Medtronic

CareLink SmartSync™ 24970A

Technical Manual

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

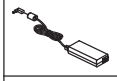
Contents

1 Introduction to 24970A

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 CareLink SmartSync Model 24970A base (referred to as the base) provides the analyzer and ECG hardware during device implant, invasive troubleshooting, and implanted device follow-up procedures.

The base includes the following features:

- Analyzer hardware and patient cable connections — Supports the electrical assessment of cardiac leads during implant.
- ECG cable connections — Collects live cardiac waveform data that you can view, measure, and record using the CareLink SmartSync Device Manager Application (referred to as the device manager app).
- USB cable connection — Charges the Model 24967 patient connector (referred to as the patient connector) and transmits data between the patient connector and the device manager app.
- Charge cradle — Charges the patient connector.
- Bluetooth® wireless technology — Method of communication with the device manager app[1].

The base is a component of the CareLink SmartSync device manager. The device manager also includes the following components:

- Patient connector — Interrogates and programs implantable devices.
- Device manager app — Primary interface of the device manager. From the device manager app, you can access the implantable device app and CareLink SmartSync PSA (Pacing System Analyzer) Application (referred to as the analyzer).

1.3 Intended use

The device manager is intended to be used to interrogate and program Medtronic implantable devices and conduct a cardiac lead analysis session during Medtronic heart device implant or invasive troubleshooting.

[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.

The base provides the analyzer and ECG hardware for use during device implant, invasive troubleshooting, and implanted device follow-up procedures. The base also provides a charge cradle and USB port to charge the patient connector. Additionally, the USB port is used to transmit data between the patient connector and the device manager app.

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

1.4 Contraindications

Do not use the base as an external pulse generator (EPG) outside of the implant procedure. In addition, the patient's age and medical condition may dictate the pacing modes and lead analyses appropriate for the patient.

1.5 Warnings

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

Battery replacement – The AA LR6 alkaline or FR6 lithium batteries that power the integrated analyzer hardware in the base must be replaced every 2 years or when they are depleted. Replace the batteries every 2 years or when the device manager app indicates that the battery charge is low. Use of a failed battery may reduce operating time and may cause user or patient injury.

Do not replace the battery while an analyzer session is in progress or when the base is connected to a patient. The battery connects to circuitry that connects directly to the patient and could provide a low-resistance path to the myocardium for electrostatic discharge (ESD) or leakage currents.

Changing polarity settings – Confirm the polarity capabilities of the cardiac lead system before changing polarity settings. Changing polarity settings could result in loss of pacing if the cardiac lead system is not set up to facilitate pacing in the polarity selected.

Cable connections – Connect all surgical cables, patient cables, and adaptors to the base before connecting the leads to the surgical or patient cable. Ensure proper atrial or ventricular lead connections are made to the surgical or patient cables. For more information on connecting surgical or patient cables to leads, refer to the instructions for use for the selected surgical or patient cable.

Connection of external devices – Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (for example, IEC 60950 for data processing equipment). All configurations must comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3rd edition of IEC 60601-1, respectively). Anyone connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Local laws take priority over the above 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 base if it has sustained impact damage. Internal components may be damaged or exposed. Use of damaged equipment may impact user or patient safety.

DDD pacing mode – Do not operate the analyzer in the DDD pacing mode when only the ventricular pacing lead is connected. Interference detected at the unconnected atrial input of the analyzer can result in false sensing and can drive the ventricular pacing rate to the Upper Rate setting.

Defibrillation or cardioversion – Whenever possible, for the safety of the patient, disconnect the base from the cardiac lead system before defibrillating or cardioverting.

Defibrillatory discharges may damage the analyzer hardware in the base when the base is connected to an indwelling cardiac lead system.

- The analyzer recovers normal operation within 2 seconds in the ventricle and within 6 seconds in the atrium for the defibrillation test pulse defined in IEC 60601-2-31.
- Test the analyzer after it is exposed to such charges.

Diagnostic ECG – Do not use the ECG display for diagnosis. Use a separate ECG device if diagnostic ECG capabilities are required.

Electric shock risk – Do not simultaneously touch the patient and any metal parts of the base (such as the USB port, power connector, or patient connector charging contacts) as voltage may be present. Application of voltage to the patient may impact user or patient safety.

Electrostatic discharge (ESD) – Discharge any static electricity from your body before touching the patient, the cable, the leads, or the base. The pacing leads provide a low-impedance pathway to the heart.

Electrosurgical units (cautery) – Do not use electrosurgical units within 15 cm (6 in) of the cardiac lead system. Electrosurgical units can cause tachyarrhythmias by inducing current on the leads.

Equipment compatibility – The device manager should be used only for the assessment of implanted cardiac lead systems for compatible implantable devices from Medtronic. Use of the device manager with implantable devices from other manufacturers may result in incompatible measurements. Medtronic does not accept responsibility for measurements taken using the device manager with implantable devices from other manufacturers.

Flammable anesthetic mixture – The device manager is not suited for use in the presence of a flammable anesthetic mixture.

Handling inserted leads – Do not touch the exposed metal of the connector ends of the leads or the exposed metal of the cable clips when handling inserted leads. Do not allow the exposed metal of the connector end of the leads or the exposed metal of the cable clips to unintentionally contact electrically conductive or wet surfaces.

High output and maximum sensitivity – Avoid using high output (high amplitude and wide pulse width) and maximum sensitivity simultaneously. This combination may result in oversensing intrinsic events, far-field sensing of intrinsic events, or sensing of paced events. The combination of high output and maximum sensitivity may include the following effects:

- Use of high atrial sensitivity (low numerical settings) may allow ventricular potentials to inappropriately inhibit or trigger the atrial output in the presence of large ventricular depolarization potentials or high output.
- High output and maximum sensitivity may result in opposite-chamber sensing of the pace output. The analyzer hardware in the base includes a safety pacing feature to prevent inappropriate inhibition of ventricular pacing due to far-field sensing.
- Use of high sensitivity in the ventricle may result in inappropriate inhibition of the ventricular output due to T-wave or myopotential sensing.

Importance of instructions for use – Before using the device manager, Medtronic recommends that you take the following actions:

- Read the device manager instructions for use.
- Read the instructions for use for the leads and implantable device.
- Carefully assess the patient condition and the implantable device system to determine the appropriate settings for tests and device programming.

Improper use of the device manager could result in erroneous programming, inadvertent pacing, improper operation of telemetry, and incorrect operation of measurement functions.

Line-powered equipment – During lead implantation and testing, use only battery-powered equipment (or line-powered equipment specifically designed for this purpose) to protect against fibrillation that may be caused by alternating currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment. An implanted lead forms a direct, low-resistance current pathway to the myocardium.

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

Modification of equipment – Do not modify any hardware or software component of the device manager. Modifications may reduce system effectiveness and impact user or patient safety. Modifying any component without the approval of Medtronic could void the user's authority to operate the equipment.

Prolonged power loss – Connect the patient to an external temporary pacemaker in the event of a prolonged power loss of more than 5 min.

Rapid atrial stimulation – Have defibrillation equipment readily available during rapid atrial stimulation. Use of high rates in the atrium can result in high-rate conduction to the ventricle. Accidental high-rate stimulation of the ventricles may result in ventricular tachycardia or fibrillation.

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

Temporary pacing – Do not leave the patient unattended when the analyzer hardware in the base provides external pacing. The analyzer is a diagnostic device. If prolonged external pacing is needed, move the patient to an external pulse generator.

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.

Autoclaving – Do not autoclave the device.

Base and power cord positioning – Position the base and its power cord so that the cord can be easily accessed and disconnected. Route all cords away from trafficked areas or secure them to prevent accidental tripping or kicking. The power cord is heavy and may pull the base from the table and cause damage to the base. If needed, secure the power cord to the table with tape, gauze, or a clamp. If it is necessary to disconnect the base from the AC power mains, the power cord is the power disconnect at the mains outlet.

Damaged equipment – Periodically, inspect the base, its case and connection ports, and all cords and cables for damage. If the base is cracked or if any of its connectors are damaged, contact your Medtronic representative. Replace the power supply and cord if they are damaged. Replace any accessory cables if the insulation or plug is damaged. Dispose of the damaged part according to local regulations or return the part to Medtronic.

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

Electrical and patient safety – The device manager is compliant with the requirements of IEC 60601-1 for electrical and patient safety.

Electrode quality – Use of high-quality silver/silver chloride (Ag/AgCl) electrodes can minimize the occurrence of small DC voltages that can block the ECG signal. Use electrodes that are fresh and from the same box. Prepare the patient's skin according to the directions provided with the electrodes.

Electromagnetic interference (EMI) – The base has been tested for compliance with industrial and medical EMI regulations. Any use outside the patient environment may result in malfunction.

Avoid excessive levels of EMI when working with analyzer functions, if possible. At high sensitivity settings and in the presence of excessive levels of interference, the analyzer may inhibit completely or revert to asynchronous pacing operation, pacing at the lower rate.

The following list includes sources of excessively strong EMI that may temporarily affect the operation of the analyzer hardware in the base:

- Electrosurgical equipment
- Diathermy equipment
- Radio frequency identification (RFID) equipment
- Some medical telemetry equipment (when operated within 1 m [about 3 feet] of the base)
- Communication transmitters such as cellular phones and two-way radios

Finger injury – To avoid a painful pinch, do not place fingers in the hinge area when lifting or closing the base lid.

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

Magnetic interference – The base includes a magnet under the charge cradle to secure the patient connector and ensure charging. The symbol on the cradle identifies the location of this magnet. Avoid placing devices or material that may be damaged by the magnetic field (such as magnetic media, watches, or other electronic devices) on top of the base.

Some tablets may be sensitive to magnetic interference. Keep strong magnetic sources (such as magnetic programming heads, patient magnets like the Model 9466 Tachy Patient Magnet, or other strong magnetic field generators) away from direct contact with the tablet when working with the device manager.

Note that the Model 24967 patient connector does not include a magnet and is not a source of magnetic interference.

Measurement function – The analyzer is designed to detect and measure pulse rate, AV interval and pulse width, and implantable device pace artifacts. The base takes these digital measurements with the assistance of optional skin electrodes that collect ECG signals. Medtronic makes no claims or warranties as to the effectiveness of this measurement function as a diagnostic tool to the physician.

Pediatric use – The device manager and its components have not been tested specifically for pediatric use.

Product and packaging labels and information – If labels or information appear to be missing from the product or packaging, contact your local Medtronic representative at the address and telephone number located on the back cover of this document.

Security – Maintain adequate physical security of the base to prevent unauthorized use that could lead to harm to patients. Bluetooth communication in the base is encrypted for security.

Single complex monitor – If the single complex monitor is selected on the analyzer, connect the patient to a separate ECG monitor in order to view a continuous ECG. The single complex monitor replaces the continuous waveform monitor on the display, eliminating your view of complete heart activity.

Use of wireless devices – The device manager 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 components of the device manager provide reasonable protection against harmful interference and provide EMC immunity in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation.

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

- Reorient or relocate the component and other devices.
- Ensure that the base is placed at the level of or on top of tables (and not below table level). Placing the base below table level can negatively impact communication and connectivity.
- Increase the separation between the component and other devices by at least 2 m (approximately 6 feet).
- Turn off any interfering equipment.

1.6.1 Environmental precautions

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

- Do not drop the base or handle it in a way that might physically damage it. The base may appear to work appropriately immediately after being dropped or mishandled, but operational damage may have occurred.
- Do not spill fluid on the base. Fluid incursion can damage the base.
- In an environment likely to cause electrostatic discharge (ESD), such as a carpeted floor, discharge any charge collected on your body before touching the base. Electrostatic discharge (ESD) may affect the base.
- Do not open the case of the base. Opening the case can make it susceptible to environmental factors and can expose the patient or user to a hazardous voltage or current.
- Do not expose the base to rapid temperature changes. Rapid temperature changes may affect proper operation. If the base is exposed to rapid temperature changes, allow the temperature to stabilize before using the base.
- Do not store or operate the base for prolonged periods of time in high humidity. Prolonged storage or operation of the base in high humidity may affect proper operation.
- Place the base on a table or other hard surface and position it to avoid contact with the patient; it is not intended to be used while supported by or in contact with the patient.

If the base is damaged, contact Medtronic at the telephone number on the back cover of this manual.

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

1.7 Regulatory compliance

1.7.1 US Federal Communications Commission (FCC)

This transmitter is authorized by rule under the Medical Device Radiocommunication Service (in part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150–406.000 MHz band in the Meteorological Aids (i.e., transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such stations, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Device Radiocommunication Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.

1.8 IT network, tablet, and data information

1.8.1 Required IT network characteristics and configuration

To use the device manager, your tablet must have both Bluetooth wireless technology and access to the Internet.

Bluetooth wireless technology

You must enable Bluetooth wireless technology on your tablet. The hardware components of the device manager communicate with the device manager app, installed on the tablet, through a Bluetooth connection.

Failure to provide Bluetooth communication access prevents the device manager components from communicating with each other and with implantable devices, which results in the following limitations:

- The device manager app is unable to establish a Bluetooth connection with the base, which prevents access to the analyzer and prevents the ability to view ECG waveforms.
- The device manager app is unable to establish a Bluetooth connection with the patient connector. The patient connector is used to interrogate and program the implantable cardiac device.

Internet

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

To set up or update the device manager, your network must have Internet access. When your network is configured to access the Internet, you can complete the following actions:

- Download and install the device manager app.
- Register the device manager app.
- Download and install software or updates necessary for the device manager to function.

Failure to provide information technology (IT) network access prevents the tablet from accessing the Internet, which results in the following limitations:

- Inability to install or update the device manager app and software components
- Inability to download firmware updates for the base and patient connector
- Inability to receive periodic updates and security enhancements that maintain the security of the device manager app
- Inability to process device manager component system logs
- Inability to authenticate the first connection between the device manager app and the base and patient connector

Note: Internet access is not required to export and print reports. However, failure to provide IT network access (for example, Wi-Fi or cellular) results in the inability to export and print reports using a wireless connection.

1.8.2 Supported tablets and technical specifications

To use the device manager, your tablet must meet certain requirements.

Note: The device manager app may not be compatible with the most current version of the tablet operating system.

For more information on the requirements, refer to the CareLink SmartSync Tablet Compatibility Technical Manual. To download or order the CareLink SmartSync Tablet Compatibility Technical Manual, go to medtronic.com/manuals.

1.8.3 Intended information flows

The implantable cardiac device lead data processes through the device manager components in the following order:

- Implantable cardiac device leads
- Base (via cables connected to the leads and to the base)
- Device manager app

The system logs process through the device manager components in the following order:

- Base
- Device manager app
- Internet
- Medtronic servers

During installation and updates, the device manager app sends your clinic registration and device manager credentials to Medtronic via the Internet for authentication. In response, Medtronic returns configuration files to the device manager app via the Internet to install or update the device manager app and component software as needed.

All information in transit is protected for security.

1.8.4 Precautions when connecting to your IT network

Connecting the device manager to an 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, updating or upgrading equipment, or changing network configurations, could introduce additional risks. Analyze, evaluate, report, and control any risks identified.

1.8.5 Data transmissions

The device manager uses Bluetooth wireless technology to allow communication between the base and device manager app. Data transmission rates over Bluetooth connections are highly dependent on the environment in which the base and tablet are used. Transmission rates may degrade based on electrical interference from other radio emitters, distance between the base and the tablet, and wireless or cellular settings on the tablet.

All data transmitted between the base and the device manager app is encrypted for data privacy. Data integrity is maintained through standard communication protocols for error detection.

1.8.6 Security

Data in the device manager app is protected by encryption. The device manager app is unable to provide data protection for data exported to another destination. Handle and store the data that you export from the device manager app in accordance with the security policy of your clinic.

To protect patient health information, the tablet must be secured with a passcode. The device manager is unable to function if a passcode is not defined. For more information on securing the tablet with a passcode, refer to the user instructions for your tablet.

To protect the device manager, Medtronic recommends that you implement the following security measures:

- Use the device manager app and device manager 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, firewalls, and wireless security policies, according to the policies of your IT department.

- When installing or updating the device manager app, if your tablet displays a message indicating that a security certificate is invalid, the installation or update process is unable to continue. For assistance, contact your local Medtronic representative.

The device manager app closes automatically when the device manager app detects a failure to maintain security.

If you suspect that a cybersecurity event has occurred, stop using the device manager app (if possible). 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

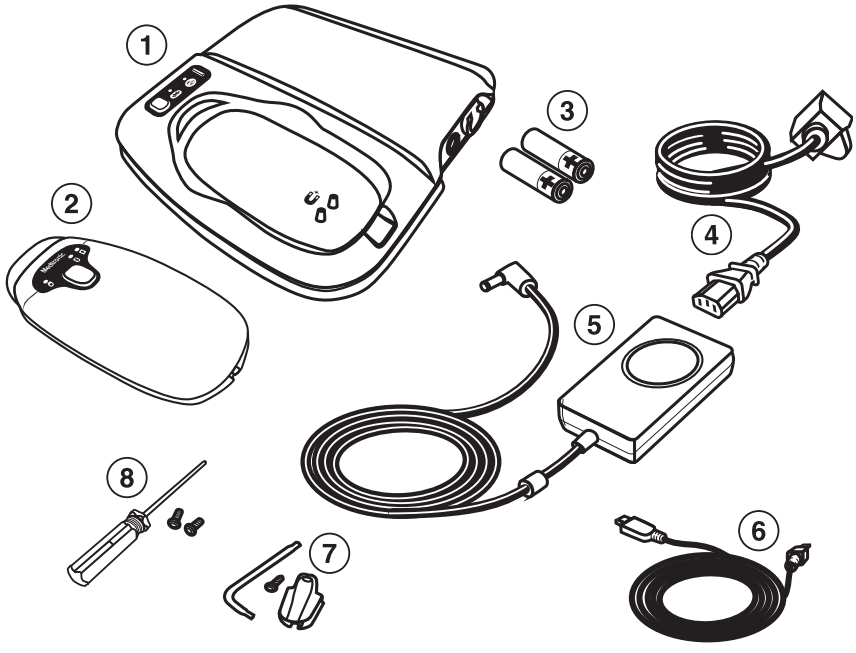
To set up the base, use the required and optional items from the base package.

The package contains the following items:

- 24970A base
- ME20A0540F03 power supply (Medtronic reorder number: 249701), 1.8 m (approximately 6 ft)
- AA LR6 alkaline batteries, quantity of 2
- 249702 USB cable, approximately 3 m (10 ft)
- #1 Phillips-head screwdriver and screws
- Literature

2.2 Components

Figure 1. System components



1 Base
2 Patient connector
3 Batteries
4 Power cord
5 Power supply
6 USB cable
7 Tether kit
8 Screwdriver and screws

Base – Encloses the analyzer hardware that connects to a patient's implantable cardiac device lead system. The analyzer assesses the electrical performance of the implantable cardiac device lead system. The base provides the communication link between the analyzer hardware and the device manager app for lead analysis. The base contains a radiofrequency (RF) transmitter and receiver.

Tablet (not included) – When the device manager app is open and connected to the base, provides the interface to assess the electrical performance and placement of implantable cardiac device lead systems.

Patient connector (not included) – Provides the communication link between the device manager app and the implantable device. The patient connector has a blue counter weight. The weight can be placed over the shoulder of the patient to hold the patient connector in place for hands-free use.

For more information about the patient connector, refer to its technical manual.

AA LR6 alkaline batteries – Provides power for the analyzer hardware within the base.

Power cord (not included) and power supply – Connects to an AC power outlet to power the base.

Tether kit (not included) – Semipermanently connects the USB cable to the patient connector. Contains a Torx wrench, screw, and cable retainer.

USB cable – Plugs into the base and patient connector to charge the patient connector and to transmit data between the patient connector and the device manager app.

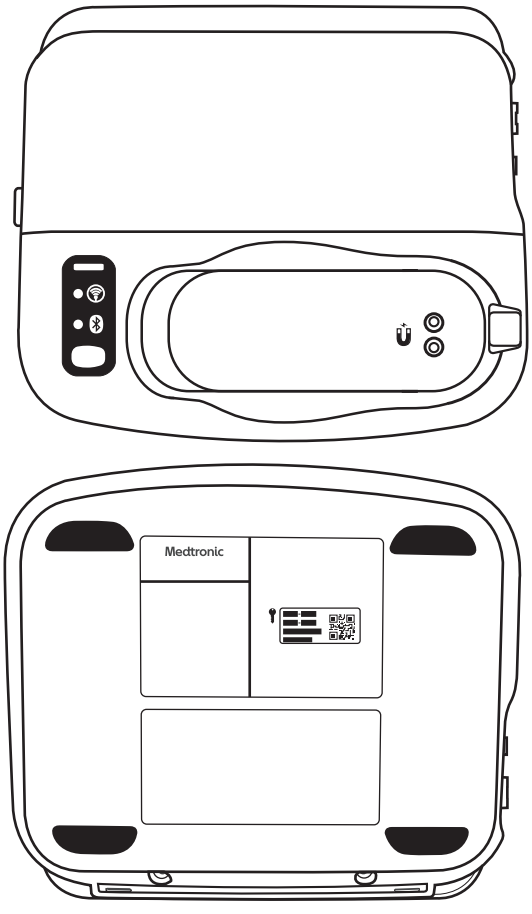
Screwdriver and screws – Removes the screws from the bottom of the base near the hinge to unfasten the battery access door. If necessary, you can replace the screws on the bottom of the base near the hinge using the 2 screws provided in the package.

Warning: Use only the components supplied by Medtronic with the base and patient connector. For example, use the base and patient connector with only the USB cable supplied by Medtronic. Use of unapproved components may reduce device effectiveness or impact user or patient safety.

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.

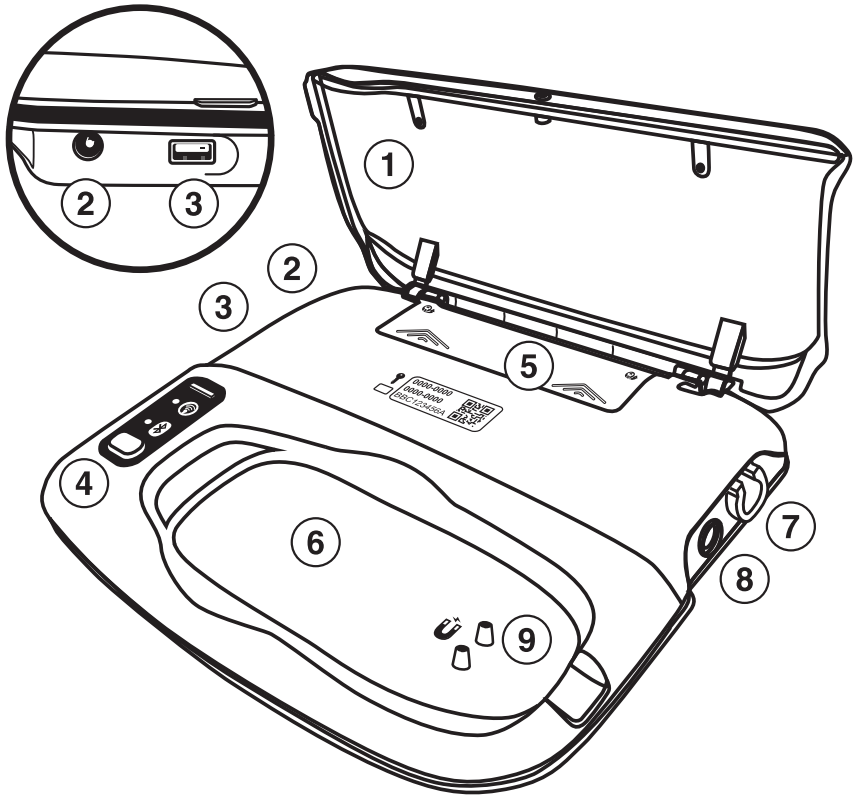
2.2.1 Top and bottom view

Figure 2. Base top and bottom view



2.2.2 Features and connection ports

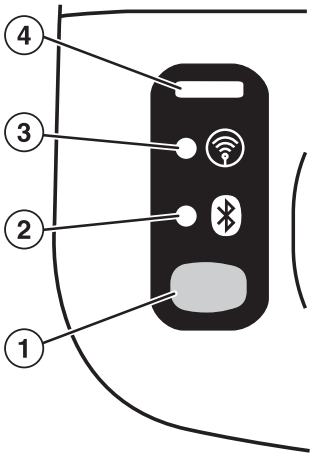
Figure 3. Base features and connection ports



1 Lid and tablet support
2 Power connection port
3 USB connection port, for use only with the 24967 patient connector and the USB cable supplied by Medtronic
4 Indicator lights and status panel
5 Battery access door
6 Charge cradle
7 Type CF surgical or patient cable connection port and analyzer green indicator light
8 Type BF ECG cable connection port
9 Charging contacts

2.2.3 Indicator lights and status panel

Figure 4. Base indicator lights and status panel



1 Button
2 Bluetooth connection status
3 Telemetry status
4 Power indicator

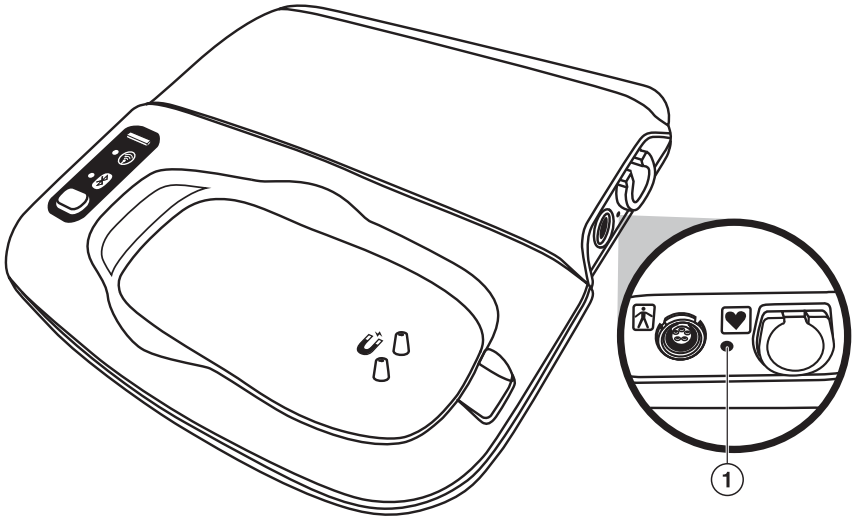
The grey button on the base allows you to complete the following actions:

- Identify the base during pairing to confirm the connection to the device manager app
- Turn on the Bluetooth wireless technology in the base if it has automatically turned off
- Reset the Bluetooth wireless technology in the base

Table 1. Base indicator lights

Icon	Indicator	Color	State	Description
	Bluetooth connection status	Blue	Slow flashing	The base is available for a connection with the device manager app.
		Blue	Rapid flashing	The connection between the base and the device manager app has been lost, and the base is attempting to reconnect to the device manager app. The base is not available for a connection with a different instance of the device manager app.
		Blue	Solid	The base is connected to the device manager app.
		None	Off	The base is disconnected from the device manager app.
	Telemetry status	Green	Solid	The base is communicating with an implantable device.
		None	Off	The base and implantable device are unable to communicate.
N/A	Power indicator	Green	Solid	The base is turned on.
		None	Off	The base is turned off.

Figure 5. Analyzer indicator light



1 Analyzer indicator light

The analyzer green indicator light flashes if the analyzer is programmed to pace and communication with the analyzer has been lost.

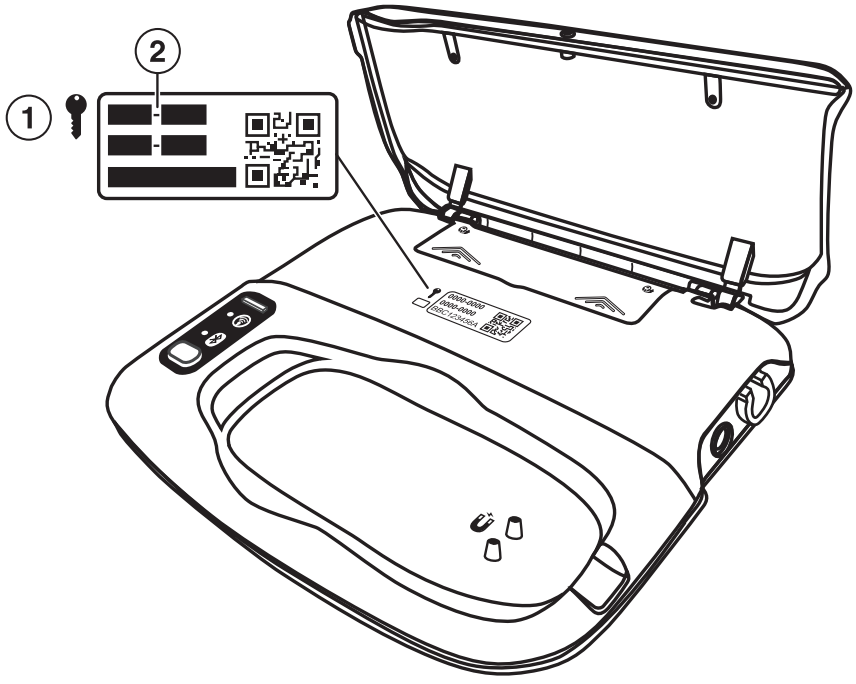
Note: To help you determine the connection status or identify issues, the device manager app displays additional indicators. For more information, refer to the device manager app help.

2.2.4 Security key

The base security key is on the base in the following locations:

- Under the lid of the base as shown in Figure 6
- On the bottom of the base as shown in Figure 2

Figure 6. Base security key



1 Security key symbol
2 Security key code

2.3 Compatible accessories

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

The following compatible accessories are available for the base:

- ME20A0540F03 power supply (Medtronic reorder number: 249701), 1.8 m (approximately 6 ft)
- 249705 AC power cord, 1.8 m (approximately 6 ft)
- 249702 USB cable, approximately 3 m (10 ft)
- 249672 tether kit
- 24967 patient connector

The following compatible cables and adaptors for the base are available in supported regions. Surgical and patient cables connect the base to cardiac leads for lead analysis. Adaptors allow surgical and patient cables to be connected to the base when their plugs are not compatible with the Type CF connection port on the base. Ground cables connect to the base and complete the electrical circuit when connected to unipolar implantable cardiac device leads.

Accessory	Length
2292 surgical cable	3.66 m (12 ft)
5103 A/V adaptor	N/A
5114 adaptor	N/A
5832 surgical cable	Approximately 3.5 m (12 ft)
5833S surgical cable	1.83 m (6 ft)
5833SL surgical cable	3.66 m (12 ft)
5473 ground cable	N/A
5436 analyzer patient cable	3.66 m (12 ft)

The following compatible ECG interface cables, ECG cables, ECG leads, and adaptors for the base are available in supported regions. ECG interface cables connect the base to ECG monitors for the display of live waveforms. ECG cables and leads connect the base to surface electrodes on the patient for the display of live waveforms. Adaptors allow ECG monitors with phono connectors to be connected to the base.

Accessory	Length
5437 ECG interface cable	6.4 m (21 ft)
5437A adaptor	N/A
2090EC ECG cable	Approximately 2.6 m (103 in)
2090ECL ECG cable	Approximately 5.5 m (215 in)
9790LA ECG leads	Approximately 1 m (40 in)
9790XLA ECG leads	Approximately 1 m (40 in)

To order any of these accessories, cables, or adaptors, contact your local Medtronic representative.

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

2.4 Setup

To download and register the device manager app, you must set up the base.

2.4.1 Installing or replacing the analyzer batteries

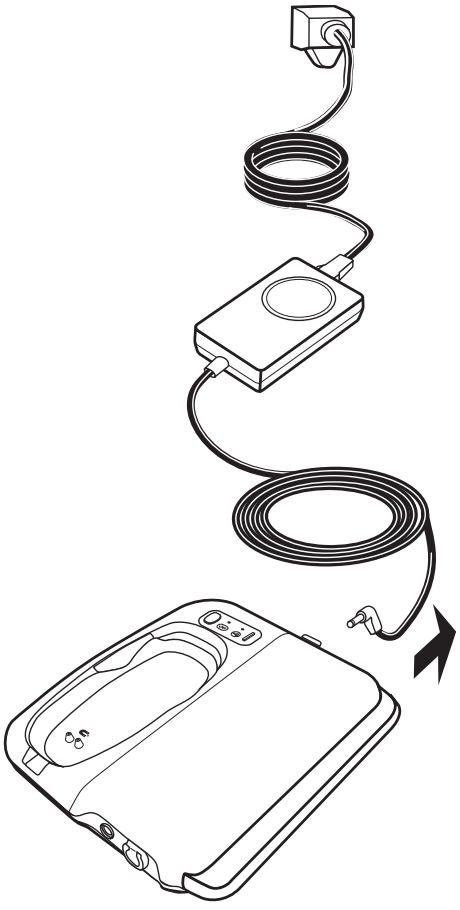
The analyzer hardware inside the base is powered by 2 AA LR6 alkaline or FR6 lithium batteries. Replace the batteries every 2 years or when prompted by the device manager app.

Cautions:

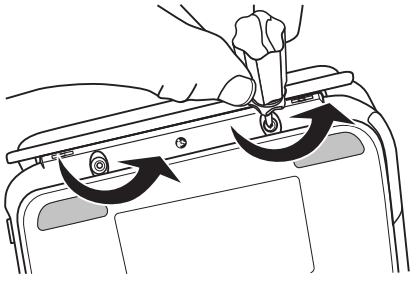
- Use only standard, nonrechargeable LR6 alkaline or FR6 lithium AA batteries in the base. The analyzer hardware is not designed to work with rechargeable batteries.
- Do not replace the battery while the base is connected to a patient or during an analyzer session. The battery connects to circuitry that connects directly to the patient and could provide a low-resistance path to the myocardium for electrostatic discharge (ESD) or leakage currents.
- Do not simultaneously touch the patient and any metal parts of the base (such as the USB connection port or patient connector charging contacts) as voltage may be present. Application of voltage to the patient may impact user or patient safety.

1. End the analyzer session and disconnect the base from the patient, if needed.

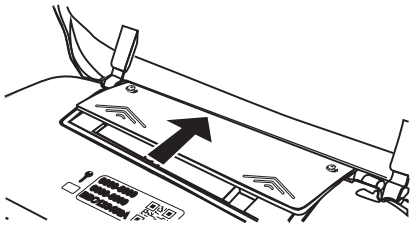
2. Unplug the power supply cord from the base, if needed.



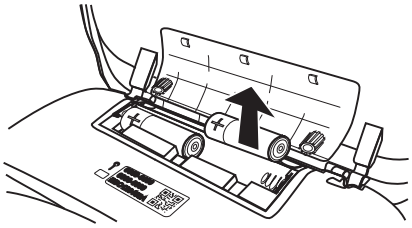
3. Using the supplied #1 Phillips-head screwdriver, remove the 2 screws from the bottom of the base near the hinge.



4. Lift the lid on top of the base.
5. To open the battery compartment, slide the battery access door backward and lift it away.

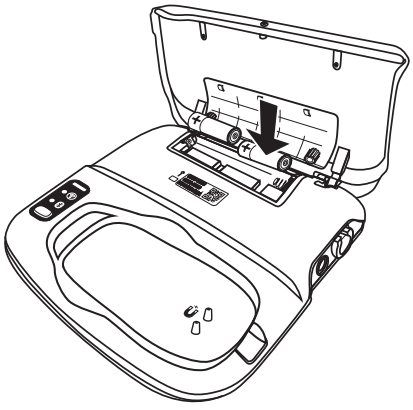


6. Remove the depleted batteries from the battery compartment.

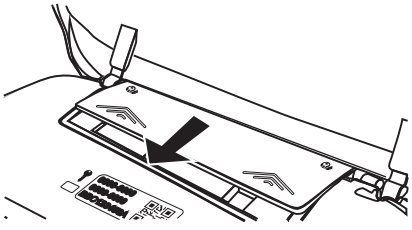


Note: Safely discard the depleted batteries according to the policies of your organization and local environmental requirements.

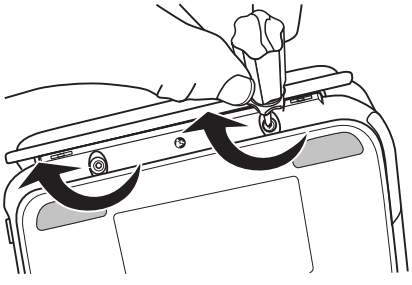
7. Install 2 new nonrechargeable AA LR6 alkaline or FR6 lithium batteries in the battery compartment. To install the batteries in the correct orientation for their polarity, refer to the diagram in the battery compartment.



8. To close the battery compartment, slide the battery access door forward until it locks into place.



9. Reinstall the screws on the bottom of the base and tighten them to secure and seal the battery access door.

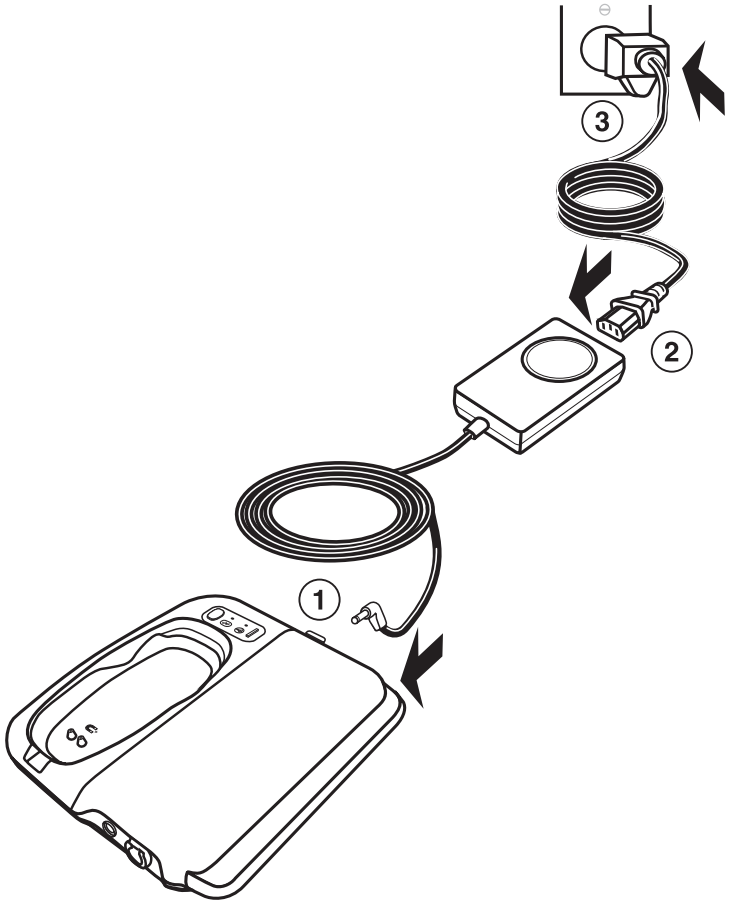


10. To turn on the base, plug the cord from the power supply back into the base.

2.4.2 Turning on the base

To turn on the base, connect the power supply to the base and to an AC power outlet (AC mains).

Warning: Use only the power supply that is supplied by Medtronic to provide power for the base.



1. Plug the cord from the power supply into the base.
2. Plug the power cord into the power supply.
3. Plug the power cord into the AC power outlet.

Notes:

- The base, power supply, and power cord form a medical electrical system when connected.
- The power supply requires a power cord that has a country-specific power supply plug. The power supply provides power for the base when the power cord is inserted into the power supply and plugged into the power outlet (AC mains).
- Position the base so that it can be easily disconnected or unplugged from the AC power outlet (AC mains).
- The third conductor in the power cord plug, if present, is a functional earth connection.

2.4.3 Downloading and registering the device manager 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 the device manager app.
3. Open the device manager app.
4. To complete the installation and register the device manager app, follow the instructions in the device manager app.
   During the registration process, the device manager app prompts you to select the serial number of the base. The base serial number is printed under the base lid and on the bottom of the base.
   The device manager app also prompts you to enter the base security key. The security key is printed in these locations on the base:
   - Under the lid
   - On the label on the bottom of the base

   To scan the security key, tap **SCAN QR**. From the QR code scanner that appears, position the QR code on the base within the scanner outline to scan and automatically enter the security key.

2.5 Connecting the base to the device manager app

To connect the base to the device manager app, the base power must be turned on, Bluetooth wireless technology in the base must be turned on, and the base must be within range of the tablet. The first time that you connect to the base, the tablet must also have an Internet connection to authenticate the base.

If the base and device manager app are unable to establish communication within 5 min after starting the connection process, the base disconnects its Bluetooth connection from the device manager app. If the base has not been connected to a device manager app for an extended time (default of 180 min), the base automatically turns off its Bluetooth wireless technology.

If the connection between the base and the device manager app is lost, the base and device manager app automatically attempt to re-establish communication. In certain situations when the connection is lost, the device manager app prompts you to press the grey button on the base to identify the base.

The device manager app saves the connection information for more than 1 base, but you can connect only 1 base to the device manager app at a time. Also, you are unable to connect the device manager app to a new base during an analyzer session.

2.5.1 Connecting the base

If you have previously paired or connected the base to the device manager app, you can connect the base quickly without reentering the security code and without needing an Internet connection:

1. Verify that the base power is turned on.
2. If the Bluetooth light on the base is off, press the grey button on the base to turn on its Bluetooth wireless technology.
3. Verify that the device manager app is open.
4. From the device manager app, tap **CONNECT** or **SELECT NEW** in the base connection area.
5. On the **Select An Accessory** window, tap the serial number of the base.
   Note: The base serial number is printed under the base lid and on the bottom of the base.
6. To confirm your connection to the base, press the grey button on the base.
7. Verify that the correct base is connected to the device manager app.
   Caution: Verify that the device manager app is connected to the correct base. Connecting to a different base can result in confusion during an analyzer session or the delay of a procedure.
   a. Tap **FLASH** in the base connection area.
      The lights on the connected base flash for several seconds.
   b. To see the lights on the connected base flash again for several seconds, tap **FLASH AGAIN**.
   c. To stop the flashing lights, press the grey button on the base.
   d. To return to the previous screen, tap <<.

2.5.2 Connecting a new base

Connect the device manager app to a new base when needed.

Note: You are unable to change device manager components during a patient session or analyzer session. If a session is in progress, you must end the session before you begin the following procedure.

1. Prepare the new base for the connection:
   a. Verify that the device manager app is open on the tablet.
   b. If the device manager app is connected to a base, tap **DISCONNECT** in the base connection area.
   c. Plug in the new base.
   d. Verify that the new base is disconnected from any previously connected device manager app.
   e. To turn on the Bluetooth wireless technology in the base, press the grey button on the base.
      When the base is available for a connection with the device manager app, the Bluetooth light on the base slowly flashes.
      When the base is turned on and within range, the device manager app automatically detects the base.
2. Initialize the connection:
   a. Ensure that the tablet is connected to the Internet.
   b. From the device manager app, tap **CONNECT** or **SELECT NEW** in the base connection area.
   c. On the **Select An Accessory** window, tap the serial number of the new base.
      Note: The base serial number is printed under the base lid and on the bottom of the base.
3. Enter the security key.
   Entering the security key ensures that communications are transmitted securely. To enter the security key, complete one of the following actions:
   - Tap **SCAN QR** and position the tablet camera over the QR code that is under the base lid.

The device manager app scans the QR code and automatically enters the security key.

- Enter the security key in the text fields. The security key is printed under the base lid and on the bottom of the base near the QR code.

4. To verify that the correct base is connected to the device manager app, tap **FLASH**.

   Caution: Verify that the device manager app is connected to the correct base. Connecting to a different base can result in confusion during an analyzer session or the delay of a procedure.

   The lights on the connected base flash for several seconds.

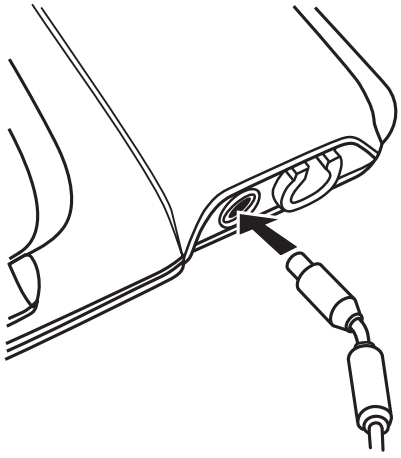
   Note: To see the lights on the connected base flash for several seconds, tap **FLASH AGAIN**.

   To return to the previous screen, tap <<.

2.6 Connecting the ECG cable

To use ECG during an analyzer session or patient session, connect the ECG cable to the base and to skin electrodes on the patient or to the ECG monitor:

1. Orient the cable plug so that the red dot or arrow faces upward.
2. Insert the cable plug into the Type BF ECG cable connection port on the side of the base.



3. Connect the other end of the cable to skin electrodes on the patient or to the ECG monitor.

   For more information on connecting the cable to the skin electrodes or ECG monitor, refer to the instructions for use for that cable. For more information on connecting cables to the Model 5437A adaptor, refer to the instructions for use for that adaptor.

2.7 Charging the patient connector battery

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

You can charge the patient connector in one of the following ways:

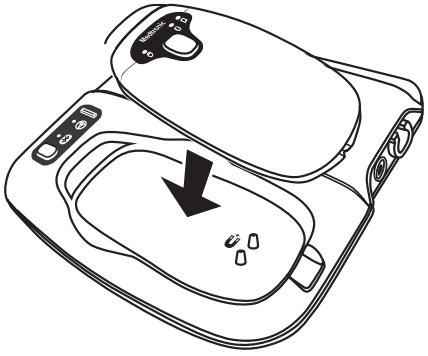
- Through the charge cradle on the base
- Through the USB cable

Alternatively, you can charge the patient connector using a power supply that is available separately. For more information, refer to the patient connector technical manual.

Note: You can use the patient connector while the patient connector is charging.

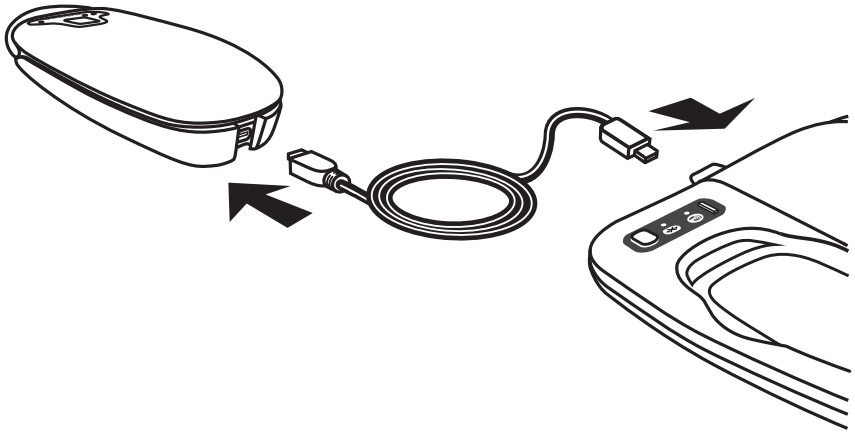
2.7.1 Charging using the base charge cradle

To charge the patient connector, turn on the base and place the patient connector on the base charge cradle. The magnet under the charge cradle secures the patient connector and ensures charging.



2.7.2 Charging using the USB cable

Charge the patient connector using the USB cable.



1. Turn on the base.
2. Open the cover located on the bottom edge of the patient connector.
3. Plug the mini-B connector of the USB cable into the patient connector.
4. Plug the type-A connector of the USB cable into the USB port on the side of the base.

Warnings:

- Use only the USB cable supplied by Medtronic with the patient connector and base. Use of an unapproved cable may damage equipment or impact user or patient safety.
- Use the USB port on the base and the USB cable supplied by Medtronic with the 24970A base and 24967 patient connector only. The USB connectivity on the base is not compatible with other equipment (such as a tablet or USB flash drive).

2.8 Troubleshooting potential interference

Interference from other electronic equipment can result in reduced quality of service and loss of communication between the base and the device manager app. To address possible interference caused by other electronic equipment, take one or more of the following measures:

- Reorient or relocate the electronic equipment.
- Move the electronic equipment farther away from the base and the tablet.
- Connect the electronic equipment to an outlet on a different circuit.
- Move the base and tablet closer together. For best results, place the base no farther than 2 m (approximately 6 ft) from the tablet to remain in range for Bluetooth communication.
- Consult Medtronic for help.

Note: To address possible interference between the patient connector and other electronic equipment, you can connect the patient connector to the base using the USB cable supplied by Medtronic. Data is transmitted between the patient connector and the device manager app through the USB connection to the base. For more information on troubleshooting potential interference, refer to the patient connector technical manual.

3 Conducting an analyzer session

3.1 Conducting an analyzer session

To assess the correct placement and the electrical performance of implantable cardiac device leads, use the analyzer.

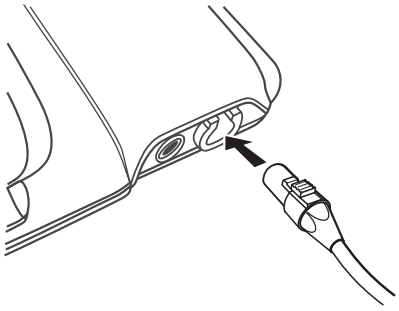
Warnings:

- Backup pacing and defibrillation should be readily available during procedures.
- Ensure proper atrial or ventricular lead connections are made to the surgical or patient cables. For more information on connecting surgical or patient cables to leads, refer to the instructions for use for that surgical or patient cable.

Caution: The analyzer provides pacing support during execution of tests. For pacing-dependent patients, ensure that the settings provide appropriate pacing before starting the test.

1. Verify the following:
   - The base power is turned on and connected to the device manager app
   - The device manager app is open
2. In the device manager app, tap **START SESSION** if necessary to return to the home screen.
3. Tap **LAUNCH ANALYZER**.

   The analyzer verifies the charge level of the analyzer batteries in the base. The device manager app displays a message if the batteries need to be replaced.
4. Connect the surgical or patient cable to the base:
   a. Orient the cable plug so that the latch faces upward.
   b. Insert the cable plug into the Type CF surgical or patient cable port on the side of the base until it clicks.

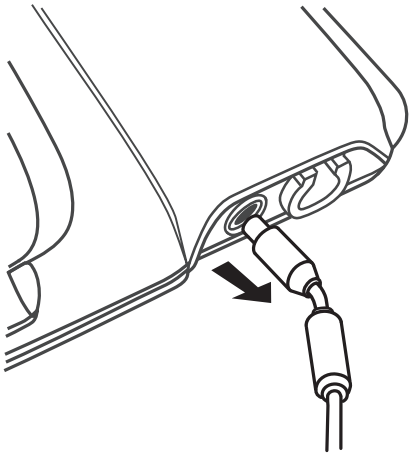


   c. Gently pull on the cable plug after inserting it to ensure that the connection is secure.
   d. Connect the other end of the cable to the cardiac device leads.

      For more information on connecting the cable to the cardiac device leads, refer to the instructions for use for that cable. For more information on connecting cables to the Model 5103 or Model 5104 adaptors, refer to the instructions for use for that adaptor.
5. Connect the ECG cable to the base. For more information, see Section 2.6.
6. From the analyzer session, use the tools on the **ANALYZER** menu to conduct the analyzer session.

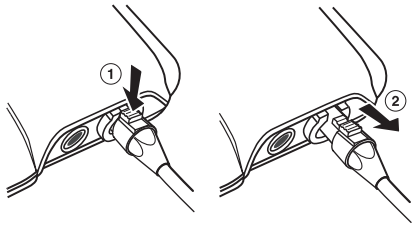
   For more information on these tools, refer to the analyzer help.
7. As you work, generate any reports needed for documentation. To view and export PDF report files, tap **SAVED REPORTS / DATA** in the menu.
8. When your measurements are complete, end the analyzer session:
   a. If the analyzer is in a pacing mode, turn it off. When you tap **END SESSION**, all pacing operations stop.
   b. Tap **END SESSION**.
   c. On the **END SESSION?** window, tap **END NOW** to end the session and return to the device manager app home screen.
9. Disconnect the ECG cable from the skin electrodes on the patient or from the ECG monitor.

10. Disconnect the ECG cable from the base by pulling the plug from the connection port.



11. Disconnect the surgical or patient cable from the cardiac device leads.
12. Disconnect the surgical or patient cable from the base as shown in the following figure.

Figure 7. Disconnecting the surgical or patient cable



1 Press down on the latch button on the cable plug.
2 Pull the cable plug straight out of the connection port on the base.

3.1.1 Measurement parameter values

All measurements and accuracies assume a noise-free environment.

Table 2. Measurement parameter values

Parameter	Range	Resolution	Accuracy	Notes
P-wave amplitude	0.125–25 mV	0.125 mV	±20%	Amplitude measurement specifications are based on a 40 ms sine^2 input signal.
R-wave amplitude	0.125–25 mV	0.125 mV	±20%	Amplitude measurement specifications are based on a 40 ms sine^2 input signal.
Impedance (Atrial)	<200; 209; 228; 247 … 2983; >3000 Ω	19 Ω	–20/+60%	Accuracy values represent absolute accuracy of an individual impedance measurement.
			±40 Ω (≤80 Ω range) when input impedance is <400 Ω ±10% (≤20% range) when input impedance is ≥400 Ω	Accuracy values represent repeatability of impedance measurements when repeat measurements are taken under the same conditions.

Table 2. Measurement parameter values (continued)

Parameter	Range	Resolution	Accuracy	Notes
Impedance (Ventricular)	<200; 209; 228; 247 … 2983; >3000 Ω	19 Ω	–20/+60%	Accuracy values represent absolute accuracy of an individual impedance measurement.
			±40 Ω (≤80 Ω range) when input impedance is <400 Ω ±10% (≤20% range) when input impedance is ≥400 Ω	Accuracy values represent repeatability of impedance measurements when repeat measurements are taken under the same conditions.

3.2 Delivering emergency VVI pacing

The device manager can deliver VVI pacing when needed in emergency situations. To do so, tap the **EMERGENCY** button at the top of the analyzer screen.

Warning: During a loss of communication in the system, emergency VVI pacing cannot be delivered. Use external pacing support or defibrillation equipment to provide appropriate therapy to the patient.

For more information about the **EMERGENCY** button and emergency VVI pacing parameters, refer to the analyzer help.

3.3 Troubleshooting

An error or an informational message is displayed on the analyzer screen if there is a problem with the base.

3.3.1 Loss of Bluetooth connection

The base uses Bluetooth wireless technology to connect to the device manager app installed on the tablet to send data. The Bluetooth light on the base indicates the status of the Bluetooth connection between the base and the device manager app.

Condition	Action	Result
The blue indicator light flashes rapidly.	To reconnect the base with the device manager app, take one of the following actions: • Check that Bluetooth is enabled on the tablet. Enable Bluetooth on the tablet if it is not enabled. • Move the tablet closer to the base and confirm that the blue indicator light on the base turns back on. For best results, place the base no farther than 2 m (approximately 6 ft) from the tablet to remain in range for Bluetooth communication. • Check that nothing is physically blocking the signal between the base and the tablet. **Note:** When the blue indicator light is flashing rapidly, the connection between the base and the device manager app has been lost, and the base is attempting to reconnect to the device manager app. To make the base available for use with a different instance of the device manager app, 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 2.5.1.	The blue indicator light is on. When the blue indicator light is on, the Bluetooth connection between the base and the device manager app is re-established.

3.3.2 Loss of communication with the analyzer

During an analyzer session, the light next to the Type CF connection port on the base flashes if the analyzer is programmed to pace and communication with the analyzer has been lost.

Condition	Action	Result
The green indicator light flashes, the analyzer is programmed to pace, and the **LOSS OF COMMUNICATION** message is displayed on the analyzer screen. Communication with the analyzer has been lost. When communication is lost, the analyzer discontinues any in-progress test and returns to programmed pacing values. The flashing light indicates that the analyzer is programmed to pace. The analyzer continues to operate for a length of time after communication is lost. If the surgical or patient cables are connected to implantable device leads, the analyzer continues to operate for 60 min. If the surgical or patient cables are not connected to leads, the analyzer continues to operate for 5 min.	To restore communication with the analyzer, take one of the following actions: • Verify that the base power is turned on and that Bluetooth is enabled on the tablet. Enable Bluetooth on the tablet if it is not enabled. • To improve connectivity, move the tablet closer to the base. For best results, place the tablet no farther than 2 m (approximately 6 ft) from the base to remain in range for Bluetooth communication. • Check that nothing is physically blocking the signal between the base and the tablet. To close the message and return to the analyzer test screen, tap **CLOSE**.	The green indicator light stops flashing and turns off. Communication between the base and the analyzer has been restored.

4 Maintaining the base

4.1 Cleaning the base

4.1.1 Cautions and notes for cleaning

Cautions:

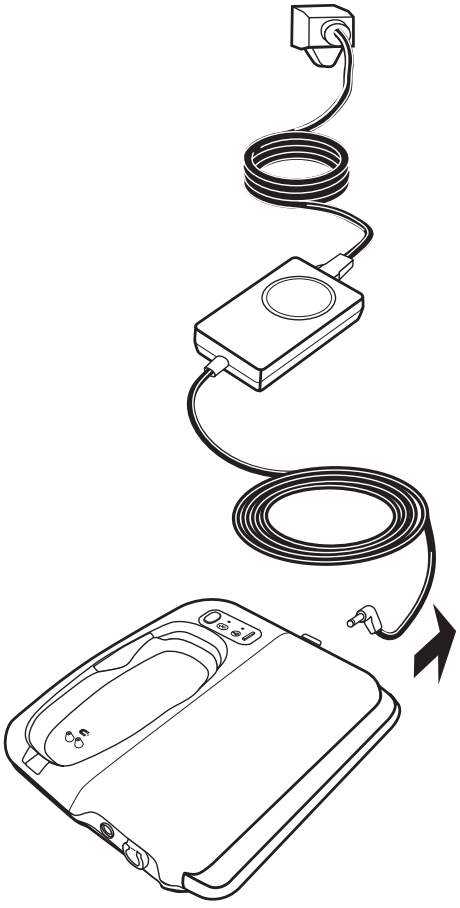
- Clean the base as needed per the policies of your organization. Use only the recommended methods to clean the base if soil accumulation is visible.
- Use only recommended cleaners on the base. Using other cleaners, solvents, or disinfectants (such as bleach, ethers, acetone, or chlorinated solvents) may damage the base plastic, circuitry, or metal components.
- Do not immerse the base in water or cleaning agents. Do not use automated machine washers. Severe damage to the base may occur.
- Do not sterilize the base by ethylene oxide, gamma radiation, or steam sterilization (autoclave). Severe damage to the device, housing, or labels may occur using these methods.

Notes:

- While cleaning the base, visually inspect its case, connection ports, power cord, and USB cable for damage. Contact your Medtronic representative if any components are damaged.
- The base is designed to withstand normal cleaning over its product life.

4.1.2 Preparing the base for cleaning

1. Disconnect the power cord from the power port on the side of the base.



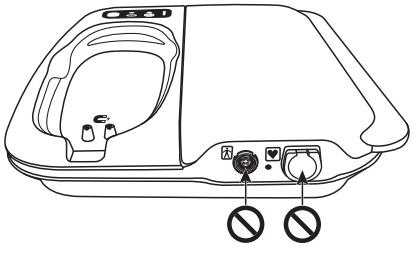
2. If a patient connector is on the base charge cradle, remove the patient connector from the charge cradle.
   Note: For information on cleaning and disinfecting the patient connector, refer to the patient connector technical manual.
3. Gather cleaning materials and prepare a clean working surface.
   Use one of the following cleaning 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

4.1.3 Cleaning the base

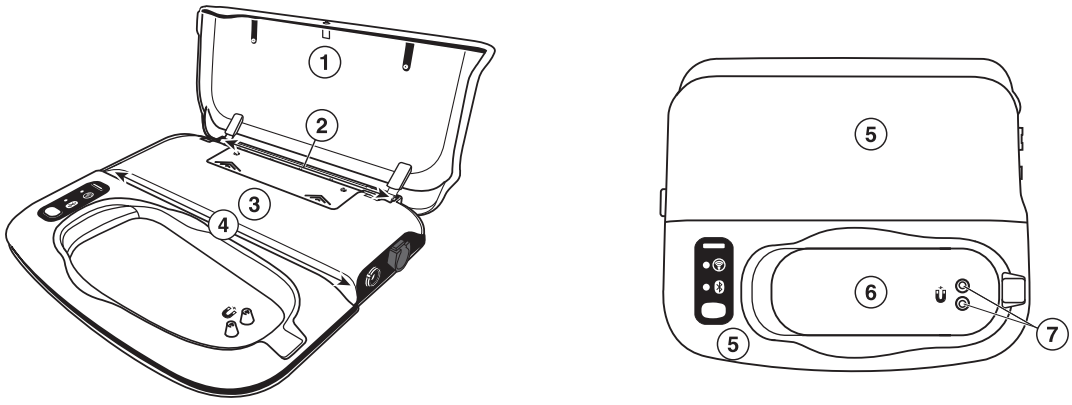
To remove soil and contaminants from the base, clean the base. To minimize drying of soil and contaminants, clean the base promptly after use.

1. To remove all visible soil, wipe all external surfaces of the base with the recommended materials listed in Section 4.1.2. Wipe only the exterior surfaces of the recessed connection ports; cleaning inside the port may damage it.



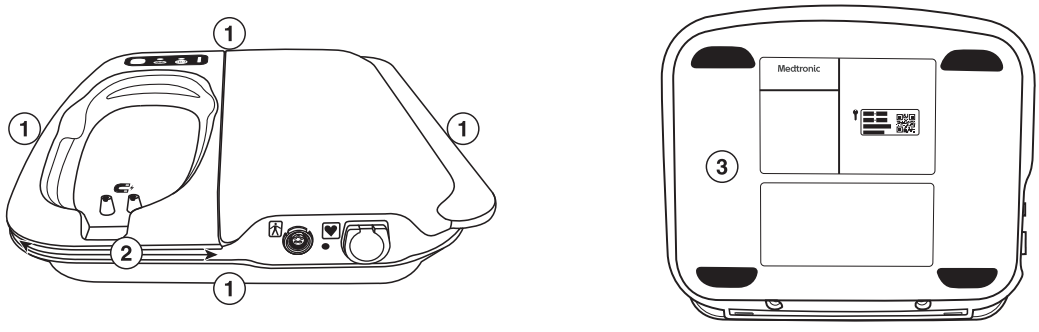
Ensure that you wipe all external surfaces that are shown in Figure 8 and Figure 9.

Figure 8.



1 Underside of the lid
2 Hinge channel area
3 Area underneath the lid
4 Tablet support notch
5 Top of the base
6 Charge cradle
7 Charging contacts

Figure 9.



1 Base sides
2 Groove
3 Bottom of the base

2. Allow the base to air dry.

When the base is dry, cleaning is complete.

4.1.4 Additional resources

For additional information about cleaning the base, contact Medtronic Instruments Technical Services:

- Phone: +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 Specifications

The base complies with the standards in the following table.

Table 3. Standards

Standards	
Electromagnetic compatibility (EMC)	EN / IEC 60601-1-2 Ed. 3 EN / IEC 60601-1-2 Ed. 4 EN 301 489-1 EN 301 489-17 EN 301 489-27
Radio	FCC CFR 47

Table 3. Standards (continued)

Patient safety	EN 60601-1, Class 2, continuous operation, Type BF applied part, Type CF applied part[a]
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.

[a] The ECG cable (Type BF), 24967 patient connector (Type BF), and surgical or patient cable (Type CF) are the only accessories that come into direct contact with the patient. The base itself is not intended to come into contact with the patient during normal use.

The following table includes base electrical specifications.

Table 4. Electrical specifications

AC power requirement	
Voltage	100–240 VAC nominal
Frequency	50/60 Hz nominal
Battery	
Type	AA alkaline (LR6) or lithium (FR6), nonrechargeable (quantity of 2)
Voltage	1.5 V each
Power supply	
Model	ME20A0540F03 power supply (Medtronic reorder number 249701)
Voltage in	100–240 VAC 0.5A at 50–60 Hz
Voltage out	5 VDC 3 A
USB cable	
Model	249702 USB cable
Voltage	5 V 0.8 A
Power	4 W
Charge cradle	
Model	24970A
Voltage	5 V 0.8 A
Power	4 W

The following table includes base physical specifications.

Table 5. Physical specifications

Physical dimension and weight	
Height	4.6 cm (1.8 in)
Width	24 cm (9.5 in)
Depth	20.8 cm (8.2 in)
Weight	0.91 kg (2.0 lbs)
Temperature limits	
Operating	10°C to 35°C (50°F to 95°F)
Storage	15°C to 30°C (59°F to 86°F)
Transport	-30°C to 55°C (-22°F to 131°F)
Humidity limits	
Operating	8% to 80%
Storage	15% to 93% at 35°C (95°F)
Transport	15% to 93% at 35°C (95°F)
Altitude	
Maximum	3000 m

The following table includes base connectivity specifications.

Table 6. Connectivity specifications

Conexus wireless telemetry	
Frequency range	402–405 MHz
Modulation	Frequency shift keying
Output power	<25 µW EIRP (<20 µW ERP)

Table 6. Connectivity specifications (continued)

Range	2–6 m
Quality of service	Monitored by applications that support Conexus wireless telemetry. The application indicates when quality of service is adequate.
Security	Conexus wireless communication is a short range wireless link (2–6 m). Security is provided by activation of the link by inductive telemetry (<20 cm distance), device ID required, and system level security controls.
Bluetooth 2.1 and 4.0	
Frequency range	2.4–2.483 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.

4.3 Expected service life and disposal of the base

4.3.1 Expected service life

The base has an expected service life of 5 years.

4.3.2 Disposal of the base

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

5 Technical information

5.1 Essential performance characteristics

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

- The device manager shall present accurate information to the physician. Inaccurate information would result in inappropriate medical or clinical treatment.
- The device manager, including any telemetry subsystems and Bluetooth communications systems, shall change only the intended parameters in the intended device when intended.
- The analyzer shall provide the intended pacing therapy. Loss of pacing therapy or insufficient pacing therapy may result in unacceptable risk, particularly for pacing-dependent patients.

5.2 Electromagnetic compatibility declaration

The following list of accessories are compliant with the requirements of IEC 60601-1-2.

Accessory	**Maximum length**
ME20A0540F03 power supply (Medtronic reorder number: 249701)	1.8 m (6 ft)
249705 AC power cord	1.8 m (6 ft)
249702 USB cable	3 m (10 ft)
24967 patient connector	N/A
2292 surgical cable	3.66 m (12 ft)
5832 surgical cable	3.5 m (12 ft)
5833S surgical cable	1.83 m (6 ft)
5833SL surgical cable	3.66 m (12 ft)
5436 analyzer patient cable	3.66 m (12 ft)
5437 ECG interface cable	6.4 m (21 ft)
2090EC ECG cable	2.6 m (103 in)
2090ECL ECG cable	5.5 m (215 in)
9790LA ECG leads	1 m (40 in)
9790XLA ECG leads	1 m (40 in)

Use of accessories other than what is specifically listed may result in increased emissions or decreased electromagnetic immunity of the 24970A base.

When you use the base, take special precautions regarding electromagnetic compatibility (EMC). The base must be installed and used according to the EMC information provided in the accompanying documents.

Avoid using the 24970A base next to or stacked with other equipment that is not part of the device manager. The device manager includes the base, patient connector, tablet, and accompanying accessories. If adjacent or stacked use is necessary, observe the 24970A base to verify normal operation in this configuration.

The 24970A base contains RF transmission and receiving capabilities. Consequently, it is possible that other equipment may interfere with the 24970A base even if that other equipment complies with CISPR emission requirements. The following is a technical summary of the RF communication properties:

Transmitting and receiving:

- Technology type: Conexus wireless telemetry, Bluetooth wireless technology
- Frequency of operation: 402 MHz to 405 MHz, 2.4 GHz to 2.483 GHz
- Modulation characteristics: Frequency shift keying, Gaussian frequency shift keying
- Field strength: less than 25 µW EIRP (less than 20 µW ERP), less than 10 mW EIRP

Guidance and manufacturer's declaration—electromagnetic emissions		
The 24970A base is intended for use in the electromagnetic environment specified below. The customer or the user of the 24970A base should assure 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 24970A base are very low and are not likely 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 24970A base is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplied buildings used for domestic purposes, provided the following warning is heeded: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as reorienting or relocating the 24970A base or shielding the location.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration—electromagnetic immunity		
The 24970A base is intended for use in the electromagnetic environment specified below. The customer or the user of the 24970A base should assure that it is used in such an environment.		
Immunity test	**IEC 60601-1-2 Ed. 4 test level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±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	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	

Guidance and manufacturer's declaration—electromagnetic immunity		
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<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 24970A base requires continued operation during power mains interruptions, it is recommended that the 24970A base 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	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°	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	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 24970A base is intended for use in the electromagnetic environment specified below. The customer or the user of the 24970A base 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 24970A base, 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[ab]. 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 24970A base is used exceeds the applicable RF compliance level above, observe the 24970A base to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the 24970A base.

[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 24970A base

The 24970A base is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 24970A base can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 24970A base 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.

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.

Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000

Medtronic USA, Inc.
Toll-free in the USA (24-hour technical consultation for physicians and medical professionals)
Bradycardia: +1 800 505 4636
Tachycardia: +1 800 723 4636

Technical manuals
www.medtronic.com/manuals

M995886A001 A
2019-08-20

M995886A001