



Medtronic

MyCareLink Smart™ Patient Reader

25000

Patient Manual

! USA

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

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Medtronic, MyCareLink Heart, MyCareLink Smart

IP20

(patient reader) This product complies with international electrical safety rating IP20 with regard to ingress of dust, other foreign objects, and water as required by IEC 60601-11.



Keep dry



Security key



Standby button



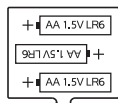
Bluetooth connection



Telemetry



Low battery



Batteries



Type BF applied part



Caution



Consult instructions for use



Follow instructions for use (blue)



Package contents



patient reader



Product documentation



Non-ionizing electromagnetic radiation



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



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.



Reorder number



Serial number



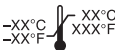
Accessories



Storage temperature



Transit temperature



Temperature limitation



Humidity limitation



For US audiences only



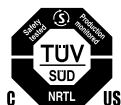
Manufacturer



Date of manufacture



Authorized representative in the European community



System meets the applicable Canadian and U.S. electrical safety standards.

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Introduction

This manual is intended to help you use the Medtronic MyCareLink Smart™ 25000 Patient Reader (patient reader).

If you have any questions setting up or using the patient reader, or if you have problems with the patient reader, please contact Medtronic. See “How to contact Medtronic” on page 29, or use the information found on the back cover of this manual.

Follow the instructions for use in this manual to properly use the patient reader. Formal training from your clinician is not required to use the patient reader properly.

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

About your patient reader

The patient reader is an electronic device that provides an easy way for your doctor to obtain information about your implanted device. The patient reader gathers this information from your implanted device and transmits it to the Medtronic CareLink network to allow your doctor to manage your care.

The patient reader is intended specifically for your use only and should only be used by you as directed by your doctor. Do not use the patient reader with other implanted devices. Unauthorized use by others with implanted devices could delay your implanted device date from reaching your doctor.

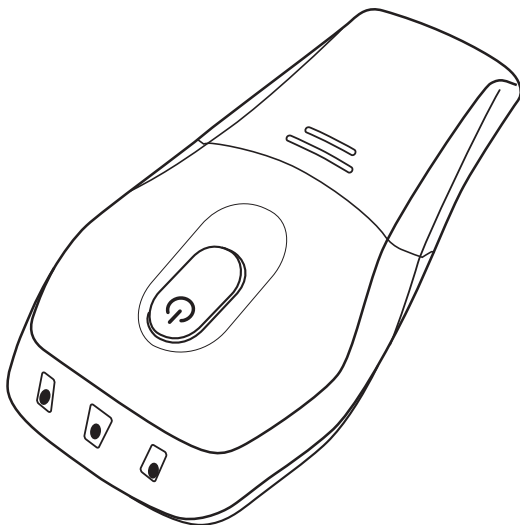


Figure 1: Patient reader

Indications for use

The patient reader is a portable electronic device that communicates with your Medtronic implanted heart device and transmits implanted heart device data to the CareLink Network via the Medtronic MyCareLink Heart™ application.

Contraindications

There are no known contraindications for the patient reader.

Warnings

Warning: If you are feeling ill, seek immediate medical attention. Do not use the patient reader 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 patient reader and your implanted heart device, follow these instructions:

- Use the patient reader as described in this manual. Save this manual.
- Use the patient reader only at the times prescribed by your doctor.

If you need further assistance, please contact Medtronic. See “How to contact Medtronic” on page 29, or use the information found on the back cover of this manual.

Warning: Do not use the patient reader if it does not operate as described in “Communicating with your implanted device” on page 19. To ensure proper operation of your implanted heart device, follow the instructions in this manual about positioning the patient reader over your implanted heart device. If you do not follow these instructions, the patient reader 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 29, or use the information found on the back cover of this manual.

Warning: Do not modify this equipment. Modifications to the equipment may impact patient reader effectiveness, and adversely affect your safety.

Warning: Important safety instructions. When using the patient reader, basic safety precautions should always be followed to

reduce the risk of electric shock, and injury to persons, including the following:

- Do not use the patient reader near water, for example, near a bath tub, wash bowl, kitchen sink or laundry tub, in a wet basement, or near a swimming pool.

Precautions

Caution: Only install the recommended batteries in the patient reader. Batteries with different physical dimensions, non-alkaline (e.g., lithium or rechargeable), or batteries with contamination on the battery terminals, may result in erratic operation of the patient reader or damage to the patient reader, specifically to the battery compartment.

Caution: Replace the batteries for the patient reader when the amber indicator light is lit. The patient reader does not function with dead batteries.

Caution: Only install new, fresh batteries that have not passed their expiration date when replacing the batteries. The patient reader may not operate properly if batteries that have passed their expiration date are installed.

Caution: Inspect battery terminals for contamination. Using batteries with contaminated terminals can result in the patient reader turning off, decreased battery life, or corrosion to the battery compartment.

Caution: Verify that the battery compartment door is fully closed when installing or replacing batteries. If the battery compartment door is not fully closed, the batteries may become dislodged or

fall out of the patient reader. If the batteries become dislodged or fall out of the patient reader, the patient reader will not operate.

Caution: Verify that the batteries are installed with correct polarity by verifying that the batteries align with the polarity markings on the inside of the battery compartment.

The patient reader requires proper battery polarity for operation. After installing the batteries, ensure that the amber indicator light is not lit. The patient reader will not operate if the batteries are not installed with correct polarity.

Contents of the patient reader package

The patient reader package includes the following items:

- One Medtronic MyCareLink Smart™ Patient Patient reader 25000
- Batteries
- Literature
- One set of 'For Your Records' labels

Battery installation

Your patient reader is internally powered by three LR6-sized (AA) alkaline batteries. Install the batteries in the battery compartment located on the bottom of the patient reader.

The patient reader requires proper battery polarity for operation. Ensure that the batteries align with the polarity markings on the inside of the battery drawer. The patient reader will not turn on or operate if the batteries are installed with incorrect polarity.

Install the batteries before each use and remove them when the patient reader is not in use. Replace the batteries when the amber indicator on the patient reader is lit.

Warning: Do not inhale or swallow the batteries. Inhaling or swallowing the batteries can cause serious physical harm.

To install the batteries, perform the following steps:

1. Open the battery packaging.
2. Open the patient reader battery compartment door.
3. Install three new LR6 (AA-sized) alkaline batteries. Verify that the batteries align with the polarity markings on the inside of the battery compartment (see Figure 2).

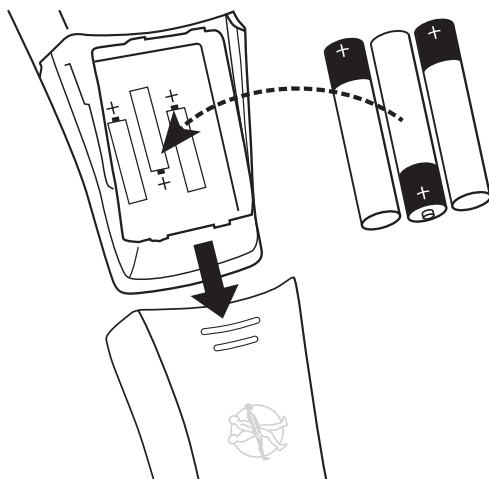


Figure 2: Install the batteries with proper polarity

Caution: Ensure that the batteries are installed with the correct battery polarity by verifying that the batteries align with the polarity markings on the inside of the battery compartment. The

patient reader requires proper battery polarity for operation. The patient reader will not turn on or operate if the batteries are installed with incorrect battery polarity.

4. Close the battery compartment door firmly.

Note: Always operate the patient reader with the battery compartment door firmly closed. If the battery compartment door is not firmly closed, the door could open and the batteries could fall out or become dislodged. The patient reader will not turn on or operate if the batteries are dislodged or have fallen out of the patient reader.

5. Discard the old batteries according to local regulations if you are replacing old batteries with new batteries.

Indicator lights and the standby button

The patient reader has three indicator lights and a standby button. See Table 1 for a description of each indicator light and the standby button.

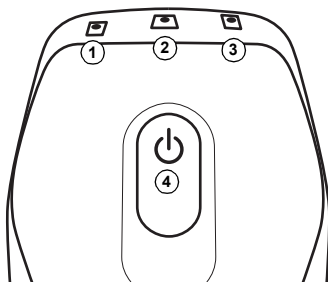


Table 1. Patient reader indicator lights and standby button

Indicator light or button	Icon	Description
1. Blue		The blue indicator light indicates if the patient reader is turned on and shows the connection between the patient reader and the smart phone or tablet. • A flashing blue light indicates that the patient reader is turning on and establishing a connection with the smart phone or tablet. • A solid blue light indicates that the patient reader is turned on and connected to the smart phone or tablet.
2. Green		The green indicator light indicates communication between the patient reader and the implanted device. When the green indicator light is lit, the patient reader is communicating with the implanted device.

Table 1. Patient reader indicator lights and standby button

Indicator light or button	Icon	Description
3. Amber		The amber indicator light shows the battery status of the patient reader. If the amber indicator light is lit, the patient reader batteries are low. Replace the batteries when the amber indicator is lit.
4. Standby button		The standby button turns on the patient reader. Note: The standby button only turns on the patient reader; it does not turn off the patient reader. The patient reader automatically turns off after approximately two minutes of inactivity.

Downloading the application

To download the application, perform the following steps:

1. Verify that your smart phone or tablet is connected to the Internet.
2. Use the browser on our smart phone or tablet to navigate to the following Medtronic website:
www.mycarelinkheart.com
3. Click on the appropriate button to install the application on your smart phone or tablet.

4. Install the application.
5. Open the application.

Bluetooth enabling between the patient reader and the application

Your patient reader is paired with the application using a Bluetooth connection.

To enable the patient reader and the application with Bluetooth, perform the following steps:

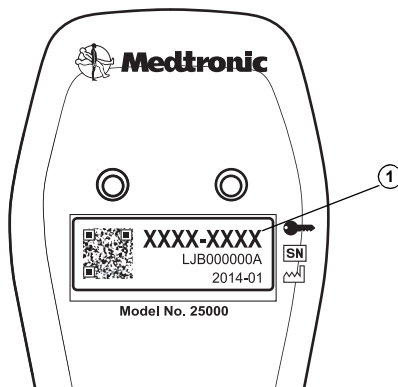
1. Verify that Bluetooth is enabled on your smart phone or tablet.
2. Start the application.
3. Press the Start button in the application.
4. Turn on the patient reader by pressing the standby button.
5. Start the application.
6. Follow the steps in the application to enable the patient reader with the application.

Security key code entry with the patient reader and the application

The device label on the bottom of the patient reader contains product symbols and the security key code. The key code will be entered into the application to pair your patient reader with the application.

To pair the patient reader with the application, perform the following steps:

1. Locate the security key code on the device label on the bottom of the patient reader on the left side of the security key symbol.



1. Security key code

Figure 3: patient reader device label including the security key code

2. Open the application.
3. Follow the prompts in the application and enter the security key code.

Once these steps are completed, your patient reader is ready to use with the application.

Communicating with your implanted device

Consider the following recommendations when using the patient reader to communicate with your implanted device:

- Find a location where you can sit comfortably when the patient reader is communicating with your implanted device.

The patient reader is not intended to be operated while you are walking, mobile, or traveling in a vehicle.

- Choose a location that receives an adequate cellular or wireless network signal.
- Hold the smart phone or tablet in a location where you can see its screen and can sit comfortably.
- Do not place the patient reader anywhere it could get wet.

To use the patient reader to communicate with your implanted device, perform the following steps:

1. Open the application from your smart phone or tablet.
2. Press the Start button in the application and follow the prompts in the application.
3. Press the standby button to turn on the patient reader.
4. Hold the patient reader over your implanted device. You may either hold the patient reader snugly against your clothing, or against your bare skin.

Note: The patient reader can become warm to the touch if it is used repeatedly for twenty minutes or more. If the patient reader has been used repeatedly for twenty minutes or more, allow it to cool for ten minutes before you use it again.

Allowing the patient reader to cool for ten minutes after twenty minutes of repeated use ensures that patient reader warmth does not cause discomfort.

5. Verify that the green indicator light is lit on the patient reader. When the green indicator light is lit, the patient reader is in acceptable proximity to the implanted device.

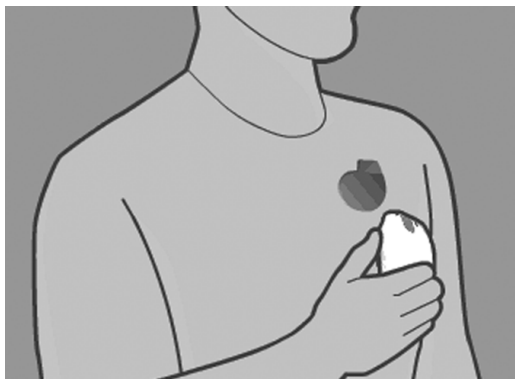


Figure 4: Patient reader held over an implanted device

6. Watch the application to follow the status of the implanted device interrogation.
7. Remove the patient reader from over your implanted device when the application indicates that the interrogation is complete.
8. View the application to follow the status of the transmission of your implanted device data from the application to the Medtronic CareLink network.
9. Remove the batteries from the patient reader and store it according to the instructions in “Storing the patient reader” on page 27.

Caution: Do not modify the patient reader or perform any service or maintenance on the patient reader while it is in use. Modifying or performing service or maintenance on the patient reader while it is in use can impact patient reader effectiveness. Contact Medtronic at the telephone number on the back cover of this manual if your patient reader is not functioning properly.

Notes:

- While the patient reader is communicating with your implanted device, remain still and make sure the patient reader is placed over your implanted device. This process typically takes less than 3 minutes.
- Your interrogation session or transmission will be interrupted if you answer an incoming phone call or open a received text message. If you interrupt the interrogation by answering the phone call or opening the text message, you will need to perform the interrogation again.
- The patient reader automatically shuts off after 2 minutes of inactivity. You can not turn off the patient reader manually by pressing the standby button.

Troubleshooting error messages

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

You can find information about the following errors:

- “Patient reader battery status” on page 23
- “Patient reader position” on page 23
- “Bluetooth connection lost” on page 24

If an error occurs while using your patient reader, your patient mobile application screen will show an error icon with an orange background, and an 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 29, or use the information found on the back cover of this manual.

Patient reader battery status

The patient reader requires batteries with power to operate properly. If the batteries need to be replaced, the following errors may occur:

Error	Action
The amber light on the patient reader head is lit.	Replace the batteries and verify that the amber is not lit.
The application screen displays an error message and emits a tone.	Replace the batteries and view the application to verify that the error message is not displayed.

Patient reader position

The patient reader must be properly positioned over your implanted device in order to communicate with it. If the patient reader is not properly positioned over your implanted device, the following errors may occur:

Error	Action
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The green indicator light is not lit.	Reposition the patient reader over your implanted device and verify that the green indicator light on the patient reader is fully lit. When the green indicator light is lit, the patient reader is communicating with the implanted device.
The application screen displays a message to place the patient reader over your implanted device.	Reposition the patient reader over your implanted device and view the application to verify that the patient reader is communicating with the implanted device.

When the patient reader is repositioned correctly, a green progress bar will appear on the application screen. When the patient reader is positioned correctly, the patient reader will resume data collection. Hold the patient reader in position until your transmission is completed.

Bluetooth connection lost

The patient reader must establish a connection with the application to transmit data. If the patient reader loses the Bluetooth connection with the application, the following errors may occur:

Error	Action
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The blue indicator light flashes	Verify that the blue indicator light on the patient reader is fully lit. When the blue indicator light is lit, the Bluetooth connection has been established between the patient reader and the application.
The application screen displays an error message and the application emits a tone.	Move your smart phone or tablet closer to the patient reader and view the application to verify that the Bluetooth connection has been reestablished.

Patient reader does not function

Error	Action
The amber, green, and blue indicator lights flash simultaneously.	If all of the indicator lights flash simultaneously when the standby button is pressed, the patient reader is no longer functioning properly and must be replaced. Contact Medtronic at the telephone number on the back cover of this manual

Traveling with your patient reader

Remove the batteries from the patient reader before traveling or flying in an airplane. Store the batteries and the patient reader either in the box the patient reader was shipped in or in a safe location before traveling or flying.

Replacing your patient reader

If your patient reader is lost or damaged, you can contact Medtronic to receive information on ordering a replacement. See “How to contact Medtronic” on page 29, or use the information found on the back cover of this manual.

Patient reader care

Do not drop your patient reader on hard surfaces. Dropping the patient reader can damage them and prevent them from functioning properly. If your patient reader has been damaged,

please contact Medtronic. See “How to contact Medtronic” on page 29, or use the information found on the back cover of this manual.

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

To clean the exterior of the patient reader, perform the following steps:

1. Dampen the cloth with a light application of one of the recommended cleaning fluids.
2. Gently wipe the exterior of the patient reader. Do not get the patient reader wet.
3. Clean the patient reader before and after each use.

The patient reader does not require any preventative inspection or maintenance.

Caution: Do not get your submerge your patient reader in fluid or damage may occur. If you get your patient reader wet and it no longer functions properly, please contact Medtronic. See “How to contact Medtronic” on page 29, or use the information found on the back cover of this manual.

Storing the patient reader

Store patient reader in the box it was shipped in when it is not being used for an interrogation.

When the patient reader is not in use, store it out of reach of pets, pests, and children.

Store the patient reader and the box in a cool, dry location.

Battery removal and disposal

Remove the three LR6-sized (AA) alkaline batteries from the patient reader when it is not in use. Store the batteries in the box the patient reader was shipped in when it is not being used.

Caution: Remove the batteries from the patient reader when the patient reader is not in use, after an interrogation, or when you are traveling with the patient reader. The batteries could leak inside the patient reader if they are not removed when the patient reader is not in use. Leakage from the batteries could damage the patient reader and cause it to not operate correctly.

If the batteries need to be replaced, discard the old batteries properly according to local regulations.

Warning: Do not inhale or swallow the batteries. Inhaling or swallowing the batteries can cause serious physical harm.

Patient reader 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.

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 patient reader. 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 patient reader, please contact Medtronic using the information found on the back cover of this manual.

Patient reader specifications

Standards (The patient reader complies with the following:)

EMC: CFR 47 Part 15

Patient Safety: IP20; IEC 60601-1, Type BF applied part, 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 distribution, storage, and transport

The temperature range for the patient reader applies to all of the following conditions:

- Distribution in the packaging
- Transport in the packaging
- Storage in the packaging
- Storage and transport after the patient reader has been removed from the packaging

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

Relative Humidity: 15% to 93%

Safe when distributed, 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 35 °C (41 °F to 95 °F)

Safe when operated at temperatures from 5 °C to 35 °C (41 °F to 95 °F) in relative humidity from 15% to 93%, non-condensing.

Atmospheric pressure range

Safe when stored or operated in an atmospheric pressure range of 700 hPa to 1060 hPa.

Maximum altitude usage

Do not use the patient reader above an altitude of 3000 meters (9,842 feet).

Expected service life

The expected service life of a patient reader is 5 years.

Electromagnetic interference

Keep your smart phone or tablet in your hand and follow the instructions in the app while interrogating your implanted device.

If you experience performance issues with your patient reader, try using it at least two meters (6 feet) away from a television, computer monitor or screen, or wireless communications equipment such as wireless home network devices, cordless telephones and their base stations, or 'walkie-talkies.' Using your patient reader near these devices could interfere with communication between your implanted heart device and the patient reader.

Safety and technical inspection

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

Consumer information and Requirements

FCC Requirements

FCC ID LF525000 (contains FCC ID T7V1316)

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 patient reader has been tested for compliance to FCC regulations. Changes or modifications of any kind could void the user's authority to operate the patient reader.

RF Exposure Guidance: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter, except in accordance with FCC multi-transmitter product procedures.



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