



Medtronic

MyCareLink™ Patient Monitor

Model 24950



Patient Manual

! USA

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

CE 0123

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Medtronic and MyCareLink

Explanation of Symbols

CE

Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directives.

0123

This symbol means that the device fully complies with the AIMD Directive 90/385/EEC (as amended by 2007/47/EC)(NB 0123) and R&TTE 1999/5/EC

IP22

(Reader) This product complies with international electrical safety rating IP22 with regard to ingress of dust, other foreign objects, and water as required by IEC 60601-11.

IP21

(Monitor base) This product complies with international electrical safety rating IP21 with regard to ingress of dust, other foreign objects, and water as required by IEC 60601-11.



Keep dry



Use only with provided power supply



Type BF applied part



Caution



Consult instructions for use



Package contents



Home monitor



Product documentation



Accessories



MyCareLink Patient Monitor



Non-ionizing electromagnetic radiation



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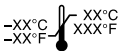
Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See [http:// recycling.medtronic.com](http://recycling.medtronic.com) for instructions on proper disposal of this product.



Reorder number



Serial number



Temperature limitation



Humidity limitation



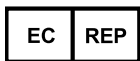
For US audiences only



Manufacturer



Date of manufacture



Authorized representative in the European community



Medical equipment with respect to electric shock, fire, and mechanical hazards, only in AAMI/ES 60601-1(2006) / A2 (2010) and CSA 22.2 NO 60601-1 CAN/CSA:2008



China RoHS



USB port



Direct current. 5V 0.3A



Refer to instruction manual

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Introduction

This manual is intended to help you use the MyCareLink Patient Monitor Model 24950.

If you have any questions setting up or using the monitor, or if you have problems with the monitor, please contact Medtronic. See “How to contact Medtronic” on page 40, or use the information found on the back cover of this manual.

If you have questions about your medical condition, talk to your doctor. Your doctor knows your medical history.

About your monitor

The monitor is an electronic device that provides an easy way for your doctor to obtain information about your heart device. The monitor gathers this information to allow your doctor to manage your care.

How your monitor gathers information from your heart device is determined by the kind of heart device you have.

Some heart devices communicate wirelessly with your monitor. Once you have set up your monitor and completed an initial manual transmission, the monitor 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. The process is silent and invisible.

Clinics typically schedule the automatic process to occur while you sleep. For this reason, the monitor must remain plugged in to a power outlet. The heart device information is sent to your clinic using the cellular phone network.

Other heart devices require you to use your monitor's reader to gather information from your heart device so your monitor can send the information to your clinic.

To find out which kind of device you have, see your heart device patient manual, or talk to your doctor.

The monitor is intended specifically for your use only. It will not work with other implanted devices and should only be used by you as directed by your doctor. Unauthorized use by others with implanted devices could interrupt the prescribed operation of their device.

Sending information at the request of your doctor or clinic

You will sometimes need to send information at times other than those 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 using the monitor” on page 21 of this manual.

Indications for use

The monitor is an external electronic device that interfaces with Medtronic implanted heart devices and a telecommunications connection to transmit

stored implanted heart device data to the physician or clinician.

Contraindications

There are no known contraindications for the monitor.

Warnings

Warning: If you are feeling ill, seek immediate medical attention. Do not use the monitor unless directed by your doctor. If there is an emergency, call your local emergency number. If your doctor has provided instructions, follow them. Waiting to seek medical attention could be dangerous to your health.

Warning: To ensure the safe operation of the monitor and your implanted heart device, follow these instructions:

Use the monitor as described in this manual. Save this manual.

Use the monitor only at the times prescribed by your doctor.

If you need further assistance, please contact Medtronic. See “How to contact Medtronic” on page 40, or use the information found on the back cover of this manual.

Warning: Do not use the monitor if the monitor does not operate as described in “Sending information using the monitor” on page 21. To ensure proper operation of your implanted heart device, follow the instructions in this manual about positioning the reader over your implanted heart device. If you do not follow these instructions, the monitor may not be recording or sending information from your implanted heart device. If you need further assistance, please contact Medtronic. See “How to contact Medtronic” on page 40, or use the information found on the back cover of this manual.

Warning: Do not modify this equipment. Modifications may impact monitor effectiveness, and adversely affect your safety.

Warning: Do not touch open ports or plugs, or insert your finger or any objects into the open ports on the monitor. Inserting your finger or objects into an open port may result in electrical shock.

Warning: Important safety instructions. When using the monitor, basic safety precautions should always be followed to reduce the risk of fire, electric shock, and injury to persons, including the following:

- Do not use the monitor near water, for example, near a bath tub, wash bowl, kitchen sink or laundry tub, in a wet basement, or near a swimming pool.
- If you suspect a gas leak, do not use the monitor and do not use a telephone in the vicinity of the leak to report a gas leak.

Precautions

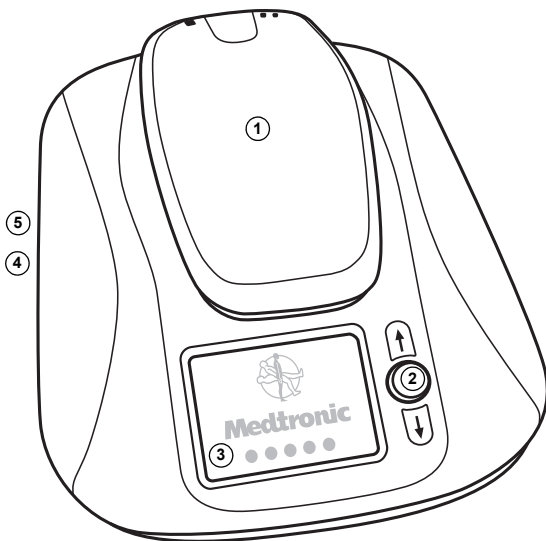
- Use only the supplied power cord with this monitor. Using a different power cord could damage the monitor and adversely affect your safety.
- Do not use the monitor within two meters (six feet) of a television, computer monitor or screen, or wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, or 'walkie-talkies.' Using your monitor near these devices could interfere with communication between your implanted heart device and the monitor.

Contents of the monitor package

You should receive the following:

- One Medtronic MyCareLink Patient Monitor Model 24950 base
- One Medtronic MyCareLink Model 24955 removable reader
- One Medtronic MyCareLink Model 24956 power cord
- One Patient Manual
- One Quick Start Guide
- One set of 'For Your Records' labels
- One Cellular Modem safety manual

About the monitor



1 Reader

4 Power LED

2 Accept Button

5 Power port

3 Monitor screen

Figure 1: Monitor base and removable reader (front view)

The monitor (Figure 2) consists of three components:

- A monitor base
 - A removable reader to gather information from your implanted heart device
 - A power cord
-



1 Power cord

2 Reader

3 Base

Figure 2: Components

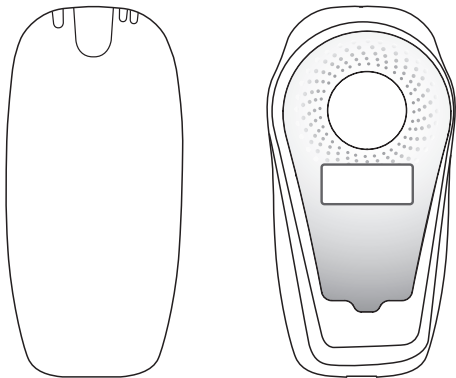


Figure 3: Monitor reader (front and back view, approximately 1/3 actual size)

Choosing a place to set up the monitor

Consider the following recommendations for choosing a place to set up the monitor:

- Place the monitor near where you sleep, preferably on a nightstand or a table. Your monitor is capable of receiving signals from your heart device up to 3 meters (10 feet) away, but you should consult your heart device manual for recommended distances specific to your device.

- Place the monitor where you can sit comfortably and see the front of the monitor.
- Place the monitor in a location that receives an adequate cellular signal.
- Place the monitor within reach of a power outlet, and position it so that it can be unplugged from the power outlet if necessary.
- Do not place the monitor anywhere it could get wet.

Setting up the monitor

Before you use the monitor you will need to plug the monitor into a power outlet.

To plug in your monitor, locate the power cord port on the left side of the monitor base. Insert the power cord end into the monitor side port, then plug the wall plug into a wall outlet.

Caution: Use only the supplied power cord with this monitor. Using a different power cord could damage the monitor and adversely affect your safety.

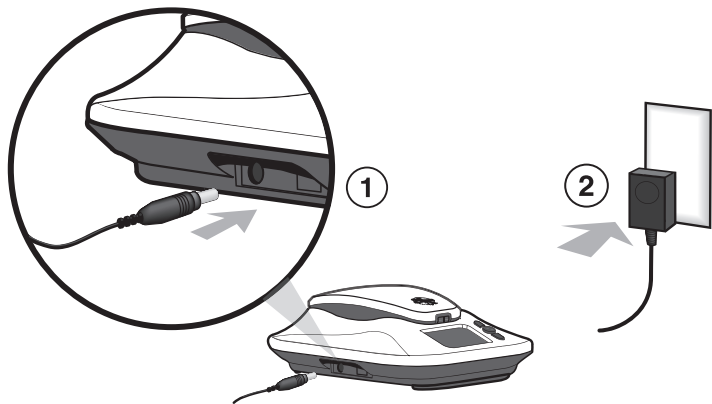


Figure 4: Plugging in the monitor

Sending information using the monitor

Use this procedure at these times:

- When completing first-time set-up.
- At the request of your doctor or clinic.

Before using your monitor:

- Turn off any television, computer monitor, or screen within two meters (six feet) of the monitor.

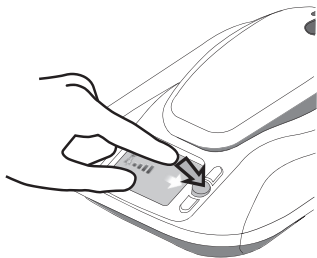
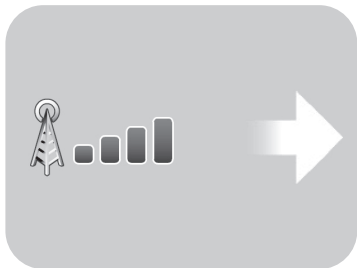
- Turn off or remove any cellular phone or other wireless device that is within two meters (six feet) of the monitor.

When you send a transmission using this procedure, your monitor screen will also show step by step instructions for you to follow. You can use these on-screen instructions to guide you through this procedure.

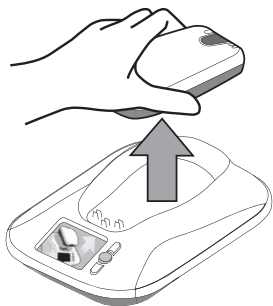
Note: If the monitor screen shows an error message icon during this procedure, refer to “Troubleshooting error messages” on page 31 of this manual.

To send information using your monitor, perform the following steps:

1. If the monitor screen is dark, press the “Accept” button on the front of the monitor to wake up the screen.
2. When monitor wake-up is complete, the monitor screen will show an image indicating that the monitor is ready to begin a transmission.

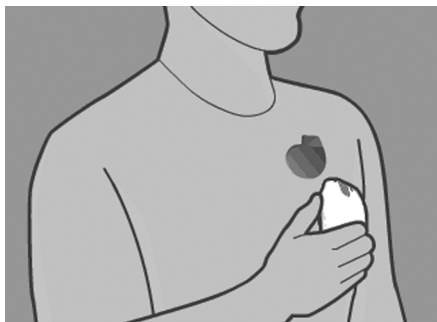


3. Press the “Accept” button. The monitor screen will show an image instructing you to pick up the reader.

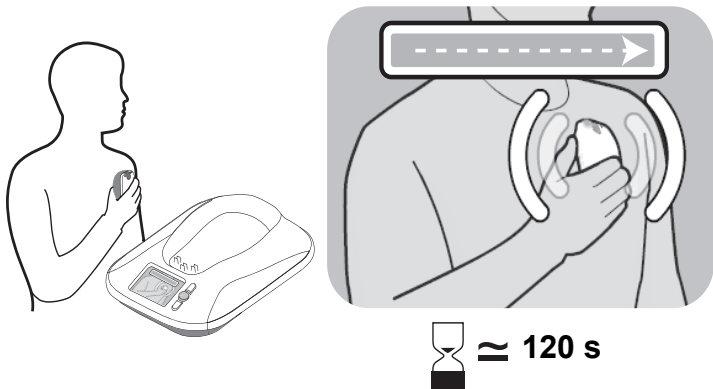


4. When the monitor screen shows an image of a reader being placed over a device, hold the reader over your implanted device. You may

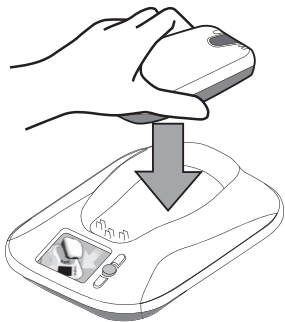
either hold the reader snugly against your clothing, or against your bare skin.



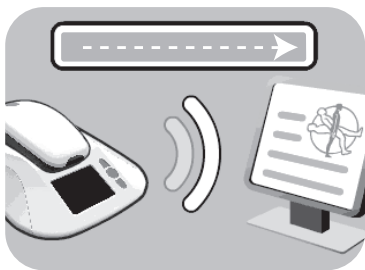
5. When the monitor begins reading data from your implanted device, the monitor screen will show a green progress bar, indicating that data is being sent from the reader to the monitor base.




- While the monitor is communicating with your implanted device, remain still and make sure the monitor reader is placed over your implanted device. This process typically takes less than 3 minutes, but may take up to 12 minutes.
6. When the monitor is finished communicating with your implanted device, the monitor will make two short tones, and the monitor screen will instruct you to return the reader to the monitor base.

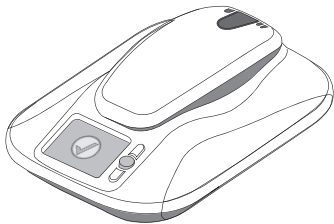


7. The monitor will send your implanted device data to the CareLink Network. The monitor screen will show a green progress bar indicating that data is being sent.



 \approx 120 s

8. Your transmission is complete when the monitor makes two short tones and the monitor screen shows a green check mark image.



Start-up screen information

When your monitor is activated by pressing the “Accept” button, your monitor screen will show a system status image with the following information:

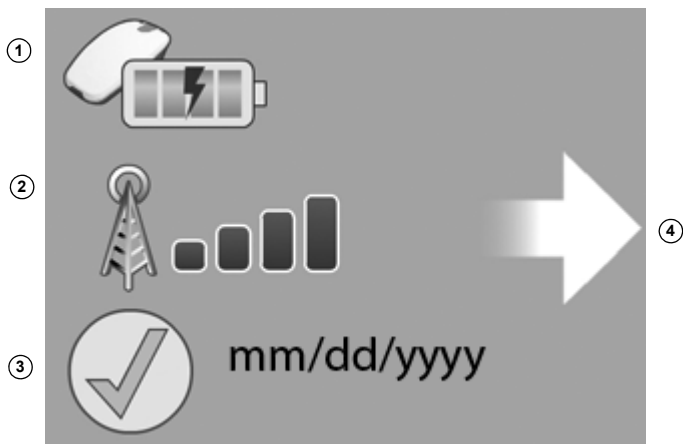


Table 1. Start screen information

Image	Description
1 Reader status icon	This area shows the status of the reader. The reader icon may show the reader is charging, missing, or has a low battery.

Table 1. Start screen information

Image	Description
2 Cellular signal icon	This icon shows the status of the monitor's connection to a cellular network
3 Last transmission	This icon shows the date of your last successful transmission to the CareLink Network. Note: The date format shown on your monitor will depend on which country you are in.
4 Start transmission icon	This icon means the monitor is ready to begin a transmission. Press the "Accept" button to begin a transmission.

Reader LED indicator lights

The monitor's reader has three LED indicator lights that indicate the status of a transmission, the connection between the reader and monitor base, and the reader's battery status.

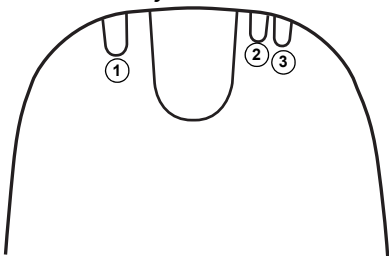


Table 2. reader LED indicator lights

Indicator Light	Description
1 Green indicator light	The green indicator light shows transmission of data between the reader and monitor base. When the green indicator light is lit, the reader is transmitting data to the monitor base.

Table 2. reader LED indicator lights

Indicator Light	Description
2 Blue indicator light	The blue indicator light shows the connection between the reader and monitor base. <ul style="list-style-type: none">• A flashing blue light means the reader is establishing a connection with the monitor base• A solid blue light means the reader and monitor base are connected.
3 Amber indicator light	The amber indicator light shows the battery status of the reader. If the amber indicator light is lit, the reader battery is low. Place the reader on the monitor base to recharge the reader battery.

When you place the reader on the monitor base, all three indicator lights will flash briefly to indicate that the reader is properly docked with the monitor base.

Troubleshooting error messages

Use the information in this section to troubleshoot the use of your monitor.

You can find information about the following errors:

- Error #3230 - “Reader not found by monitor base” on page 33
- Error #3248 - “Reader battery status” on page 34
- Error #5704 - “No cellular signal” on page 35
- “Reader position” on page 36
- “System errors” on page 37

If you receive an error message while using your monitor, your monitor screen will show an error icon with an orange background, and a 4 digit error number.

Some error messages may include an animated demonstration to help you correct the problem. Follow these instructions to resolve the error.

For some errors, you will be instructed to contact Medtronic. See “How to contact Medtronic” on page 40, or use the information found on the back cover of this manual.

Reader not found by monitor base

If the monitor base is unable to communicate with the reader, the monitor screen will show Error #3230 - No reader found by monitor base.

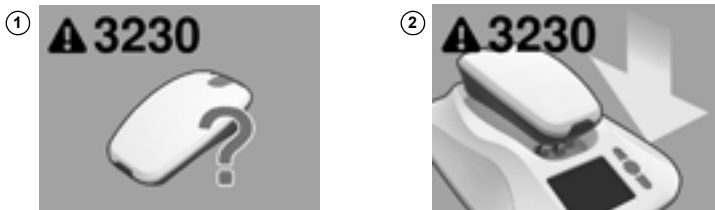


Figure 5: No reader found by monitor base

This can occur when:

- The reader is off the monitor base, and has powered down.
- The reader is off the base station and has no battery life remaining.
- The reader is out of range of the monitor base.

To restore communication between the reader and monitor base, return the reader to the monitor base cradle, and wait for the error message to disappear. If returning the reader to the monitor base does not correct the error, please contact Medtronic. See “How to contact Medtronic” on page 40, or use the

information found on the back cover of this manual.

Reader battery status

The monitor reader includes a rechargeable battery. If the reader battery needs to be recharged, the monitor's screen will show Error #3248 - Recharge Reader. In addition, the amber LED indicator light on the reader head may be lit.

- To recharge the reader, place the reader on the monitor base. Recharging the reader battery will take approximately 20 minutes.

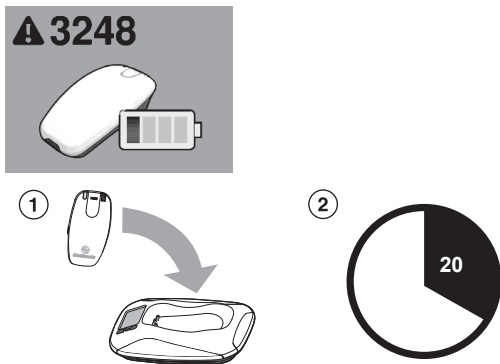


Figure 6: Reader battery status

Note: The monitor reader should be replaced when your reader battery no longer recharges, or only holds a charge for a brief period. If you are unable to complete a transmission without receiving the Recharge Reader error message, please contact Medtronic. See “How to contact Medtronic” on page 40, or use the information found on the back cover of this manual.

No cellular signal

Your monitor uses a cellular telephone connection to transmit implanted device data to your doctor.

If your monitor does not have adequate cellular service connection, the monitor’s screen will show Error #5704 - No cellular signal. See Figure 7

- Change the orientation of the monitor by rotating the monitor base.
- Change the location of your monitor so it is near a window or outside wall. Remember, your monitor should be placed within 3 meters (10 feet) of where you sleep.
- If you are unable to find an adequate cellular signal for your monitor, please contact

Medtronic. See “How to contact Medtronic” on page 40, or use the information found on the back cover of this manual.



Figure 7: No cellular signal

Reader position

The reader must be properly positioned over your implanted device in order to communicate with it.

If the reader is moved out of position during a transmission, you will hear 3 short tones from your monitor, and see the Reader Placement Problem image on the monitor screen. See Figure 8.

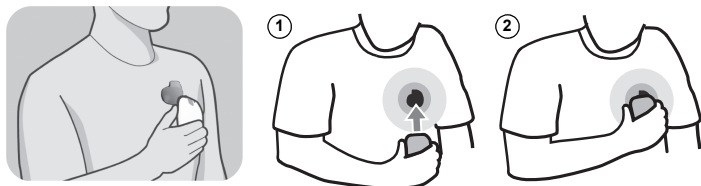


Figure 8: Reader placement problem

- Reposition the reader over your implanted device.
- When the reader is repositioned correctly a green progress bar will appear on the monitor screen. When the reader is positioned correctly, the monitor will resume data collection. Hold the reader in position until your transmission is completed.

System errors

If your monitor encounters a system error, your monitor screen will show a system error icon and an error message code.

This image indicates that your monitor has encountered an internal error, and does not mean that there is a problem with your implanted heart device.

If this occurs, restart the monitor by disconnecting then reconnecting the monitor's power supply.

If restarting your monitor does not correct the error, please contact Medtronic. See "How to contact Medtronic" on page 40, or use the information found on the back cover of this manual.

Refer to the error code shown on your monitor screen to help Medtronic identify the problem.



Figure 9: System error

Traveling with your monitor

Note: Your monitor will work in most locations. However, in some locations, cellular service may not be available. If you are planning on traveling with your monitor, please contact Medtronic to confirm availability of coverage.

Replacing your power supply or reader

If your power supply or monitor reader is lost or damaged, you can contact Medtronic to receive information on ordering a replacement. See “How to contact Medtronic” on page 40, or use the information found on the back cover of this manual.

Monitor care

Do not drop your monitor or reader on hard surfaces. Dropping the monitor or reader can damage them and prevent them from functioning properly. If your monitor or reader has been damaged, please contact Medtronic. See “How to contact Medtronic” on page 40, or use the information found on the back cover of this manual.

You can clean the exterior of your monitor by using a clean cloth and light application of water, hydrogen peroxide, alcohol (methyl, ethyl or Isopropyl) or a mild detergent.

The monitor does not require any preventative inspection or maintenance.

Caution: Do not get your monitor wet. If you get your monitor wet, please contact Medtronic. See “How to contact Medtronic” on page 40, or use the information found on the back cover of this manual.

How to contact Medtronic

Patients in the United States

To speak directly with a Patient Services Specialist, call 1-800-929-4043. Our staff is available Monday through Friday from 8:00 AM to 5:00 PM (Central Standard Time).

Medtronic is dedicated to providing you with the most up-to-date information available about your monitor. Website information is available 24 hours a day.

- Medtronic website: www.medtronic.com
- Medtronic CareLink Network information: www.medtronic.com/patients/carelink

Patients outside the United States

If you have questions that are not covered in this manual or you want more in-depth information about your heart monitor, please contact Medtronic using the information on the back cover of this manual.

Monitor specifications

Open Source Software

The operating system for this device includes open source software.

Information on open source software licensing can be found at www.medtronic.com/mycarelink/monitor/software

Standards (The monitor complies with the following:)

EMC: CFR 47 Part 15

Patient Safety: IP22 (monitor base); IP21 (reader); IEC 60601-1, ETL, Type BF applied part (reader), ordinary, continuous operation, Class II, not

suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

Recommended environmental conditions during storage and transport

Temperature: -40 °C to 70 °C (-40 °F to 158 °F)

Relative Humidity: 5% to 95%

Safe when stored or transported in temperatures from -40 °C without relative humidity control to 70 °C at a relative humidity of 5% to 95%, including condensation.

Recommended operating conditions

Temperature: 5 °C to 40 °C (41 °F to 104 °F)

Safe when operated at temperatures from 5 °C to 40 °C (41 °F to 104 °F) in relative humidity from 15% to 93%, non-condensing.

Power supply

To assure compliance to the specified standards, use only the power supply that came with your monitor: Medtronic Model Number 24956.

Rated Voltage AC 100 - 240V

Rated Line Frequency 50 - 60Hz

Current 0.5A Max. at 90 VAC input

The power supply is to be used for mains disconnection.

Expected service life

The expected service life of a monitor is 5 years.

Disposal

Follow local regulations for proper disposal of this product. Do not dispose of this product in the unsorted municipal waste stream. This product contains materials that can harm the environment. See <http://recycling.medtronic.com> for instructions on proper disposal of this product.

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.

If you experience performance issues with your Model 24950 MyCareLink Monitor, try using it at least two meters (6 feet) away from all wireless communication devices such as cellular phones, television monitors, or computer screens.

Safety and technical inspection

An annual safety and technical inspection of the monitor is not required.

Consumer information and Requirements

Declaration of conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment and Directive 90/385/EEC on Active Implantable Medical Devices.

FCC Requirements

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.

FCC ID LF524950

FCC ID LF524955 (contains FCC ID T7V1315)

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. 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 Device Radiocommunication Service (in part 95 of the FCC Rules) and may not interfere with stations operating in the 400.15-406 mhz band in the meteorological aids, meteorological satellite, and earth exploration satellite services (i.e. transmitter and receivers used to communicate weather data) and must accept any interference received, including interference that may cause undesired operation. This transmitter shall be used only in accordance with FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communication Commission there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

Industry Canada Requirements

IC ID 3408D-24950

IC ID 3408D-24955 (contains IC ID 216Q-1315)

Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

“This device may not interfere with stations operating in the 400.150-406.000 MHz band in the meteorological aids, meteorological-satellite, and earth exploration-satellite services and must accept any interference received, including interference that may cause undesired operation.”



Medtronic

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