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UC200500780   EN   Market release
3 x 8 inches (76 mm x 203 mm)

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PtMan_mdvtldct

Medtronic

MEDTRONIC CARELINK® MONITOR

Model 2490C Patient Manual

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

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Explanation of symbols on the device

Medical equipment with respect to electric shock, fire, and mechanical hazards, only in accordance with UL60601-1, and CAN/CSA C22.2 no. 601.1
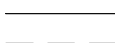
Type B equipment

Wireless communication enabled

Caution: Consult accompanying documents
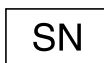
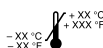Class II medical equipment

Direct current

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.

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Serial number

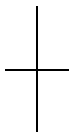SN

Temperature limitations

The following are trademarks of Medtronic:

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Introduction

This manual is intended to help you use the Medtronic CareLink Monitor Model 2490C.

If you have any questions that are not answered by this manual, or if you have any problems with the monitor, talk to your doctor. Your doctor knows your medical history and can give you the help you need.

About your monitor

The Medtronic CareLink Monitor Model 2490C is designed to automatically gather information from your implanted heart device. This automatic wireless communication between your heart device and the monitor takes place at times scheduled by your doctor or clinic. Sending heart device information to your clinic using wireless technology does not require you to interact with your monitor. Clinics typically schedule this automatic process to occur while you sleep.

The gathered heart device information is sent over a telephone line to your clinic using a toll-free number. The monitor must always be plugged into a telephone wall jack and a power outlet for this reason.

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The monitor will also send wireless heart device alerts to your clinic automatically. The information sent to your clinic helps your doctor manage your care.

Your phone will be busy while the monitor is sending information. For more information, see "Sending information with your monitor" on page 13.

The monitor is intended specifically for your use only. It will not work with other implanted devices and should be used only by you as directed by your doctor.

Sending information at the request of your doctor or clinic

You will sometimes need to send information at times other than those previously scheduled by your doctor or clinic. These times are:

- when completing first-time setup, to allow automatic wireless communication between your monitor and your heart device

- at the request of your doctor or clinic

See, "Sending information with your monitor" on page 13.

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Warnings

Warning: If you are feeling ill and you think you might need to go to the hospital, *seek medical attention immediately.* If there is an emergency, call 911. If your doctor has provided other instructions, follow them. Do not use the monitor to send your heart device information to your doctor unless you have already contacted your doctor and your doctor has requested that you use the monitor.

Warning: To ensure the safe operation of your implanted device, use the monitor only as described in this manual and at the times prescribed by your doctor.

Warning: Do not use the monitor if the monitor does not operate as described in "Sending information with your monitor" on page 13. If you need further assistance, contact your clinic.

Precautions

* Use only the supplied power cord with this monitor.

* Always leave the monitor plugged into a working power outlet and a telephone wall jack.

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- Do not use a mobile phone while using the monitor.

- If possible, avoid using the telephone while using the monitor. Your phone line will be "busy" while the monitor is sending data.

   Note: *In the case of an emergency,* you can use your phone to call for help. If you have an emergency while using the monitor, press the Start/Stop button to stop the monitor and to ensure your phone line is available.

- Do not get your monitor wet. Liquids can damage the monitor. If you get your monitor wet, contact your clinic for instructions.

Choosing a place to set up your monitor

Choose a place to set up your monitor. Follow these recommendations for choosing the right spot:

- Place the monitor within ten feet (three meters) of where you sleep, preferably on a night stand or a table.

- Place the monitor within reach of a telephone wall jack.

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- Place the monitor within reach of a power outlet.

- Do not place the monitor anywhere it can get wet.

Setting up your monitor

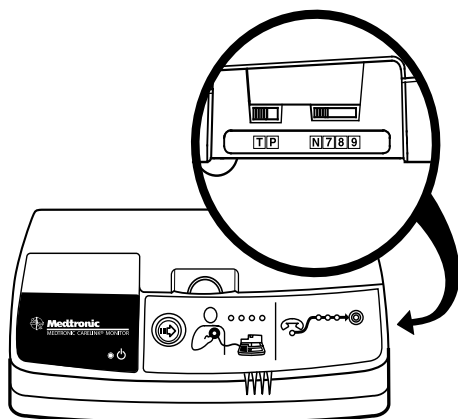Before you use your monitor, you will need to:

1. Check the telephone line settings.
2. Connect the monitor to a telephone wall jack.
3. Plug the monitor into a power outlet.

You may connect a telephone to the monitor to make and receive telephone calls, but this is not required for the monitor to work correctly. For more information see, "Connecting the monitor to a telephone wall jack and power outlet" on page 11.

Note: The monitor will not work with mobile phones.

Checking the telephone line settings

Before using the monitor, make sure that the telephone line settings are correct. There are two telephone line settings on the monitor, **N-7-8-9** and **T-P**. See Figure 1.

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Figure 1 Telephone line settings

N-7-8-9 – This setting is used if the number 7, 8, or 9 needs to be dialed to reach an outside telephone line. **N** means no number needs to be dialed and is the most common setting for home use.

Select the setting that is appropriate for the telephone line you will be using. If you are staying in a hotel, you may have to set the switch to **7**, **8** or **9** to get an outside line.

T-P – This setting is used to select a tone (T) or pulse (P) telephone line. T is the most common setting.

Select the setting that is appropriate for the telephone line that you will be using. Telephone line settings may be selected when the monitor is plugged in.

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If you have questions about the telephone line, contact your local telephone carrier or hotel front desk.
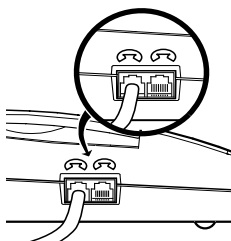
Connecting the monitor to a telephone wall jack and power outlet
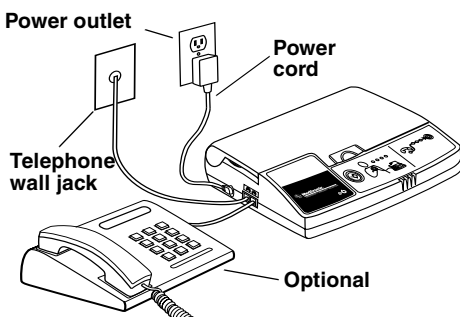
Figure 2 Monitor connected to a telephone wall jack, a power outlet, and a telephone (connecting a telephone is optional).

To set up the monitor, you will need to:

1. Make sure that you have the monitor, the telephone cord, and the power cord supplied with the monitor. You may use the telephone cord provided with the monitor or any telephone cord with standard connectors.

2. Locate the telephone plugs on the side of the monitor.

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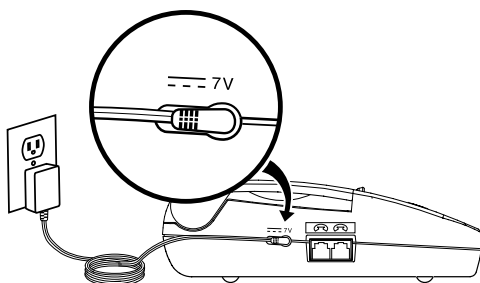PatntR05**

Figure 3 Telephone plugs

3. Plug one end of the telephone cord into either of the telephone plugs on the side of the monitor. See Figure 3.

4. Plug the other end of the telephone cord into the telephone wall jack.

   Note: You may connect a telephone to the monitor to make and receive phone calls, but this is not required for the monitor to work correctly. The set up is similar to an answering machine.

5. Connect the power cord to the monitor. See Figure 4.

   Caution: Use only the power cord supplied with the monitor to plug the monitor into the power outlet.

6. Plug the power cord into the power outlet.

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Figure 4 Connecting the power cord

If this is the first time setting up the monitor, you will need to allow wireless communication between the monitor and your heart device. To do this, see "Sending information with your monitor" on page 13. The monitor is ready for use.

## Sending information with your monitor

Use this procedure at these times:

- when completing first-time setup, to allow automatic wireless communication between your monitor and your heart device

- at the request of your doctor or clinic

Before using your monitor:

- Turn any television sets within six feet (two meters) of the monitor.

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- Turn off any computer monitors or screens within six feet (two meters) of the monitor.

- Make sure the monitor Power light is on.

Antenna

**Start/Stop button**

Power light

Display panel
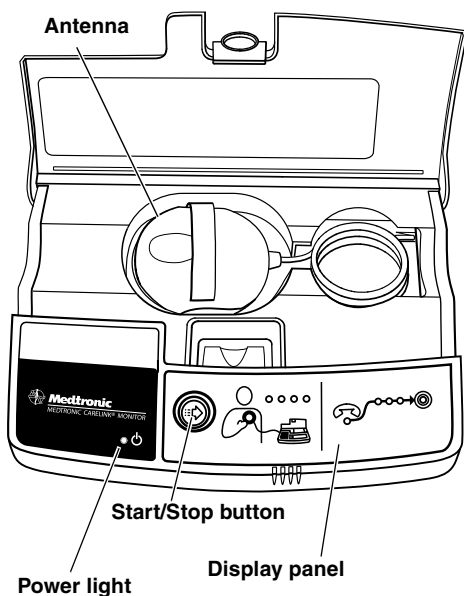
Figure 5 Monitor (front view, approximately 1/4 actual size)

Perform the following steps:

1. Press the Start/Stop button on the front of the monitor to send your heart device information to your clinic. See Figure 5.

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2. Place the antenna over your implanted device, holding it snugly against your clothing. The hand strap on the antenna should face away from you. See Figure 6.

The Antenna Position Status light will be off if the antenna is correctly placed. Reposition the antenna over your heart device if the orange Antenna Position Status light starts flashing. See Figure 6.
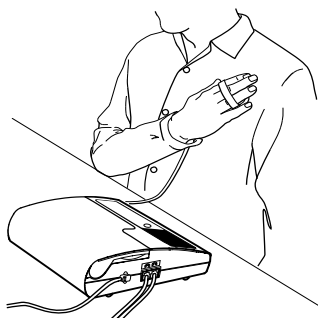
Figure 6 Positioning the antenna

3. Watch the status lights on the display panel on the front of the monitor. See Figure 7.

Each of these status lights has a different meaning when you use the monitor to send your heart device information.

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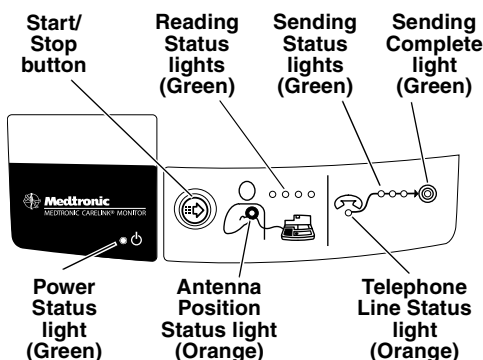
Figure 7 Start/Stop button and
status lights

4. The four green Reading Status
   lights fill and flash as the
   monitor gathers information
   from your implanted heart
   device. This process takes less
   than three minutes.

   When the Reading Status lights
   are flashing, make sure that the
   Antenna Position Status light
   remains off. When the monitor
   is finished collecting data from
   your heart device, the status
   lights stop flashing and turn off.
   The monitor beeps twice and
   automatically dials the toll-free
   number.

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5. Remove the antenna from over your implanted device when you hear the monitor dialing. Put the antenna back into the storage area.

   Note: The monitor emits high-pitched tones when dialing the preprogrammed, toll-free number.

6. The three green Sending Status lights start flashing when the monitor is sending data. This process typically takes less than three minutes but can take up to sixty minutes.

   Caution: *In the case of an emergency*, you can use your phone to call for help. If you have an emergency while using the monitor, press the Start/ Stop button to stop the monitor and to ensure your phone line is available.

   When the monitor is done sending information, the green Sending Complete light comes on and the monitor beeps twice.

   The monitor automatically returns to resting mode. You can then use the telephone to make or receive calls.

   Note: If you must stop before the session is complete, remove the antenna from over your

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implanted device and press the Start/Stop button. When you are ready to restart the session, follow the procedure in "Sending information with your monitor" on page 13.

Green status lights

The green lights indicate the following information (see Figure 7):

- whether the monitor is plugged in to the power outlet

- the heart device information reading status

- the heart device information sending status

The green Power Status light should always be on. If the green Power Status light is off, verify that the power cord is plugged into a power outlet.

When using the monitor to send information make sure the Reading Status lights flash and fill.

After the reading is complete, the Sending Status lights begin to flash.

Repeat the procedure in "Sending information with your monitor" on page 13, if:

- the Reading Status lights stop flashing and remain lit for more than three minutes

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- the Sending Status lights flash or remain lit for more than one hour

- you must stop the monitor before your heart device information is sent

Orange status lights

The two orange lights on the front of the monitor are status lights (see Figure 7). The status lights are:

- Antenna Position Status
- Telephone Line Status

The orange status lights should not be lit when you are using the monitor. If either of these status lights remains on or you hear short beeps after pressing the Start/Stop button, try the recommendations in the following paragraphs.

Antenna Position Status

If the orange Antenna Position Status light begins flashing and you hear short beeps:

- Make sure the hand strap on the top of the antenna is facing out and away from you. See Figure 6.

- Slowly reposition the antenna over your implanted device.

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When the antenna is repositioned correctly, the orange Antenna Position Status light will turn off, the green Reading Status lights will begin flashing, and the monitor will resume data collection.

Telephone Line Status

If the orange Telephone Line Status light flashes:

- Make sure that the telephone line settings are correct. See "Setting up your monitor" on page 9. If you need help determining the type of telephone line you are using, contact your local telephone carrier.

  Note: Telephone line settings may be selected when the monitor is plugged in.

  Note: Verify that your telephone line is analog. The monitor was designed to work with analog telephone lines. If you need help determining the type of telephone line you are using, contact your local telephone carrier.

- Make sure the telephone line connections are intact.

- Test the telephone wall jack to make sure it is working. Connect a telephone to the

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telephone wall jack and make an outside call. If you cannot call out, connect the monitor to a different telephone wall jack.

Note: If the data transmission is interrupted due to Call Waiting, the monitor automatically redials and sends your implanted device information. If the monitor does not begin redialing, check that the telephone connections are intact.

Traveling with your monitor

When using your monitor away from home:

- Place the monitor within ten feet (three meters) of where you sleep, preferably on a night stand or a table.

- If you are using a telephone line that requires you to dial a number to make an outside call (usually **9**), make sure that the telephone line settings are correct. See "Checking the telephone line settings" on page 9.

- The monitor is designed for use in the continental United States, Alaska, and Hawaii.

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Monitor care

Do not drop your monitor on hard surfaces. Contact your clinic if the monitor has been dropped.

Clean the outside with a clean, dry cloth.

Caution: Do not get your monitor wet. Liquids can damage the monitor. If you get your monitor wet, contact your clinic for instructions.

For more information about your monitor see:

http://www.medtronic.com/carelink

Monitor specifications

Standards (The monitor complies with the following:)
EMC: CFR 47 Part 15

Patient Safety: UL/CUL/IEC 60601-1:1998 + A1:1991 + A2:1995, Type B, ordinary, continuous operation, externally powered, not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

Power Requirement
See the label on the supplied power cord.

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Testing

Electromagnetic Compliance (EMC) testing shows that the monitor provides reasonable protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If the monitor does cause harmful interference to other devices or is negatively impacted by other devices, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the devices.

- Increase the separation between the devices.

- Consult Medtronic for help.

The monitor has been tested for compliance to FCC regulations. Changes or modifications of any kind not expressly approved by Medtronic could void the user's authority to operate the monitor.

This transmitter is authorized by rule under the Medical Implant Communications Service (47 C.F.R. Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e. transmitters and receivers used to

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communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation.

This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference."
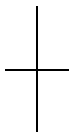
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Consumer Information and FCC Requirements

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

1. This equipment complies with Part 68 of the FCC rules. On the bottom of this equipment is a label that contains, among other information, the FCC registration number and Ringer Equivalence Number (REN) for this equipment. If requested, provide information to your telephone company.

2. The REN is useful to determine the quantity of devices you may connect to your telephone and still have all of those devices ring when your number is called. In most, but not all areas, the sum of the RENs of all devices should not exceed five (5.0). To be certain of the number of devices you may connect to your line, as determined by the REN, you should call your local telephone company to determine the maximum REN for your calling area.

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3. If your Model 2490C Medtronic CareLink Monitor causes harm to the telephone network, the Telephone Company may discontinue your service temporarily. If possible, the company will notify you in advance. But if advance notice isn't practical, you will be notified as soon as possible. You will be advised of your right to file a complaint with the FCC.

4. Your telephone company may make changes in its facilities, equipment, operations, or procedures that could affect the proper operation of your equipment. If it does, you will be given advance notice so as to give you an opportunity to maintain uninterrupted service.

5. If you experience trouble with this equipment, Model 2490C Medtronic CareLink Monitor, please contact Medtronic, Inc. Minneapolis, MN, 1-800-551-5544, for repair/warranty information. The telephone company may ask you to disconnect this equipment from the network until the problem has been corrected or you are sure that the equipment is not malfunctioning.

6. There are no repairs that can be made by the customer to the Model 2490C Medtronic CareLink Monitor.

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7. This equipment may not be used on coin service provided by the telephone company. Connection to party lines is subject to state tariffs. Contact your state public utility commission or corporation commission for information.

8. This transmitter is authorized by rule under the Medical Implant Communications Service (47 C.F.R. Part 95) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (i.e. transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation.

9. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference."

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