Medtronic

24967

Technical Manual

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

Contents

1 Introduction to Model 24967

1.1 Explanation of packaging and product symbols

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

	Consult instructions for use at medtronic.com/manuals.
CE	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.
IP2X	Ingress protection
	Use only with specified power supply
	Class II ME equipment
	Type BF applied part
	Type CF applied part
	Humidity limitation
	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 recycling.medtronic.com for instructions on proper disposal of this product.
	Direct current
	Manufacturer
	Date of manufacture
EC REP	Authorized representative in the European Community
! USA	For US audiences only
Rx Only	**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician
REF	Reorder number
SN	Serial number
	Package contents
	Product documentation
	Accessories
	Magnetic Resonance (MR) Unsafe
	Bluetooth connection
	Wireless communication enabled
	Telemetry enabled
	Caution: Strong magnet
	Follow instructions for use (blue)
	Low battery

	Keep dry
	ACMA (Australian Communications and Media Authority) and the New Zealand Ministry of Economic Development Radio Spectrum Management compliance mark for Australia and New Zealand
	System meets the applicable Canadian and US IEC safety standards
	Technical Conformity (Ministry of Internal Affairs and Communications) mark for Japan
	Temperature limit
	Transit temperature
	Storage temperature
	Security key
	Base
	24967 patient connector
	249701 power supply for the 24970A base
	249705 power cord for the 24970A base
	249651 power supply for the 24967 patient connector
	249672 tether kit
	249702 USB cable
	249671 weight kit

1.2 Description

The Model 24967 patient connector (referred to as the patient connector) communicates with Medtronic implantable devices, which enables you to interrogate and program the implantable device during implant or patient follow-up appointments.

To interrogate and program implantable devices, the patient connector uses the following communication methods:

- Low-frequency inductive telemetry
- Bluetooth® wireless technology[1]

Multiple Medtronic apps are compatible with the patient connector. The patient connector features can vary, depending on the app that you use. For information on the patient connector features that are available for the app, refer to the app help.

1.3 Intended use

The patient connector is intended to be used with Medtronic apps to interrogate, analyze, and/or program implantable Medtronic devices. The patient connector uses Bluetooth technology to transmit data to a Medtronic app for further processing.

The patient connector is intended for use by healthcare professionals or Medtronic representatives in a clinical or hospital environment.

1.4 Contraindications

There are no known contraindications for the use of this device.

1.5 Warnings

These warnings apply in general to using the patient connector. For more information related to specific implantable device models, see the reference guides for the implantable device and the software.

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

Battery exposure – Exposing the patient connector to cold temperatures may result in a loss of performance and shortened patient connector service life.

Connection of external devices – Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards. All configurations must comply with the requirements for medical electrical systems; see IEC 60601-1 and IEC 60601-1-1. Anyone connecting additional equipment to medical electrical equipment is configuring a medical system and is therefore responsible for ensuring that the system complies with the requirements for medical electrical systems. Local laws take priority over the previously mentioned requirements. If in doubt, consult your local Medtronic representative or Medtronic Technical Services. See the back cover for contact information.

Damage due to impact – Do not use the patient connector if it has sustained impact damage. Internal components may be damaged or exposed. Use of damaged equipment may impact user or patient safety.

Magnetic resonance (MR) unsafe – The patient connector is MR Unsafe. Do not bring the patient connector into Zone 4 (magnet room), as defined by the American College of Radiology.

Modification of equipment – Do not modify this equipment. Modifications may reduce system effectiveness and impact user or patient safety. Modifying the patient connector without the approval of Medtronic could void the user's authority to operate the equipment.

Radiofrequency (RF) interference – Portable and mobile RF communications equipment can interfere with the operation of the patient connector. There is no guarantee that the patient connector will not receive interference or that any particular transmission from the patient connector will be free from interference.

Unauthorized use – The patient connector can be used with any compatible tablet onto which the app is installed. Inappropriate programming could result if an untrained person obtains the patient connector and uses it with a patient's Medtronic implantable heart device.

Use of unapproved power supply – Use only the power supply provided by Medtronic with the patient connector. Use of an unapproved power supply can damage equipment or impact user or patient safety.

1.6 Precautions

This device has been tested for compliance with FCC regulations. Changes or modifications of any kind not expressly approved by Medtronic could void the user's authority to operate this device.

Attaching the tether kit – Do not overtighten the screw when attaching the tether kit.

Autoclaving – Do not autoclave the patient connector.

Damaged equipment – Periodically inspect the patient connector, connection port, and power supply cord for damage. If the case of the patient connector is cracked, or if the power supply connector is damaged, contact your Medtronic representative. Replace the power supply if it is damaged. Dispose of the damaged power supply according to local regulations or return the part to Medtronic.

Do not immerse – Prevent liquid from entering the patient connector. Do not immerse the patient connector or any accessories in any liquid, and do not clean them with glycol ethers or aromatic or chlorinated hydrocarbons.

Maintenance and service – Do not modify or perform any maintenance or service on the patient connector while you are using it. Modifying or maintaining the patient connector while it is in use can lower its effectiveness. If the patient connector is not working properly, contact your Medtronic representative.

Product and packaging labels and information – If labels or information appear to be missing from the product or packaging, contact your local Medtronic representative.

Security – Maintain adequate physical security of the patient connector to prevent unauthorized use that could lead to harm to patients. Install periodic updates for the Medtronic apps used with the patient connector. These updates help keep the interface between the tablet and the patient connector secure. Medtronic inductive telemetry uses short-range communication to protect patient information. If the patient connector fails, there is no risk of patient harm.

Sterility – The patient connector is not sterile and cannot be sterilized. For applications in which a sterile environment must be maintained, place the patient connector inside of the Medtronic Model 6177 sterile sleeve.

Use of wireless devices – The patient connector incorporates radiofrequency (RF) communications components that may affect other devices and equipment in the medical environment. The use of wireless devices in the medical environment must be evaluated and authorized by the responsible organization. RF interference may affect device performance.

Electromagnetic compatibility (EMC) compliance testing shows that the patient connector provides reasonable protection against harmful interference and provides EMC immunity in a typical medical installation. The use of wireless devices in the medical environment must be evaluated and authorized by the responsible organization. However, there is no guarantee that interference will not occur in a particular installation.

If the patient connector does cause harmful interference to other devices or is negatively impacted by other devices, correct the interference by taking one or more of the following measures:

- Reorient or relocate the patient connector and other devices.
- Increase the separation between the patient connector and other devices by at least 2 m(approximately 6 ft). Other devices include, but are not limited to, cellular phones, computer screens, wireless network devices, and two-way radios.
- Turn off any interfering equipment.

1.6.1 Environmental precautions

Although the patient connector was designed to withstand normal use, take the following precautions to avoid damage from environmental stresses:

- Do not drop or mishandle the patient connector; damage may occur. Even if the patient connector works immediately after being dropped, operational damage may have occurred that may not be observed immediately.
- Do not spill fluid on the patient connector. Fluid incursion can cause damage to the patient connector.
- In an environment likely to cause electrostatic discharge (ESD), such as a carpeted floor, discharge any charge collected on your body before touching the patient connector. The patient connector may be affected by ESD.
- Do not open the case of the patient connector. Opening the case of the patient connector can make it susceptible to environmental factors and can expose the patient or user to a hazardous voltage or current.
- Do not expose the patient connector to rapid temperature changes. Rapid temperature changes may affect proper operation of the patient connector. If the patient connector is exposed to rapid temperature changes, allow the temperature to stabilize before using the patient connector.
- Do not store or operate the patient connector for prolonged periods of time in high humidity. Prolonged storage or operation of the patient connector in high humidity can affect proper operation.

If the patient connector is damaged, contact your Medtronic representative.

Other environmental factors can impair the performance of the patient connector. Always use good health management practices to prevent environmental damage to the patient connector.

1.7 Regulatory compliance

1.7.1 US Federal Communications Commission (FCC)

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.

1.8 IT network, tablet, and data information

1.8.1 Required IT network characteristics and configuration

To use the patient connector with Medtronic apps, your tablet must have both Bluetooth wireless technology and access to the Internet.

Bluetooth wireless technology

The patient connector uses Bluetooth wireless technology to communicate with the Medtronic app installed on the tablet. If Bluetooth wireless technology is disabled on the tablet, you are unable to interrogate, analyze, and program Medtronic implantable devices.

Internet

To configure your network and tablet, follow the processes and policies of your organization.

Your network must have Internet access, which allows you to complete the following actions:

- Download and install Medtronic apps.
- Download and install Medtronic app updates.
- Download and install software updates for the patient connector.
- Register, download, and install Medtronic app configuration files from Medtronic, if the Medtronic app allows it.
- Send downloaded implantable device data to Medtronic web services, such as the CareLink Network.

1.8.2 Supported Medtronic apps and tablets

For a list of Medtronic apps and tablets that are compatible with the patient connector, go to medtronic.com/24967.

1.8.3 Intended information flows

The implantable device data is processed through the components in the following order:

- Implantable device
- Patient connector
- Medtronic app

The system logs are processed through the components in the following order:

- Patient connector
- Medtronic app
- Internet
- Medtronic web services, depending on the Medtronic app

When you install or update Medtronic apps and component software, some apps send the following information to Medtronic via the Internet for authentication:

- Clinic registration
- Security credentials

In response, Medtronic sends configuration files to the app via the Internet to complete the installation or update. The configuration files allow the Medtronic app to connect and communicate with the components.

All information in transit is protected for security.

1.8.4 Precautions when connecting to your IT network

Connecting this system to an information technology (IT) network that includes other equipment could result in unforeseen risks to patients, operators, or third parties. Changes to your IT network, such as adding, disconnecting, and upgrading equipment or changing network configurations, could also introduce additional risks. Analyze, evaluate, report, and control any risks identified.

1.8.5 Data transmissions

The patient connector uses wireless technology to communicate with the implantable device and the Medtronic app installed on the tablet. Data transmission rates over wireless connections are highly dependent on the environment in which the patient connector is used. Transmission rates may degrade based on electrical interference from other radio emitters, distance between the patient connector and the implantable device and tablet, and wireless or cellular settings on the tablet. All data transmitted between the patient connector and the implantable device and app is encrypted for data privacy. Data integrity is maintained through standard communication protocols for error detection.

1.8.6 Security

To protect the app data, Medtronic apps use encryption.

Medtronic apps are unable to protect data that is exported from the app. When you export data from the app, use your clinic security policies for data handling and storage.

Medtronic recommends that you implement the following security measures:

- Use the Medtronic app and components only on a managed, trusted network. Verify that your Wi-Fi networks comply, at minimum, with wireless standard 802.11b, 802.11g, or 802.11n, and use WPA2 or stronger encryption.
- Secure your network with industry best practices, which can include antivirus software, firewall, and wireless security policies, according to the policies of your IT department.
- To help protect patient health information, implement security measures, such as a passcode.
- When installing or updating Medtronic apps, if your tablet displays a message indicating that a security certificate is not valid, the installation process is unable to continue. For assistance, contact your Medtronic representative.

If you suspect a cybersecurity event has occurred, stop using the app (if possible) and contact your IT security or biomedical department for information on how to confirm and respond to the suspected incident.

2 Setup and configuration

2.1 Contents of package

Each patient connector package contains all of the required and optional items to set up the patient connector.

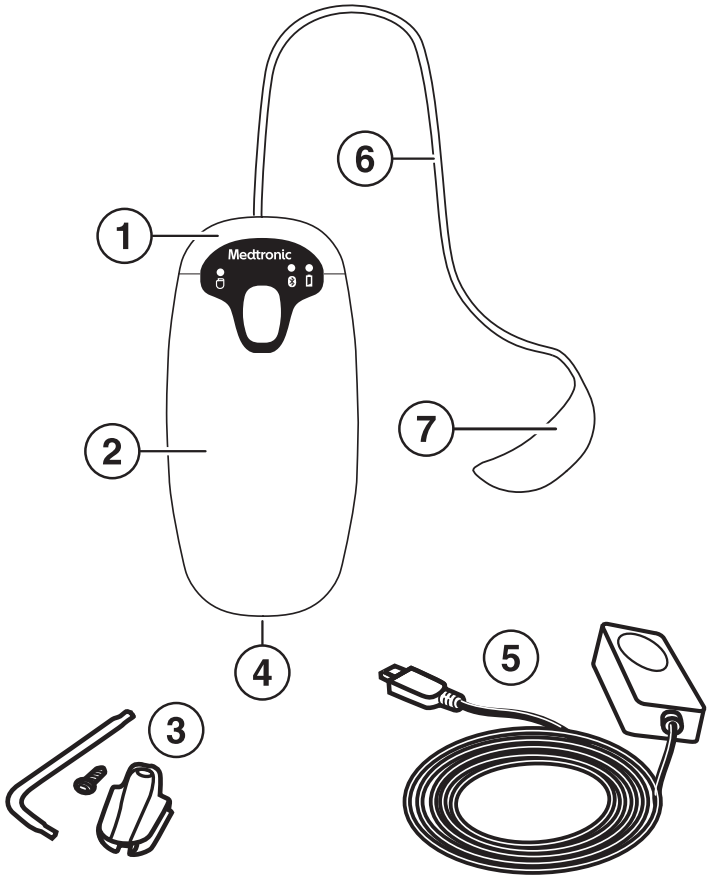
The patient connector package contains the following items:

- Patient connector
- Model MENB1020A0500XXX power supply (Medtronic reorder number 249651)
- Model 249672 tether kit
- Literature

Note: The patient connector does not contain a magnet.

2.2 Components

Figure 1. Patient connector components



1 Nose
2 Patient connector
3 Tether kit
4 Power supply connector
5 Power supply
6 Cord
7 Weight (blue)

Nose – Attaches the cord and weight to the patient connector.

Patient connector – Provides the communication link between the app and implantable device.

Tether kit – Semipermanently connects the patient connector to the power cord. The tether kit contains a Torx wrench, screw, and cable retainer.

Power supply connector – Connects the power supply to the patient connector.

Power supply – Connects to an AC power outlet to charge the patient connector battery.

Cord – Connects the patient connector to the weight.

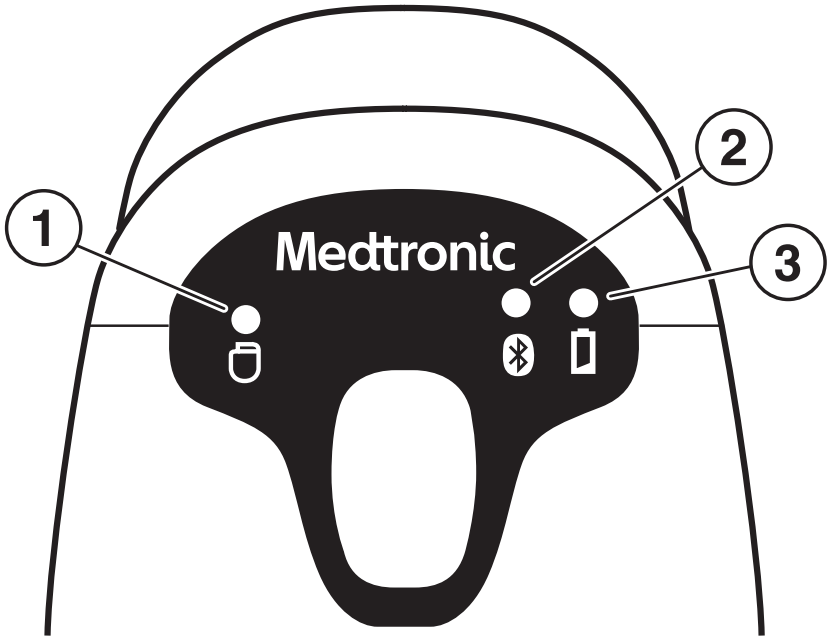
Weight – Holds the patient connector in place for hands-free use.

Tablet (not included) – Provides the interface to communicate with the implantable device.

Warning: Do not modify this equipment. Modifications may reduce system effectiveness and impact user or patient safety. Modifying the device without the approval of Medtronic could void the user's authority to operate the equipment.

2.2.1 Status lights

Figure 2. Patient connector status lights



1 Telemetry
2 App connection
3 Battery

Table 1. Status light descriptions

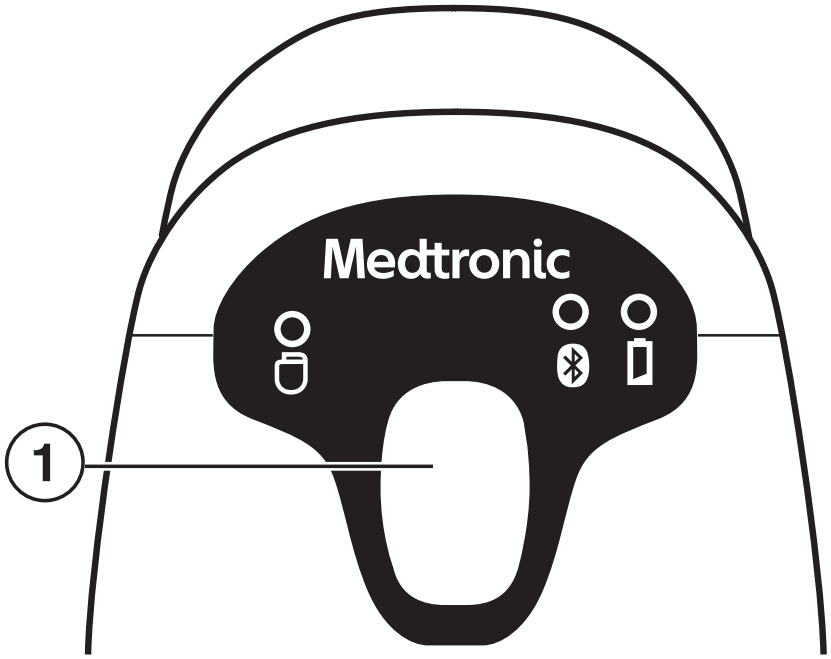
Status light	Icon	Color	State	Description
Telemetry		Amber	Solid	The patient connector is out of range of the implantable device.
		Amber	Flashing	The connection between the patient connector and the implantable device has been lost.
		Green	Solid	The patient connector and implantable device are able to communicate.
		None	N/A	The patient connector and implantable device are unable to communicate.
App connection		Blue	Slow flashing	The patient connector is available for a connection with the Medtronic app.
		Blue	Fast flashing	The patient connector is attempting to reconnect to an app on a specific tablet and is not available for a connection with a different tablet.
		Blue	Solid	The patient connector is connected to the Medtronic app.
		None	N/A	The patient connector is disconnected from the Medtronic app.
Battery		Amber	Solid	The battery is low. Recharge the battery.
		Green	Flashing	The battery is charging.
		Green	Solid	The patient connector is connected for charging and the battery is fully charged.
		None	N/A	The battery is fully charged. When all of the status lights are off, the patient connector has no charge. Recharge the battery.

2.2.2 Patient connector button

The button on the patient connector allows you to turn on the patient connector, or confirm the connection between the patient connector and the Medtronic app.

If you press and hold the patient connector button for at least 5 seconds, the patient connector restarts.

Figure 3. Patient connector button



1 Patient connector button

2.2.3 Turning off the patient connector

The patient connector turns off automatically after 5 min if it is not connected to a Medtronic app. For more information, see Table 2.

To terminate any active Bluetooth connection, press and hold the patient connector button for at least 5 seconds until the blue light on the patient connector flashes at a slow rate.

Table 2. Automatic shutdown timing

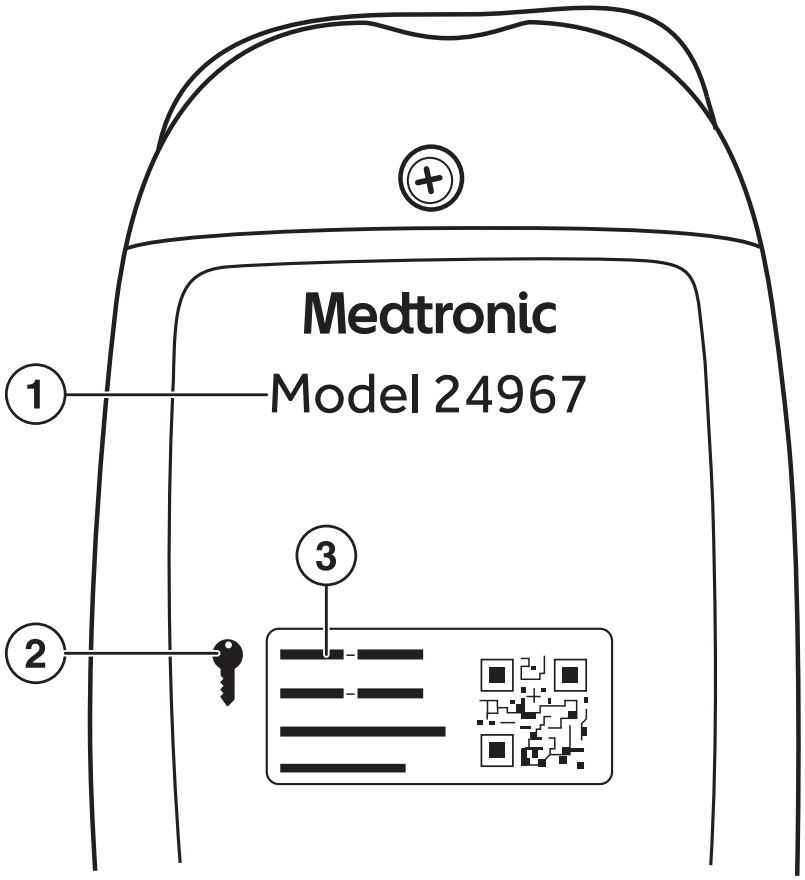
State	Automatic shutdown
Charging	Never
Connected to a Medtronic app (the blue light is solid)	When patient connector battery is depleted
Attempting to reconnect (the blue light is flashing rapidly)	When patient connector battery is depleted
None of the preceding conditions apply	After 5 min

Note: If 3 hours pass with no Bluetooth connection with a Medtronic app, the Bluetooth radio in the patient connector turns off.

2.2.4 Pairing information

The information printed on the bottom of the patient connector allows you to pair the patient connector with the app.

Figure 4. Patient connector pairing information



1 Model number
2 Security key symbol
3 Security key code

2.3 Compatible accessories

Medtronic recommends that you use the compatible accessories that are supplied by Medtronic.

Table 3. Compatible accessories

Accessory	Model
Power supply, 2 m (approximately 6.5 ft)	MENB1020A0500XXX (Medtronic reorder number 249651)
Tether kit	249672
Weight kit	249671
Sterile sleeve	6177
Base	24970A
USB cable, approximately 3 m (10 ft)	249702

To order the accessories, contact your Medtronic representative.

Warning: Use only components supplied by Medtronic. Use of unapproved components may reduce device effectiveness or impact user or patient safety.

2.4 Setup

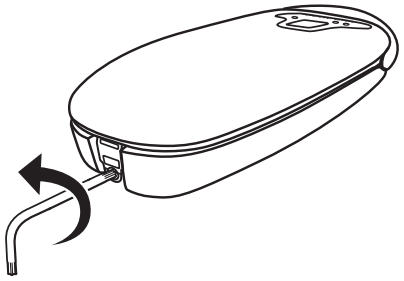
2.4.1 Installing the app

1. Verify that the tablet is connected to the Internet.
   The tablet must show sufficient signal strength to connect to the network.
2. Download and install the app.
3. Open the app, then follow the installation instructions.

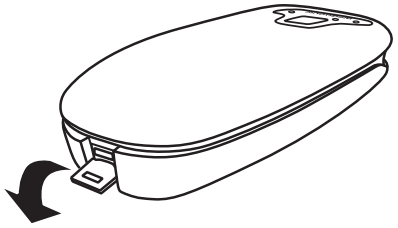
2.4.2 Attaching the tether kit

The tether kit provides a way to semipermanently attach the patient connector to the power supply cord or the USB cable. This is an optional configuration.

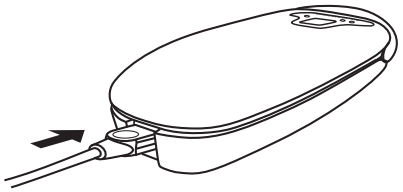
1. From the power supply connector cover, use the wrench supplied by Medtronic to remove the screw.



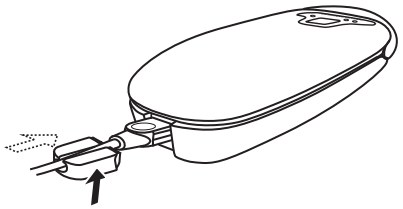
2. Pull back the power supply connector cover.



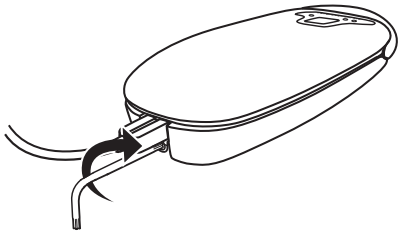
3. Plug the power supply or the mini-B connector of the USB cable into the patient connector.



4. Slide the cable retainer over the power supply plug of the power cord or the USB cable connector.



5. Insert the screw into the bottom of the cable retainer and tighten the screw using the wrench supplied by Medtronic.
   Caution: Do not overtighten the screw when attaching the tether kit.



Warning: Use only the components supplied by Medtronic. Use of unapproved components may reduce patient connector effectiveness or impact user or patient safety.

2.5 Charging the patient connector battery

Caution: Charge the patient connector before use. If the patient connector is not adequately charged before beginning a procedure, you may not be able to complete that procedure.

Charge the patient connector using the Medtronic power supply. If you are using the Model 24970A base, you can charge the patient connector using the base cradle or the USB cable supplied by Medtronic. For more information, refer to the base technical manual.

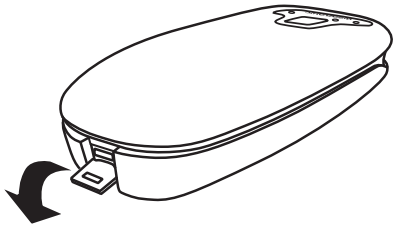
Notes:

- The patient connector and power supply form a medical electrical system when connected.
- When plugged into the AC power outlet (AC mains), the power supply provides 5 V power to the patient connector for battery charging and nonbattery operation.
- Position the patient connector so that it can be easily disconnected or unplugged from the AC power outlet (AC mains).
- The third conductor in the power supply plug, if present, is a functional earth connection.
- If the operational time between charges decreases or the patient connector's internal rechargeable battery no longer retains a charge, contact Medtronic for a replacement.
- You can use the patient connector while the patient connector is charging.

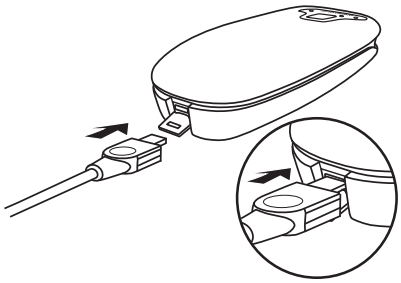
2.5.1 Charging using the power supply

Connect the power supply to the patient connector and the AC power outlet (AC mains).

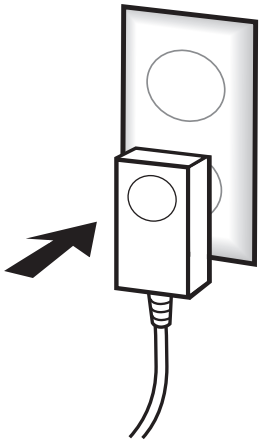
1. Pull back the power supply connector cover.



2. Connect the power supply cord to the patient connector.



3. Plug the power supply into the AC power outlet (AC mains).



Warning: Use only the power supply from Medtronic to power the patient connector. Use of an unapproved power supply may damage equipment or impact user or patient safety.

2.6 Pairing the patient connector with the app

The patient connector uses a Bluetooth connection to communicate with the app that is installed on the tablet.

Note: Multiple patient connectors can be used with the app, but only 1 patient connector can be paired with the app at a time.

1. On the tablet, verify that Bluetooth communication is enabled.
2. Open the app, then follow the instructions.

3. When prompted by the app, select the patient connector from the list.
   Notes:
   - The serial number is printed on the bottom of the patient connector.
   - If the patient connector does not appear in the list, press the patient connector button.
4. Enter the security key code, then follow the app instructions.
5. Accept the Bluetooth pairing request.
6. Complete the configuration steps in the app, if applicable.

2.7 Troubleshooting potential interference

Interference between the patient connector and other electronic equipment can result in reduced quality of service. Reduced quality of service can result in slow data transmission speeds or poor communication strength.

To address possible interference between the patient connector and other electronic equipment, take one or more of the following actions:

- Reorient or relocate the electronic equipment.
- Increase the separation between the patient connector and the electronic equipment.
- Connect the electronic equipment to an outlet on a different circuit, if the patient connector is plugged into the outlet for charging.
- Move the patient connector and tablet closer together.
- If you are using the Model 24970A base, connect the patient connector to the base using the USB cable supplied by Medtronic. For more information, refer to the base technical manual.
- For assistance, contact your Medtronic representative.

3 Conduct a patient session

3.1 Communicating with an implantable device

Caution: Only use the patient connector to communicate with the intended implantable device. Avoid placing the patient connector over an unintended active implantable device. Placing the patient connector over an unintended active implantable device can interfere with that device, potentially affecting its operation.

Caution: Charge the patient connector before use. If the patient connector is not adequately charged before beginning a procedure, you may not be able to complete that procedure.

Notes:
- To ensure strong Bluetooth communication, make sure that the tablet is no farther than 2 m (6.5 ft) from the patient connector during the patient session.
- For the best telemetry performance, do not use the patient connector close to sources of electrical noise or interference.
- The patient connector, blue weight, and cord come into physical contact with the patient during normal use of the device. If the patient connector is being used in a sterile environment, place the sterile sleeve over the patient connector.

1. Open the app.
2. To turn on the patient connector, press and release the patient connector button.
3. Place the patient connector over the implantable device. Position the patient connector so the bottom of the patient connector is parallel to and within 5 cm of the implantable device.
   Note: For hands-free use, unwrap the blue weight and cord from the patient connector and place the weight over the patient's shoulder.
4. Ensure that the telemetry status light on the patient connector is green. The telemetry status light is brighter when there is a stronger signal from the implantable device.
5. Take one of the following actions:
   - When communicating with an implantable device using low-frequency inductive telemetry, leave the patient connector over the implantable device until the communication is complete. Communication can take up to 5 min.
   - When communicating with an implantable device using Bluetooth telemetry, you can set aside the patient connector once the telemetry status light on the patient connector is green. Keep the patient connector within 2 m (6.5 ft) of the implantable device.
6. To complete the task, follow the app instructions.

Note: If there is an extended period of inactivity, such as after a patient session has ended, the Bluetooth radio turns off automatically. To turn on the Bluetooth radio, press the patient connector button.

3.2 Troubleshooting

If there is a problem with the patient connector, an error or an informational message appears in the app. The message may have an animated demo with directions on how to resolve the condition.

3.2.1 Patient connector position

When you position the patient connector incorrectly over the implantable device, the telemetry status light changes.

Condition	Action	Result
The telemetry status light is amber.	For issues between the patient connector and implantable device, take one of the following actions: • Reposition or rotate the patient connector. • Move the patient connector closer to the implantable device. • Move the patient connector to another location that is within 2 m (6.5 ft) of the implantable device. • Remove any sources of electromagnetic interference (EMI) that can affect the telemetry signal. **Note:** Additional implanted devices can interfere with the communication between the patient connector and the intended implanted device. When patients have multiple implanted devices, reposition the patient connector closer to the intended implanted device to improve communication.	When the telemetry status light turns green, the patient connector can successfully communicate with the implantable device. When the communication from the implanted device is stronger, the telemetry status light is brighter.
The telemetry status light is off.	Confirm that the implantable device is a Medtronic device, then reposition the patient connector over the Medtronic implantable device.	When the telemetry status light turns green, the patient connector is able to successfully communicate with the implantable device. When the communication from the implanted device is stronger, the telemetry status light is brighter.

Note: The patient connector is only compatible with Medtronic implantable devices.

3.2.2 App connection lost

The patient connector pairs with a Medtronic app to send data. If the patient connector loses the Bluetooth connection with the app, the following condition occurs:

Condition	Action	Result
The blue light on the patient connector flashes rapidly.	To reconnect the patient connector with the app, take any of the following actions: • Check that Bluetooth communication is enabled on the tablet. Enable Bluetooth communication on the tablet if it is not enabled. • Move the tablet closer to the patient connector and ensure that the blue light on the patient connector is on. • Check that nothing physical is blocking the signal between the patient connector and the tablet. **Note:** When the blue light is flashing rapidly, the patient connector is attempting to automatically reconnect to an app on a	The blue light changes from flashing to solid. The patient connector has established a Bluetooth connection with the Medtronic app.

Condition	Action	Result
	specific tablet. To make the patient connector available for use with a different tablet, press and hold the grey button for at least 5 seconds until the blue light flashes at a slow rate. Then follow the connection instructions in Section 2.6.	

4 Maintenance

4.1 Cleaning and disinfecting the patient connector

4.1.1 Cautions and notes for cleaning and disinfecting

Cautions:

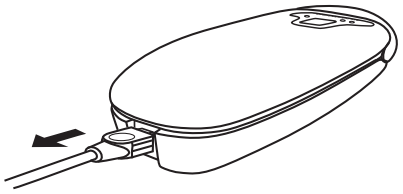
- Clean and disinfect the patient connector as needed according to the policies of your organization. Use only the recommended methods to clean and disinfect the patient connector. Depending on the level of contamination, such as exposure to blood or body fluid, Medtronic recommends cleaning and disinfecting the patient connector promptly after use to minimize drying and cross contamination.
- Use only recommended cleaners and disinfectants on the patient connector. Using other cleaners, solvents, or disinfectants (such as bleach, ethers, acetone, or chlorinated solvents) can damage the patient connector plastic, circuitry, or metal components.
- Do not immerse the patient connector in water or cleaning agents. Do not use automated machine washers. Severe damage to the patient connector can occur.
- Do not sterilize the patient connector by ethylene oxide, gamma radiation, or steam sterilization (autoclave). Severe damage to the device, housing, or labels can occur using these methods.

Notes:

- While cleaning the patient connector, visually inspect it for damage. Contact your Medtronic representative if any components are damaged.
- The patient connector is designed to withstand normal cleaning and disinfecting over its product life.
- The following disinfecting procedure has been tested and shown to achieve a log 4.8 or greater reduction in pathogens. If your organization or application requires a higher level of disinfection, place the patient connector inside a sterile barrier (such as the Medtronic Model 6177 sterile sleeve).
- During procedures in a sterile environment, or when cross contamination is a concern, place the patient connector inside a sterile barrier (such as the Medtronic Model 6177 sterile sleeve).
- The power cord, USB cable, and optional tether kit accessories cannot be disinfected effectively. If these accessories become contaminated, discard the accessory and contact Medtronic for a replacement. When using the optional tether kit to secure the USB cable or power cord, place the patient connector inside of the sterile sleeve to limit patient contact and reduce the device's exposure to contamination.

4.1.2 Preparing the patient connector for cleaning and disinfecting

1. If the patient connector is plugged into a power source, unplug it. If you are using the optional tether kit, only unplug the cord from the power source.

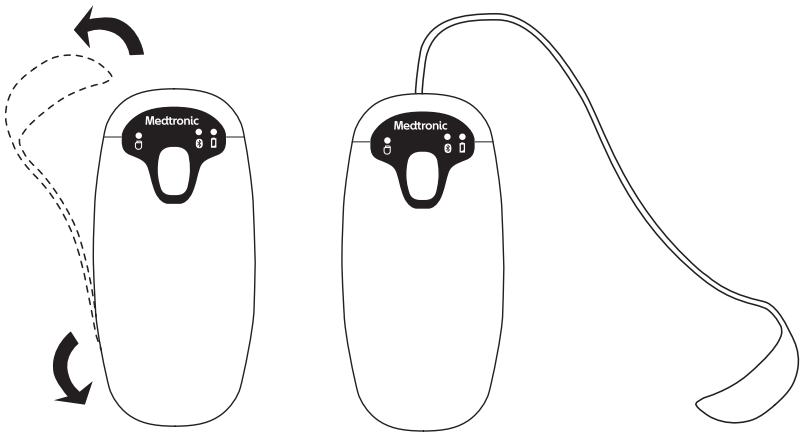


2. If the patient connector is turned on, turn off the patient connector:
   a. To terminate any active Bluetooth connection, press and hold the patient connector button for at least 5 seconds until the blue light on the patient connector flashes at a slow rate.
   b. Wait 5 min for the patient connector to turn off.
      When the patient connector turns off, the status lights turn off.
3. Prepare a clean working surface, then gather the cleaning and disinfecting materials.
   Medtronic recommends that you use one of the following cleaning and disinfecting materials:
   - 70% isopropyl alcohol prep pad
   - Sterile gauze pad or sponge dampened with 70% isopropyl alcohol

Do not use the following cleaning and disinfecting materials:

- Bleach
- Ethers
- Acetone
- Chlorinated solvents

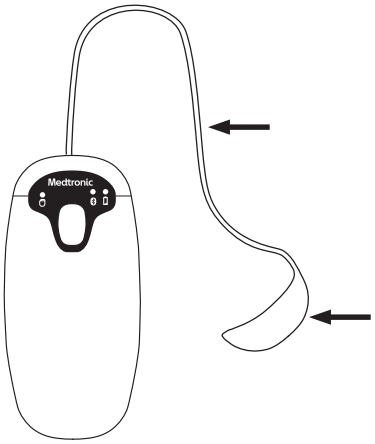
4. Unwrap the blue weight from around the patient connector and fully extend the cord.



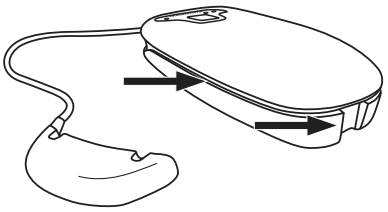
4.1.3 Cleaning the patient connector

Cleaning physically removes soil and contaminants from the patient connector. After each use, promptly clean the patient connector to minimize the drying of soil and contaminants.

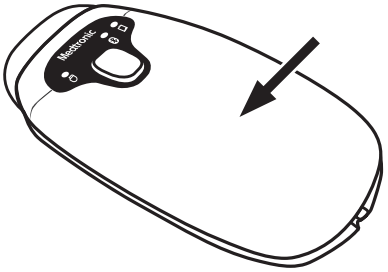
1. To remove all visible soil, wipe all external surfaces of the patient connector with the recommended materials listed in Section 4.1.2.
   a. Wipe the blue weight and its cord.



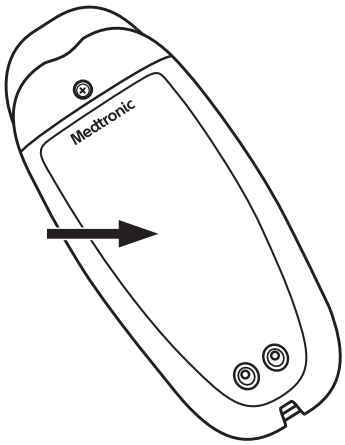
   b. Wipe all sides of the patient connector, including the power supply area and cord channel.



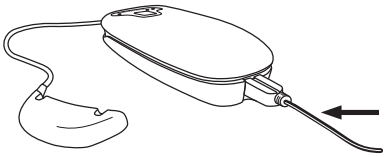
c. Wipe the top of the patient connector.



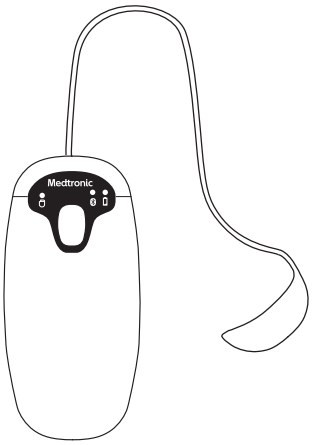
d. Wipe the bottom of the patient connector.
To avoid damaging the charge contacts, carefully wipe and remove any visible soil.



e. If the optional tether kit is installed, wipe the power supply cord or USB cable for approximately 1 m (3 ft) extending from the patient connector.



2. Allow all components to air dry. Leave the blue weight fully extended until all components are dry.
Note: If you are disinfecting the patient connector after cleaning, you do not need to allow the components to dry.



When the patient connector is dry, cleaning is complete.

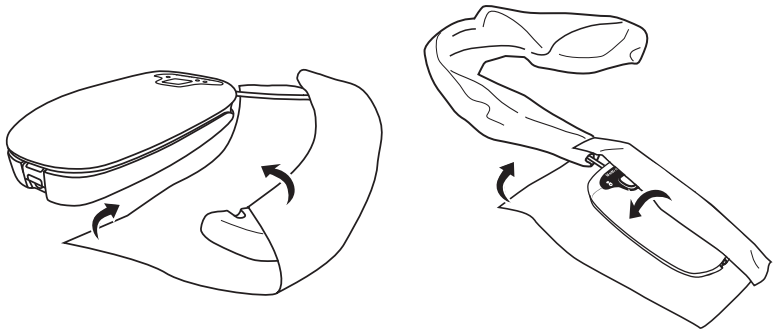
4.1.4 Disinfecting the patient connector

Disinfection is intended to kill residual pathogens after cleaning. Disinfection may be required depending on the level of contamination, such as exposure to blood or body fluid. To determine when to disinfect the patient connector, follow the policies of your organization.

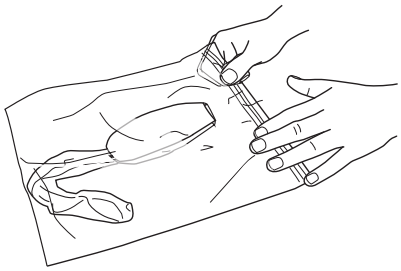
Successful disinfection depends upon thorough initial cleaning.

1. Before you disinfect the patient connector, thoroughly clean all external surfaces using the steps in Section 4.1.3.
2. If the optional tether kit is installed, remove the tether kit and unplug the USB cable or power cord. To seal the connector port contacts, reinstall the power supply connector cover.

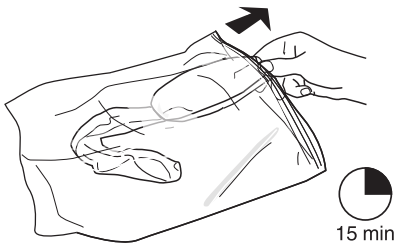
   The USB cable, power cord, and optional tether kit accessories cannot be disinfected effectively. If these accessories become contaminated, remove them from the patient connector and discard. To replace these accessories, contact your Medtronic representative.
3. To disinfect the patient connector, use the recommended materials listed in Section 4.1.2.
4. Fully wrap all external surfaces of the patient connector with the damp prep pads, sterile gauze pads, or wipes.
   a. To completely cover the blue weight and its cord, wrap them lengthwise.
   b. To completely cover the patient connector, wrap all sides of the patient connector.



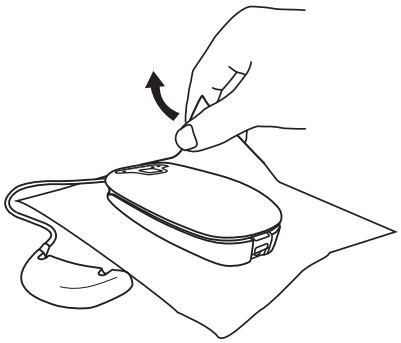
5. To maintain a wet or damp exposure time of 15 minutes, place all wrapped patient connector components inside a plastic bag or container. To reduce evaporation, seal the bag or container.



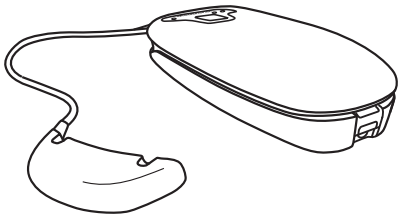
6. After 15 minutes have elapsed, remove all wrapped patient connector components from the plastic bag or container.



7. Remove the damp prep pads, paper wipes, or sterile gauze pads from the exterior of the patient connector, cord, and blue weight.



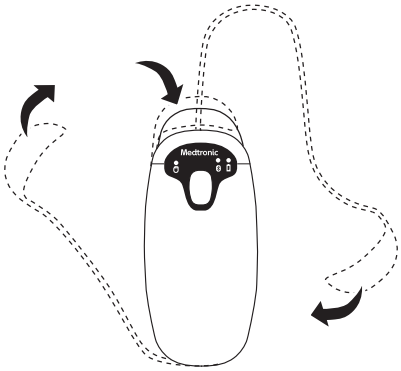
8. Safely discard the damp prep pads, paper wipes, or sterile gauze pads according to the policies and procedures of your organization.
9. Allow the components to air dry on a clean surface. Leave the blue weight fully extended until all components are dry.



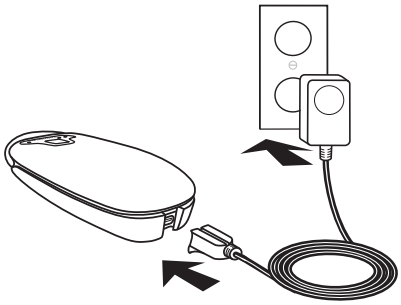
When the patient connector is dry, disinfection is complete.

4.1.5 Reassembling the patient connector

1. Rewrap the blue weight all the way around the patient connector. Secure the weight in the top of the retention channel.



2. Install a new replacement tether kit with a new USB cable or power supply, if needed. This is an optional configuration.



4.1.6 Additional resources

For additional information about cleaning and disinfecting the patient connector, contact Medtronic Instruments Technical Services:

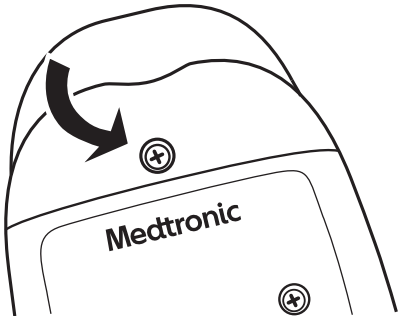
- Telephone: +1 800 638 1991
- Email: tshelp@medtronic.com

For more information and resources on cleaning and disinfecting medical devices, visit the Centers for Disease Control and Prevention (CDC) and Healthcare Infection Control Practices Advisory Committee (HICPAC) websites.

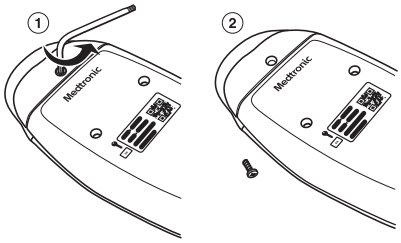
4.2 Replacing the patient connector nose, cord, and weight

If the patient connector nose, cord, and weight become damaged, you must replace them. To order the replacement parts, contact your Medtronic representative.

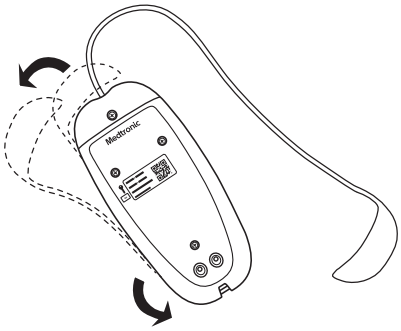
1. Locate the screw on the nose of the patient connector.



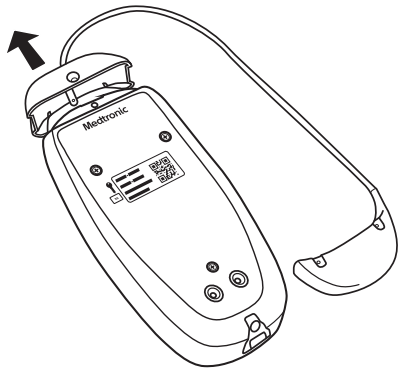
2. To remove the screw, use the wrench supplied by Medtronic.



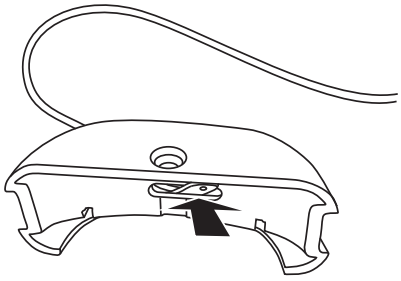
3. Unwrap the blue weight from around the patient connector and fully extend the cord.



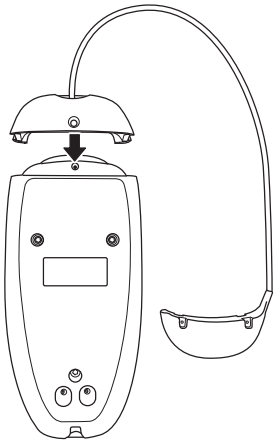
4. Remove the nose, cord, and weight.



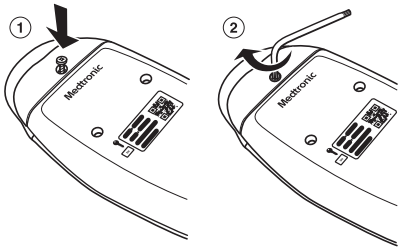
5. Using the new parts, thread the cord with the weight through the hole in the nose.



6. Attach the new nose to the patient connector.
   a. Align the blue insert with the pins on the nose.
   b. Align the screw holes on the blue insert and nose.



7. Wrap the blue weight around the patient connector and insert the screw into the screw hole. To tighten the new nose, use the wrench supplied by Medtronic.



4.3 Software updates

When you open the app, the software updates are automatically pushed to the patient connector. Updates can take up to 5 min. Before you use the app, wait until the update is complete.

4.4 Specifications

The patient connector complies with the standards in the following table.

Table 4. Standards

Radiofrequency wireless specifications and applicable standards	
EMC	EN / IEC 60601-1-2 Ed. 3 EN / IEC 60601-1-2 Ed. 4 EN 301 489-1 EN 301 489-17 EN 301 489-31
Radio	FCC CFR 47
Patient safety	EN 60601-1, Class 2, continuous operation, Type BF applied part
IEC 60529 Degrees of Protection Provided by Enclosures (IP Code)	
Ingress	This product complies with international electrical safety rating IP2X with regard to ingress of dust, other foreign objects, and water as required by IEC 60601-1.

The following table includes electrical specifications for the patient connector.

Table 5. Electrical specifications

AC power requirement	
Voltage	100–240 VAC nominal
Frequency	50/60 Hz nominal

Table 5. Electrical specifications (continued)

Battery	
Type	Li-polymer, rechargeable
Capacity	1500 mAh
Charge duration	Standby: 15 days Operating: 3 hours (typical)
Voltage	3.7 V

The following table includes the charger specifications.

Table 6. Patient connector charger specifications

Power supply	
Model	MENB1020A0500XXX power supply (Medtronic reorder number 249651)
Voltage in	100–240 VAC 0.5 A at 50–60 Hz
Voltage out	5 VDC 3 A
Electrical shock protection class	Class II
Intended duty	Continuous
USB cable	
Model	249702 USB cable
Voltage	5 V 0.8 A
Power	4 W
24970A charge cradle	
Model	24970A
Voltage	5 V 0.8 A
Power	4 W

The following table includes the patient connector physical specifications.

Table 7. Physical specifications

Physical dimension and weight	
Length Width Depth Weight	16.7 cm (6.6 in) 7.3 cm (2.9 in) 3.0 cm (1.2 in) 0.25 kg (0.55 lb)
Temperature limits	
Operating Storage Transport	10°C to 35°C (50°F to 95°F) 15°C to 30°C (59°F to 86°F) –30°C to 55°C (–22°F to 131°F)
Humidity limits	
Operating Storage Transport	8% to 80% 15% to 93% at 35°C (95°F) 15% to 93% at 35°C (95°F)
Altitude	
Maximum	3000 m

The following table includes the patient connector connectivity specifications.

Table 8. Connectivity specifications

Low-frequency inductive telemetry	
Frequency range	150 kHz to 200 kHz
Modulation	Frequency shift keying, phase shift keying, on-off keying
Output power	<20 dBµA/m @ 10 m
Range	10 cm
Quality of service	Monitored by the application. The application indicates when the quality of service is adequate.
Security	Low-frequency inductive telemetry is a short range wireless link (10 cm). Security is provided by proximity to the implantable device.

Table 8. Connectivity specifications (continued)

Bluetooth wireless technology 2.1 and 4.0	
Frequency range	2.4 GHz to 2.483 GHz
Modulation	Gaussian frequency shift keying
Output power	<10 mW EIRP
Range	Class 2, 10 m
Quality of service	Monitored by the application. The application indicates when the quality of service is adequate.
Security	Authentication required, encryption implemented per the Bluetooth protocol.

4.5 Expected service life and disposal of the patient connector

4.5.1 Expected service life

The patient connector, including the internal battery, has an expected service life of 5 years. If you notice decreased operational time between battery charges or that the battery no longer holds its charge, contact Medtronic to get a replacement patient connector.

4.5.2 Disposal of the patient connector

Return the patient connector to Medtronic for proper disposal. Contact Medtronic at the address or telephone number on the back cover for information on returning the patient connector.

5 Technical information

5.1 Essential performance characteristics

The patient connector has the following essential performance characteristics, as tested in compliance with IEC 60601-1 and IEC 60601-1-2:

The patient connector shall transmit accurate information between the implantable device and Medtronic apps. Inaccurate information could result in inappropriate medical or clinical treatment.

5.2 Electromagnetic compatibility declaration

The following list of accessories were included in the system, demonstrating compliance with the requirements of IEC 60601-1-2 2007 clauses 7 and 8:

Accessory	**Maximum length**
Model MENB1020A0500XXX Power Supply (Medtronic reorder number 249651)	2 m (approximately 6.5 ft)

Use of accessories other than what is specifically listed may result in increased emissions or decreased immunity of the patient connector.

The patient connector needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and used according to the EMC information provided in the accompanying documents.

The patient connector should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the patient connector should be observed to verify normal operation in the configuration in which it will be used.

The patient connector contains RF transmission and receiving capabilities. Consequently, it is possible that other equipment may interfere with the patient connector even if that other equipment complies with CISPR emission requirements. The following is a technical summary of the RF communication properties.

Transmitting and receiving:

- Frequency of operation: 150 kHz to 200 kHz, 2400 MHz to 2483.5 MHz
- Modulation characteristics: 18K0M1D or 74K4F1D, FHSS, DTS
- Field strength: Less than 30 dBµA/m @ 10 m, less than 10 mW EIRP

Guidance and manufacturer's declaration—electromagnetic emissions		
The patient connector is intended for use in the electromagnetic environment specified below. The customer or the user of the patient connector should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment—guidance**
RF emissions CISPR 11	Group 1	The RF emissions from the patient connector are very low and are unlikely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A (tested to Class B limits)	
Harmonic emissions IEC 61000-3-2	Class A	The patient connector 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 patient connector is intended for use in the electromagnetic environment specified below. The customer or the user of the patient connector should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11 (per IEC 60601-1-2 Ed. 3)	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the patient connector requires continued operation during power mains interruptions, it is recommended that the patient connector be powered from an uninterruptible power supply or a battery. **Note:** U_T is the AC mains voltage prior to application of the test level.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11 (per IEC 60601-1-2 Ed. 4)	100% dip for 0.5 cycle at 0° 100% dip for 0.5 cycle at 45° 100% dip for 0.5 cycle at 90° 100% dip for 0.5 cycle at 135° 100% dip for 0.5 cycle at 180° 100% dip for 0.5 cycle at 225° 100% dip for 0.5 cycle at 270° 100% dip for 0.5 cycle at 315° 100% dip for 1 cycle at 0° 30% dip for 25 cycles at 0° 100% dip for 250 cycles (5 s) at 0°	100% dip for 0.5 cycle at 0° 100% dip for 0.5 cycle at 45° 100% dip for 0.5 cycle at 90° 100% dip for 0.5 cycle at 135° 100% dip for 0.5 cycle at 180° 100% dip for 0.5 cycle at 225° 100% dip for 0.5 cycle at 270° 100% dip for 0.5 cycle at 315° 100% dip for 1 cycle at 0° 30% dip for 25 cycles at 0° 100% dip for 250 cycles (5 s) at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the patient connector requires continued operation during power mains interruptions, it is recommended that the patient connector be powered from an uninterruptible power supply or a battery. **Note:** U_T is the AC mains voltage prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration—electromagnetic immunity			
The patient connector is intended for use in the electromagnetic environment specified below. The customer or the user of the patient connector should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment—guidance**
Conducted RF IEC 61000-4-6	3 V_{RMS} (volts root-meansquare) 150 kHz to 80 MHz	10 V	Portable and mobile RF communications equipment should be used no closer to any part of the patient connector, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 0.35\sqrt{P}$
Conducted RF IEC 61000-4-6 (per IEC 60601-1-2 Ed. 4)	6 V_{RMS} (volts root-meansquare) ISM and Amateur radio bands between 150 kHz and 30 MHz	10 V_{RMS} (volts root-meansquare) ISM and Amateur radio bands between 150 kHz and 30 MHz	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 0.35\sqrt{P}$ for 80 MHz to 800 MHz $d = 0.70\sqrt{P}$ for 800 MHz to 2.5 GHz where 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range[a,b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF Proximity fields IEC 61000-4-3 (per IEC 60601-1-2 Ed. 4)	9 V/m to 28 V/m per Table 9.	9 V/m to 28 V/m per Table 9.	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

[a] 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, consider an electromagnetic site survey. If the measured field strength in the location in which the patient connector is used exceeds the applicable RF compliance level above, observe the patient connector to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the patient connector.

[b] Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the patient connector			
The patient connector is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the patient connector can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the patient connector as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter**		
	150 kHz to 80 MHz $d = 0.35\sqrt{P}$	**80 MHz to 800 MHz** $d = 0.35\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 0.70\sqrt{P}$
0.01 W	0.035 m	0.035 m	0.070 m
0.1 W	0.11 m	0.11 m	0.22 m
1 W	0.35 m	0.35 m	0.70 m
10 W	1.1 m	1.1 m	2.0 m
100 W	3.5 m	3.5 m	7.0 m
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 watts (W) according to the transmitter manufacturer.			

Recommended separation distances between portable and mobile RF communications equipment and the patient connector
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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M995887A001 A
2019-08-20

M995887A001