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Size: 4.25 x 6.75 in (108 x 171 mm)

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Medtronic

MyCareLink Relay™ Home Communicator 24960

Patient Manual

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CareLink, Medtronic, Medtronic CareLink, MyCareLink, MyCareLink Relay

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1 Introduction

This manual is intended to help you use the Medtronic MyCareLink Relay™ home communicator Model 24960 (also referred to as "the communicator" in this manual).

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

If you are feeling 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.

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 Patient Services Specialist, call **1-800-929-4043**. Staff is available Monday through Friday from 7:00 AM to 7:00 PM (Central Standard Time).

For more information, visit www.medtronic.com.

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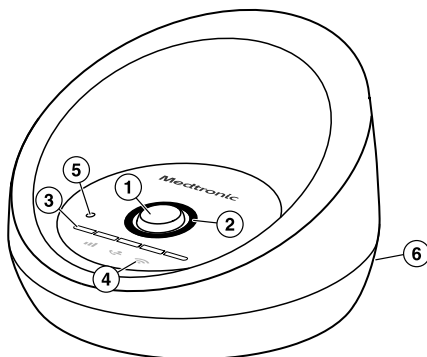
3 What is the MyCareLink Relay home communicator?

The MyCareLink Relay 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 is designed to connect wirelessly to your implanted heart device automatically when your implanted heart device is within range of the communicator.

The communicator transmits your implanted heart device information to the Medtronic CareLink network using a cellular phone network (by default) or through your home WiFi network (optional setup). For instructions on how to connect the communicator to WiFi, see Chapter 5, "Optional: Connecting the communicator to WiFi", page 10.

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Elements of the communicator

Figure 1. Communicator

1 Button
2 Light ring
3 Progress bar
4 Icons
5 Light sensor
6 Power port and power indicator
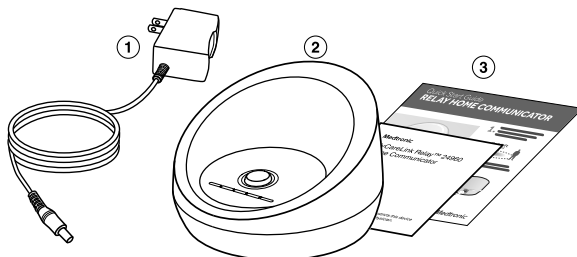
How do I use the communicator?

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

If you are requested to do so by your clinician, it is possible to send a transmission manually (see Chapter 7, "Sending a manual transmission", page 16).

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4 Setting up the communicator

Package contents

1. Power supply
2. Communicator
3. Literature

Where do I place the communicator?

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

- Place the communicator within reach of a power outlet. Position the communicator so that you can unplug it from the power outlet if necessary.
- Place the communicator within about 3 meters (10 feet) of where you sleep, preferably on a night stand or table.

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Starting up the communicator

To start using the communicator, perform the following steps:

1. Insert the power supply cord end into the power port on the back side of the communicator.
2. Plug the power supply wall plug into a power outlet.
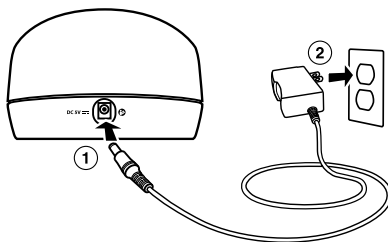
Setup is complete when the green light ring stops spinning, turns solid, and a 2 part, rising tone plays. No further action is needed.

Note: If you see something other than a solid green ring, see Chapter 8, "Troubleshooting", page 19.

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.

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5 Optional: Connecting the communicator to WiFi

If you are having difficulty getting a cellular connection (Section 8.1, "Cellular connection error", page 20), you can connect your communicator to a WiFi network by performing the steps in the following sections (Section 5.1 - Section 5.3).
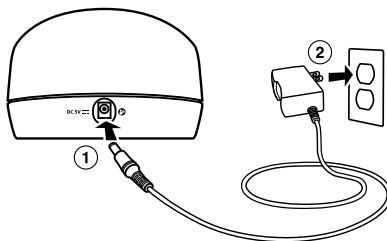
Note: To see a short, step-by-step video, go to www.MCLRelayWiFi.com.

Note: To get help from a Medtronic Patient Services Specialist, call **1-800-929-4043**.

5.1 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.

1. Insert the power supply cord end into the power port on the back side of the communicator.
2. Plug the power supply wall plug into a power outlet.

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## 5.2 Connect to the communicator hotspot

1. Open the list of WiFi networks using a computer, tablet, or smartphone.

Windows computer	Click the wireless network icon to open the **Wireless Network Connection** window. This icon is often located in the lower right corner of the screen.
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.

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3. When prompted for a password, enter the security key from the label on the bottom of the communicator.

    The security key is located to the left of the key symbol. In this example, the security key is "12345678".
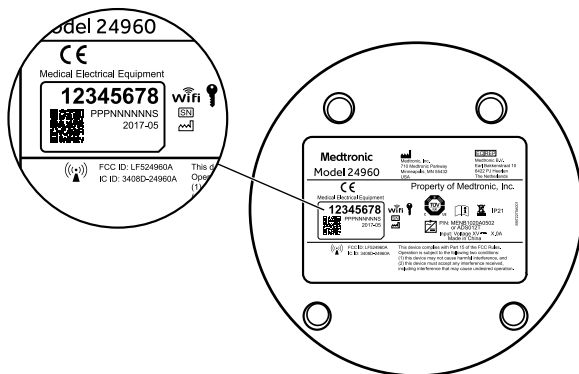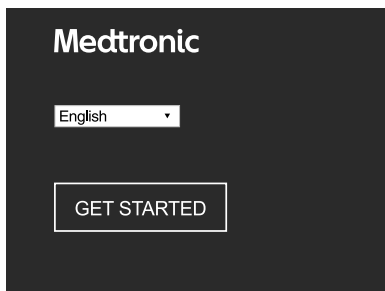

Note: You might see a message that says **connected, no internet**. You can ignore this message and proceed to the next task.

5.3 Connect to your WiFi 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://".

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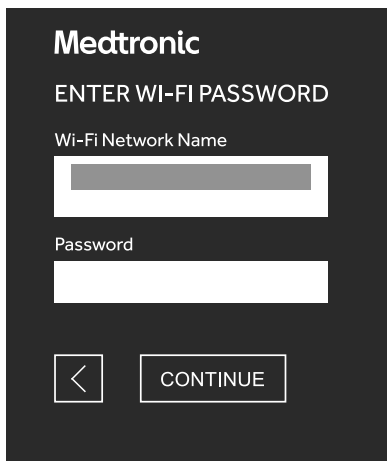
2. Select your language and click **GET STARTED**.

3. Select your WiFi network and click **CONTINUE**.

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4. Enter your WiFi password and click **CONTINUE**.

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ENTER WI-FI PASSWORD

Wi-Fi Network Name

Password

〈   CONTINUE

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

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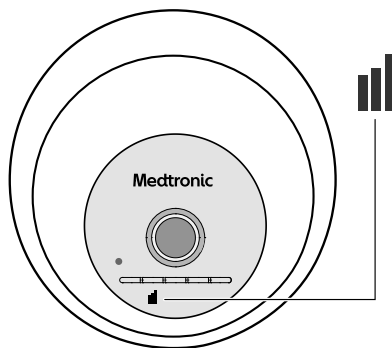The communicator is connected!

Your setup is complete. You can close this browser window.
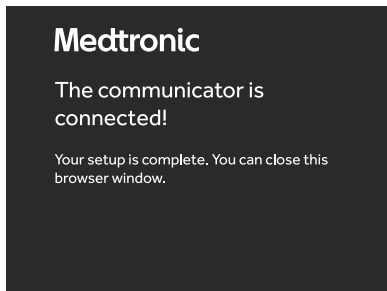
6. WiFi setup is complete. Close the Internet browser.

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Note: As part of this process, your device (computer, tablet, or smartphone) was temporarily disconnected from your home WiFi network. Your device should automatically reconnect to your WiFi network.
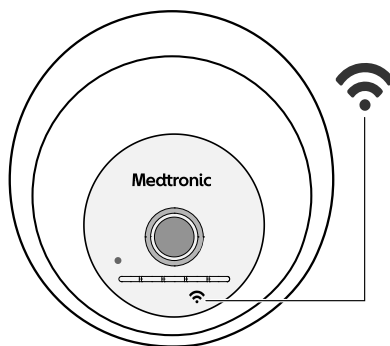
6 Checking the connection status

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 5 seconds.


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- If the communicator is connected to WiFi, the WiFi signal icon lights up green for 5 seconds.
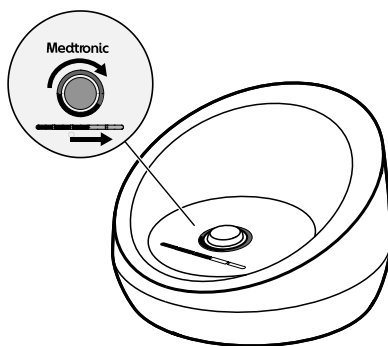

7 Sending a manual transmission

Use these steps to send information from your implanted heart device to the Medtronic CareLink network. Do so only at the request of your doctor or clinic.

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1. Press and hold the button for 2 seconds.

   When the light ring starts to spin and a short tone plays, release the button.
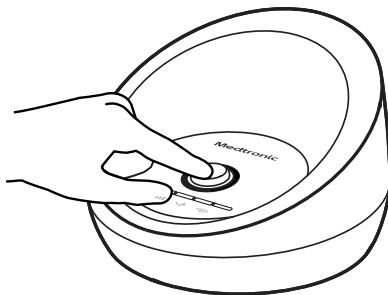

   Note: If you press the button and the bottom of the light ring flashes green 3 times with a 4 part tone playing, the communicator is busy. Wait and try again later.

2. The light ring continues to spin, and the progress bar will start to fill in, indicating that the data is being sent from your implanted heart device to the communicator.

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3. Stay within about 3 meters (10 feet) of the communicator until all the bars in the progress bar are lit.

   When this process is complete, the light ring and progress bar light up solid green. A short, 3 part rising tone plays.
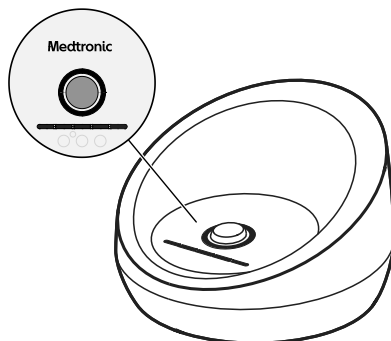
Notes:

- The communication process typically takes 3 to 12 minutes. Stay within range of the communicator during this process.

- After the transmission is successful, you can leave the area. The communicator will send your implanted heart device data to the Medtronic CareLink network where your doctor or clinic can access it.

- If the progress bar does not fill completely and a 3 part, descending tone plays, the transmission was not successful. Go back to Step 1.

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8 Troubleshooting

When an error occurs (Table 1), an icon lights up orange, the communicator flashes the bottom segment of the light ring, and a tone plays.

**Note:** To play the tone again, press the button.

For additional assistance, contact Medtronic. See Chapter 2, "How to contact Medtronic", page 5.

Table 1. Errors

Type	Tone	How to fix
Cellular connection	1 high note and 1 low note play twice	Section 8.1, "Cellular connection error", page 20
WiFi connection	1 high note and 1 low note	Section 8.2, "WiFi connection error", page 21
System	1 short note and 1 long note	Section 8.3, "System error", page 22
Enrollment	1 long note and 3 short notes	Section 8.4, "Enrollment error", page 23

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8.1 Cellular connection error

- **Error:** The cellular signal icon lights up orange, and the bottom segment of the light ring flashes orange. The communicator plays an error tone (1 high note and 1 low note play twice).
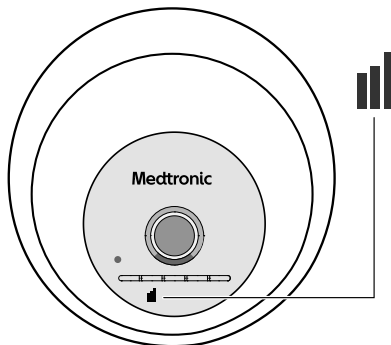

- **Cause:** The communicator does not have an adequate cellular connection.
- **Action:** Unplug the communicator and move it to a place where it might receive a better cellular signal (for example, next to a window).

  If that does not resolve the error, connect the communicator to WiFi using the instructions in Chapter 5, "Optional: Connecting the communicator to WiFi", page 10.

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8.2 WiFi connection error

- **Error:** The cellular and WiFi signal icons light up orange, and the bottom segment of the light ring flashes orange. The communicator plays an error tone (1 high note and 1 low note).
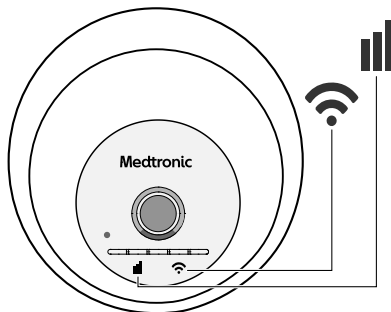

- **Cause:** This error occurs if you previously connected the communicator to WiFi, and there is no connection available.
- **Action:** Unplug your Internet router and plug it back in. Give the router time to start up, then do the same with the communicator.

  Ensure that the WiFi network name and password have not changed. If they have changed, follow the instructions in Chapter 5, "Optional: Connecting the communicator to WiFi", page 10 to enter the new information.

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

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8.3 System error

- **Error:** The system error icon lights up orange, and the bottom segment of the light ring flashes orange. The communicator plays an error tone (1 short note and 1 long note).
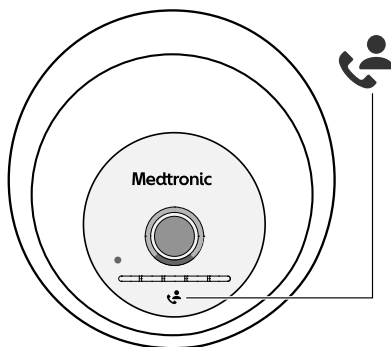
- **Cause:** This error indicates that the communicator has encountered an internal error.

  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 5.

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8.4 Enrollment error

- **Error:** The system error icon lights up orange, and the bottom segment of the light ring flashes green. The communicator plays an error tone (1 long note and 3 short notes).
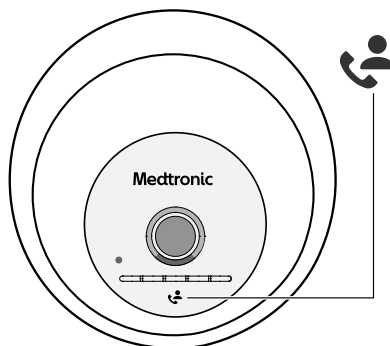
- **Cause:** This error indicates that your clinician has not completed your enrollment in the Medtronic CareLink network.

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

- **Action: Contact your clinic** and ask them to complete your enrollment.

  Note: It can take up to 24 hours for the communicator to update following your enrollment. If the error continues and you know that your clinician has completed your enrollment, try unplugging and plugging in the communicator.

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9 Indications for use and contraindications

Indications for use

The communicator is intended for patients who have an implanted heart device.

The communicator is an external electronic device. It uses a telecommunications connection to transfer data between the patient's implanted heart device and the Medtronic CareLink network automatically. The clinician retrieves the patient's implanted heart device data from the Medtronic CareLink network for clinical review.

The communicator is intended for your use only. Only use it as directed by your doctor. Unauthorized use by others with implanted devices could interrupt the prescribed operation of their device.

Contraindications

There are no known contraindications for the communicator.

10 Warnings and precautions

Warnings

- If you are feeling sick, get medical attention immediately. If you have an emergency, call your local emergency number. If your doctor has

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given you instructions, follow them. Waiting to get medical attention could be dangerous to your health.

- To operate the communicator safely, follow these instructions:
  - Use the communicator as described in this manual. Save this manual.
  - Only send a manual transmission at the times your doctor tells you to.
- Do not use the communicator if it does not operate as described in this manual. If you need further assistance, contact Medtronic.
- Do not modify this equipment. Modifications can make the communicator less effective, which can negatively affect your safety.
- Use of this equipment next to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers, and cables other than those specified or provided by Medtronic could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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- When using the communicator, basic safety precautions should always be followed to reduce the risk of fire, electric shock, and injury to persons.
  - Do not use the communicator near water. For example, do not use it near a bathtub, wash bowl, kitchen sink, or laundry tub.

Precautions

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

11 Additional information

Can I travel with the communicator?

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

If you are planning on traveling to a location where there might not be good cellular reception, you could use a personal WiFi network.

Check to see if the location has WiFi. The communicator will not work with all WiFi network types. It is set up to work with most personal

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networks. To set up WiFi when you arrive, follow the steps in Chapter 5, "Optional: Connecting the communicator to WiFi", page 10.

How do I replace 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 5.

Communicator care

Do not drop the communicator on hard surfaces. Dropping the communicator can damage it and prevent it from functioning properly. If the communicator has been damaged, contact Medtronic. See Chapter 2, "How to contact Medtronic", page 5.

You can clean the exterior of the communicator by using a clean, damp cloth with a light application of water, hydrogen peroxide, alcohol (methyl, ethyl, or isopropyl), or a mild detergent.

The communicator does not require any preventative inspection or maintenance.
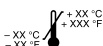
Precaution: Do not immerse the communicator in water. If you get it wet and it stops working, contact Medtronic.

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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.

12 Explanation of symbols

Symbol	Explanation
☛	Security key
WiFi	WiFi key
REF	Reorder number
SN	Serial number
☂	Keep dry.
☐	Use only with provided power supply.
⚠	Caution
📖	Consult instructions for use.
📦	Package contents
◯	Home communicator

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Symbol	Explanation
📖	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.
+ XX °C / + XXX °F / − XX °C / − XX °F	Temperature limitations
(%)	Humidity limitation
🏭	Manufacturer
ᴍ	Date of manufacture
EC REP	Authorized representative in the European Community
ⓨ	China RoHS. See product label for the Environmentally Friendly Use Period (EFUP) in years.
ⓔ	China RoHS indicating product contains no hazardous substances.
━ ━ ━	Direct current

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Symbol	Explanation
TÜV SÜD (c / US)	System meets the applicable Canadian, U.S., and IEC safety standards.
ACMA mark	ACMA (Australian Communications and Media Authority and the New Zealand Ministry of Economic Development Radio Spectrum Management standards) symbol for Australia and New Zealand
Storage temperature symbol	Storage temperature
Transit temperature symbol	Transit temperature
+	Accessories
Follow instructions symbol	Follow instructions for use (blue symbol).
C E	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.

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13 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.

Recommended environmental conditions during storage

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

Relative humidity: 15% to 90% at 35°C (95°F)

Storage air pressure extremes: 70 kPa – 106 kPa

Recommended environmental conditions during transport

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

Relative humidity: 15% to 90% at 35°C (95°F)

Transport air pressure extremes: 70 kPa – 106 kPa

Recommended operating conditions

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

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

Relative humidity: 15% to 90% at 35°C (95°F)

Operating atmospheric pressure: 70 kPa – 106 kPa

Power supply

To ensure compliance to the specified standards, use only the power supply that came with the communicator, MENB1020A0502-XXX or ADS012T.

- Rated voltage AC: 100 V – 240 V
- Rated line frequency: 50 Hz – 60 Hz
- Current: 0.5 A Max.

The power supply is to be used for mains disconnection.

Expected service life

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

Safety and technical inspection

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

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Transmitting and receiving

Frequency of operation	Modulation characteristics	RF output power
2.4-2.4835 GHz	Gaussian frequency shift keying (GFSK)	Less than 1 W EIRP
2.4-2.4835 GHz (WiFi)	Direct sequence spread spectrum (DSSS) Complementary code keying (CCK) Orthogonal frequency division multiplexing (OFDM)	Less than 1 W EIRP
1.85-1.91, 1.93-1.99 GHz (UMTS B2)	16 quadrature amplitude modulation (16QAM)	Less than 2 W EIRP
1.71-1.755, 2.11-2.155 GHz (UMTS B4)	16 quadrature amplitude modulation (16QAM)	Less than 1 W EIRP
824-849, 869-894 MHz (UMTS B5)	16 quadrature amplitude modulation (16QAM)	Less than 7 W ERP
1.85-1.91, 1.93-1.99 GHz	Single carrier frequency division multi-	Less than 2 W EIRP

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Frequency of operation	Modulation characteristics	RF output power
(LTE B2)	ple access (SC-FDMA)	
1.71-1.755, 2.11-2.155 GHz (LTE B4)	Single carrier frequency division multiple access (SC-FDMA)	Less than 1 W EIRP
824-849, 869-894 MHz (LTE B5)	Single carrier frequency division multiple access (SC-FDMA)	Less than 7 W ERP
698-716, 728-746 MHz (LTE B12)	Single carrier frequency division multiple access (SC-FDMA)	Less than 30 W ERP

14 Federal Communications Commission (FCC) compliance information

FCC ID: LF524960A (contains FCC ID: LF524960)

The communicator 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 communicator.

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Size: 4.25 x 6.75 in (108 x 171 mm)

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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.

15 Glossary

Home 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.

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

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