



Medtronic

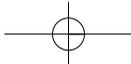
You and Your SynchroMed[®] Activator

Model 8831 Activator for Your SynchroMed[®] or SynchroMed[®] EL
Implantable Drug Pump



Patient Manual

Caution: Investigational Device. Limited by federal law (U.S.A.) to investigational use.
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 Activator, is one small way we try to help.

Welcome to the Medtronic family. We wish you well.

Explanation of Symbols

Status Light Symbols



Successful Dose Activation



Incomplete Communication



Interval Lockout



Activator Battery Status

Miscellaneous Symbols



IEC 60601-1, Type BF Equipment



Attention: See accompanying documents



Caution: This device contains a strong magnet. Proximity to recording tape and disks should be avoided.

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

Refer to the instructional label on the SynchroMed Activator for all applicable approvals.

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FCC INFORMATION

The following is communications regulation information on the Model 8831 SynchroMed® Activator.

FCC ID: LF58831

This device complies with Part 15 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.

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.

INTRODUCTION

You have been supplied with a Model 8831 SynchroMed® Activator that enables you to activate a programmed dose of medication prescribed by your doctor from your SynchroMed® or SynchroMed® EL Implantable Drug Pump.

The SynchroMed Activator is one part of the system that was prescribed for you and should be used only according to the instructions given in this manual and those provided by your doctor.

This manual will describe how to:

- activate a dose of medication from your pump;
- determine if an activation was successful;
- determine if enough time has elapsed since your previous dose to allow you to activate another; and
- understand the meaning of the lights on the back of your SynchroMed Activator and of the audio signals from the device.

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 end of this manual.

SYNCHROMED® ACTIVATOR DESCRIPTION

The SynchroMed Activator can “talk” and “listen” to your SynchroMed pump. When you activate your device, it sends a command to the pump to deliver a physician-programmed dose of medication. The SynchroMed Activator can also determine the timing of your most recent dose. Additionally, the SynchroMed Activator “talks” to you. Through a series of lights and beeps, the SynchroMed Activator tells you if you are successful in your attempt to activate the dose, if you are trying to activate a dose too soon since your last activation, and if the battery that powers your SynchroMed Activator is good.

Your doctor will program your pump to accept commands from your SynchroMed Activator. Your doctor will program the number of doses per 24 hours you may receive and the interval before you may give yourself another dose, also known as the **Interval Lockout**.

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

Use with Other Implanted Devices—The SynchroMed Activator can be used only with the SynchroMed family of pumps. The SynchroMed Activator is not compatible with other programmable pumps. The SynchroMed Activator may interfere with the operation of other implantable devices. Tell your doctor if you have another implanted device.

 **Warning**

Radio signals (telemetry) from the SynchroMed Activator may interfere with the performance of other implantable devices. Do not try to use the SynchroMed Activator to program another implantable device.

Additionally, the SynchroMed Activator operates best in an environment free from strong electromagnetic interference (EMI). Examples of sources of EMI include, but are not limited to: strong computer monitors, television sets, and other electronic equipment.

 **Caution**

The magnet in your SynchroMed Activator may interact with other implanted devices, impacting their operation or resetting their programs. If you have other implanted devices, talk with your doctor about the magnet in your SynchroMed Activator. Remember to keep your SynchroMed Activator away from cards with magnetic strips (credit/bank cards) and from computer monitors and TVs.

Refer to the SynchroMed pump patient manual for information about equipment and conditions that may affect the operation of your pump. If the SynchroMed Activator quits working, your symptoms may recur.

SYNCHROMED ACTIVATOR COMPONENTS AND FEATURES

This section describes the components and features of your SynchroMed Activator.

The Activation Button is located on the top of the SynchroMed Activator (Figure 1), as is the battery cover.

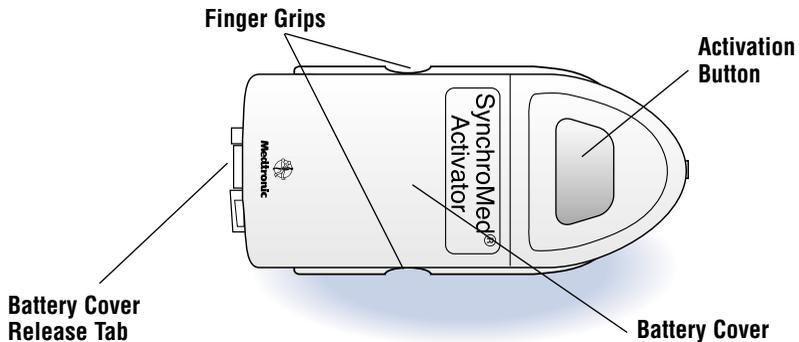


Figure 1. SynchroMed Activator top view.

On the bottom of the SynchroMed Activator (Figure 2), you will see four indicator lights and a “target” represented by a drawing of a hand holding a SynchroMed Activator.

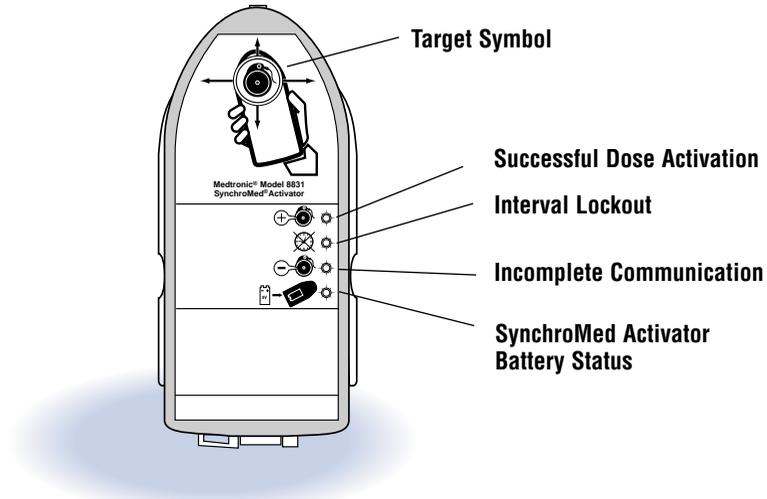


Figure 2. SynchroMed Activator bottom view.

When you use your SynchroMed Activator, the four indicator lights will help you understand how well the SynchroMed Activator is communicating with your pump. Each of the lights represents a different message:

- Successful **dose activation**
- **Interval lockout**
- **Incomplete communication**
- SynchroMed Activator Battery status

Refer to page 25 for a detailed explanation of each message.

Battery

Your SynchroMed Activator runs on one 9-volt battery. You should replace the battery in your SynchroMed Activator after every 12 weeks of typical use or when the battery light on the back of the SynchroMed Activator begins to blink or does not turn on.

If the battery in your SynchroMed Activator is good, the green battery light on the back of the device will remain lit. If the battery in your SynchroMed Activator begins to run low, the battery indicator light on the back panel will begin to blink.

The SynchroMed Activator performs a self test each time a battery is installed. You will see all of the lights on the back of the SynchroMed Activator turn on and you will hear a beep when you replace the batteries in your SynchroMed Activator.

Replacing the 9-Volt Battery

Replace the battery in your SynchroMed Activator at least once every 12 weeks, or when the battery light on the back of the SynchroMed Activator begins to blink.

 **Warning**

Do not use a mercury or zinc-air battery. Do not use rechargeable batteries.

Dispose of depleted batteries according to local regulations.

To remove the battery compartment cover (Figure 3):

1. Hold the SynchroMed Activator with one hand.
2. Press in the release button on the end of the SynchroMed Activator.
3. Lift off the cover.

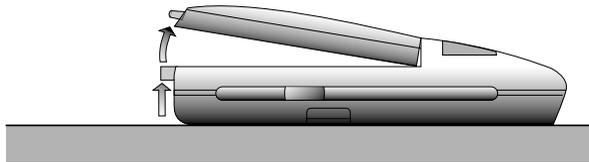


Figure 3. Battery compartment cover removal.

To replace the battery compartment cover:

1. Place the center hook on the edge of the cover into the center slot on the SynchroMed Activator (Figure 4).
2. Lower the battery compartment cover.
3. Press down the end of the cover to lock it in place.

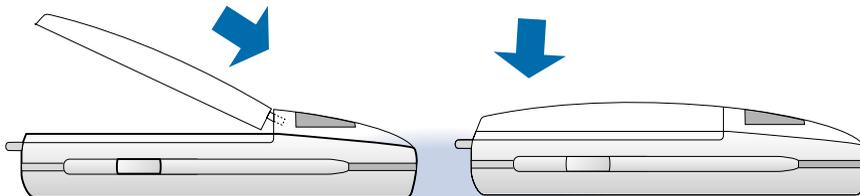


Figure 4. Battery compartment cover replacement.

To remove the battery:

1. Remove the battery cover.
2. Place one finger on the edge of the battery near the center bottom.
3. Lift the battery out of the compartment. To avoid damage to the SynchroMed Activator, do not use excessive force.

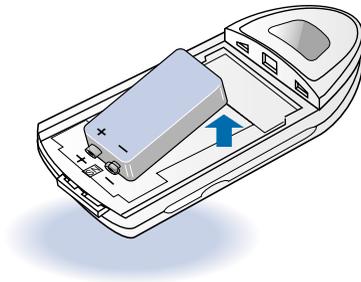


Figure 5. Battery removal.

Note: When not using the SynchroMed Activator for more than 4 weeks, remove the battery to prevent corrosive damage to the device.

To install the battery:

1. Check the battery well for positive [+] and negative [-] contacts. Match them with the {+} and {-} symbols in the battery compartment.
2. Press the battery down fully into the battery compartment without using excessive force.

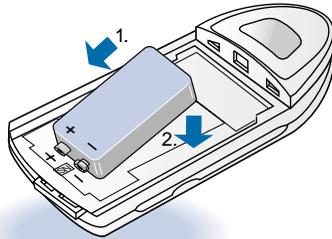


Figure 6. Battery installation.

3. Replace cover.

 **Caution**

Do not press the Activation Button during battery installation, because the SynchroMed Activator may “lock-up” and become non-functional. If you think your SynchroMed Activator has locked up, remove the battery and insert a fresh battery.

STORING YOUR ACTIVATOR IN ITS POUCH

When you are not using your Activator, store it in its pouch. Items such as bank or credit cards (with magnetic strips) and floppy disks may be damaged by the magnet in your Activator. The pouch contains a hard metal shield that protects these types of items from the magnet (Figure 7).

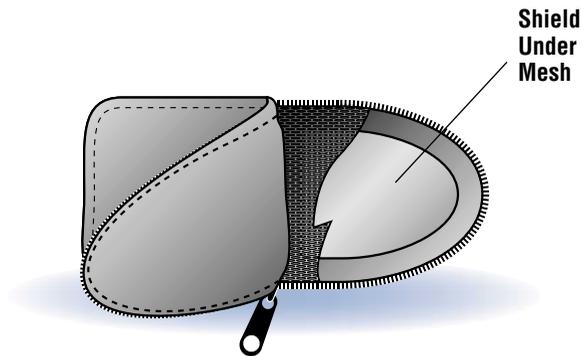


Figure 7. Pouch with magnetic shield.

Place the Activator in the pouch so that the back of the Activator (the side with the lights) is against the side of the pouch that contains the shield (Figure 8).

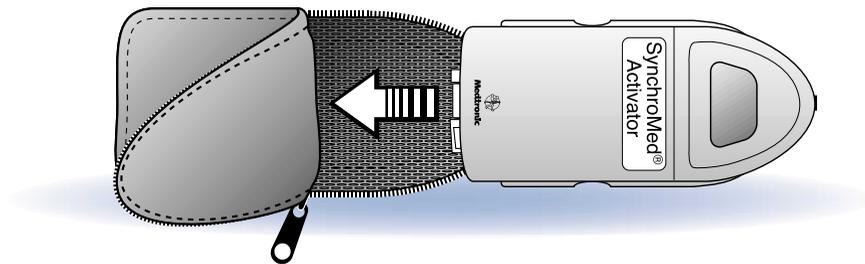


Figure 8. Storing your Activator in its pouch.

ACTIVATION BUTTON

When you place the SynchroMed Activator over the pump and depress the Activation Button on your SynchroMed Activator, the SynchroMed Activator and the pump “talk” to each other.

A clock in the SynchroMed Activator keeps track of your interval lockout periods. You cannot activate more doses than your doctor prescribes in one 24-hour period.

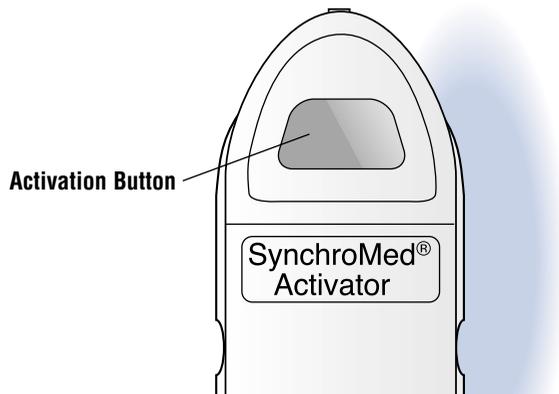


Figure 11. Activation button.

When you depress the activation button on the SynchroMed Activator, you will receive one of several messages in the form of lights and audible signals (refer to page 25, “Understanding the SynchroMed Activator Lights and Sounds”).

POSITIONING AND USING YOUR SYNCHROMED ACTIVATOR

When you are ready to activate a dose, hold the SynchroMed Activator steadily over your drug pump for at least three seconds after you have pressed the activation button. You must hold the SynchroMed Activator steadily to ensure that the SynchroMed Activator and the pump communicate.

Note: If the SynchroMed Activator is not properly centered over the pump after the activation button is pressed, successful communication between the SynchroMed Activator and the pump may not take place.

How to use the SynchroMed Activator with your pump:

- Hold the SynchroMed Activator by the finger grips (Figure 1) on the sides of the device.
- Use the target symbol on the back of the SynchroMed Activator to help you align the SynchroMed Activator over the center of your pump (Figure 9).
- Press the Activation Button and hold.
- While the SynchroMed Activator is looking for the pump, you will hear continuous beeping. After you find the pump and the SynchroMed Activator communicates with it, the beeping will stop. You may need to move the SynchroMed Activator in a circular motion near your implanted pump in order for your SynchroMed Activator to “find” your pump.

Note: If you move the SynchroMed Activator away from the pump too soon, the beeping will start again. If this happens, realign the SynchroMed Activator and try again.

- When your SynchroMed Activator has successfully communicated with your pump, you will hear a sequence of beeps (refer to page 25, “Activator Lights and Sounds”).

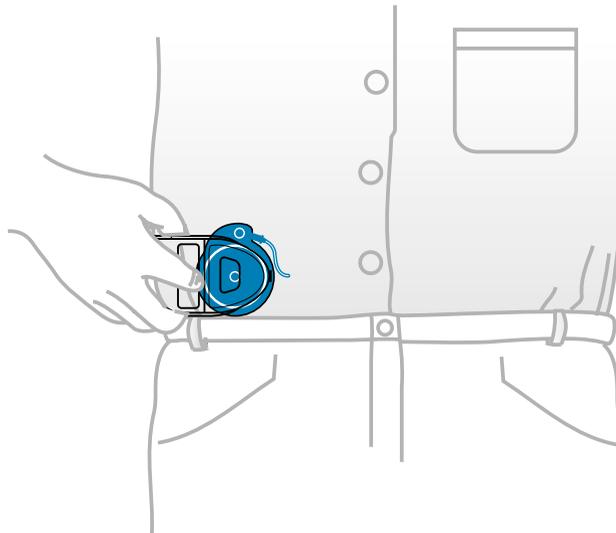


Figure 9. Correct placement of the SynchroMed Activator over a pump.

INITIALIZATION

After you receive your SynchroMed Activator and each time your pump is reprogrammed or refilled, you must press the activation button to begin the interval lockout. (Refer to page 18, "Positioning and Using Your SynchroMed Activator," and follow activation instructions).

When the interval lockout period is over, you will be able to activate a dose.

Remember your SynchroMed Activator cannot activate a dose the first time you use it. Instead, the device sets an **interval lockout** period the first time you activate after:

- you first receive your SynchroMed Activator,
- your pump is refilled, or
- your doctor reprograms your pump.

Activate your pump using your SynchroMed Activator as soon as possible after refill or programming to start the **interval**

lockout period the doctor has set. Ask your doctor how long this period lasts for you. You can activate a dose as soon as the **interval lockout** time ends, if needed.

Figure 10 shows one example of a series of events from pump refill to interval lockout end. Note that activation is permitted outside the interval lockout period only.

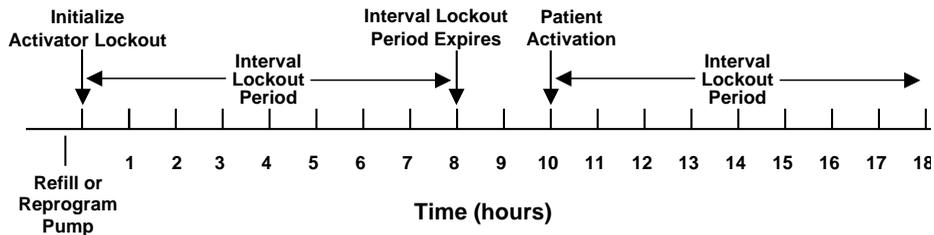


Figure 10. Graphic representation of activation and interval lockout period.

UNDERSTANDING THE SYNCHROMED ACTIVATOR LIGHTS AND SOUNDS

This section explains the light and sound messages your SynchroMed Activator sends you. Refer to Figure 2 as you read the text below.

On the row of lights on the back of your SynchroMed Activator, the top light (SUCCESS) turns green immediately after you successfully activate a dose.

If you try to activate a dose too soon after your last activation, a yellow light (second from the top) will turn on (**INTERVAL LOCKOUT**).

If you try to activate a dose, and communication is not established with your pump, the third light in the row will turn on yellow (**INCOMPLETE COMMUNICATION**).

The green light at the bottom of the row (BATTERY STATUS) will remain green during activation as long as the 9-volt battery in your SynchroMed Activator is good. When the battery is low, the light will begin to blink green. (The light will not turn on at all if the battery is too low to operate the SynchroMed Activator.)

All lights remain on for 8 seconds.

Your SynchroMed Activator produces different series of beeps for various messages:

- Three beeps (ascending tones) in rapid succession mean a **dose activation** was successful.
- Two beeps (ascending tones) in rapid succession mean your SynchroMed Activator was initialized following a programming session with your doctor.
- Two beeps (descending tones) in rapid succession mean one of the following:
 - You tried to activate a dose too soon following your most recent activation.

- You tried to activate too many doses within a 24-hour period (more than prescribed by your doctor).
- Your SynchroMed Activator did not communicate completely with your pump within 10 seconds.
- Your pump has not been programmed for SynchroMed Activator use

The beeper cannot be turned off, and the volume is not adjustable.

Note: If you hear two beeps (descending tones), but you believe that your **interval lockout** period is over, try once more to activate a dose. If you are still unsuccessful, check your records to determine the number of doses activated in the past 24 hours (refer to pages 39-40).

Table 1. SynchroMed Activator Lights and Sounds

SynchroMed Activator Indicator Light	SynchroMed Activator Light Color	SynchroMed Activator Sounds
Successful dose activation	Green light	3 beeps (ascending tones)
Interval lockout	Yellow light	2 beeps (descending tones)
Incomplete communication	Yellow light	2 beeps (descending tones)
SynchroMed Activator battery status	Green light=good Green light blinking= replace battery	None
Initialization	Yellow light	2 beeps (ascending tones)

TROUBLESHOOTING

The following table presents potential difficulties that might occur when you are trying to use your SynchroMed Activator, and possible solutions for those difficulties.

Table 2. Troubleshooting

If this happens	This might be why	Try these steps
No lights appear to be functioning	<ul style="list-style-type: none"> • Sunlight may be obscuring the view • No battery • Very low battery • Battery placement incorrect 	<ul style="list-style-type: none"> • Shade the lights or move into a darker area • Replace the battery • Check to see that the battery is inserted correctly
The beeper does not sound, but the battery light is on	<ul style="list-style-type: none"> • You may not be able to hear the beeper because of noise around you • The beeper may be broken 	<ul style="list-style-type: none"> • Move to a quieter area • Call your doctor

If this happens

The SynchroMed Activator does not respond to button presses•

This might be why

- Button may be broken
- No battery
- Very low battery

Try these steps

- Check to see that the battery is inserted correctly
- Replace the battery
- Call your physician if you you have checked and replaced the battery, but your Activator is still not responding

If this happens

SynchroMed Activator indicates that communication with pump was incomplete; (incomplete light is yellow and two descending tones sound)

This might be why

- SynchroMed Activator is not close enough (within 5 cm) to the pump
- The SynchroMed Activator is not aligned properly with the pump
- The SynchroMed Activator was moved too quickly away from the pump
- Excessive EMI (proximity to strong computer monitors or other electronic equipment)

Try these steps

- Realign the SynchroMed Activator using the target on the device
- Ensure that the SynchroMed Activator is in contact with the skin or clothing directly over the pump; if necessary, ask someone to help you
- Position the SynchroMed Activator over the pump at least 3 seconds after you push the activation button. Do not move the SynchroMed Activator quickly away from the pump location
- Move away from possible EMI sources such as TV's or large computer monitors

If this happens

After communication with the pump, the SynchroMed Activator continually beeps and all lights flash

All lights are on, but the device is non-functional

This might be why

- The pump has a memory error
- Self-test has failed

Try these steps

- Call your doctor immediately
- Remove battery and insert new battery
- Contact your physician

Following are some guidelines for using your SynchroMed Activator.

Do:

- Use your SynchroMed Activator only as your doctor has explained to you.
- Handle your SynchroMed Activator with care. Do not drop, throw, or toss your SynchroMed Activator, or immerse it in water or any other liquid.
- Keep a fresh 9-volt battery on hand so that you can replace the SynchroMed Activator battery when needed.

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;
- your symptoms have dramatically changed; or
- your SynchroMed Activator beeps continually following communication with the pump, and all lights flash.

CLEANING AND CARE

The SynchroMed Activator is a precision instrument and should be handled with care.

Disassembling or tampering with the internal components of the SynchroMed Activator could damage it and make it inoperable.

Although the SynchroMed Activator construction is rugged, it should be protected against sharp blows or physical shocks. Do not drop or toss your SynchroMed Activator.

Clean the outside of the SynchroMed Activator with a slightly damp cloth. Mild household cleaners will not damage the case or labels. Your SynchroMed Activator is water resistant, not waterproof. Do not immerse the SynchroMed Activator in water or any other liquid.

Be careful to prevent moisture from entering the SynchroMed Activator.

 **Caution**

Do not immerse the SynchroMed Activator in liquid, or clean it with aromatic or chlorinated hydrocarbons, or acetone (for example, bleach or nail polish remover).

If the battery contacts require cleaning, clean them with a cotton swab dampened with rubbing alcohol. **Do not use a pencil eraser or sandpaper.**

Replace a depleted battery to ensure proper operation and to prevent corrosion.

SPECIFICATIONS

Model 8831 SynchroMed Activator Specifications

Power Source: 9-volt alkaline (type 6LR61 or 6F22E) battery

Operating Temperature: 49°F—110°F (9°C—43°C)

Storage Temperature: -40°F—150°F (-40°C—65°C)

Relative Humidity: 10—95%

SynchroMed Activator Size: Approximately 5.3x2.4x1.2 inches
(13.5x6.1x3.0 cm)

SynchroMed Activator Weight: Approximately 7 oz (198g)
(including battery)

Battery Life: 12 weeks (average)

GLOSSARY

Dose Activation—The initiation of a command from your SynchroMed Activator to your SynchroMed pump that tells the pump to activate a prescribed dose of medication.

Incomplete Communication—The failure of your SynchroMed Activator to complete delivery of a message to your pump.

Interference—Anything that reduces the effectiveness or interferes with the communication between your SynchroMed Activator and pump.

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

Retain the following information for your records and for your doctor.

Date of Activation	Time of Activations
--------------------	---------------------

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

Date of Activation

Time of Activations

**MEDTRONIC® NEUROLOGICAL EQUIPMENT
LIMITED WARRANTY
(U.S. Customers Only)**

- A. This Limited Warranty provides the following assurance to the purchaser of the Medtronic® Model 8831 SynchroMed® Activator hereafter referred to as “Equipment”:
- (1) Should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the delivery of the Equipment to the purchaser, Medtronic will at its option: (a) repair or replace any part or parts of the Equipment; (b) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement Equipment or (c) provide a functionally comparable replacement Equipment at no charge.

- (2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement Equipment.
- B. To qualify for Limited Warranty set forth in Section A(1), the following conditions must be met:
- (1) The Equipment must be returned to Medtronic within thirty (30) days after discovery of the defect (Medtronic may, at its option, repair the Equipment on site).
 - (2) The Equipment must not have been repaired or altered outside of Medtronic's factory in any way which, in the judgment of Medtronic, affects its stability and reliability. The Equipment must not have been subjected to misuse, abuse, or accident.

C. This Limited Warranty is limited to its express terms. In particular:

- (1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE, OR MALFUNCTION OF THE EQUIPMENT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.
- (2) This Limited Warranty is made only to the purchaser of the Equipment. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

- (3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.
- (4) No person has any authority to bind Medtronic to any representation, condition, or warranty except this Limited Warranty.

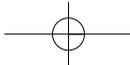
* This Limited Warranty is provided by Medtronic, Inc., 710 Medtronic Parkway NE, Minneapolis, MN 55432-5604. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

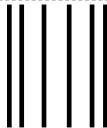
SERVICE

The SynchroMed Activator has been carefully engineered and tested to provide long, trouble-free service. If repair or service is necessary, call Medtronic at 1-800-328-0810.

To register the activator for service covered by the limited warranty, complete and mail the warranty registration card inserted in this manual.

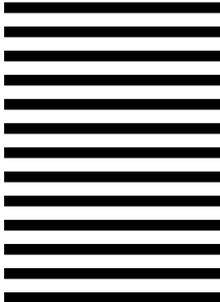
A serial number, located within the battery compartment identifies each activator. If you write or call Medtronic about your activator, refer to the serial number.





NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

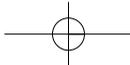
BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 7611 MINNEAPOLIS, MN



POSTAGE WILL BE PAID BY ADDRESSEE

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DEVICE REGISTRATION MS LN385
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Medtronic

When Life Depends on Medical Technology

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