

Medtronic

MyCareLink Home™ Communicator Model 26900

Patient Manual

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1 Introduction

This manual is intended to help you use the Medtronic MyCareLink Home™ communicator Model 26900 (referred to as “the communicator”).

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

Warning: If you feel sick, get medical help immediately. If you have an emergency, call your local emergency number. If your doctor has given you instructions, follow them. Waiting to get medical attention could be dangerous to your health.

2 How to contact Medtronic

If you have any questions about setting up or using the communicator, or if you have problems with the communicator, contact Medtronic.

To get help from a Medtronic CareLink™ Network Stay Connected Service agent, call **1 800 929 4043**. Staff is available Monday through Friday from 7:00 AM to 7:00 PM (Central Time).

For more information, visit www.medtronic.com.

3 Description

The MyCareLink Home communicator is an electronic device that transfers information between your implanted heart device and the Medtronic CareLink™ Network (an internet-based secure server). The communicator allows your doctor to manage your care remotely.

The communicator sends your heart device information to the Medtronic CareLink Network using a cellular phone network (by default) or through your home Wi-Fi™* network (optional setup)¹. For instructions on how to connect the communicator to your Wi-Fi network, see *Chapter 6, Connecting the communicator to your Wi-Fi network, page 23*.

3.1 How do I use the communicator?

By keeping the communicator plugged in and within 3 meters (10 feet) of where you sleep, transmissions of your implanted heart device data will occur automatically. Transmissions are automatically available to your clinic.

If your clinician requests, you can send a transmission manually. See *Chapter 8, Sending a manual transmission, page 32*.

¹ Wi-Fi™* and Wi-Fi™* logo are trademarks of Wi-Fi Alliance®.

3.2 Intended purpose

The communicator transfers data between a patient's heart device and the Medtronic CareLink Network. The clinic retrieves the data from the Medtronic CareLink Network.

3.3 Intended users

The communicator is intended to be used by patients who have a compatible heart device. Patients may also have caregivers who help with their care.

3.4 Intended patient population

The communicator is intended to be used by patients who have a compatible heart device.

3.5 Indications

The communicator does not have an indication for use. It does not diagnose, treat, or prevent a disease or condition, and it does not provide therapy.

3.6 Contraindications

There are no known reasons why patients should not use the communicator.

3.7 Expected clinical benefits

The communicator allows clinicians to remotely review patients' heart device data. Reviewing device data can include the following clinical benefits:

- Early identification of clinically significant cardiac or device events
- A reduction in cardiac-related in-office visits and emergency room visits
- A reduction in hospitalizations and length of hospital stays
- An improvement in quality of life
- A potential reduction in mortality
- A potential reduction in inappropriate shocks for patients with an implantable cardioverter defibrillator

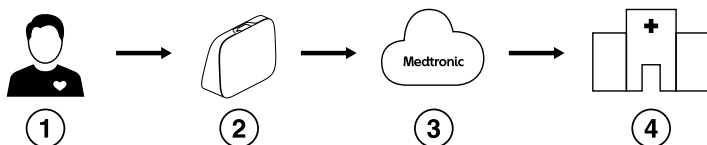
3.8 Information flow

The communicator uses Bluetooth®* wireless technology to connect to your heart device when you are within range². It uses an internet connection to send your heart device data to the Medtronic CareLink Network. Your clinician can review your

heart device data through the CareLink Network to remotely monitor your heart device activity.

The following graphic shows the information flow from your heart device to your clinic.

Figure 1.



- 1 Your heart device
- 2 Your communicator
- 3 Medtronic CareLink Network
- 4 Your clinic

3.9 Indicator lights

The following table describes status indicator lights that can appear on the communicator. See *Chapter 9, Troubleshooting, page 34* for steps to take when you see the orange error icons.

The communicator uses an ambient light sensor to turn off the indicator lights when the room gets dark. The communicator is still on and working.

² The Bluetooth[®]* word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Medtronic is under license.

Table 1. Explanation of indicator lights

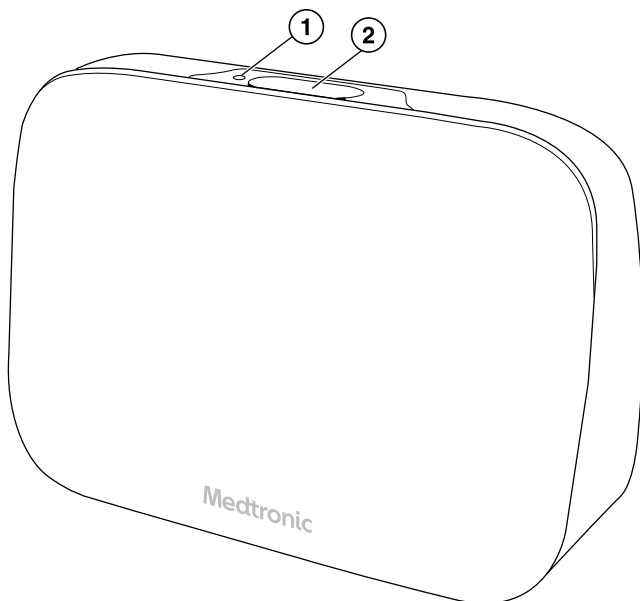
Light	Meaning
	The communicator is starting up when the green ring is spinning.
	The communicator is on and working properly.
	The system is busy and not ready to send a manual transmission.
	The steps for transmission are complete.
	The communicator is sending a transmission.
	The communicator is connected to a cellular network.
	The communicator is connected to a Wi-Fi network.
	There is a system error.
	There is a cellular connection error.
	There is a Wi-Fi network connection error.

Table 1. Explanation of indicator lights (continued)

Light	Meaning
	There is an enrollment error.
1 2 3	The numbers 1, 2, and 3 may appear in any combination. These are error reference numbers that you can provide to Medtronic.

3.10 Front of the communicator

Figure 2.



1 Ambient light sensor

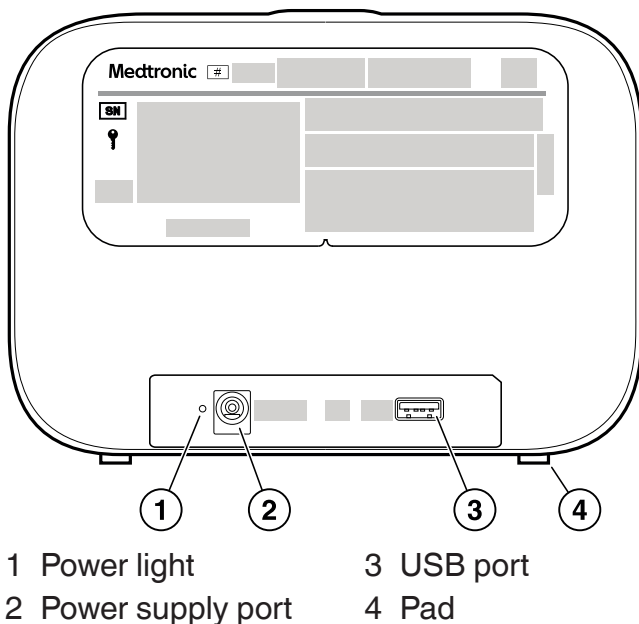
2 Button

Ambient light sensor – Turns off the speaker and the indicator lights on the front of the communicator when the room is dark.

Button – Initiates communicator actions.

3.11 Back of the communicator

Figure 3.



Power light – Is on when the communicator is receiving power.

Power supply port – Connects the power supply to the communicator.

USB port – For use only with Medtronic components.

Pad – Provides support to keep the communicator upright.

4 Warnings, precautions, and potential adverse events

4.1 Warnings

Warning: If you feel sick, get medical attention immediately. If you have an emergency, call your local emergency number. If your doctor has given you instructions, follow them. Waiting to get medical attention could be dangerous to your health.

Warning: Use the communicator as described in this manual in order to operate it safely. Save this manual.

Warning: Send a manual transmission only when your doctor tells you to.

Warning: Do not use the communicator if it does not work as described in this manual. If you need assistance, contact Medtronic.

Warning: Do not modify this equipment. Modifications can make the communicator less effective, which can negatively affect your safety.

Warning: Avoid using the communicator next to or stacked with other equipment. Using the communicator next to or stacked with other equipment could result in improper operation. If such use is needed, the communicator and the other equipment should be observed to verify that they are operating normally.

Warning: Use of accessories, transducers, and cables other than those provided by Medtronic could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Warning: Do not use the communicator near water. For example, do not use it near a bathtub, wash bowl, kitchen sink, or laundry tub. When you use the communicator, follow basic safety precautions to reduce the risk of fire, electric shock, and injury to persons.

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this device could result.

Warning: Keep cables and cords out of the reach of children or anyone at risk of strangulation.

Warning: Keep the communicator plugged in to the power outlet. The communicator must be powered on to send a transmission.

Warning: The communicator will not operate when there is a power outage. If a power outage occurs, connect the communicator to an alternative power source.

Warning: Do not misuse or damage the communicator. If the communicator is damaged, contact Medtronic. Damage to the communicator can result in the following hazards:

- Sharp edges that can cause a laceration (cut).
- Electric shock from the power supply that can cause burn, pain, and tingling.
- Broken pieces that can cause choking if the pieces are swallowed.
- Loud sounds from the speaker that can cause tinnitus (ringing in the ears).

4.2 Precautions

Caution: Use only the power supply that came with this communicator. Using a different power supply could damage the communicator and adversely affect your safety.

4.3 Potential adverse events

The following are known potential adverse events associated with misuse of the communicator:

- Burns
- Choking
- Failure to provide intended data
- Laceration (cut)
- Pain

- Strangulation
- Tingling
- Tinnitus (ringing in the ears)

For warnings and precautions that describe these adverse events, see *Section 4.1, Warnings, page 15* and *Section 4.2, Precautions, page 17*.

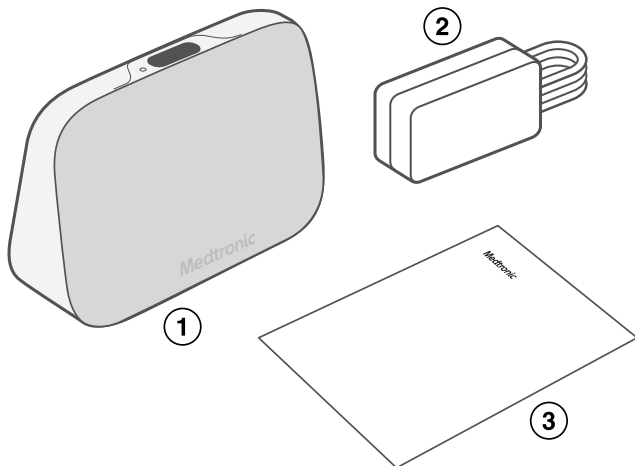
4.4 Reporting a serious incident

If a serious incident related to the communicator occurs, immediately report the incident to your doctor.

5 Setting up the communicator

5.1 Package contents

Figure 4.



1 Communicator

3 Literature

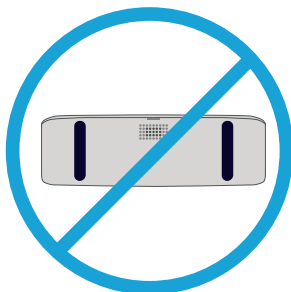
2 Power supply

5.2 Setup

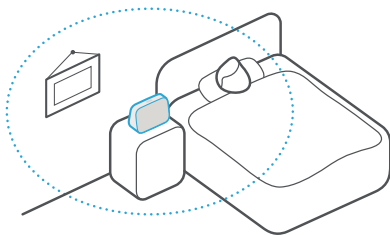
1. Ensure your communicator is placed upright with the navy-blue pads down.



Do not place the communicator on its back.

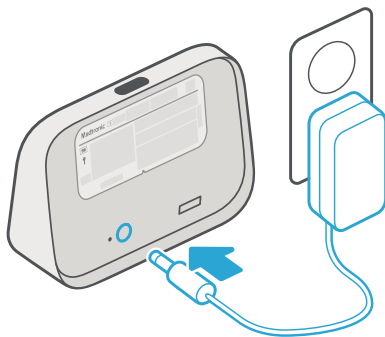


2. Place the communicator within 3 meters (10 feet) of where you sleep.



Note: Other electronic devices can be near the communicator (for example, on the same nightstand), but they should be kept at least 30 centimeters (12 inches) from the communicator.

3. Connect the power supply to your communicator and a power outlet.



Notes:

- Position the communicator so that you can unplug it from the power outlet if needed.
- Do not connect the power supply to a power outlet that is controlled by a wall switch.

4. Wait for the system to start.

The green ring will spin while the system is starting. This can take several minutes.



5. Setup is complete when the green ring is fully lit. A tone will also play. No further action is needed.



6 Connecting the communicator to your Wi-Fi network

Medtronic recommends that you connect the communicator to a Wi-Fi network to ensure a robust connection for your communicator.

- To connect the communicator to your Wi-Fi network at home, complete the steps in *Section 6.1, Connect to your network at home, page 24*.
- To connect the communicator to your Wi-Fi network from the clinic or hospital, complete the steps in *Section 6.2, Connect to your network from the clinic or hospital, page 28*.

If you are having difficulty connecting the communicator to your Wi-Fi network using the steps in *Section 6.1* or *Section 6.2*, you can connect the communicator to a Wi-Fi network using the communicator hotspot. See *Section 9.6, Alternative method for connecting to your Wi-Fi network, page 37*.

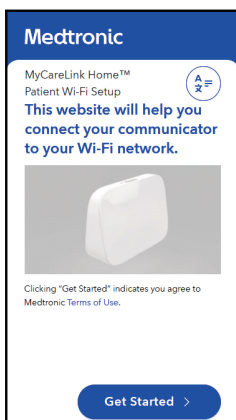
Note: The communicator automatically connects to a cellular network if the communicator isn't connected to a Wi-Fi network. A Wi-Fi network connection is not required to use the communicator.

6.1 Connect to your network at home

1. Ensure that you have your Wi-Fi network name and password available.
2. Get your tablet, smartphone, or computer.
3. Open an internet browser and go to **www.MCLHomeWiFi.com**.

Note: To change your language, tap  and select your language.

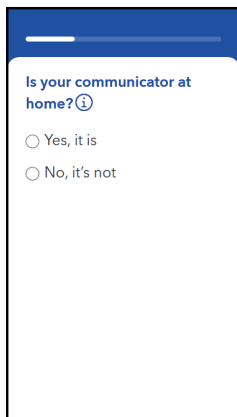
4. Tap **Get started**.



5. Ensure that your communicator is plugged into power and tap **Yes it is**.



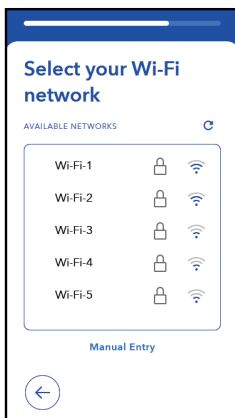
6. When asked if your communicator is at home, tap **Yes, it is**.



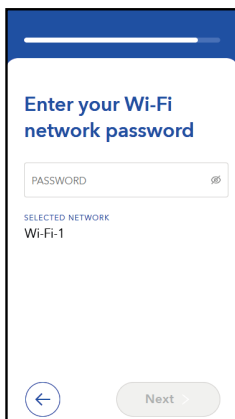
7. Enter the communicator serial number and security key from the label on the back of the communicator and tap **Next**.



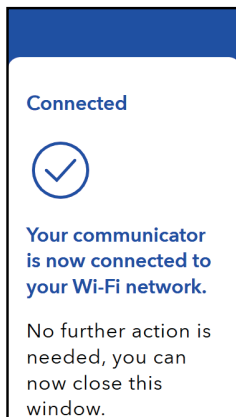
8. Select your Wi-Fi network name from the list.



9. Enter your Wi-Fi network password and tap **Next**.



10. A confirmation message is displayed when the communicator has successfully connected to your Wi-Fi network.



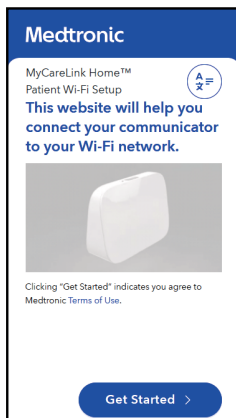
11. Wi-Fi network setup is complete. Close the internet browser.

6.2 Connect to your network from the clinic or hospital

1. Ensure that you have your Wi-Fi network name and password available.
2. Get your tablet, smartphone, or computer.
3. Open an internet browser and go to **www.MCLHomeWiFi.com**.

Note: To change your language, tap  and select your language.

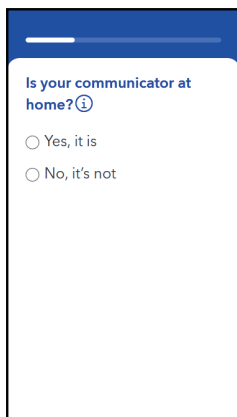
4. Tap **Get started**.



5. Ensure that your communicator is plugged into power and tap **Yes it is**.



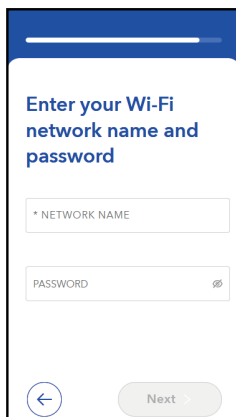
6. When asked if your communicator is at home, tap **No, it's not**.



7. Enter the communicator serial number and security key from the label on the back of the communicator and tap **Next**.

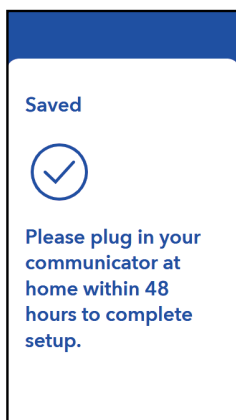


8. Enter your Wi-Fi network name and password and tap **Next**.



A screenshot of a mobile application interface for Wi-Fi setup. The screen has a blue header bar. Below it, the text "Enter your Wi-Fi network name and password" is displayed in blue. There are two input fields: the first is labeled "* NETWORK NAME" and the second is labeled "PASSWORD" with a small eye icon to its right. At the bottom left is a blue circular button with a white left-pointing arrow. At the bottom right is a grey button labeled "Next".

9. A confirmation message is displayed. Plug in your communicator at home within 48 hours to complete setup.



7 Checking the connection status

To check the connection status of the communicator, press the button for less than 1 second.

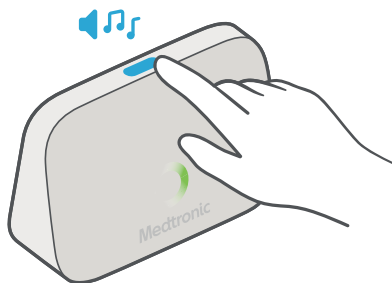
- If the communicator is connected to the cellular network, the cellular signal icon  lights up green for 15 seconds.
- If the communicator is connected to a Wi-Fi network, the Wi-Fi signal icon  lights up green for 15 seconds.

8 Sending a manual transmission

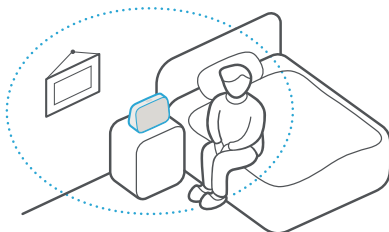
Use these steps to send information from your heart device to the Medtronic CareLink Network. Send a transmission only if your doctor or clinic requests.

1. Press and hold the button for 2 seconds to start the transmission.

A tone will play and the green ring will start to spin.



2. Stay within 3 meters (10 feet) of your communicator during the transmission.



3. Wait for the progress bar to fill. This can take a few minutes.



4. After the progress bar fills, a checkmark will appear and a tone will play. No further action is needed.



9 Troubleshooting

If an error occurs, an orange icon lights up on the communicator, and a tone plays. This chapter describes the causes of communicator errors and actions you can take to resolve them. None of these errors indicate an issue with your implanted heart device.

This chapter also includes an alternative method for connecting to your Wi-Fi network.

Contact Medtronic for assistance. See *Chapter 2, How to contact Medtronic*, page 6.

9.1 Cellular connection error

- **Error:** The orange cellular signal icon  lights up. The communicator plays an error tone 2 times.
- **Cause:** The communicator does not have a good cellular connection.
- **Action:** Unplug the communicator and move it to a place where it might receive a better cellular signal (for example, next to a window).

If that does not resolve the error, connect the communicator to a Wi-Fi network. See *Chapter 6, Connecting the communicator to your Wi-Fi network, page 23.*

9.2 Wi-Fi network connection error

- **Error:** The orange Wi-Fi network error icon  lights up and flashes. The communicator plays an error tone 2 times.
- **Cause:** This error occurs if you have previously connected the communicator to a Wi-Fi network but there is now no Wi-Fi network connection available, and a cellular connection is unavailable. If a cellular connection is available, the green cellular icon  appears along with the orange Wi-Fi error icon .
- **Action:** Try to reconnect to the Wi-Fi network. Unplug your internet router and plug it back in.

Give the router time to start up. Then, unplug the communicator and plug it in again.

Ensure that the Wi-Fi network name and password have not changed. If they have changed, follow the instructions in *Chapter 6, Connecting the communicator to your Wi-Fi network, page 23* to enter the new information.

If the error persists, try unplugging the communicator and moving it to a place that might get better reception.

9.3 System error

- **Error:** The orange system error icon  lights up. The communicator plays an error tone 3 times.
- **Cause:** This error indicates that the communicator has encountered an internal error.

It does **not** indicate an issue with your implanted heart device.

- **Action:** Restart the communicator by unplugging it and plugging it back into the power outlet.

For additional assistance, contact Medtronic. See *Chapter 2, How to contact Medtronic, page 6*.

9.4 Enrollment error

- **Error:** The orange enrollment error icon  lights up. The communicator plays an error tone 2 times.
- **Cause:** Your clinician has not completed your enrollment in the Medtronic CareLink Network.
- **Action:** Contact your clinic and ask them to complete your enrollment.

For additional assistance, contact Medtronic.
See *Chapter 2, How to contact Medtronic*,
page 6.

9.5 Error reference numbers

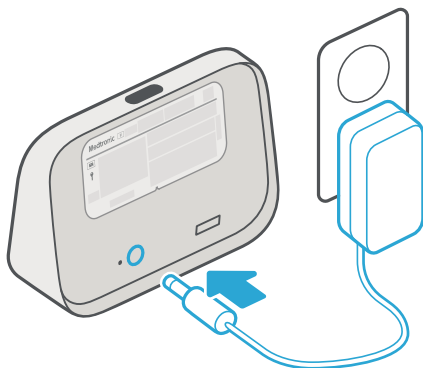
If you press the communicator button when an error is present, any combination of the error reference numbers **1 2 3** may appear. If you choose to call Medtronic for assistance, you can share these reference numbers during the call. See *Chapter 2*.

9.6 Alternative method for connecting to your Wi-Fi network

If you were unable to connect your communicator to your Wi-Fi network using the steps in *Chapter 6*, complete the steps in this section to connect your communicator using a hotspot.

9.6.1 Plug or replug the communicator

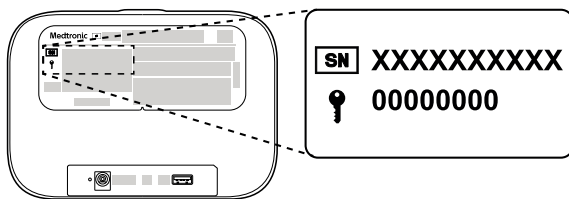
Plug the power cord into the communicator and into a power outlet. If the communicator is already plugged in, unplug it and plug it back in.



9.6.2 Connect to the communicator hotspot

1. Open the list of Wi-Fi networks using your computer, tablet, or smartphone.
 - **Windows computer** – Click the wireless network icon and open the Wi-Fi settings.
 - **Mac computer** – Click the Wi-Fi menu icon in your menu bar. The Wi-Fi menu will open.
 - **Most tablets and smartphones** – Go to **Settings > Wi-Fi**. Ensure that **Wi-Fi** is turned on.
2. From that list, click **Medtronic-xxx** to connect, where **xxx** is the last 3 numerical digits of the communicator serial number.
3. When prompted for a password, enter the security key from the label on the back of the communicator. If you see an option to connect using a security key, select that option, and then enter the security key.

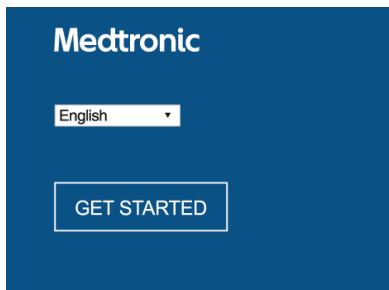
The security key is located to the right of the key symbol. In this example, the security key is “00000000”.



Note: You might see a message that says **connected, no internet**. You can ignore this message and proceed to the next task.

9.6.3 Connect to your network

1. Open an internet browser and go to **<http://www.MCLRelayWiFi.com>**. Ensure that you type the address exactly as it appears, including “http://”.
2. Select your language and click **GET STARTED**.

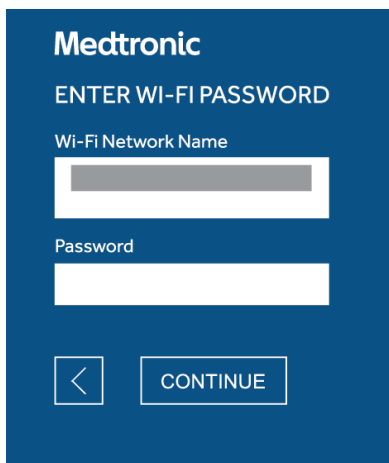


3. Select your Wi-Fi network and click **CONTINUE.**



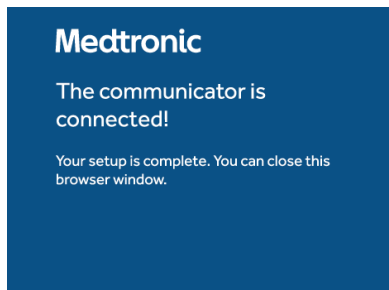
The image shows a blue screen with the Medtronic logo at the top. Below the logo, the text "WI-FI NETWORK SETUP" is displayed. Underneath, it says "Please select a Wi-Fi Network". A white box contains three options: "Wi-Fi-1", "Wi-Fi-2", and "Wi-Fi-3". At the bottom left is a circular arrow icon, and at the bottom right is a button labeled "CONTINUE".

4. Enter your Wi-Fi network password and click **CONTINUE.**



The image shows a blue screen with the Medtronic logo at the top. Below the logo, the text "ENTER WI-FI PASSWORD" is displayed. Underneath, it says "Wi-Fi Network Name" followed by a text input field. Below that, it says "Password" followed by another text input field. At the bottom left is a back arrow icon, and at the bottom right is a button labeled "CONTINUE".

5. A confirmation message is displayed when the communicator has successfully connected to your Wi-Fi network.



6. Wi-Fi network setup is complete. Close the internet browser.

Note: As part of this process, your device (computer, tablet, or smartphone) was temporarily disconnected from your Wi-Fi network. Your device should automatically reconnect to your Wi-Fi network.

9.6.4 Troubleshooting Wi-Fi network connectivity

If you were unable to connect to a Wi-Fi network, the Wi-Fi network might be incompatible with the communicator. The communicator does not work with all Wi-Fi network types. It is set up to work with most personal networks. If you're repeatedly unsuccessful at connecting to a Wi-Fi network, try connecting to a different Wi-Fi network.

10 Additional information

10.1 Can I travel with the communicator?

If you plan to travel, talk to your doctor to determine whether you should bring your communicator. The communicator will work in most locations by using a cellular connection. However, cellular service might not be available in all locations.

If you plan to travel to an area where there might not be reliable cellular reception, you can use a personal Wi-Fi network. Check to see if the location has a Wi-Fi network. The communicator does not work with all Wi-Fi network types. It is set up to work with most personal networks. To set up Wi-Fi when you arrive, follow the steps in *Chapter 6, Connecting the communicator to your Wi-Fi network, page 23*.

If you will be traveling by plane, you may refer to the website for the Transportation Security Administration (TSA) for information about traveling with medical equipment: <https://www.tsa.gov>.

10.2 Replacing the communicator or power supply

If the power supply or communicator is lost or damaged, contact Medtronic to order a replacement. See *Chapter 2, How to contact Medtronic, page 6*.

10.3 Cleaning and care

The communicator does not require preventive inspection or maintenance.

Do not drop the communicator on hard surfaces. Dropping the communicator can damage it and prevent it from working properly. If the communicator has been damaged, contact Medtronic.

You can clean the communicator as needed. Use a mild solution of water and one of the following cleaners: dish detergent, isopropyl alcohol, ammonium hydroxide, hydrogen peroxide, acetic acid, sodium hypochlorite, or quaternary ammonium compounds. Lightly apply the cleaning solution to a cloth, and wipe the communicator surface clean.

See the packaging of the cleaning agent for warnings, precautions, or disposal instructions related to the cleaning agent.

Precaution: Do not immerse the communicator in water. If the communicator gets wet and it stops working, contact Medtronic.

10.4 Return for proper disposal

Return the communicator to Medtronic for disposal. To obtain a prepaid return shipping label, go to www.medtronic.com/carelinkmonitorreturns.

Do not throw the communicator in the garbage.
Electronic waste must be disposed of properly.

See <http://recycling.medtronic.com> for information about recycling.

Follow local regulations for proper disposal of the product packaging.

10.5 Security

The communicator is designed to securely transmit your heart device data. Data is encrypted while in transit to the CareLink Network.

The communicator periodically checks for software updates to stay current with any security or software improvements. These updates are installed automatically, and you do not have to take any action.

Contact Medtronic if you have reason to suspect a security incident with the communicator.

Maintain physical security of the communicator.
Lack of physical security puts the communicator at risk.

The communicator software uses network ports to send and receive data. Ports are both incoming and outgoing.

When connecting the communicator to a Wi-Fi network, follow these security measures:

- Only connect to trusted and secured Wi-Fi networks.
- Check your home Wi-Fi network for security risks before you use it to connect to the communicator. Secure your Wi-Fi network using good security practices.

Check the security of your home Wi-Fi network if you make changes to it. Changes to your Wi-Fi network could introduce security risks. Changes to your Wi-Fi network include configuration changes or changes to your Wi-Fi network components, hardware, software, or firmware.

11 Explanation of symbols

To see which symbols apply to this product, refer to the package label and product.

Symbol	Explanation
	Security key
	Reorder number
	Serial number
	Keep dry
	Use only with provided power supply.
	Caution

Symbol	Explanation
	Consult instructions for use
	Package contents
	Communicator model
	Product documentation
	Non-ionizing electromagnetic radiation
	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.
	Manufacturer
	Date of manufacture
	Authorized representative in the European Community
	Importer
	China RoHS. See product label for the Environmentally Friendly Use Period (EFUP) in years.

Symbol	Explanation
	China RoHS indicating product contains no hazardous substances.
	USB connector
	Alternating current
	Direct current
	System meets the applicable Canadian, U.S., and IEC safety standards.
	ACMA (Australian Communications and Media Authority and the New Zealand Ministry of Economic Development Radio Spectrum Management standards) symbol for Australia and New Zealand
	MIC (Ministry of Internal Affairs and Communications) symbol for Japan
	Humidity limitation
	Humidity limitation
	Temperature limit
	Accessories
	Follow instructions for use (blue symbol).

Symbol	Explanation
	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.
IP21	The product complies with international electrical safety rating IP21 with regard to ingress of dust, other foreign objects, and water, as required by IEC 60601-1-11.
IP22	The product complies with international electrical safety rating IP22 with regard to ingress of dust, other foreign objects, and water, as required by IEC 60601-1-11.
	FCC (Federal Communications Commission) symbol is employed on electronic products manufactured or sold in the United States to certify that the electromagnetic interference from the product is under the limits approved by the Federal Communications Commission.
	Class II equipment
	Model number
	Medical device

Symbol	Explanation
	Unique Device Identifier
	Power cord
	Type BF applied part
	Recycle
	Bluetooth wireless technology
	Bluetooth wireless technology
	Wi-Fi wireless networking technology
	Wireless communication enabled

12 Specifications

Standards

The communicator complies with the following:

EMC: CFR 47 Part 15

Patient Safety: IP21, IEC 60601-1, ordinary, continuous operation, Class II, not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

Protection from ingress: IP21. This means that the communicator is protected from ingress in the following 2 ways:

- Against access to hazardous parts with a finger or object greater than 12.5 mm in diameter
- Against vertically falling water drops when the communicator is sitting upright

The communicator is moisture resistant but not waterproof.

Recommended environmental conditions during storage and transport in between uses

Temperature: -25°C to 70°C (-13°F to 158°F)

Relative humidity: $\leq 90\%$, non-condensing, at 5°C to 35°C (41°F to 95°F)

Water vapor pressure: ≤ 50 hPa at $>35^{\circ}\text{C}$ to 70°C (95°F to 158°F)

Storage and transport air pressure extremes:
 106 kPa to 70.1 kPa

Store the communicator within the ranges listed here. If it's exposed to conditions outside these ranges, it may be damaged and may not work. If you need assistance, contact Medtronic.

Recommended operating conditions

Allow 2 hours prior to starting up the communicator when transitioning from storage to operating conditions.

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

Relative humidity: 15% to 90%, non-condensing

Water vapor partial pressure: ≤50 hPa

Operating atmospheric pressure: 106 kPa to 70.1 kPa

Power supply

The power supply is considered part of the communicator. To ensure compliance to the specified standards, use only the power supply that came with the communicator, WA-24B12Fx-AAK³.

- Rated voltage AC: 100 V – 240 V
- Rated line frequency: 50 Hz – 60 Hz
- Current AC: 1.0 A Max.

Expected service life

The expected service life is a minimum of 5 years. To find out how to order a replacement, contact

³ Where x is a variable letter dependent on country.

Medtronic. See *Chapter 2, How to contact Medtronic, page 6*.

Safety and technical inspection

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

Transmitting and receiving

Frequency of operation	Modulation characteristics	RF output power
2.4-2.4835 GHz (Bluetooth® Low Energy)	Gaussian frequency shift keying (GFSK)	Less than 1 W EIRP
2.4-2.4835 GHz (Wi-Fi)	Direct sequence spread spectrum (DSSS) Complementary code keying (CCK) Orthogonal frequency division multiplexing (OFDM)	Less than 1 W EIRP
5.15-5.25 GHz (Wi-Fi)	Direct sequence spread spectrum (DSSS) Complementary code keying (CCK)	Less than 1 W EIRP

Frequency of operation	Modulation characteristics	RF output power
	Orthogonal frequency division multiplexing (OFDM)	
5.25-5.35 GHz (Wi-Fi)	Direct sequence spread spectrum (DSSS) Complementary code keying (CCK) Orthogonal frequency division multiplexing (OFDM)	Less than 1 W EIRP
5.47-5.73 GHz (Wi-Fi)	Direct sequence spread spectrum (DSSS) Complementary code keying (CCK) Orthogonal frequency division multiplexing (OFDM)	Less than 1 W EIRP
5.735-5.835 GHz (Wi-Fi)	Direct sequence spread spectrum (DSSS) Complementary code keying (CCK) Orthogonal frequency division multiplexing (OFDM)	Less than 1 W EIRP

Frequency of operation	Modulation characteristics	RF output power
1.85-1.91, 1.93-1.99 GHz (LTE B2)	Quadrature phase shift keying (QPSK) 16 quadrature amplitude modulation (16QAM) 64 quadrature amplitude modulation (64QAM)	Less than 200 mW EIRP
1.71-1.755, 2.11-2.155 GHz (LTE B4)	Quadrature phase shift keying (QPSK) 16 quadrature amplitude modulation (16QAM) 64 quadrature amplitude modulation (64QAM)	Less than 200 mW EIRP
824-849, 869-894 MHz (LTE B5)	Quadrature phase shift keying (QPSK) 16 quadrature amplitude modulation (16QAM) 64 quadrature amplitude modulation (64QAM)	Less than 200 mW EIRP
698-716, 728-746 MHz	Quadrature phase shift keying (QPSK)	Less than 200 mW EIRP

Frequency of operation	Modulation characteristics	RF output power
(LTE B12)	16 quadrature amplitude modulation (16QAM) 64 quadrature amplitude modulation (64QAM)	
777-787, 746-756 MHz (LTE B13)	Quadrature phase shift keying (QPSK) 16 quadrature amplitude modulation (16QAM) 64 quadrature amplitude modulation (64QAM)	Less than 200 mW EIRP
1.71-1.78, 2.11-2.20 GHz (LTE B66)	Quadrature phase shift keying (QPSK) 16 quadrature amplitude modulation (16QAM) 64 quadrature amplitude modulation (64QAM)	Less than 200 mW EIRP

13 Electromagnetic compatibility declaration

Testing shows that the communicator protects against electromagnetic interference that may cause harm in a typical home healthcare environment. There is no guarantee that interference will not occur in a particular environment. If the communicator causes harmful interference to other devices or if it is negatively impacted by other devices, try to correct the issue using the following actions:

- Place the devices in new positions or locations.
- Increase the separation between the devices.
- Contact Medtronic for help.

If you experience performance issues with your communicator, try using it at least 3 meters (10 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 communicator near these devices could interfere with communication between your implanted heart device and the communicator.

Note: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radio navigation

service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

Guidance and manufacturer's declaration — electromagnetic emissions
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The communicator is intended for use in the electromagnetic environment specified below. The user should make sure that it is used in such an environment.
--

Emissions test	Compliance	Electromagnetic environment – guidance
Conducted and radiated RF emissions, CISPR 11	Group 1, Class B	The communicator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interfer-

Guidance and manufacturer's declaration — electromagnetic emissions		
		ence in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	The communicator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration — electromagnetic immunity			
The communicator is intended for use in the electromagnetic environment specified below. The user should make sure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance

Guidance and manufacturer's declaration — electromagnetic immunity			
Electro- static dis- charge (ESD) IEC 61000 -4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	The relative humidity should be at least 5%.
Electrical fast tran- sient/burst IEC 61000 -4-4	±2 kV for power supply lines ±2 kV for input/out- put lines	±2 kV for power supply lines ±2 kV for input/out- put lines	Mains power quali- ty should be that of a typ- ical residen- tial environ- ment.
Surge IEC 61000 -4-5	±0.5 kV, 1 kV line-to-line ±0.5 kV, 1 kV, 2 kV line-to- ground	±0.5 kV, 1 kV line-to- line ±0.5 kV, 1 kV, 2 kV line-to- ground	
Voltage dips, short interrup- tions and voltage variations	Dips: 0 % U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°,	Dips: 0 % U_T ; 0,5 cycle At 0°, 45°, 90°, 135°, 180°,	Mains power quali- ty should be that of a typ- ical residen- tial environ-

Guidance and manufacturer's declaration — electromagnetic immunity			
on power supply in- put lines IEC 61000 -4-11	225°, 270°, and 315° 0 % U _T ; 1 cycle and 70 % U _T ; 25/30 cy- cles Single phase: at 0° Interrup- tions: 0 % U _T ; 250/300 cycle	225°, 270°, and 315° 0 % U _T ; 1 cycle and 70 % U _T ; 25/30 cy- cles Single phase: at 0° Interrup- tions: 0 % U _T ; 250/300 cycle	ment. The communica- tor will not operate when there is a power outage.
Power fre- quency (50/60 Hz) magnetic field IEC 61000 -4-8	30 A/m	30 A/m	Power fre- quency magnetic fields in a typical resi- dential envi- ronment are not expect- ed to affect

Guidance and manufacturer's declaration — electromagnetic immunity

			the commu- nicator.
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Note: U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration — electromagnetic immunity

The communicator is intended for use in the electromagnetic environment specified below. The user should make sure that it is used in such an environment.

Portable and mobile RF communications equipment should be used no closer to any part of the communicator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance Recommended separation distance:

Guidance and manufacturer's declaration — electromagnetic immunity			
Conducted RF IEC/EN 61000-4-6	3 V _{RMS} 150 kHz to 80 MHz outside ISM and amateur radio bands ^a	3 V _{RMS}	$d = 1.2\sqrt{P}$
IEC 61000-4-6	6 V _{RMS} 150 kHz to 80 MHz in ISM and amateur radio bands ^a	6 V _{RMS}	$d = 2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz
P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in m.^b Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should			

Guidance and manufacturer's declaration — electromagnetic immunity

be less than the compliance level in each frequency range.^{c,d} Interference may occur in the vicinity of equipment marked with the following symbol:



Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- ^a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- ^b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
- ^c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the

electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the communicator is used exceeds the applicable RF compliance level above, the communicator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the communicator.

^d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 6 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the communicator
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The communicator is intended for use in an electromagnetic environment specified below. The customer or the user of the communicator should assure that it is used in such an environment.
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Recommended separation distances between portable and mobile RF communications equipment and the communicator				
Rated max output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = (3.5/V_1) \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = (12/V_2) \sqrt{P}$	80 MHz to 800 MHz $d = (12/E_1) \sqrt{P}$	800 MHz to 2.7 GHz $d = (23/E_1) \sqrt{P}$
0.01	0.12	0.20	0.12	0.23
0.1	0.37	0.63	0.38	0.73
1	1.17	2.00	1.20	2.30
10	3.69	6.32	3.79	7.27
100	11.67	20.00	12.00	23.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters m can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in W according to the transmitter manufacturer.				

Recommended separation distances between portable and mobile RF communications equipment and the communicator

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

14 Glossary

Communicator – Instrument used in the patient's home that receives data from an implanted heart device and transmits that data to the Medtronic CareLink Network.

Medtronic CareLink Network – Internet-based secure server where transmitted heart device data is stored so that a clinician can log in and access the information.

Wi-Fi – A wireless networking technology that allows computers and other devices to communicate over a wireless signal.

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