 in. Hg)

Personal Therapy Manager Size: Approximately 16.5x6.1x3.0 cm
(6.5x3.5x1.5 inches)

Personal Therapy Manager Weight: Approximately 284 g
(10 oz) (including batteries)

Battery Life: 6 weeks (typical)

Special Notice

The Medtronic Model 8832 SynchroMed II Personal Therapy Manager is designed for use with the SynchroMed II Pump. The functions of the Personal Therapy Manager are not compatible with any other devices. For information regarding difficulties which may be encountered using the Personal Therapy Manager, consult the other portions of this manual.

Travel or International Use

When traveling, always carry the ID card that was issued with your implantable pump. Follow all directions issued by your doctor when traveling.

You may want to carry extra AAA batteries when traveling overseas, although they may be readily available, depending on your destination.



SPECIAL PROCEDURES

This section describes the following procedures:

- Interrogation
- Patient Diary Use
- Setting the Volume
- Calibration
- Touchscreen Backlight Use
- Reset Procedure

Interrogation

When you interrogate your pump, the Personal Therapy Manager receives updated information from the pump. This information is a useful tool for your physician.

To interrogate your pump, press the toolkit button on the Patient Option Screen (Figure 4), then press the pump alarm button , and finally, the interrogate pump button . The Personal Therapy Manager will begin to beep, and the light on the **telemetry module** will begin to flash. Position your Personal Therapy Manager over your pump and move it around slowly in that area until the beeping stops and the light remains on. You will hear three ascending tones when successful interrogation is complete. If you hear two descending tones, the interrogation failed, and you should repeat the attempt.

Patient Diary Use

Your Personal Therapy Manager is equipped with a Patient Diary (Figure 22) that allows your doctor to track how well your therapy is providing you relief from your symptoms.

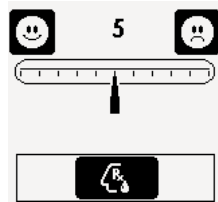


Figure 22. Patient Diary Screen.

You may be required to make an entry in your patient diary:

- prior to dose activation
- following dose activation
- at specific times of the day

When you make an entry, you will see a ruler on the Patient Diary Screen (Figure 23).

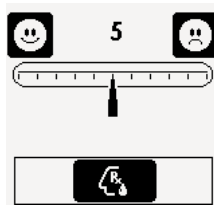


Figure 23. Patient Diary Screen.

Each small vertical line on the ruler in the middle of the screen represents a number, 0 through 10. The pointer on the screen points to the number currently selected. You can either drag the pointer left or right on the ruler, or touch a vertical line to bring the pointer to the number you desire.

Select a number that represents how you feel. A lower number means your symptoms are less intense. A higher number means your symptoms are worse.

After you make an entry into the patient diary, press the button at the bottom of the screen (the patient-activated dose button or the write diary button) to continue. After you press the button, your Personal Therapy Manager will either turn off or begin looking for your pump.

Setting the Volume

Your Personal Therapy Manager uses audio signals to communicate various messages, such as:

- Successful and unsuccessful dose activation;
- Request for patient diary entry; and
- Searching for pump.

To set the volume on your Personal Therapy Manager, press the Toolkit Screen button on the bottom right of the Patient Option Screen (Figure 24).

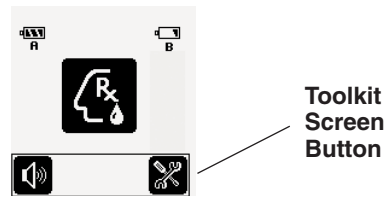


Figure 24. Accessing the Toolkit Screen.

On the Toolkit Screen, you will see a speaker button:



The volume setting changes each time you push this button.

Calibration

The Personal Therapy Manager will require periodic calibration (e.g., at initial assembly and after the batteries have completely depleted). The figures presented below represent the calibration instructions that will be presented on the Personal Therapy Manager. Follow the instructions on the screen to calibrate the device.

Note: Use a stylus to touch as closely as possible to the exact center of the target symbols.

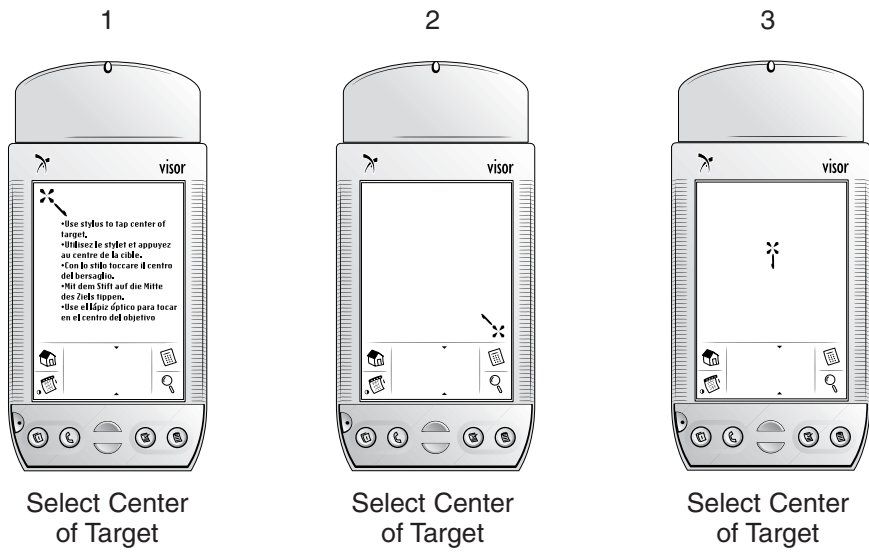


Figure 25. Calibration Instructions.

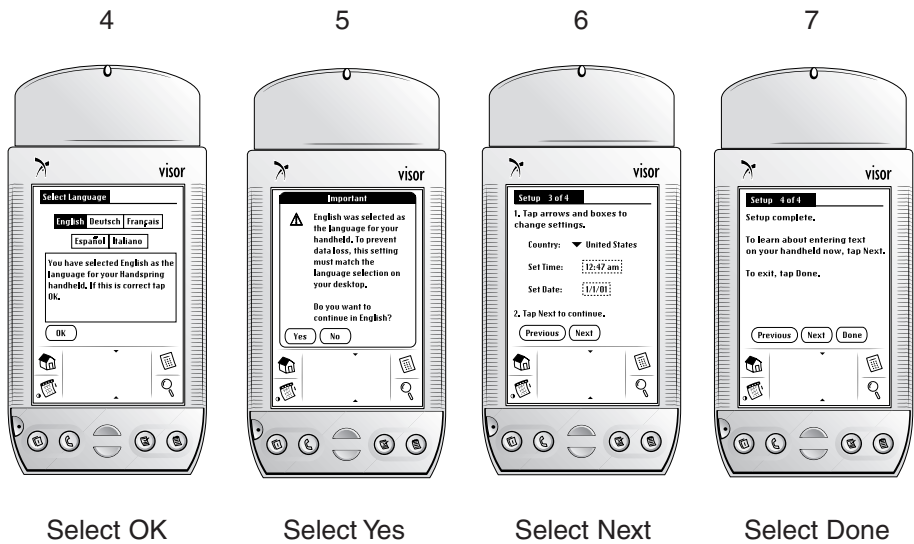


Figure 26. Calibration instructions.

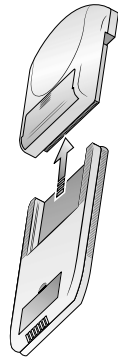
Note: The Personal Therapy Manager reads the time of day from the implantable pump. Do not reset the time on the Personal Therapy Manager Calibration Screens.

Touchscreen Backlight Use

Your Personal Therapy Manager is equipped with a backlight that illuminates the touchscreen under dark or limited lighting conditions. To turn on the backlight, press and hold the half-moon shaped ON/OFF button for approximately 2 seconds when you turn on your Personal Therapy Manager.

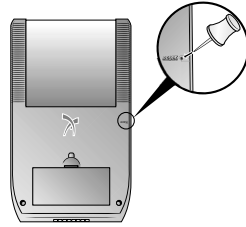
Resetting Your Personal Therapy Manager

To reset your Personal Therapy Manager:



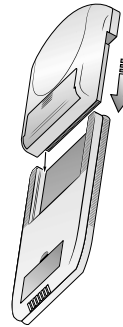
Remove telemetry module

Step 1



Use a push pin or other tool to push in the reset button

Step 2



Replace telemetry module

Step 3

INSIDE BACK COVER



Medtronic
When Life Depends on Medical Technology

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Internet: www.medtronic.com
Tel. 1-763-505-5000
Toll-free 1-800-328-0810
Fax 1-763-505-1000

© Medtronic, Inc. 2002
All Rights Reserved

221094001