

EXHIBIT 5

Instruction Manual

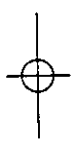
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Synergy[™] EZ

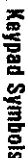
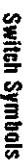




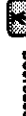






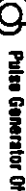
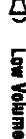



MODEL 7435 PATIENT PROGRAMMER



USER MANUAL



Device Symbols

	Keypad Symbols		Stimulation Control Switch Symbols
	Pulse Generator On		Amplitude
	Pulse Generator Off		Pulse Rate
	Decrease		Pulse Width
	Increase		
	Statuslight Symbols		Beeper Control Switch Symbols
	Pulse Generator On		Volume Off
	Pulse Generator Off		Low Volume
	Pulse Generator Battery		High Volume
	Programmer Battery		

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⚠ Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

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General Warning

The Medtronic® Synergy™ EZ Model 7435 Patient Programmer (the "Programmer") is designed to program the adjustable parameters of the Medtronic® Synergy™ Model 7427 Implantable Pulse Generator (the "pulse generator"). Do Not attempt to use the programmer on another device (for example, a cardiac pacemaker). Radio signals from the patient programmer may interfere with the performance of other implantable devices.

FCC INFORMATION

The following is communications regulation information on the Synergy™ EZ Model 7435 Patient Programmer.

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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.

ABOUT THIS BOOKLET

For over 30 years, stimulation has helped thousands of patients manage their pain. This has also improved their quality of life. Your stimulation system may be used with other pain treatments like physical therapy or medicine. Stimulation will not cure your pain. It may, however, reduce your pain to a tolerable level. As a result, you may be able to resume your daily activities.

This booklet provides you with the following:

- What to expect as you recover from surgery
 - Definition of pain and stimulation
 - Description of your implanted system and how it works to manage your pain
 - Description of your patient programmer, how to use it and care for it
 - Steps to take to help you solve problems or identify when you should call your doctor
 - How to live with your stimulation system
 - Answers to common questions
 - Important terms that appear as **bold text**; these terms are listed in the glossary at the end of this booklet
- Ask your doctor to explain anything that is unclear.

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RECOVERING FROM SURGERY

Healing

It takes several weeks to heal from surgery. You will feel some discomfort from the incision(s). You will also have some pain at the pulse generator site for 2 to 6 weeks. This pain is normal.

Physical Therapy and Medications

Your physician may also prescribe physical therapy, medication, or both to help manage your pain. Always follow your doctor's instructions for the therapy(ies) prescribed.

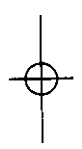


Activities

During your recovery (about 6 weeks), follow your doctor's advice. Avoid activities where you must bend, stretch, or twist your body; this can move your leads and alter your stimulation.

To prevent lead movement, **AVOID** the following activities during your recovery:

- Lying on your stomach
- Reaching over your head
- Turning from side to side
- Bending forward, backward, or from side to side
- Lifting more than 5 pounds



As you begin to feel better, you should be able to return to activities such as:

- Bathing or showering
- Sexual activity
- Working at home or at your business
- Hobbies or other activities such as walking, gardening, cycling, or swimming
- Traveling

Remember that returning to your daily activities should make you feel better, not worse. Discuss this with your doctor first.

Note: As you adjust to life with better pain control, you may want to try activities that you could not perform before your surgery. Discuss this with your doctor first.



WHAT IS PAIN?

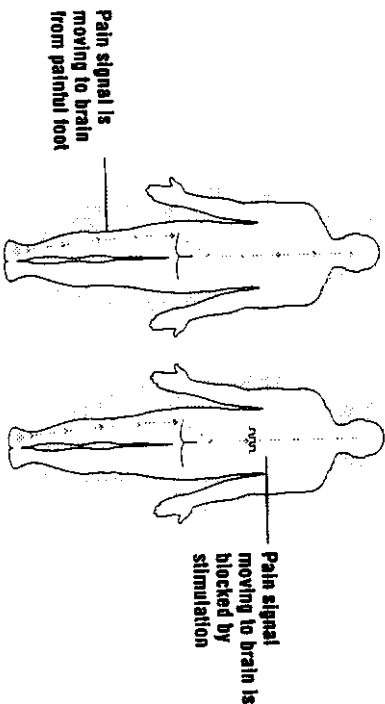
Nerve signals from all over your body travel to your spinal cord, and then to your brain. Your brain translates nerve signals into feelings such as pressure, itching, tingling, or pain. It is your brain that feels pain, not the area of your body where the signal started.

WHAT IS STIMULATION AND HOW DOES IT MANAGE PAIN?

Stimulation delivers of tiny electrical pulses to the spinal cord. This blocks the pain signal as it travels to the brain. If the signal does not reach the brain, the pain is not "felt."

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Note: Stimulation will not cure your pain nor will it block sharp pain caused by a recent injury.



Stimulation blocks pain signals as they move to the brain.

WHAT DOES YOUR STIMULATION SYSTEM LOOK LIKE?

A typical stimulation system has five implanted parts: one pulse generator, two leads, and two extensions.

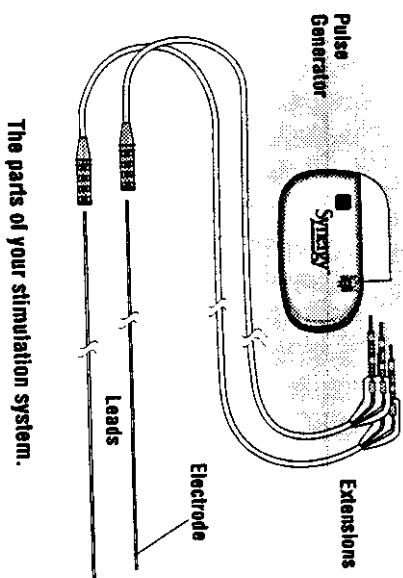
Pulse Generator: The pulse generator is the power source of your system. It contains a special battery and electronics to control the stimulation you feel.

Note: In time, the battery inside your pulse generator will wear out. When this occurs, your pulse generator will need to be surgically replaced.

Lead(s): The lead (pronounced "lead") is a thin wire covered with a protective coating. The lead has small metal electrodes near the tip. The lead is surgically placed with the metal electrodes near your spinal cord. The electrodes transmit tiny electrical pulses to the area where your pain signals will be blocked.

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Extension(s): The extension is a thin wire placed under the skin. It also is covered with a protective coating. The extension connects to the pulse generator at one end and to the lead at the other end.



The parts of your stimulation system.

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HOW DOES YOUR STIMULATION SYSTEM WORK?

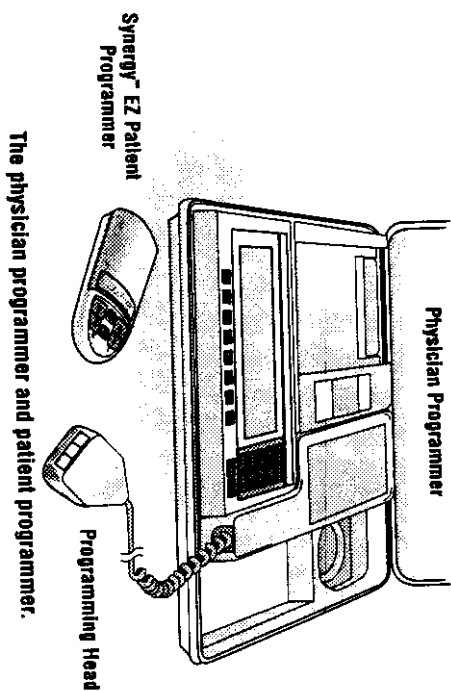
After your surgery, your doctor used a small computer (physician programmer) to send stimulation instructions to your pulse generator. These instructions control the stimulation you feel.

A programming head connects to the computer. The programming head transfers instructions from the computer to your pulse generator. The instructions are stored in your pulse generator. If needed, your doctor can use the programmer to change the instructions.

You have been given a patient programmer to use with your system. It allows you to turn your pulse generator on and off. It also allows you to fine tune your stimulation. Your doctor or nurse will explain how to use the patient programmer. Refer to "Using the Patient Programmer," on page 30.

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A special code inside your pulse generator allows only programming from the physician or patient programmer; other devices are not able to program your pulse generator.



The physician programmer and patient programmer.

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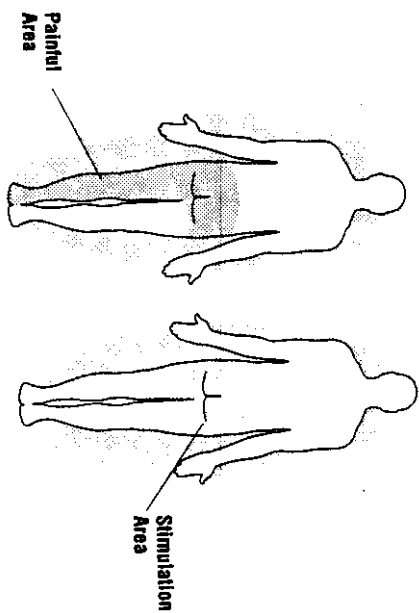
HOW DOES STIMULATION FEEL?

Your pulse generator sends tiny electrical pulses through the extension to the lead. The electrical pulses move through the lead and electrodes to the area where your pain signals will be blocked.

To most patients, these pulses feel like tingling in the pain area. Sensations vary from patient to patient.

When your pulse generator is turned on, the tingling slowly increases until it levels off. When your pulse generator is turned off, the tingling slowly decreases until it stops.

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Stimulation feels like tingling in the area of pain.

As your spine moves, you may sense an increase or decrease in the stimulation. It may seem as though the pulse generator is turning on or off. When you bend over or move suddenly you may even feel an uncomfortable "jolt" or "shock."

Do not be alarmed if these sudden changes in stimulation occur. The instructions inside your pulse generator have not changed. Your movement has probably caused your spinal cord to move closer to or farther from the lead electrodes. For a moment, the stimulation may feel more or less intense than it should.

Sudden changes in stimulation like these are most common during the recovery period. They usually decrease as you heal and the lead becomes more secure in your spinal column.



WHAT DOES THE PATIENT PROGRAMMER DO?

Use the patient programmer with only your implanted pulse generator. **DO NOT** use the programmer on other devices (such as, a cardiac pacemaker).

Warning

Signals (telemetry) from the patient programmer may disrupt the function of other implanted devices.

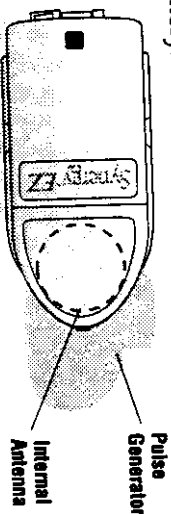
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- Your programmer is easy to use. You can use it to:
- Turn the pulse generator on or off.
 - Adjust the stimulation of your pulse generator.
 - Check the battery status of the pulse generator and the programmer.
 - Confirm that the pulse generator has received instructions from the programmer.

HOW DOES THE PATIENT PROGRAMMER WORK?

The patient programmer sends signals to your pulse generator. These signals tell the pulse generator to turn on or off or to change stimulation.

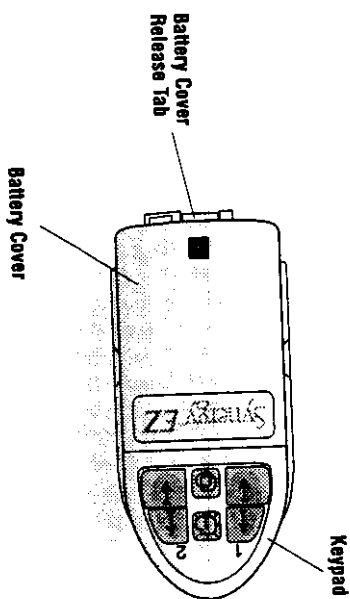
The pulse generator also sends signals to the patient programmer. Signals from the pulse generator confirm changes you have made. Signals also tell you the status of the pulse generator battery.



The programmer placed over the pulse generator.





PATIENT PROGRAMMER FEATURES

This section describes the features of the patient programmer.

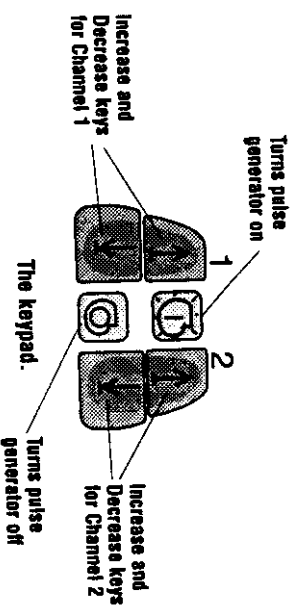




The patient programmer.





Keypad



The keypad has 6 keys: pulse generator On  and Off  keys, and Increase  and Decrease  keys for Channel 1 and Channel 2.

Note: Pressing any key on the programmer turns it on. If no keys are pressed in 8 seconds, the programmer will turn off.



On and Off Keys
Press the On  and Off  keys to turn the pulse generator on and off.

Channel 1 and Channel 2 Keys
Your implanted system affects different pain areas. Channel 1 Increase  and Decrease  keys adjust the stimulation for one area; Channel 2 Increase  and Decrease  keys adjust stimulation for the other area. Your doctor will explain the effects of changing stimulation for one channel versus the other.

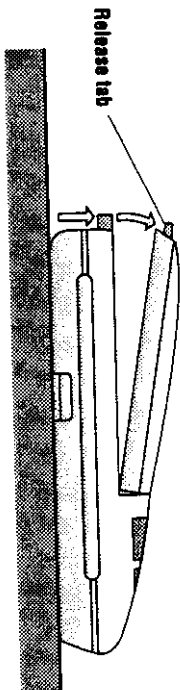
Note: A **Stimulation Control switch**, under the battery cover, is used to select the **amplitude, rate, or pulse width**. These are the settings you will adjust with the Increase  and Decrease  keys.

Battery Cover

When the battery cover is removed you can replace the battery or access the Stimulation Control Switch.

Removing the Battery Cover

1. Hold the programmer with one hand.
2. Lift the battery cover release tab on the end of the programmer. Lift off the cover.

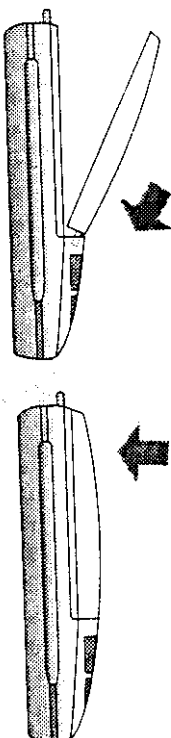


Remove the battery cover.

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Replacing the Battery Cover

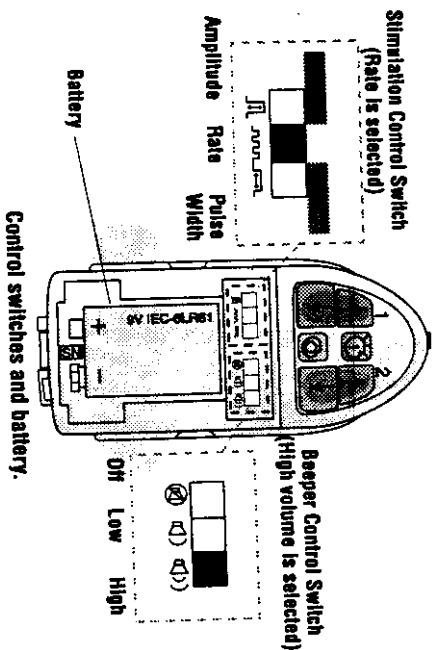
1. Place the center hook on the edge of the cover into the center slot in the programmer.
2. Lower the battery cover.
3. Press down the end of the cover to lock it in place.



Replace the battery cover.

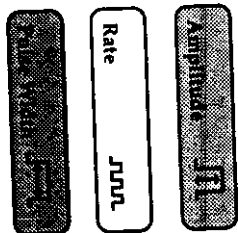
Control Switches and Battery

The Control switches and battery are located beneath the battery cover.



Control Switches

Stimulation Control Switch
 You can adjust three settings with the Stimulation Control switch: amplitude, rate, and pulse width. Colors and symbols identify each setting (see below). Changing these settings will help you find the highest level of comfort and pain relief.



The amount or "volume" (strength or intensity) of stimulation required to mask your pain. This is the setting most often adjusted by patients.

The number of pulses per second; rate feels like "tapping."

The length or duration of the electrical pulse. A longer pulse covers a larger area.

Note: The Increase ↑ and Decrease ↓ keys on your keypad adjust the selected stimulation control.

Beeper Control Switch

The programmer beeps each time a change is received by your pulse generator. Turn the beeper off @ or set the volume to low ⇨ or high ⇨ with the Beeper Control switch.

Table 1. Beeper description.

If you hear	It means
One beep	You have pressed the On/Off or Increase/Decrease key and the change was successfully received by your pulse generator.
Three rapid beeps	You tried to adjust the amplitude, pulse width, or rate beyond the highest and lowest settings. You tried to increase amplitude, rate, or pulse width with the pulse generator turned Off. You reduced amplitude to its lowest setting.

Battery

A 9-volt battery provides the power for the patient programmer. You may use an alkaline or carbon-zinc battery. An alkaline battery is better for longer battery life. Battery life depends on how often the programmer is used. Typically, a new battery should provide about 3 months of use. Always keep a fresh battery at hand.

Warning

Do not use a mercury or zinc-air battery.

Notes:

- When not using the programmer for more than 4 weeks, remove the battery to prevent damage to the device.
- Make sure that a fresh 9-volt battery is always at hand so that you can turn your pulse generator on and off or adjust the stimulation settings when necessary.

Symbols and Status Lights

The back of your programmer displays symbols and status lights. These will help you during a programming session.

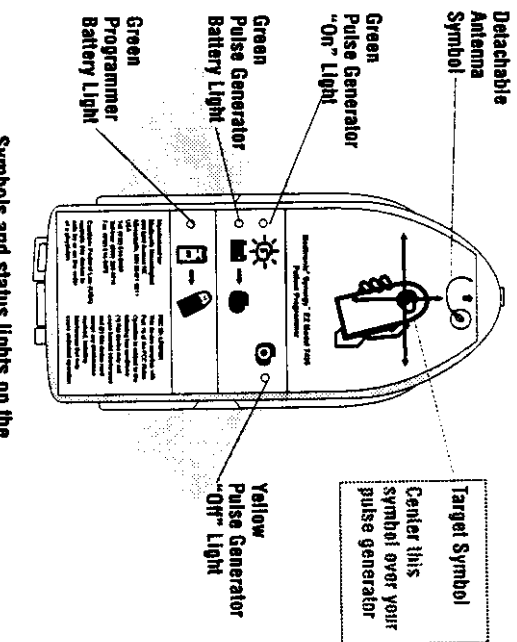
Symbols

A target symbol helps you center your programmer over the pulse generator. An antenna symbol directs you to the antenna connector. An optional, detachable antenna can be plugged in here.

Status Lights

When lit or blinking, the status lights tell you the following:

- whether the pulse generator is on or off,
- the pulse generator battery status,
- the programmer battery status.



Symbols and status lights on the back of the patient programmer.

USING THE PATIENT PROGRAMMER

This section is organized as follows:

- Placing the Programmer Over the Pulse Generator
- Checking the Pulse Generator Battery
- Turning the Pulse Generator On and Off
- Adjusting Your Stimulation

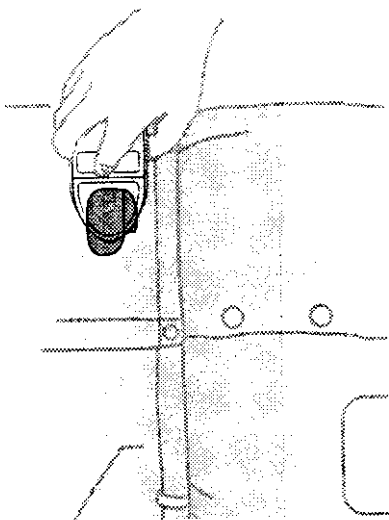
Placing the Programmer Over the Pulse Generator

Place the programmer over your pulse generator. Use the target symbol on the back of the programmer to help you

To send and receive signals, hold the programmer steady over the pulse generator for at least 1 second while pressing any key.

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Note: The center of the programmer target symbol is in line with the center of the keypad. This is also the center of the internal antenna.



Center target symbol over the pulse generator.
(Place against clothing or skin.)

Note: A detachable antenna is also available. This is helpful for patients who cannot reach their pulse generator. Refer to Accessories for more information.

 **Checking the Pulse Generator Battery**

The Pulse Generator Battery light on the back of the programmer tells you the status of your pulse generator battery.

To check the pulse generator battery:

1. Place the programmer over your pulse generator. Use the target symbol on the back of the programmer to help you center the programmer over your pulse generator.
2. If your pulse generator is off, press the off key. If your pulse generator is on, press the on key. Hold the programmer over the pulse generator for at least 1 second.
3. Confirm that the green Pulse Generator Battery light on the back of the programmer is lit. Refer to Table 2 for more information about the pulse generator battery light.

Note: Move indoors or into the shade if sunlight blocks your view of the programmer lights.

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Table 2. Pulse Generator Battery  lights.

When this happens	It Means
Green Pulse Generator Battery light is on for 8 seconds after pressing any key.	Pulse generator battery is good.
Green Pulse Generator Battery light is blinking for 8 seconds after pressing any key.	The pulse generator battery is low. Call your doctor's office.
Green Pulse Generator Battery light is off after pressing any key.	Reposition programmer and try again. Interference from electrical equipment can cause lights to remain off. Move to another room and try again. If the light remains off, the pulse generator battery is probably near depletion. The pulse generator should be reviewed with a physician programmer. Contact your doctor immediately.

Turning the Pulse Generator On and Off

Turn your pulse generator on when:

- You require pain relief, or
- You want to adjust the amplitude, rate, or pulse width.

Turn your pulse generator off when:

- The amplitude is set at the lowest setting and you do not need stimulation;
- You are using equipment that could be harmful to you or others if you should receive a sudden shock (for example, driving a car);
- You are having a medical or dental procedure that could affect the operation of your pulse generator (such as a diagnostic x-ray like mammography); or
- You are passing through a theft detector or a security device such as those used in department stores and airports.

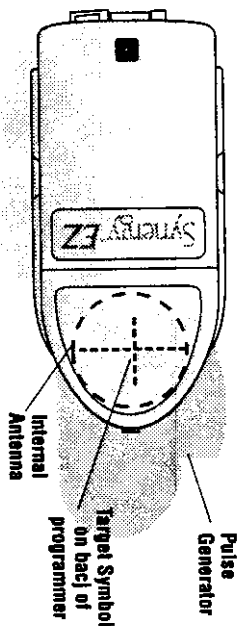
Notes:

Turning the pulse generator off extends the battery life of your pulse generator. When the battery wears out, the pulse generator must be surgically replaced. You will want to make it last as long as possible.

Decreasing the amplitude to the lowest setting will not turn off the pulse generator.

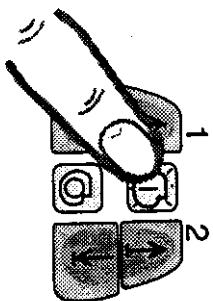
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- To turn the pulse generator on:**
1. Place the programmer over your pulse generator. Use the target symbol on the back of the programmer to help you center the programmer over your pulse generator.



Place the programmer over the pulse generator.

2. Press the Pulse Generator On key and hold the programmer over the pulse generator for 1 second. If the beeper is on, you should hear one beep to confirm that a change has occurred.



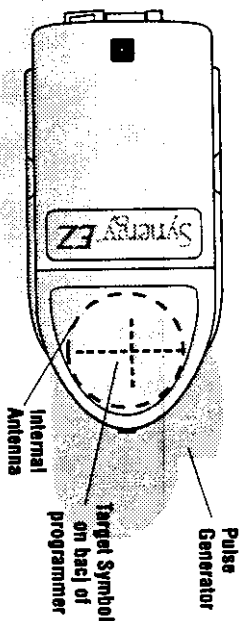
Press the Pulse Generator On key.

3. Check that the green Pulse Generator On light on the back of the programmer is lit; this indicates that the pulse generator was successfully turned on (Table 3). This light stays on for 8 seconds after you release the key.

Note: The pulse generator will turn on with the settings last programmed.

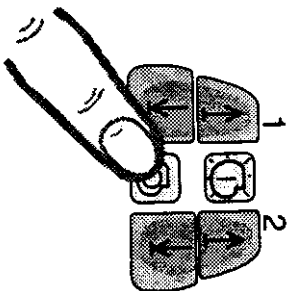
To turn the pulse generator off:

1. Place the programmer over your pulse generator. Use the target symbol on the back of the programmer to help you center the programmer over your pulse generator.



Place the programmer over the pulse generator.

2. Press the Pulse Generator Off key and hold the programmer over the pulse generator for 1 second. If the beeper is on, you should hear one beep to confirm that a change has occurred.



Press the Pulse Generator Off key.

3. Check that the yellow Pulse Generator Off light on the back of the programmer is lit; this indicates that the pulse generator was successfully turned off (refer to Table 3). This light stays on for 8 seconds after you release the key.

Note: Move indoors or into the shade if sunlight blocks your view of the programmer lights.

Table 3. Pulse Generator On and Off lights.

When	It Means
The green Pulse Generator On light is lit for 8 seconds after pressing any key.	Pulse generator is on.
The yellow Pulse Generator Off light is lit for 8 seconds after pressing any key.	Pulse generator is off.
Neither Pulse Generator On or Off light is lit after pressing any key.	The programmer does not know if the pulse generator is on or off. Refer to "Troubleshooting," page 74.



Adjusting Your Stimulation

Table 4 provides some general guidelines for when you should adjust your stimulation. Your doctor will provide more complete guidelines.

	Press Key
Adjust the Amplitude	
Before you adjust rate or pulse width	3
Before you turn the pulse generator Off	3
When the tingling is not strong enough	3
When the tingling is too strong	3
Adjust the Pulse Width	Action Key
If the tingling does not cover your pain area	3
If the tingling seems to cover too much area	3
Adjust the Rate	Action Key
If the tapping is uncomfortable	3 or 3

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Programming Tips

The following tips are helpful when using the patient programmer.

Caution

To avoid unpleasant stimulation, always decrease the amplitude to the lowest setting before turning your pulse generator Off or adjusting the rate or pulse width of your pulse generator. After rate or pulse width are set, slowly increase the amplitude to your highest comfort level.

- Always set your pulse generator to the lowest settings that provide pain relief. The higher the settings, the faster your pulse generator battery will wear out. When the battery wears out, the pulse generator must be surgically replaced. You will want to make it last as long as possible.
- Select amplitude, rate, or pulse width using the Stimulation Control switch. The Increase ↑ and Decrease ↓ keys will adjust the stimulation setting that you select.

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- Channel 1 and Channel 2 Increase ↑ and Decrease ↓ keys cannot be used at the same time.
- Both channels always have the same rate. Either set of channel keys will adjust the rate.
- The Channel 1 Increase ↑ and Decrease ↓ keys adjust the amplitude or pulse width for Channel 1. The Channel 2 Increase ↑ and Decrease ↓ keys adjust the amplitude or pulse width for Channel 2.
- The pulse generator must be on to increase amplitude, rate, and pulse width. However, the pulse generator may be either on or off to decrease the amplitude, rate, or pulse width.

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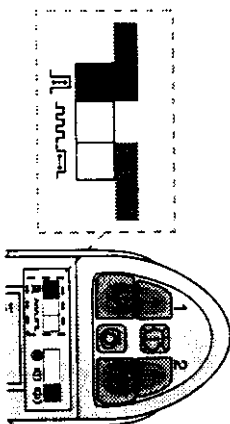
- Use the lights on the back of the programmer to confirm that a change is taking place. The Pulse Generator On or Off lights, the Programmer Battery light, and the Pulse Generator Battery light should be lit after sending a change to the pulse generator. This confirms that the pulse generator is turned on or off, and that the pulse generator and the programmer batteries are good. These lights stay on for 8 seconds after you release the key.
- If the beeper is on, the programmer will beep once for each change that is programmed into your pulse generator. Your programmer will beep 3 times if you try to increase a stimulation setting when the pulse generator is off. It will also beep 3 times if you have reached the lowest or highest setting for the selected setting.
- You can increase or decrease settings more quickly by pressing and holding down the desired key. Every 1/2 second, the programmer will send a change to the pulse generator.

45

Decreasing the Amplitude to the Lowest Setting

Always decrease the amplitude for each channel to the lowest setting before adjusting pulse width and rate or turning your pulse generator Off.

1. Remove the battery cover.
2. Move the Beeper Control switch to low \Downarrow or high \Uparrow .
3. Move the Stimulation Control switch to amplitude \perp .



Move the Stimulation Control switch to amplitude.

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4. Place the programmer over your pulse generator. Use the target symbol on the back of the programmer to help you center the programmer over your pulse generator.
 5. Press and hold the Decrease \downarrow key under Channel 1 until the programmer beeps rapidly three times. This reduces the amplitude of Channel 1 to the lowest setting.
- Note: The pulse generator may be on or off when decreasing amplitude.
6. Repeat steps 2 through 5 for other channel if desired.
 7. Replace the battery cover.

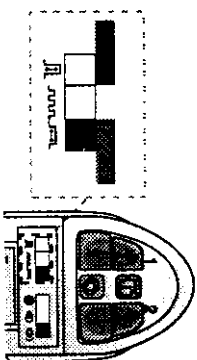
47

Adjusting the Pulse Width

1. Remove the battery cover.
2. Decrease the amplitude of desired channel to the lowest settings as described on pages 46 - 47.







Caution

To avoid unpleasant stimulation, always decrease the amplitude to the lowest setting before adjusting the pulse width or rate of your pulse generator. After rate or pulse width is set, slowly increase the amplitude to your highest comfort level.



Move the Stimulation Control switch to pulse width.

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3. Move the Stimulation Control switch to pulse width .
4. Place the programmer over your pulse generator. Use the target symbol on the back of the programmer to help you center the programmer over your pulse generator.
5. Press Pulse Generator On  to turn on the pulse generator.
6. Press the Increase  or Decrease  key under the desired channel to make a change.
7. Move the Stimulation Control switch to amplitude .
8. Place the programmer over your pulse generator.
9. Press the Increase  key under the desired channel to assess the change. Repeat steps 2 through 9 until the change is acceptable.
10. Repeat steps 2 through 9 for the other channel if desired.
11. Replace the battery cover.

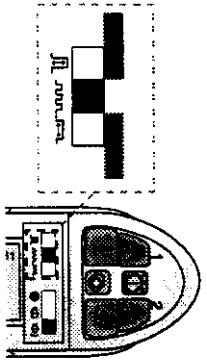
49

Adjusting the Rate

1. Remove the battery cover.
2. Decrease the amplitude of both channels to the lowest settings as described on pages 46 - 47.


Caution

To avoid unpleasant stimulation, always decrease the amplitude to the lowest setting before adjusting the pulse width or rate of your pulse generator. After rate or pulse width is set, slowly increase the amplitude to your highest comfort level.



Move the Stimulation Control switch to rate.

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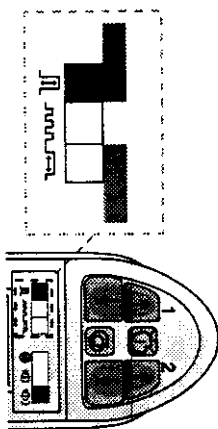
3. Move the Stimulation Control switch to rate **JL**.
4. Place the programmer over your pulse generator. Use the target symbol on the back of the programmer to help you center the programmer over your pulse generator.
5. Press Pulse Generator On  to turn on the pulse generator.
6. Press the Increase **↑** or Decrease **↓** key under either channel to make a change.

Note: Either set of channel keys adjust the rate; both channels always have the same rate.
7. Move the Stimulation Control switch to amplitude **JL**.
8. Place the programmer over your pulse generator.
9. Press the Increase **↑** key under the desired channel to assess the change. Repeat steps 2 through 9 until the change is acceptable.
10. Replace the battery cover.

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Adjusting the Amplitude


1. Remove the battery cover.
2. Move the Stimulation Control switch to amplitude Jfl.

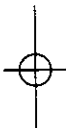


Move the Stimulation Control switch to amplitude.

FCC ID: LF57434



3. Place the programmer over your pulse generator. Use the target symbol on the back of the programmer to help you center the programmer over your pulse generator.
4. Press Pulse Generator On  to turn on the pulse generator.
5. Press the Increase \uparrow or Decrease \downarrow key under the desired channel to make a change.
6. Repeat steps 3 through 5 for the other channel if desired.
7. Replace the battery cover.

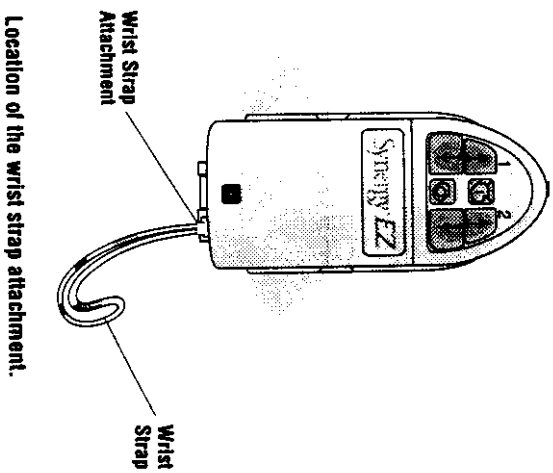


ACCESSORIES

Wrist Strap and Carrying Case

A wrist strap is packaged with the patient programmer and can be used to help you avoid dropping it. The wrist strap is attached near the battery cover release tab. A carrying case is also enclosed with the programmer. Store the patient programmer in the carrying case to protect it.

FCC ID: LF57434



Detachable Antenna

A detachable antenna is available for patients who cannot reach their pulse generator. When connected, the detachable antenna turns off the programmer's internal antenna.

Caution

Do not attach the antenna to your wound with the adhesive discs until the pulse generator incision is healed.

Note: When the detachable antenna is not used, keep the rubber plug in the antenna connector of the patient programmer. The rubber plug helps keep water out of the programmer.

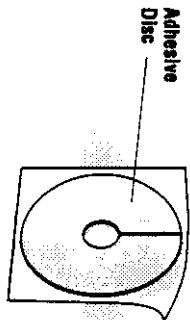
FCC ID: LF57434

To keep the antenna in place, use the adhesive discs supplied with the antenna. The adhesive discs are hypoallergenic. This helps reduce the chance of irritation. If irritation occurs, consult your doctor.

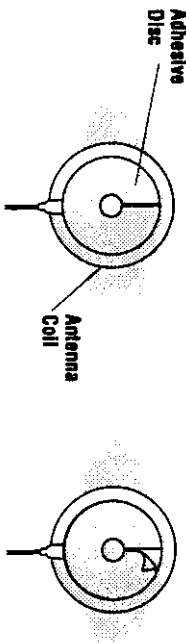
Replace the adhesive discs every day. Before replacing an old disc with a fresh one, clean your skin using an antibacterial soap and dry thoroughly.

Attaching the Antenna Over the Pulse Generator

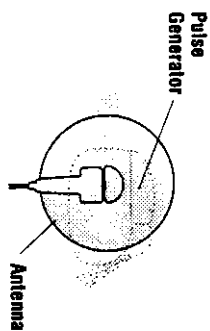
1. Remove adhesive disc from square sheet.



2. Attach disc to antenna coil. Remove protective covering.

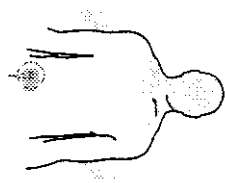


3. Center antenna over pulse generator.



Note: The antenna must be properly centered over the pulse generator for programming to occur.

4. Press antenna firmly in place.



Connecting the Antenna to the Patient Programmer

1. Pull out the rubber plug on the patient programmer to reveal the antenna connector.

Note: The antenna connector is located on the end of the programmer near the keypad.

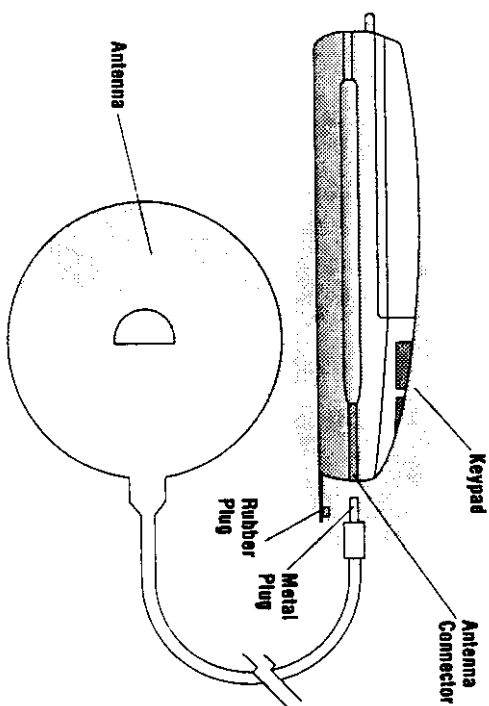
2. Insert the antenna's metal plug into the antenna connector and push the metal plug until it clicks into place.

Disconnecting the Antenna

1. Grasp the plug and pull it straight out. Do not pull on the cable because this may break the wires.

2. Insert the rubber plug in to the antenna connector.

Note: Keep the rubber plug in the antenna connector when not in use. This helps keep water out of the programmer.



The detachable antenna and patient programmer.

Caring for the Antenna

If you use the detachable antenna you should wash it daily with mild soap and water.

Note: Do not allow the metal plug end of the cord to get wet.

1. Disconnect the antenna from the programmer before cleaning.
2. Wash the antenna with mild soap and water.
3. Rinse the antenna. Make sure no soap remains on it.
4. Dry the antenna with a clean towel immediately after washing.

Note: When not in use, store the antenna in a plastic bag to protect it from dust.

FCC ID: LF57434



Caring for your Skin

Skin may become irritated from the pressure of the antenna or from an allergic reaction to the adhesive used to hold the antenna in place. Therefore, it is very important to keep the skin in this area clean and dry. Inspect the area every day to see that the skin remains healthy.

Caution

If you notice swelling or redness in the area where you place the antenna, contact your doctor before using the antenna again.

Clean the skin over the pulse generator with an antibacterial soap and change the antenna adhesive discs daily.

If the discs irritate your skin, you may want to wear a soft, snug-fitting undergarment to protect your skin and then tape the antenna to the outside of the undergarment.



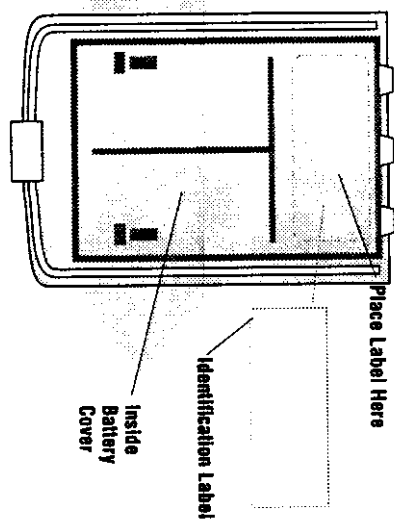
CARING FOR YOUR PATIENT PROGRAMMER

Identification Label


Your patient programmer comes with an identification label.

1. Fill in the label (name, phone number, etc.) with permanent ink.
2. Peel off the backing and stick the label to the inside of the battery cover.

Note: Do not place the label over the ridges on the battery cover.



Placement of the identification label in the battery cover.

 **Checking the Programmer Battery**

The Programmer Battery light is located on the back of the programmer. It tells you the status of your programmer battery.

To check the programmer battery: Press any key on the patient programmer keypad. The green Programmer Battery light will respond. Refer to Table 5 for more information about the Programmer Battery light.

Notes:

When not using the programmer for more than 4 weeks, remove the battery to prevent damage to the patient programmer.

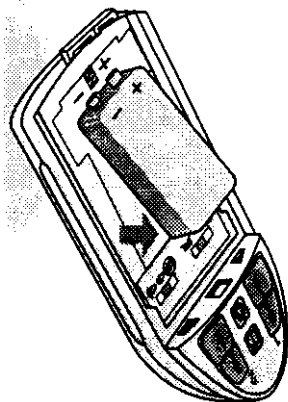
Make sure that you always have a fresh 9-volt battery at hand. This allows you to turn your pulse generator on and off or adjust the stimulation settings when needed.

Table 5. Programmer Battery  light.

When	It Means
Green Programmer Battery light is on for 8 seconds after pressing any key.	Programmer battery is OK.
Green Programmer Battery light is blinking after pressing any key.	Programmer battery is low. Replace with new 9-volt battery.
Green Programmer Battery light is off after pressing any key.	Replace with new 9-volt battery.

Removing the Battery

1. Remove the battery cover.
2. Place one finger on the edge of the battery between the Control switches.
3. Lift the battery out of the compartment without using excessive force.



Remove the battery.



Installing the Battery

An alkaline battery is recommended for longer battery life.

Warning

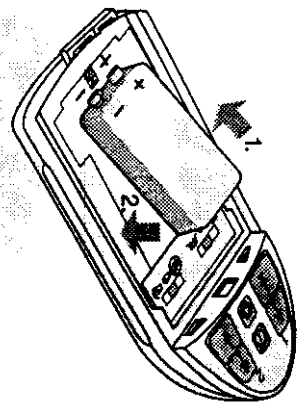
Do not use a mercury or zinc-air battery.

1. Check the battery label 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.

Note: The programmer performs a self-test when the battery is inserted. A successful check is indicated by a single flash of the Status lights followed by a short beep. If this does not occur, the self-test has failed. Refer to "Troubleshooting," page 74.

3. Replace the battery cover.

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Install the battery.

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Cleaning and Care

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

Caution

Do not immerse the programmer in liquid. Do not clean it bleach, nail polish remover 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 patient programmer.
- When not using the programmer for more than 4 weeks, remove the battery to prevent corrosion of the patient programmer.





Service

The Synergy EZ Patient Programmer has been designed and tested to provide long, trouble-free service. If repair or service is needed, call Medtronic at 1-800-328-0810.

To register the programmer for service covered by the warranty, complete and mail the warranty registration card. It is inserted in this manual.

The serial number is, located on a label within the battery compartment. It identifies each Synergy EZ Patient Programmer. If you write or call Medtronic about your patient programmer, refer to the serial number.

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TROUBLESHOOTING

This section will help you solve problems or identify when to call your doctor. Problems are described in the left column. The blue text in the right column lists possible causes of the problem (Causes); the bold text in the right column describes how to correct the problem (Action).

Note: If your problem is not solved after several attempts, or if your problem is not described here, contact your doctor.

Problem	Causes and Action
<i>If you're too uncomfortable with your current stimulation to think about how to change it.</i>	<ol style="list-style-type: none"> 1. Turn the pulse generator off. 2. Reduce the amplitude, rate, and pulse width for Channel 1. 3. Reduce the amplitude and pulse width for Channel 2. The rate for both channels was reduced in Step 2. 4. Turn the pulse generator on. 5. Reset the rate and pulse width for each channel. 6. Reset amplitude last.

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Problem
No lights turn On after you try to program your pulse generator.

Causes and Action
No battery, depleted battery, battery in backwards. Replace the battery; use a new 9-volt battery.
Sunlight may be blocking your view of the programmer lights.
If you are outdoors, move indoors or into the shade.

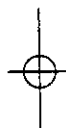
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Problem	Causes and Action
<i>The Programmer Battery light turns on, but none of the Pulse Generator lights are on.</i>	Programmer or detachable antenna is not correctly centered over pulse generator. Reposition programmer or antenna and try again.
<i>The Pulse Generator battery light is blinking or it has been blinking and is now off.</i>	The pulse generator battery is low or depleted. Contact your doctor.
<i>The programmer does not work with the detachable antenna connected.</i>	Antenna not connected correctly. Disconnect the antenna, plug it in, and try again. The antenna is not centered over the pulse generator. Refer to centering instructions on page 57. The antenna is broken. Try programming without the detachable antenna. Replace detachable antenna with a new one.



Problem	Causes and Action
<i>You want to check your pulse generator without changing the settings.</i>	If the Pulse Generator is off, push the Off key. The yellow Pulse Generator Off light should be lit. If the pulse generator is on, push the On key. The green pulse generator On light should be lit. Refer to "Checking the Pulse Generator Battery" for more information.
<i>You feel stimulation but you're unsure if both channels are working.</i>	<ol style="list-style-type: none"> 1. Decrease the amplitude for both channels to the lowest setting. 2. Slowly increase the amplitude of Channel 1 until you feel stimulation. 3. Decrease the amplitude of Channel 1 to lowest setting. 4. Slowly increase the amplitude of Channel 2 until you feel stimulation. 5. If you do not feel stimulation for one channel, contact your doctor. 6. If both channels are working, reset both channels to a comfortable setting.





Problem

The Pulse Generator lights are off when you press any key.

Causes and Action

The programmer or detachable antenna is not centered correctly over the pulse generator.
Reposition the programmer or antenna and try again.

The programmer was removed from the pulse generator too soon.

Hold the programmer over the pulse generator for at least 1 second after pressing a key.

Radio signals from appliances, computers, machinery, etc. are affecting your programmer.

Move to a different room and try again.

Remove the detachable antenna and try again.

The programmer failed the self-test.

The Status lights do not flash and the beeper does not beep when a fresh battery is installed.

Remove battery, press any key, turn the beeper to low or high, and reinsert a fresh battery. The status lights should flash and you should hear one beep.

If this does not occur, contact your doctor.



Problem

The beeper does not sound. Only the Programmer Battery light is on.

Causes and Action

The beeper is not on.
Set the beeper control switch to low or high and listen to be sure it is working.

The programmer or detachable antenna is not positioned correctly over the pulse generator.

Reposition the programmer or antenna and try again.

The programmer was removed from the pulse generator too soon.

Hold the programmer over the pulse generator for at least 1 second.

Radio signals from appliances, computers, machinery, etc. are affecting your programmer.

Move to a different room and try again.

Remove the detachable antenna and try again.

Problem
You feel a programming change after pressing a key, but the beeper didn't beep and the Pulse Generator On or Off lights did not light.

Causes and Action

The programmer was too far away from the pulse generator. The pulse generator might have received the signal to change but did not tell the programmer what it did.
Hold the programmer closer to you pulse generator, line up the target signal to reposition and try again.
An electrical appliance blocked your pulse generator radio signal from telling the lights and beeper to turn on.
1. Move to another room. Press any key to check the lights.
2. Line up the target symbol and try again.
The programmer was moved away too soon after pressing the keys.
Hold the programmer over the pulse generator for at least 1 second after pressing a key.

Problem
You do not feel stimulation right away after turning your pulse generator on or you feel stimulation after you turned the pulse generator off.

Causes and Action

Your doctor programmed a feature called SoftStart/Stop so that your stimulation will start and stop gradually. Allow about 8 seconds for your pulse generator to turn on and off.
The programmer or detachable antenna is not positioned correctly over your pulse generator.
Reposition the programmer or antenna over the pulse generator and try again.
Your amplitude is set at its lowest setting.
Slowly increase the amplitude until you feel stimulation.

Problem	Causes and Action
<i>Your pulse generator will not turn on.</i>	<p>The programmer or detachable antenna is not centered correctly over the pulse generator. Reposition the programmer or antenna and try again.</p> <p>The programmer was removed from the pulse generator too soon. Hold the programmer closer to your pulse generator, line up the target symbol, and try again. Hold the programmer over the pulse generator for at least 1 second. The green Pulse Generator On light should be lit for 8 seconds after the key is pressed. Try again.</p> <p>Your amplitude is set at the lowest setting and you don't feel the stimulation. Slowly increase the amplitude until you feel stimulation.</p>



Problem	Causes and Action
<i>You spill fluid on your programmer.</i>	<p>Dry it with a towel.</p>
<i>Your programmer falls into water.</i>	<p>Remove programmer from water. Wipe it with a towel dampened with clean tap water. Remove the battery cover and battery. Dry battery compartment with a towel. Allow battery compartment to dry at room temperature for as long as possible (24 hours recommended). Replace battery. Shake the programmer; if you hear water inside, or if it doesn't work properly, return to Medtronic for service.</p> <p>The programmer is designed to withstand falls of short distances. Try the programmer; it should work. If it does not work, return to Medtronic for service.</p>



LIVING WITH YOUR STIMULATION SYSTEM

Patient Identification Card

When you leave the hospital, your doctor will give you an identification card. This card supplies basic information about your pulse generator and identifies your doctor in the event of an accident. Your identification card allows you to bypass security arches or wands such as those used in airports. Carry this card with you at all times. If you move, change doctors, or lose your card, contact Medtronic for a new card.

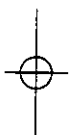
The diagram shows a rectangular card divided into two sections: 'Front' and 'Back'. The 'Front' section contains a logo for 'SYNERGY™ NEUROSTIMULATION SYSTEM' and 'PATIENT IDENTIFICATION'. Below this is a warning: 'The bearing of this card has an IMPLANTED STIMULATION SYSTEM. This card is used to deliver electrical stimulation to the spinal cord.' There are fields for 'Model Number', 'Serial Number', and 'Implant Date'. A large empty box is provided for 'Lead Model'. At the bottom of the front section, it says 'Medtronic Neurologics, Minneapolis, MN 55431' and 'Telephone: (612) 572-5200 Fax: (612) 572-0810'. The 'Back' section contains fields for 'Patient's Name', 'Address', 'In emergency, please contact', 'Physician Name', and 'Phone Number'.

Patient identification card.

When to Call Your Doctor

Your doctor will schedule follow-up visits every 6 months. Your doctor will check your pulse generator and make sure you are receiving the most appropriate treatment. However, you should contact your doctor if any of the following events occur:

- You have pain, redness, or swelling at the incision(s) later than 6 weeks after surgery.
- Your pulse generator is not working properly.
- You are not getting enough pain relief.
- You feel discomfort or pain during stimulation. Turn the pulse generator off first, then call your doctor.
- You feel no stimulation, "tingling," when the pulse generator is on.
- You cannot turn the pulse generator on or off.



- You are unable to adjust stimulation with your patient programmer.
- Stimulation changes or stops and your pain returns.
- The area of stimulation has changed dramatically (for example, moving from your right leg to your left leg).
- The Pulse Generator Battery light on your patient programmer is blinking.
- The Pulse Generator Battery light on your patient programmer was blinking but is now off, regardless of which key you press.



Do's and Don'ts

By following the guidelines listed below, you can ensure that your patient programmer will function properly.

Do:

- Keep your patient programmer out of the reach of children.
- Use your patient programmer only as explained to you by your doctor or as discussed in this manual.
- Handle your patient programmer with care. It is a sensitive device that can be damaged by rough handling.
- Remove a worn-out battery from your patient programmer and replace it with a new one. Worn-out batteries can damage electronic circuits.
- Keep a fresh 9-volt battery available so that you can turn your pulse generator on and off or adjust the stimulation settings when needed.

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- Turn your pulse generator Off when not in use. The pulse generator battery is not replaceable. When it wears out, the pulse generator must be surgically replaced, so you will want to make it last as long as possible.

- Go to all follow-up appointments. Reschedule if an appointment is missed.

- Carry your patient identification card with you at all times.

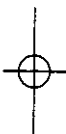
Don't:

Warning

Do not use potentially dangerous equipment (cars, power tools, etc.) when your pulse generator is on. What may feel like a sudden increase in stimulation ("jolt" or "shock") could cause you to lose control of the equipment you are using. Set the amplitude to the lowest setting and turn the pulse generator off.

- Don't do any strenuous activity, such as heavy lifting or running, without first talking to your doctor.

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Electromagnetic Interference (EMI)
Strong electrical fields, such as those produced by radio towers or some industrial equipment, can affect the function of your pulse generator. This can cause uncomfortable stimulation (a "jolt" or "shock"). This problem is called **electromagnetic interference**, or EMI.

Most household appliances and office equipment do not produce interference strong enough to affect your pulse generator.

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You can normally operate the following household items and office equipment:

- Microwave ovens
- Televisions, AM/FM radios, VCRs, cellular phones, etc.
- Tabletop appliances such as toasters, blenders, electric can openers, and food processors
- Hand-held items such as hair dryers, electric shavers, and remote controls
- Appliances such as washers, dryers, garage door openers, electric stoves, and vacuum cleaners
- Electric blankets and heating pads
- Personal computers, electric typewriters, copiers, and fax machines

Note: Be sure that appliances and equipment are properly installed and in good working condition before using them.



Strong interference could cause your pulse generator to deliver inappropriate or additional stimulation to your spinal cord. Turning the pulse generator Off may reduce the effect of interference.

Devices or equipment to AVOID:

- Theft detectors
- Airport/security screening devices
- Electric arc welding equipment
- Electric substations and power generators
- CB or ham radio antenna
- Electric induction heaters used in industry to bend plastic
- TV/radio transmitting towers
- Electric steel furnaces



If you suspect that an electric or magnetic device is interfering with your pulse generator, move away from the device or, if possible, turn the device off. Then use the patient programmer to turn your pulse generator on or off.

Warning

Use care when approaching security arches (such as those found in airports, libraries, and some department stores) as these devices can cause inappropriate or additional stimulation if you pass through them. Similarly, avoid airport security wands.

When approaching these devices, do the following:

1. Show your Medtronic identification card to security staff. Ask that you be allowed to bypass the security device, request a hand search, or ask that the security device be turned Off.
2. If passing through the security device is unavoidable, reduce the amplitude to its lowest setting.

3. Turn the pulse generator off.
4. Approach the security device slowly. If any stimulation is felt, back out of the security device immediately without changing body position. If no stimulation is felt, move quickly through to the other side.

Battery and Device Disposal

Dispose of depleted batteries and worn out devices according to local requirements.

Medical and Dental Procedures

With proper precautions, most medical procedures are unlikely to interfere with your pulse generator. Tell any medical staff that you have an implanted stimulation system. Decrease your amplitude to its lowest setting and turn the pulse generator off before all medical and dental procedures.

Some common medical and dental procedures that should not affect your pulse generator include:

- Diagnostic x-rays such as dental x-rays—Exception: some x-rays that require tight enclosure of the area where your pulse generator is implanted (such as mammography) may require adjustment to lessen pressure.
- Dental drills and ultrasonic probes used to clean teeth—Exception: These should not be used directly over your implant site.

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- Therapeutic ultrasound and electrolysis—Exception: These should not be used directly over your implant site.

Other medical procedures produce high levels of interference. Consult your doctor about risks and benefits of procedures such as:

- Electrosurgery (surgery performed by electrical methods)
- Diathermy (heat treatment)
- Lithotripsy (the crushing of a blockage within the urinary tract using electrical methods)
- Radiation therapy (i.e. cancer treatment)
- Magnetic Resonance Imaging (MRI)—not recommended

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COMMONLY ASKED QUESTIONS

What does stimulation feel like?

The electrical pulses delivered by your pulse generator usually feels like tingling in the area of your pain.

Can I turn my pulse generator on or off?

Yes. You can use your patient programmer to turn your pulse generator on and off.

Will I be able to adjust the stimulation?

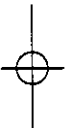
Yes. You can use your patient programmer to fine tune the amplitude, pulse width, and rate. However, this depends on the instructions your doctor has stored in your pulse generator.

What should I do if I have trouble turning my pulse generator on?

Be sure to wait at least 8 seconds to feel stimulation after turning your pulse generator on. If you do not feel any stimulation after 8 seconds, try again to turn the pulse generator on while holding the patient programmer directly over the pulse generator. If you still cannot turn your pulse generator on, contact your doctor.

How long will the battery in my pulse generator last?

The battery life of the pulse generator depends on the number of hours you use it each day and how strong the stimulation must be to control your pain. Your doctor can give you an estimate once your pulse generator settings have been determined.





Can the battery be recharged?

No.

How is the pulse generator battery replaced?

The entire pulse generator must be surgically replaced because the pulse generator's battery is sealed within the device. This replacement procedure usually does not include replacement of the lead(s) or extension(s).

How large is the pulse generator?

The pulse generator is oval and approximately 3 inches long, 2.4 inches wide, and 0.5 inches thick.



Will the pulse generator show through my clothes?

Depending on your body build, the pulse generator may appear as a small bulge under the skin. However, your doctor will try to place the pulse generator in an area that is most comfortable and cosmetically acceptable.

Will my system limit my activities?

Generally, no—you should be able to resume your normal daily activities. However, be sure to consult your doctor before undertaking any particularly strenuous activities such as heavy lifting.

What happens if my pulse generator stops working?

Stimulation will stop and your pain may return. If this happens, contact your doctor.





What should I do if the stimulation changes or becomes painful?

Use your patient programmer to turn your pulse generator off and contact your doctor.

What does it mean if I can feel stimulation only sometimes?

Your doctor may have programmed your pulse generator to turn on and off at regular intervals. However, if you so not receive adequate pain relief, contact your doctor.

Is it normal for the stimulation to increase or decrease when I change position?

Generally, stimulation should feel constant. However, abrupt movements or changes in posture can make the stimulation feel more or less intense due to the position of the electrode(s) relative to your spinal cord.



Will a microwave oven interfere with the pulse generator?

No.

How often should my doctor check the pulse generator?

Your pulse generator should be checked once every 6 months. However, your doctor may want to see you more or less often depending on your condition.

What happens at a follow-up visit?

Your doctor will assess any changes in your medical condition, check your pulse generator's battery level, monitor any drugs you are taking, and answer any questions you may have. As your condition changes, your physician may also reprogram your pulse generator.

Will my pulse generator be affected by the change to the year 2000?

No. Your pulse generator is not affected by actual dates. It is not synchronized in any way to calendar time.



How often will I have to replace the battery in my patient programmer?

Battery life depends on how often the programmer is used. Typically, a patient can expect at least 3 months of use from a new battery. Always keep a fresh battery available.

SPECIFICATIONS

Power Source:	9-volt alkaline battery (type 6LR61 or 6F22E)
Operating Temperature:	+49 to +110°F +9 to +44°C
Storage Temperature:	-40 to +150°F -40 to +65°C
Relative Humidity:	10% to 85%
Atmospheric Pressure:	14.8 in. Hg to 31.3 in. Hg (500hPa to 1060hPa)
Programmer Size:	Approximately 7.6 x 2.4 x 0.5 inches
Programmer Weight:	Approximately 6 oz
Battery Life:	3 months (average)

SPECIAL NOTICE

The Medtronic® Synergy™ EZ™ Patient Programmer (the "Programmer") Model 7435 is designed to program the adjustable parameters of the Medtronic® Synergy™ Implantable Pulse Generator (IPG) Model 7427. The programming functions of the Programmer are not compatible with any other devices. For information regarding difficulties which may be encountered using the Programmer, consult the other portions of this manual.

**MEDTRONIC® NEUROLOGICAL
SYNERGY™ MODEL 7435 PATIENT PROGRAMMER
LIMITED WARRANTY
(U.S. Customers Only)**

A. This Limited Warranty provides the following assurance to the purchaser of the Medtronic® Model 7435 Patient Programmer, 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 Neurological, 800 53rd Avenue NE, Minneapolis, MN 55421-9811. 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.

GLOSSARY

Amplitude—The amount or "volume" (strength or intensity) of stimulation required to mask your pain. This setting is adjusted most often by patients.

Beeper Control Switch—Located under the battery cover. It lets you turn the beeper Off or set the volume to Low or High.

Electrode—The small metal conductor near the tip of the lead that is placed near your spinal cord. Electrodes deliver tiny pulses of electricity to the area where your pain signals will be blocked.

Electromagnetic Interference (EMI)—Interference caused by the energy field generated by electrical or magnetic devices such as airport security systems or television transmitting towers.

Extension—A thin wire that connects the pulse generator to the lead.

Status Lights—Four status lights are located on the back of the patient programmer. They tell you whether the pulse generator is On or Off, the pulse generator battery status, and the patient programmer battery status.

Lead—A wire with small metal electrodes near the tip that is implanted near the nerves to be stimulated.

Patient Programmer—A hand-held device that allows you to turn your pulse generator On and Off and finely adjust some of the stimulation settings programmed by your doctor.

Physician Programmer—The small computer your doctor uses to send stimulation instructions to your pulse generator.

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Pulse Generator—The power source of your system. It contains a special battery and electronics to control the stimulation you feel. The device can be implanted either in the abdomen or below the collarbone.

Pulse Width—The length or duration of an electrical pulse.

Rate—The number of stimulation pulses delivered each second.

Spinal Cord—This is your body's information center. Nerve signals from throughout your body travel to your spinal cord, and then to your brain.

Stimulation—The delivery of tiny electrical pulses to the spinal cord. Stimulation is used in pain management to block the pain signal as it travels from the spinal cord to the brain.

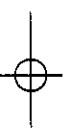
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Stimulation Control Switch—Located under the battery cover. You can adjust three settings with the stimulation control switch: amplitude, rate, and pulse width.

Stimulation Settings—The settings that can be adjusted to affect the stimulation you feel. These settings are amplitude, pulse width, and rate.

Stimulation System—An implanted system that delivers tiny electrical pulses to the area in your body where your pain signals will be blocked.

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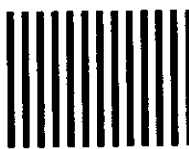


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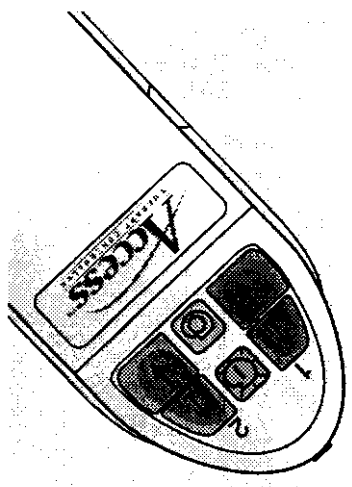
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MODEL 7436 THERAPY CONTROLLER

FCC ID: LF57434



USER MANUAL



Device Symbols

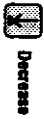
Keypad Symbols



Pulse Generator On



Pulse Generator Off

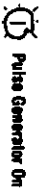


Decrease

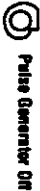


Increase

Status Light Symbols



Pulse Generator On



Pulse Generator Off



Pulse Generator



Programmer

**Stimulation Control
Switch Symbols**



Amplitude



Pulse Rate

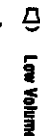


Pulse Width

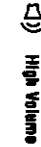
**Beeper Control
Switch Symbols**



Volume Off



Low Volume



High Volume

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⚠ **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

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⚠ General Warning

The Medtronic® Access™ Model 7436 Therapy Controller (the "controller") is designed to program the adjustable parameters of the Medtronic® Kinetra™ Model 7428 Neurostimulator (or "pulse generator"). Do Not attempt to use the programmer on another device (for example, a cardiac pacemaker). Radio signals from the therapy controller may interfere with the performance of other implantable devices.

FCC INFORMATION

The following is communications regulation information on the Synergy™ EZ Model 7435 Patient Programmer.

FCC ID: LF57434

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

The Access™ Model 7436 Therapy Controller is a portable, handheld device designed for use with the Kinetra™ Model 7428 Neurostimulator. It may be used by patients or their doctors.

The therapy controller can be used by patients or doctors to:

- Turn the pulse generator on or off.
- Check the status of the pulse generator and therapy controller batteries.
- Confirm that the pulse generator has received information from the therapy controller.
- Adjust the stimulation of the pulse generator within the physician-set limits. This feature is made available only to patients who need it.

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ABOUT THIS GUIDE

This guide is divided into two sections. The first section discusses the primary use and care of the therapy controller. The second section discusses the additional uses that are available with the therapy controller. Important terms are listed in a glossary at the end of this booklet.

Primary Use and Care of the Therapy Controller includes:

- Description of the therapy controller
- How to use and care for the therapy controller
- Steps to take to help you solve problems

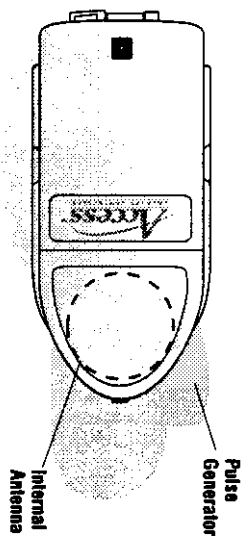
Additional Features of the Therapy Controller

Note: This section should be used by patients only as authorized by their doctors.

COMMON USE AND CARE OF THE ACCESS™ THERAPY CONTROLLER

Therapy Controller Function

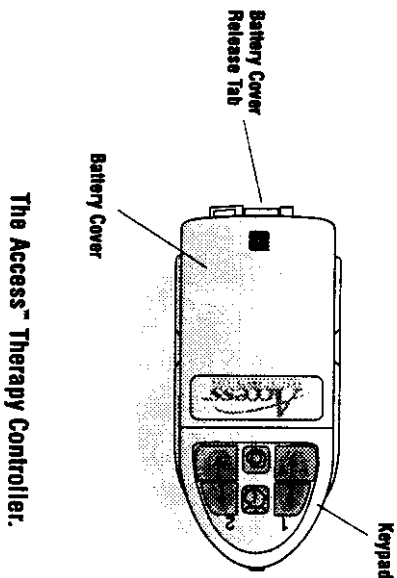
An antenna is located beneath the keypad inside the therapy controller. When the therapy controller is held over an implanted pulse generator and the keys are pressed, the internal antenna sends a coded radio signal to the pulse generator. A special code within the pulse generator protects it from accidental programming by any device other than the therapy controller or the physician programmer.



The controller placed over the pulse generator.

Therapy Controller Features

This section describes the features of the therapy controller.

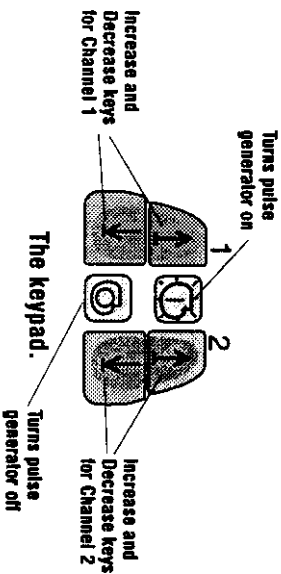


The Access™ Therapy Controller.


Keypad

The keypad has 6 keys: Pulse Generator On and Off keys, and Increase and Decrease keys for Channel 1 and Channel 2.

Note: Pressing any key on the therapy controller automatically turns it on. If no keys are pressed in 8 seconds, the therapy controller automatically turns off.







On/Off Keys

The On  and Off  keys turn the pulse generator on and off.

Channel 1 and Channel 2 Keys

The channel keys are active only for some patients, depending on their needs. Doctors should inform patients if they have use of these keys. If these keys are inactive, nothing will happen if they are accidentally pressed; however, the programmer will emit three beeps.

For patients with access to the channel keys, Channel 1 Increase  and Decrease  keys adjust the stimulation for one implanted lead. Channel 2 Increase  and Decrease  keys adjust stimulation for the other implanted lead.

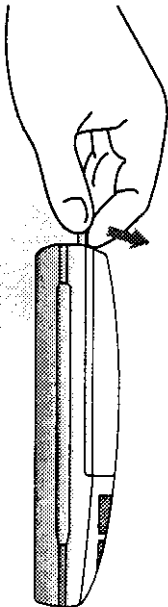
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Battery Compartment

The battery and Control switches are located beneath the battery cover.

Removing the Battery Cover

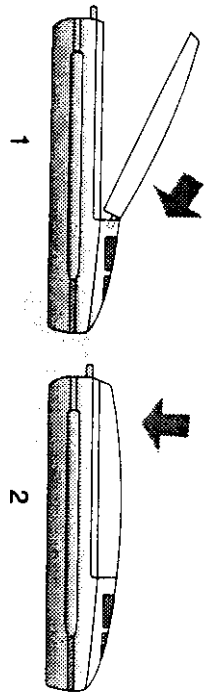
1. Hold the therapy controller with one hand.
2. Lift the battery cover release tab on the end of the controller and lift off the cover.



Remove the battery cover.

Replacing the Battery Cover

1. Place the center hook on the edge of the cover into the center slot in the controller as shown below.
2. Lower the battery cover.
3. Press down the end of the cover to lock it in place.



Replace the battery cover.

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Battery

A rectangular 9-volt battery provides the power for the therapy controller. You may use an alkaline or carbon-zinc battery. An alkaline battery is recommended for longer battery life.

Warning

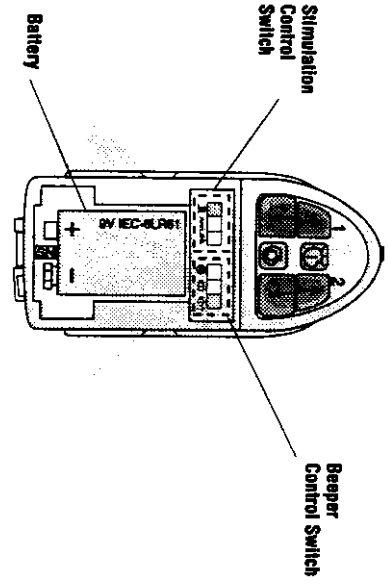
Do not use a mercury or zinc-air battery.

Notes:

When not using the therapy controller for more than 4 weeks, remove the battery to prevent damage to the device.

Make sure a fresh 9-volt battery is always available so that you can turn your pulse generator on and off when necessary.

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Battery and Control switches.

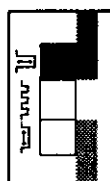
Stimulation Control Switch

For many patients, the Stimulation Control switch has been turned off by their doctor. Patients should not be alarmed if the switch is accidentally moved; nothing will happen.

Some patients, however, will have one control—the amplitude (stimulation intensity)—turned on.

For patients who have the amplitude turned on:

This switch should be set in the left position, lined up with the gray box or μ symbol. If the switch is accidentally moved, push it to the left as shown.



Note: When the amplitude is turned on, the Increase \uparrow and Decrease \downarrow keys on the keypad adjust the amplitude.

Beeper Control Switch

The **Beeper Control switch** is set to high \Rightarrow volume when shipped. When using the therapy controller, the beeps can be used as a guide (see Table 1).

Table 1. Beeper description.

If you hear	It means
One beep	You have pressed the On/Off or Increase/Decrease (if applicable) key and the change was successfully received by the pulse generator.
Three rapid beeps	<p>You pressed an Increase or Decrease key and these keys are turned off.</p> <p>If the Increase/Decrease keys are on:</p> <ul style="list-style-type: none"> • You tried to adjust the pulse generator beyond the lowest or highest settings. • You tried to increase stimulation with the pulse generator turned off. • You reduced amplitude to its lowest setting.

Symbols and Status Lights

The back of the therapy controller displays symbols and Status lights that are helpful when using the therapy controller.

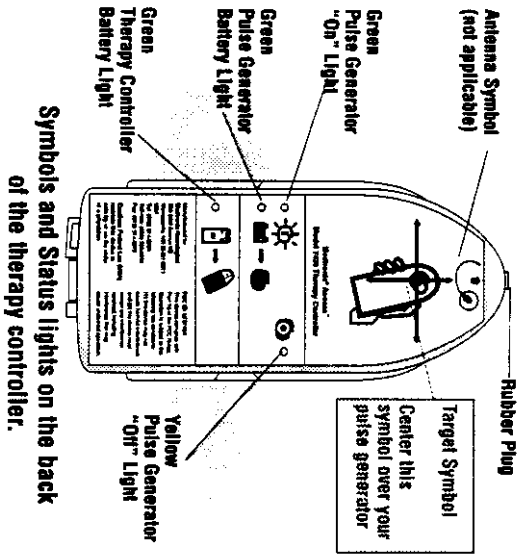
Symbols

A target symbol helps you position the controller over the pulse generator. An antenna symbol directs you to an antenna connector; this is not used with your system.

Note: To help maintain water resistance, keep the rubber plug in the antenna connector.

Status Lights

When lit or blinking, the Status lights tell you whether the pulse generator is on or off, the pulse generator battery status, and the therapy controller battery status. Refer to Table 2 (page 19) and Table 3 (page 22) for more information.



USING THE THERAPY CONTROLLER

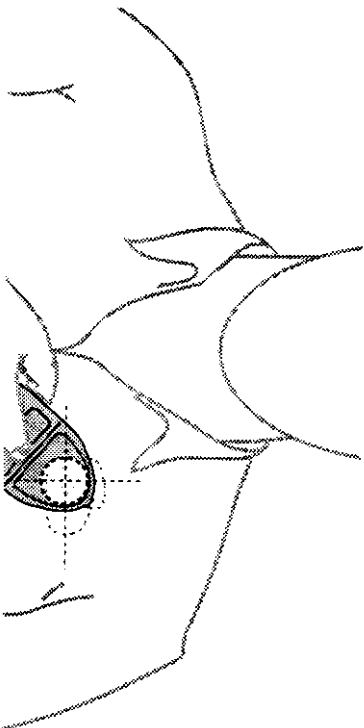
The following sections provide instructions for using the therapy controller:

- Placing the Controller Over the Pulse Generator
- Checking the Pulse Generator Battery
- Turning the Pulse Generator On and Off
- Adjusting the Amplitude (if applicable)

Placing the Controller Over the Pulse Generator

The controller must be held steady over the pulse generator for at least 1 second while any key is pressed. Use the target symbol on the back of the therapy controller to help center the controller over the pulse generator.

Note: The center of the controller target symbol is in line with the center of the keypad (center of the internal antenna).



Place the target symbol over the pulse generator.

Checking the Pulse Generator Battery

The Pulse Generator Battery light on the back of the controller displays the status of the pulse generator battery.

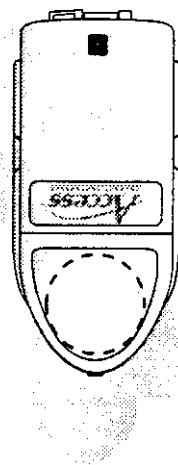
To check the pulse generator battery:

1. Place the controller over the pulse generator. Use the target symbol on the back of the controller to help you position the controller over the pulse generator.
2. If the pulse generator is off, press the **Off** key. If the pulse generator is on, press the **On** key. Hold the controller over the pulse generator for 1 second.
3. Remove the controller from the pulse generator to view the status lights on the back of the controller. Confirm that the green Pulse Generator Battery light is lit. This light stays on for 8 seconds after you release the key.

Note: Move indoors or into the shade if sunlight blocks your view of the controller lights.

Table 2. Pulse Generator Battery   lights.

When	If Means
Green Pulse Generator Battery light is on for 8 seconds after pressing any key.	Pulse generator battery is good.
Green Pulse Generator Battery light is blinking for 8 seconds after pressing any key.	The pulse generator battery is low.
Green Pulse Generator Battery light is off after pressing any key.	Reposition controller and try again. Interference from electrical equipment can cause lights to remain Off. Move to another room and try again. If the light remains Off, the pulse generator battery is probably near depletion. The pulse generator should be reviewed with a physician programmer. Patients should contact their doctor immediately.



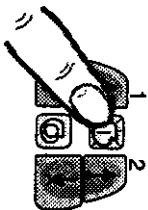
Place the controller over the pulse generator.

Turning the Pulse Generator On and Off
 Patients should turn their pulse generator on and off as advised by their doctor.

To turn the pulse generator on:

1. Place the controller over the pulse generator. Use the target symbol on the back of the controller to help you center the controller over the pulse generator.

2. Press the Pulse Generator On key and hold the controller over the pulse generator for 1 second. The controller should beep once to confirm that a change has occurred.




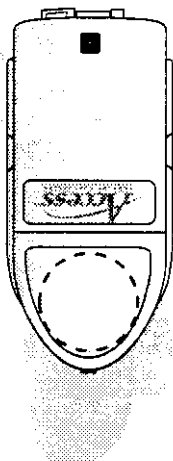
Press the Pulse Generator On key.

3. Check that the green Pulse Generator On light on the back of the controller is lit; this indicates that the pulse generator was successfully turned on (Table 3). This light stays on for 8 seconds after you release the key.

Note: The pulse generator will turn on with the settings last programmed.



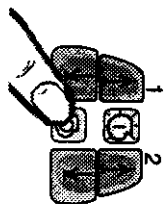
1.  To turn the pulse generator off: Place the controller over the pulse generator. Use the target symbol on the back of the controller to help you center the controller over the pulse generator.



Place the controller over the pulse generator.

2. Press the Pulse Generator Off key and hold the controller over the pulse generator for 1 second. The controller should beep once to confirm that a change has occurred.





Press the Pulse Generator Off key.

3. Check that the yellow Pulse Generator Off light on the back of the controller is lit; this indicates that the pulse generator was successfully turned off (refer to Table 3). This light stays on for 8 seconds after you release the key.

Note: Move indoors or into the shade if sunlight blocks your view of the controller lights.

Table 3. Pulse Generator On and Off lights.

When	It Means
The green Pulse Generator On light is lit for 8 seconds after pressing any key.	Pulse generator is on.
The yellow Pulse Generator Off light is lit for 8 seconds after pressing any key.	Pulse generator is off.
Neither Pulse Generator On or Off light is lit after pressing any key.	The controller does not know if the pulse generator is on or off. Refer to "Troubleshooting."


Adjusting the Amplitude (stimulation intensity)

Notes:

- The amplitude can be adjusted using the therapy controller only if this function was turned on with the physician programmer. Patients should confirm this with their doctor.
- The Channel 1 Increase ↑ and Decrease ↓ keys adjust the amplitude for one lead; the Channel 2 Increase ↑ and Decrease ↓ keys adjust the amplitude for the other lead.
- The pulse generator must be on to increase amplitude, but may be either on or off to decrease amplitude.
- The controller will beep once for each change that is successfully programmed into the pulse generator. The controller will beep 3 times if you try to increase amplitude when the pulse generator is Off or if you have reached the lowest or highest limit for the amplitude.

- You can increase or decrease more quickly by pressing and holding down the desired key. Every 1/2 second, the controller will send a change to the pulse generator.

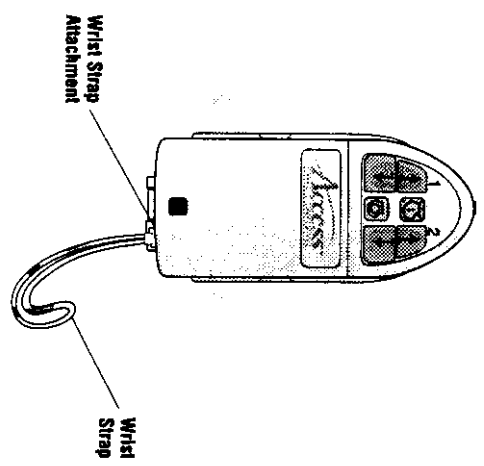
To adjust the amplitude:

1. Place the controller over the pulse generator. Use the target symbol on the back of the controller to help you position the controller over the pulse generator.
2. Press Pulse Generator On  key to turn on the pulse generator.
3. Press the Increase ↑ or the Decrease ↓ key under the desired channel to make a change.
4. Repeat steps 1 through 3 for other channel if desired.

ACCESSORIES

Wrist Strap and Carrying Case

A wrist strap is packaged with the therapy controller and can be used to help you avoid dropping it. The wrist strap may be attached to the controller on the loop near the battery cover release tab. A carrying case is also enclosed with the controller. Store the therapy controller in the carrying case to protect it.



Location of the wrist strap attachment.

CARING FOR THE THERAPY CONTROLLER

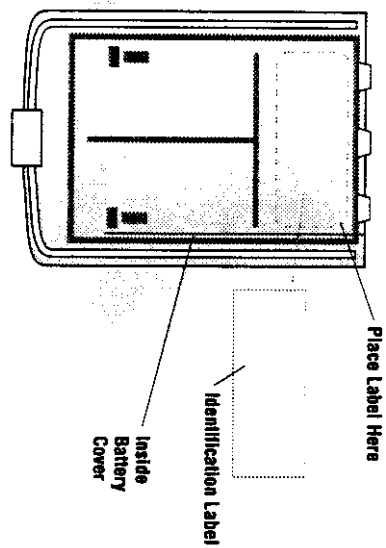
Identification Label

The therapy controller comes with an identification label.

1. Fill in the information (name, phone number, etc.) with permanent ink.
2. Peel off the backing and stick the label to the underside of the battery cover.

Note: Do not place the identification label over the ridges on the battery cover.

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Placement of the identification label in the battery cover.

 **Checking the Therapy Controller Battery**

The Therapy Controller Battery light on the back of the controller tells you the status of the controller battery.

To check the controller battery: Press any key on the therapy controller keypad; the green Therapy Controller Battery light will respond. Refer to Table 4 for more information about the Therapy Controller Battery light.

Notes:

When not using the controller for more than 4 weeks, remove the battery to prevent damage to the device.

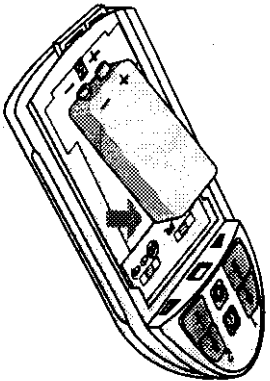
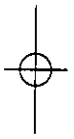
Make sure that you always have a fresh 9-volt battery available so that you can turn the pulse generator on and off or adjust the stimulation when necessary.

Table 4. Therapy Controller Battery  lights.

When	It Means
Green Therapy Controller Battery light is on for 8 seconds after pressing any key.	Controller battery is OK.
Green Therapy Controller Battery light is blinking after pressing any key.	Controller battery is low. Replace with new 9-volt battery.
Green Therapy Controller Battery light is off after pressing any key.	Replace with new 9-volt battery.

Removing the Battery

1. Remove the battery cover.
2. Place one finger on the edge of the battery near the keypad (between the control switches).
3. Lift the battery out of the compartment without using excessive force.



Remove the battery.



Installing the Battery

An alkaline battery is recommended for longer battery life.

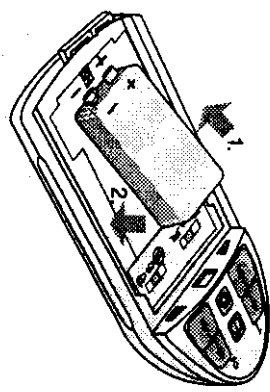
Warning

Do not use a mercury or zinc-air battery.

1. Match the [+] and [-] symbols on the battery with the [+] and [-] symbols in the battery compartment. Insert the battery into the compartment, symbol end first.
2. Press the battery down fully into the battery compartment without using excessive force.

Note: The controller performs a self-test when the battery is inserted. A successful check is indicated by a short beep and a flash of the Status lights. If this does not occur, the self-test has failed. Refer to "Troubleshooting," page 38.

3. Replace the battery cover.



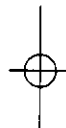
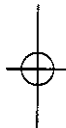
Install the battery.

Cleaning and Care

- The therapy controller is a precision instrument and must be handled with care.
- Do not take apart or tamper with the controller; this could affect its performance.
- Protect the controller from sharp blows or physical shocks.
- Clean the outside of the controller with a slightly damp cloth. Mild household cleaners will not damage the case or labels.
- The therapy controller is not waterproof. Do not allow moisture to get inside the device.

Caution

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



- 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 therapy controller.
- When not using the controller for more than 4 weeks, remove the battery to prevent corrosion of the therapy controller.



Service

The Access Therapy Controller has been designed and tested to provide long, trouble-free service. If repair or service is needed, call Medtronic at 1-800-328-0810.

To register the programmer for service covered by the warranty, complete and mail the warranty registration card. It is inserted in this manual.

The serial number is, located on a label within the battery compartment. It identifies each Access Therapy Controller. If you write or call Medtronic about your therapy controller, refer to the serial number.

Battery and Device Disposal

Dispose of depleted batteries and worn out devices according to local regulations.

TROUBLESHOOTING

Problems are described below in the left column. The blue text in the right column lists possible causes of the problem (Explanation); the bold text in the right column describes how to correct the problem (Action).

Note: If the problem is not solved after several attempts, or if the problem is not described here, contact your doctor or your Medtronic representative.

Problem	Explanation and Action
<i>No lights turn on after you try to program your pulse generator.</i>	No battery, depleted battery, battery in backwards. Replace the battery; use a new 9-volt battery.

Sunlight may be blocking your view of the controller lights. **If you are outdoors, move indoors or into the shade.**

Problem

The controller battery light turns on, but none of the pulse generator lights are on.

Explanation and Action

Controller not centered over pulse generator. Reposition controller and try again.

The pulse generator battery light is blinking and is now off.

The pulse generator battery is low or depleted. Contact your doctor or your Medtronic representative.

You want to check the pulse generator without changing the setting.

Push the OFF key if the pulse generator is off. The yellow Pulse Generator Off light should be lit. Push the On key if the pulse generator is on. The green Pulse Generator On light should be lit. Refer to "Checking the Pulse Generator Battery" for more information.

Problem

The pulse generator lights are off when you press any key.

Explanation and Action

The controller is not positioned correctly over the pulse generator. Reposition the controller and try again.

The controller was removed from the pulse generator too soon. Hold the controller over the pulse generator for at least 1 second after pressing a key.

Radio signals from appliances, computers, machinery, etc. are affecting the controller. Move to a different room and try again.

The pulse generator battery is depleted. Contact your doctor or your Medtronic representative.

The programmer failed the self-test. Remove battery, press any key, turn the beeper to low or high, and reinsert a fresh battery. The status lights should flash and you should hear one beep. If this does not occur, contact your doctor.

The Status lights do not flash and the beeper does not beep when a fresh battery is installed.

Problem
The beeper does not sound. Only the controller battery light is On.

Explanation and Action
The beeper is not on.
Set the beeper control switch to low or high and listen to be sure it is working.

The controller is not positioned correctly over the pulse generator.
Reposition the controller and try again.

The controller was removed from the pulse generator too soon.
Hold the controller over the pulse generator for at least 1 second.

Radio signals from appliances, computers, machinery, etc. are affecting the controller.
Move to a different room and try again.

Problem
The pulse generator will not turn on.

Explanation and Action
The controller is not positioned correctly over the pulse generator.
Reposition the controller and try again.

The controller was removed from the pulse generator too soon.
Hold the controller closer to the pulse generator, line up the target symbol and try again. Hold the controller over the pulse generator for at least 1 second. The green Pulse Generator On light should be lit for 8 seconds after the key press. Try again.

Problem
You spill fluid on the controller.

Explanation and Action
Dry it with a towel.

The controller falls into water.

1. Remove controller from water.
2. Wipe it with a towel dampened with clean tap water.
3. Remove the battery cover and battery.
4. Dry battery compartment with a towel.
5. Allow battery compartment to dry at room temperature for as long as possible (24 hours recommended).
6. Replace battery.
7. Shake the controller; if you hear water inside, or if it doesn't work properly, return to Medtronic for service.

The controller falls off a cabinet or table.

The controller is designed to withstand short drops. Try the controller; it should work. If it doesn't work, return to Medtronic for service.

ADDITIONAL FEATURES

This section discusses the additional features available with the therapy controller.

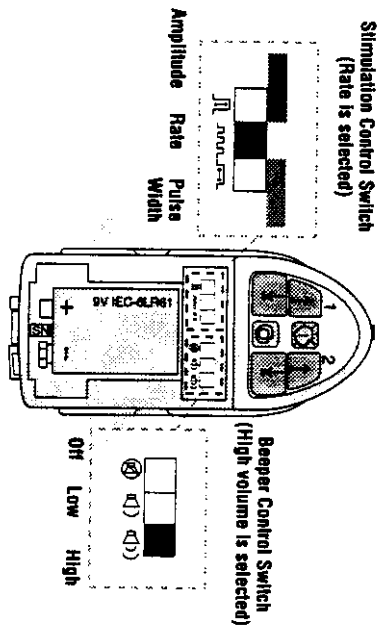
Control Switches

This section describes the Control switches and the additional stimulation settings that can be adjusted within the physician-set limits. Limits are programmed into the pulse generator with the physician programmer.

Note to doctors: Refer to the *Memory/Mod™ Model 7459 Software Programming Guide for Kinetra™ Neurostimulation Systems* for instructions on programming limits.

Note to patients: This section should be used by patients only as authorized and discussed with their doctor.

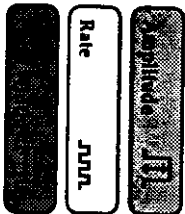
The Control switches are located beneath the battery cover.



Control switches.

Stimulation Control Switch

Three settings can be adjusted with the Stimulation Control switch: amplitude, rate, and pulse width. Each setting is identified with colors and symbols as shown below.



The amount or "volume" (strength or intensity) of stimulation.

The number of pulses per second.

The length or duration of the electrical pulse.

Note: The Increase ↑ and Decrease ↓ keys on your keypad adjust the selected stimulation control.

Beeper Control Switch

The beeper volume can be turned off Ⓚ or set to low Ⓛ or high Ⓧ with the Beeper Control switch (see Table 5). The therapy controller is shipped with volume set to High.

Table 5. Beeper description.

If you hear	It means
One beep	You have pressed the On/Off or Increase/Decrease (if applicable) key and the change was successfully received by the pulse generator.
Three rapid beeps	You tried to adjust the pulse generator beyond the lowest or highest settings. You tried to increase amplitude, rate, or pulse width with the pulse generator turned off. You reduced amplitude to its lowest setting.

Adjusting the Stimulation

Programming Information

The following tips will be helpful when using the therapy controller.

- Always set the pulse generator to the lowest possible settings that provide adequate symptom relief. The higher the settings, the faster the pulse generator battery will wear out. When the battery wears out, the pulse generator must be surgically replaced, so you want to make it last as long as possible.
- Select amplitude, rate, or pulse width using the Stimulation Control switch; the keypad adjusts the stimulation setting selected.
- The Channel 1 Increase and Decrease keys adjust the amplitude or pulse width for one lead; the Channel 2 Increase ↑ and Decrease ↓ keys adjust the amplitude or pulse width for the other lead.

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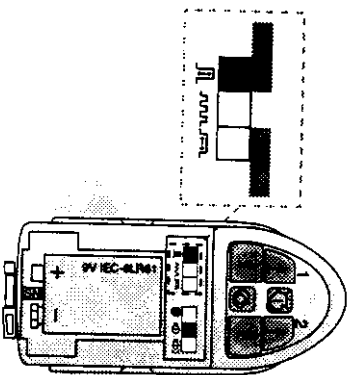
- Either set of channel keys will adjust the rate; both channels always have the same rate.

- The pulse generator must be on to increase amplitude, rate, and pulse width, but may be either on or off to decrease them.
- If the beeper is on, the controller will beep once for each change that is successfully programmed into the pulse generator. The controller will beep 3 times if you try to increase a stimulation setting when the pulse generator is off or if you have reached the lowest or highest limit for the selected setting.
- You can increase or decrease more quickly by pressing and holding down the desired key. Every 1/2 second the controller sends a change to the pulse generator unless you have reached the lowest or highest limit for the selected setting.

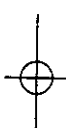



Adjusting the Amplitude

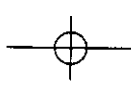
1. Remove the battery compartment cover.
2. Move the Stimulation Control switch to amplitude.



Move the Stimulation Control switch to amplitude.

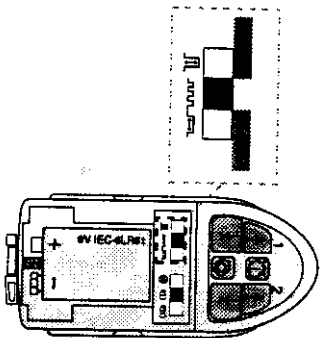


3. Place the controller over the pulse generator. Use the target symbol on the back of the controller to help you position the controller over the pulse generator.
4. Press Pulse Generator On  key to turn on the pulse generator.
5. Press the Increase ↑ or the Decrease ↓ key under the desired channel to make a change.
6. Repeat steps 1 through 5 for the other channel if desired.
7. Replace the battery cover.






Adjusting the Pulse Width

1. Remove the battery compartment cover.
2. Move the Stimulation Control switch to pulse width.

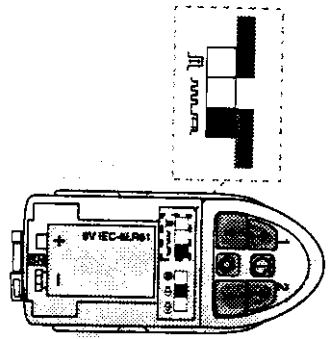


Move the Stimulation Control Switch to pulse width.




3. Place the controller over the pulse generator. Use the target symbol on the back of the controller to help you position the controller over the pulse generator.
4. Press Pulse Generator On  key to turn on the pulse generator.
5. Press the Increase  or the Decrease  key under desired channel to make a change.
6. Repeat steps 1 through 5 for the other channel if desired.
7. Replace the battery cover.

Adjusting the Rate

1. Remove the battery compartment cover.
2. Move the Stimulation Control switch to rate.



Move the Stimulation Control switch to rate.

3. Place the controller over the pulse generator. Use the target symbol on the back of the controller to help you position the controller over the pulse generator.
4. Press Pulse Generator On  key to turn on the pulse generator.
5. Press the Increase  or the Decrease  key under either channel to make a change.
Note: Either set of channel keys adjust the rate; both channels always have the same rate.
6. Replace the battery cover.

GLOSSARY

Amplitude—The intensity of stimulation.

Beeper Control Switch—Located under the battery cover. It lets you turn the beeper off or set the volume to low or high.

Physician Programmer—The small computer used to send stimulation instructions to the pulse generator.

Status Lights—Four Status lights are located on the back of the therapy controller. They tell you whether the pulse generator is on or off, the pulse generator battery status, and the therapy controller battery status.

Pulse Generator—The power source of your system. It contains a special battery and electronics to control stimulation.

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Pulse Width—The length or duration of an electrical pulse.

Rate—The number of stimulation pulses delivered each second.

Stimulation Control Switch—Located under the battery cover. You can adjust three settings with the stimulation control switch: amplitude, rate, and pulse width.

Stimulation Settings—The settings that can be adjusted to affect stimulation. These settings are amplitude, pulse width, and rate.

Therapy Controller—A hand-held device that allows you to turn your pulse generator on and off and adjust some of the stimulation settings programmed with the physician programmer.

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SPECIFICATIONS

Power Source:	9-volt alkaline battery (type 6LR61 or 6F22E)
Battery Life:	3 months (average)
Operating Temperature:	+9 to +44°C (+49 to +110°F)
Storage Temperature:	-40 to +65°C (-40 to +150°F)
Relative Humidity:	10% to 85%
Atmospheric Pressure:	500 hPa to 1060 hPa (14.8 in. Hg to 31.3 in. Hg)
Controller Size:	Approximately 13,6 x 6,6 x 3,1 cm
Controller Weight:	Approximately 170 g

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SPECIAL NOTICE

The Medtronic® Synergy™ EZ™ Patient Programmer (the "Programmer") Model 7435 is designed to program the adjustable parameters of the Medtronic® Synergy™ Implantable Pulse Generator (IPG) Model 7427. The programming functions of the Programmer are not compatible with any other devices. For information regarding difficulties which may be encountered using the Programmer, consult the other portions of this manual.

**MEDTRONIC® NEUROLOGICAL
ACCESS™ MODEL 7436 THERAPY CONTROLLER
LIMITED WARRANTY
(U.S. Customers Only)**

A. This Limited Warranty provides the following assurance to the purchaser of the Medtronic® Model 7436 Therapy Controller, 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 Neurological, 800 53rd Avenue NE, Minneapolis, MN 55421-9611. 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.

FCC ID: LF57434



BUSINESS REPLY MAIL

FIRST CLASS MAIL PERMIT NO. 7811 MINNEAPOLIS, MN

POSTAGE WILL BE PAID BY ADDRESSEE

MEDTRONIC NEUROLOGICAL
IMPLANT REGISTRATION SERVICE
PO BOX 1250
MINNEAPOLIS MN 55440-9087

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES



IMPORTANT: Please detach, fill out, and mail this card to register your programmer.
(The serial number is located under the 9-volt battery.)

**Access™ Therapy Controller Model 7436
Warranty Registration Card**

Serial Number: [N|F|D] _____ Purchase Date: _____ (Mo) _____ (Day) _____ (Yr)

Name: _____ (Last) _____ (First)

Address: _____ (Street) _____ (City) _____ (State) _____ (Zip)

City: _____ (City) _____ (State) _____ (Zip)

Zip Code: _____ (City) _____ (State) _____ (Zip)

Phone: _____ (Area Code) _____ (Number)

Implant Physician Name: _____ (Last) _____ (First)

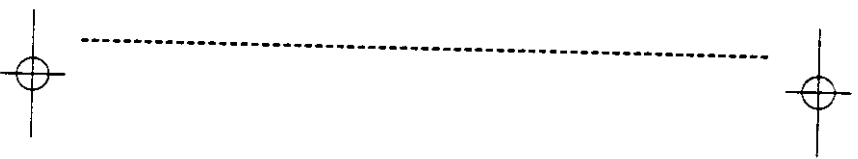
Hospital Name: _____ (Name) _____ (Address) _____ (City) _____ (State) _____ (Zip)

Address: _____ (Street) _____ (City) _____ (State) _____ (Zip)

City: _____ (City) _____ (State) _____ (Zip)

State: _____ (State) _____ (City) _____ (Zip)

Zip Code: _____ (City) _____ (State) _____ (Zip)





Medtronic Neurological
800 53rd Avenue NE
Minneapolis, MN 55421-9811
USA
Tel: (612) 514-5000
Toll-free: (800) 328-0810
FAX: (612) 514-5078

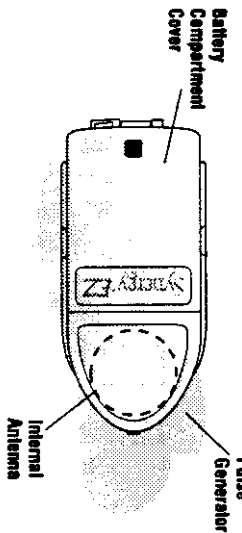
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Synergy™ EZ™ Patient Programmer

Quick Programming Guide

To turn the pulse generator on or off:

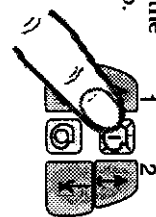
1 Position the programmer over your pulse generator.



2 To turn the pulse generator on:

a) Press the Pulse Generator **On** key. Listen for the confirmation beep.

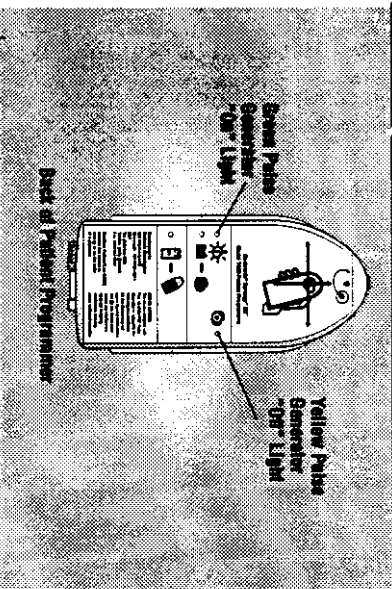
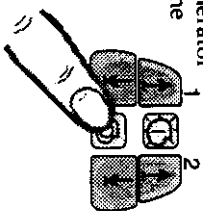
b) Check that the green Pulse Generator **On** light is lit. This light stays on for 8 seconds after you release the key.



3 To turn the pulse generator off:

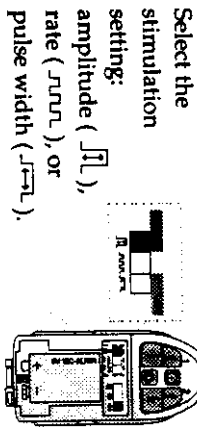
a) Press the Pulse Generator **Off** key. Listen for the confirmation beep.

b) Check that the yellow Pulse Generator **Off** light is lit. This light stays on for 8 seconds after you release the key.



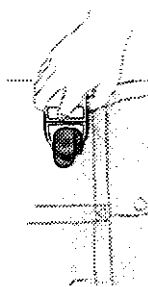
To adjust amplitude, rate, or pulse width:

1 Remove the battery compartment cover.



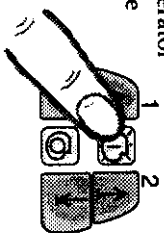
2 Select the stimulation setting:

amplitude (\uparrow), rate (\uparrow), or pulse width (\uparrow).

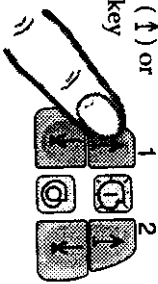


3 Position the programmer over your pulse generator.

4 Press the Pulse Generator On key. Listen for the confirmation beep.



5 Press the Increase (\uparrow) or the Decrease (\downarrow) key under desired channel to make a change. You should hear one beep for each change.



6 Repeat steps 2-5 for other stimulation settings. Replace the battery compartment cover.

If the Patient Programmer beeps:

SOUND	ACTION
one beep	You have pressed the On/Off or Increase/Decrease key and the change was received by the pulse generator.
three rapid beeps	Indicates one of the following: <ul style="list-style-type: none"> You tried to adjust the pulse generator beyond the lowest or highest settings You tried to increase stimulation with the pulse generator turned off. You reduced amplitude to its lowest setting.

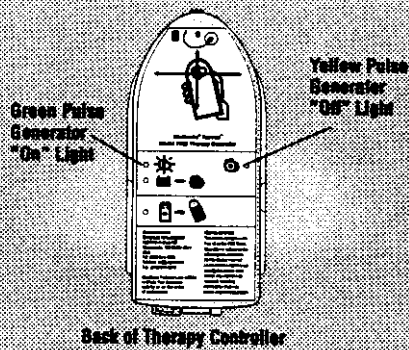
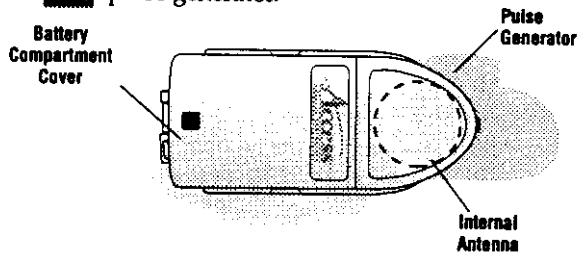
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Access™ Therapy Controller

Quick Programming Guide

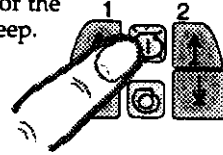
To turn the pulse generator on or off:

- 1** Position the controller over your pulse generator.



- 2** To turn the pulse generator on:

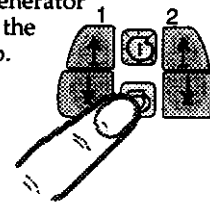
- a) Press the Pulse Generator **On** key. Listen for the confirmation beep.



- b) Check that the green Pulse Generator **On** light is lit. This light stays on for 8 seconds after you release the key.

- 3** To turn the pulse generator off:

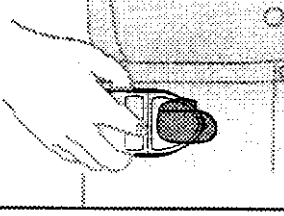
- a) Press the Pulse Generator **Off** key. Listen for the confirmation beep.



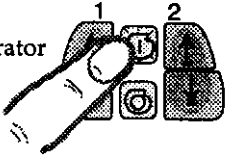
- b) Check that the yellow Pulse Generator **Off** light is lit. This light stays on for 8 seconds after you release the key.

To adjust amplitude:

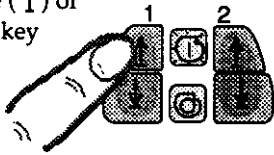
1 Position the controller over your pulse generator.



2 Press the Pulse Generator On key. Listen for the confirmation beep.



3 Press the Increase (↑) or the Decrease (↓) key under desired channel to make a change. You should hear one beep for each change.



If the Therapy Controller beeps:

SOUND	ACTION
one beep	You have pressed the On/Off or Increase/Decrease key and the change was received by the pulse generator.
three rapid beeps	Indicates one of the following: <ul style="list-style-type: none"> • You tried to adjust the pulse generator beyond the lowest or highest settings. • You tried to increase stimulation with the pulse generator turned off. • You reduced amplitude to its lowest setting.

