

FREQUENTLY ASKED QUESTIONS



MyCareLink Smart™ Patient Monitor

MyCareLink Smart (Reader)

Q: What do the lights on the Patient Reader mean?

A: Amber light: Reader batteries are low.

Green light: Connection is established between the Reader and implanted device.

Solid blue light: Bluetooth® connection established between the Reader and smartphone or tablet

Blinking blue light: Bluetooth connection is not established between the Reader and smartphone or tablet



Q: How many interrogations or transmissions can occur before the MyCareLink Smart Reader batteries will need to be replaced?

A: The Patient Reader is designed to provide several transmissions on fresh batteries. The condition and quality of batteries vary; thus the number of transmissions before the amber battery indicator is triggered will vary as well.

TIP: Take the batteries out after each use. For each additional use, insert the batteries and turn on the Reader, wait for approximately 10 seconds. If the amber indicator light is on, the Reader batteries are low. Replace the batteries when the amber indicator is on.

Q: After the user presses the gray button once, the MyCareLink Smart Application (App) continues to animate and instruct the user to press the button. Should the user press the button again?

A: No. The finger animation on mobile devices may be seen several times after pressing the button once. The MyCareLink Smart App is searching for the Reader via Bluetooth in order to establish a Bluetooth connection. This may take several seconds because the MyCareLink Smart App is going through the mobile device operating system for this process.

Q: What happens if the button on the Reader is pressed multiple times?

A: Nothing will happen. Repeated button pressing will not impact the interrogation or transmission process.

Q: How long does the Reader remain on?

A: The Reader will timeout and power down if:

- The Reader sits idle (no communication from the MyCareLink Smart App) for 2 minutes
- Bluetooth pairing is not completed within 5 minutes
- The security code is not properly entered within 5 minutes

Medtronic

Same Household

Q: If two people in the same household (each member has a Medtronic implanted pacemaker) would like to use the MyCareLink Smart Monitor System, do they need two Readers?

A: Yes, each Medtronic implanted device is paired to one Reader only.

NOTE: If the users only have one mobile device and use the same app, they will need to re-pair their Reader each time they transmit.

Q: Is the Reader paired one-to-one to a patient's implanted device? For example, what if there are multiple Medtronic implanted device patients in a nursing home?

A: Yes, It is required that each patient receive his or her own individual Reader and that Reader is paired one-to-one to a patient's implanted device.

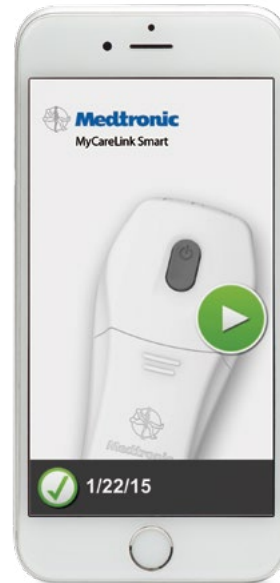
NOTE: When multiple Readers are available for pairing, the user will be prompted by the MyCareLink Smart App to select a Reader by serial number. See example below.



Q: How does a family member or caregiver know if a patient's transmission was successful (assuming they have the app on their phone, for the patient to use)?

What if multiple family members assist the patient, will they be able to check when the last transmission occurred?

A: The screen snap example below shows the last transmission sent on "this" mobile device of the MyCareLink Smart App home screen. The date of the last transmission would be associated with the last time this specific mobile device was used. They would not be able to view if a transmission occurred on a different mobile device. If multiple family members are helping and using their own mobile device, checking the MyCareLink Connect™ Website would be the best way of knowing when the last transmission occurred. This option is limited to four friends or family members.



General

Q: How large is the MyCareLink Smart App?

A: The app will take-up 25-30MB of storage on the patient's phone.

Q: How much data does each transmission use?

A: Each transmission sent is comparable to sending one email. If the patient is connected to Wi-Fi, no data from the patient's data plan will be used.

Q: Can the patient use his or her smartphone during the interrogation or transmission?

A: When answering an incoming call or opening a text message, the interrogation session or transmission will be interrupted. If the user interrupts the interrogation by answering a call or opening a text message, they will need to repeat the interrogation.

Q: What happens if an incoming call comes during the transmission?

A: If the patient answers the call after the implanted device interrogation portion, then the app will attempt to transmit the data to the CareLink Network in the background.

Q: What if patients lose their mobile device? Is there a data security issue?

A: Security encryption channels have been established through each step of the transmission process. The mobile device does not store/save patient device diagnostic data or Patient Health Information (PHI) on the mobile device. So there is not a concern regarding MyCareLink Smart monitoring if the mobile device is lost. After the patient's device diagnostic data is transmitted, no implanted device data remains on the mobile device. If the checkmark is not received on the mobile device indicating that a transmission was made to the CareLink Network, the data is deleted on the mobile device after 15 minutes.

Q: What if patients change or buy new smartphones/tablets?

A: Follow the installation and setup instructions as if they had just received the Reader for the first time. Follow the same procedure as initial setup.

Q: How will patients receive notifications of software or Reader updates?

A: All updates to the the Reader software (firmware) come through the installed MyCareLink Smart App. If there is an app update available, patients will be prompted to download the update before starting their transmission. If there is a firmware update available, that will happen automatically. The screen (shown below) will appear on the phone or tablet, and will take approximately 3 minutes to complete.



For more information go to www.medtronicheart.com or call CareLink Patient Services at 1 (800) 929-4043 Monday-Friday (8 a.m. - 5 p.m. CT)



Bluetooth is a registered trademark of Bluetooth SIG, Inc.

These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability, alert notifications, and patient messages are subject to Internet connectivity and access, and service availability. The CareLink, MyCareLink Patient Monitors, and MyCareLink Smart Readers must be on and in range of the device. Physician alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

Brief Statement: Medtronic MyCareLink™ Patient and CareLink™ Monitors, MyCareLink Smart™ Monitoring System (including the MyCareLink Smart Reader and MyCareLink Smart Application), Medtronic CareLink™ Network, Medtronic CareLink™ Mobile Application, and Medtronic MyCareLink Connect™ Website

Intended Use

The MyCareLink Patient Monitor, CareLink Monitor, MyCareLink Smart Monitoring System, and CareLink Network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. CareLink Mobile Application is intended to provide current CareLink Network customers access to CareLink Network data via a mobile device for their convenience. The CareLink Mobile Application is not replacing the full workstation, but can be used to review patient data when a physician does not have access to a workstation. The MyCareLink Connect Website is intended to provide patients, their friends/family and caregivers messages regarding transmission status of patient device diagnostic data to the CareLink Network. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. CareLink Network and MyCareLink Connect Website availability and mobile device accessibility may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the Internet is required for the CareLink Mobile App and MyCareLink Smart Monitoring System and subject to coverage availability. Standard text message and data rates apply. Message frequency depends on account settings and clinic scheduling.

For US Text SMS Messages:

- Reply HELP for text message Help (Non-Medical information regarding text messaging).
- Reply STOP to cancel the text messages. Alternatively the user can change account settings via the MyCareLink Connect Website: www.MyCareLinkConnect.com.
- User must be 18 years or older or have permission from a parent or guardian to participate. Terms and Conditions are available at: www.MyCareLinkConnect.com.

Supported Text Message Carriers: Our participating carriers include (but not limited to): AT&T®, Sprint®, Boost®, Verizon® Wireless, U.S. Cellular®, T-Mobile®.

Web browsers currently supported by the MyCareLink Connect Website are: Microsoft® Internet Explorer® for Windows®, versions 9.0 and higher; Apple Mobile Safari® for iOS, versions 8.0 and higher and Safari® 7.1 on OSX; Google® Chrome 31®, Mozilla Firefox® 33; and Opera® 26. Cookies are enabled. JavaScript is enabled.

Contraindications

There are no known contraindications.

Warnings and Precautions

The MyCareLink Patient Monitor, CareLink Monitors, and MyCareLink Smart Monitoring System must only be used for interrogating compatible Medtronic implantable devices. While using the MyCareLink Patient Monitor and CareLink Monitors do not use a cellular phone while the antenna is positioned over the implanted device.

The MyCareLink Smart Patient Monitor may be used internationally. The MyCareLink Patient Monitor, and CareLink Monitors are intended for use within the prescribing country.

See the device manuals for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 929-4043 and/or consult Medtronic's website at www.medtronic.com.

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

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