



Medtronic

REVEAL LINQ™



Medical procedure and EMI precautions

Manual for Health Care Professionals

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CareLink, Medtronic, Medtronic CareLink, Reveal, Reveal LINQ, TUNA

1 Medical procedure and EMI precautions

1.1 Introduction

This manual is intended for physicians and other health care professionals who treat patients who have a Medtronic Reveal LINQ insertable cardiac monitor. To view this manual online or to download it, refer to the Medtronic Manual Library at www.medtronic.com/manuals.

The "Warnings, precautions, and guidance for clinicians performing medical procedures" section of this document is useful to health care professionals who perform medical procedures on patients with Medtronic insertable cardiac monitor systems and who consult with the patients' cardiologists. This section provides warnings, precautions, and guidance related to medical therapies and diagnostic procedures that may cause serious injury to a Reveal LINQ patient, interfere with a Reveal LINQ insertable cardiac monitor (device), or permanently damage the device.

The "Warnings, precautions, and guidance related to electromagnetic interference (EMI)" section of this document provides precautions and other information related to electromagnetic interference (EMI) that is helpful to patients in their daily living. Health care professionals can review the information with their patients and use it as a reference for post-procedure consultations.

For guidance on unusual or new medical procedures or potential EMI scenarios you are concerned about when treating Reveal LINQ patients that are not addressed in this manual, contact Medtronic as follows:

- In the United States, contact a Medtronic representative, Medtronic Technical Services at tshelp@Medtronic.com or at 1 800 505 4636, or Medtronic Patient Services at 1 800 551 5544.
- Outside the United States, contact a Medtronic representative.

Caution regarding concomitant device implants: – If the Reveal LINQ patient has an implanted pacemaker or defibrillator, the automatic detection of arrhythmia episodes in the Reveal LINQ device may be affected by the paced heart rhythm. To minimize the possibility of the Medtronic CareLink Programmer programming head and telemetry interfering with a pacemaker or defibrillator, do not hold the Patient Assistant activator or the programming head directly above an implanted device not manufactured by Medtronic while the Reveal LINQ programmer application is active.

1.2 Warnings, precautions, and guidance for clinicians performing medical procedures on Reveal LINQ patients

The influence of medical equipment on Reveal LINQ device performance varies considerably according to the type of unit and energy levels employed. In situations where risks are known, the patient's Reveal LINQ device health care provider should interrogate the device and save the device data before performing a medical procedure that may impact device data. After the medical procedure and at the patient's and clinician's earliest convenience, the patient's Reveal LINQ device health care provider should check device function.

The following subsections provide warnings, precautions, and guidance for health care providers that perform the specified medical procedures on Reveal LINQ patients.

1.2.1 Ablation (RF ablation or microwave ablation)

Ablation is a surgical technique in which radio frequency (RF) or microwave energy is used to destroy cells by creating heat. Ablation may temporarily affect Reveal LINQ device data collection, cause device electrical reset, or damage the device. To avoid such effects, observe the following precautions:

- The ablation equipment should not directly contact the Reveal LINQ device.
- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.

If an electrical reset occurs, the patient's Reveal LINQ device health care provider should reprogram device parameters, as needed.

1.2.2 Diagnostic radiology (x-rays, mammograms, CT scans, and fluoroscopy)

Normally, the accumulated dose from diagnostic radiology, such as from chest x-rays, is not sufficient to damage the Reveal LINQ device. If the device is not directly exposed to the radiation beam, no risk of interference with device function occurs. However, the following precautions apply to mammograms, CT scans (if the device is directly in a CT scan beam), and some forms of high-intensity fluoroscopy.

Mammography – Mammography involves compressing the breast between two plates in order to take various x-ray views. During the mammography procedure, manipulation or angular stress of the Reveal LINQ device between the plates could cause tissue trauma, vascular trauma, or pain, or affect device sensing. Before scheduling a mammogram, the cardiologist and mammography clinician should weigh the potential risks against the benefits and evaluate other diagnostic options. To minimize device manipulation or angular stress that a mammography procedure can cause, allow sufficient time for the Reveal LINQ device pocket and incision to heal before performing a mammography procedure.

CT Scan – A CT scan is a computerized process in which two-dimensional x-ray images are used to create a three-dimensional x-ray image. If the patient undergoes a CT scan procedure and the Reveal LINQ device is exposed to the CT scan beam, oversensing may occur for the duration of time that the device is in the beam.

Fluoroscopy – Fluoroscopy is an x-ray procedure that makes it possible to see internal organs in motion by producing a video image. Similar interference as described for CT scan may be observed for some forms of high-intensity fluoroscopy.

1.2.3 Diagnostic ultrasound

Diagnostic ultrasound is an imaging technique that is used to visualize muscles and internal organs, their size, structures, and motion as well as any pathological lesions. It also is used for fetal monitoring and to detect and measure blood flow. Diagnostic ultrasound, such as echocardiogram, poses no risk of electromagnetic interference.

1.2.4 Diathermy treatment (including therapeutic ultrasound)

Diathermy is a treatment that involves the therapeutic heating of body tissues. Diathermy treatments include high frequency, short wave, microwave, and therapeutic ultrasound. Except for therapeutic ultrasound, do not use diathermy treatments on Reveal LINQ patients. Diathermy treatments may result in serious injury or damage to the Reveal LINQ device. Therapeutic ultrasound is the use of ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body. Therapeutic ultrasound is acceptable if treatment is performed with a minimum separation distance of 15 cm (6 in) between the applicator and the Reveal LINQ device. If you have specific concerns about particular patient conditions and the use of diathermy, contact Medtronic.

1.2.5 Electrosurgery

Electrosurgery (including electrocautery, electrosurgical cautery, and Medtronic Advanced Energy surgical incision technology) is a process in which an electric probe is used to control bleeding, to cut tissue, or to remove unwanted tissue. Electrosurgery may temporarily affect Reveal LINQ device data collection, cause device electrical reset, or damage the device. To avoid such effects, observe the following precautions:

- The electrosurgery equipment should not directly contact the Reveal LINQ device.
- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.

If an electrical reset occurs, the patient's Reveal LINQ device health care provider should reprogram device parameters, as needed.

1.2.6 External defibrillation and cardioversion

External defibrillation and cardioversion are therapies that deliver an electrical shock to the heart to convert an abnormal heart rhythm to a normal rhythm. Medtronic cardiac devices are designed to withstand exposure to external defibrillation and cardioversion. While damage to a cardiac device from an external shock is rare, the probability increases with increased energy levels. Use the lowest clinically appropriate energy. Do not place defibrillation paddles directly over the Reveal LINQ device, and try to avoid having the device between the paddles when defibrillating. Defibrillation may lead to tissue damage, device reset, or loss of stored data. After defibrillation and at the patient's and clinician's earliest convenience, the Reveal LINQ device health care provider should check device function. If an electrical reset occurs during external defibrillation or cardioversion, the Reveal LINQ device health care provider also needs to reprogram device parameters.

1.2.7 Hyperbaric therapy (including hyperbaric oxygen therapy, or HBOT)

Hyperbaric therapy is the medical use of air or 100% oxygen at a higher pressure than atmospheric pressure. Hyperbaric therapies with pressures exceeding 4 ATA (approximately 30 m or 100 ft of seawater) may affect Reveal LINQ device function or cause device damage. To avoid or mitigate risks, do not expose Reveal LINQ patients to pressures exceeding 4 ATA.

1.2.8 Lithotripsy

Lithotripsy is a medical procedure that uses mechanical shock waves to break up kidney or gallbladder stones. Lithotripsy can permanently damage the Reveal LINQ device if it is at the focal point of the lithotripsy beam. If lithotripsy is required, keep the focal point of the lithotripsy beam at least 5 cm (2 in) from the device. If lithotripsy is performed closer than 5 cm (2 in) from the device, the Reveal LINQ device health care provider should check device function at the patient's and clinician's earliest convenience.

1.2.9 Magnetic resonance imaging (MRI)

An MRI is a type of medical imaging that uses magnetic fields to create an internal view of the body. Reveal LINQ is an MR Conditional device. If certain criteria are met and the warnings and precautions provided by Medtronic are followed, patients with an MR Conditional device are able to undergo an MRI scan. For details on performing MRI scans on a Reveal LINQ device patient, contact the patient's cardiologist or Medtronic to obtain the Reveal LINQ MRI Technical Manual or to get answers to your questions.

1.2.10 Radiation therapy

Exposing the Reveal LINQ device to therapeutic levels of ionizing radiation (such as that produced by cobalt machines or linear accelerators used for cancer treatment) may trigger inappropriate episode detection or corrupt the data stored in memory. After radiation therapy and at the patient's and clinician's earliest convenience, the Reveal LINQ device health care provider should check device function. Cumulative radiation levels above 5 Gy may permanently damage the device.

1.2.11 Radiotherapy

Radiotherapy is a cancer treatment that uses radiation to control cell growth. Exposing the Reveal LINQ device to direct or scattered neutrons may cause electrical reset of the device, errors in device function, errors in diagnostic data, or loss of diagnostic data. To help reduce the chance of electrical reset due to neutron exposure, deliver radiotherapy treatment using photon beam energies less than or equal to 10 MV. The use of conventional x-ray shielding during radiotherapy does not protect the device from the effects of the neutrons. If photon beam energies exceed 10 MV, Medtronic recommends that the Reveal LINQ device health care provider interrogate the device immediately after radiotherapy treatment. If an electrical reset occurs, the patient's Reveal LINQ device health care provider should reprogram device parameters, as needed. Electron beam treatments that do not result in neutron production will not cause electrical reset of the device.

1.2.12 Transcutaneous electrical nerve stimulators (TENS)

TENS therapy (including neuro muscular electrical stimulation or NMES) is a pain control technique that uses electrical impulses passed through the skin to stimulate nerves. Using TENS equipment can affect the data stored in the cardiac device.

1.2.13 Transurethral Needle Ablation (Medtronic TUNA® therapy)

Transurethral needle ablation is a surgical procedure used for benign prostatic hyperplasia (BPH) in which precisely focused, conducted radiofrequency energy is used to ablate prostate tissue. Reveal LINQ patients may conditionally undergo procedures that use the Medtronic TUNA system. To avoid affecting Reveal LINQ device function when performing the TUNA procedure, position the return electrode on the lower back or lower extremity at least 15 cm (6 in) away from the Reveal LINQ device.

1.3 Warnings, precautions, and guidance related to electromagnetic interference (EMI) for Reveal LINQ patients

The Reveal LINQ cardiac monitor is not affected by most household electrical items. However, the electromagnetic energy fields of certain electrical items may temporarily affect the cardiac monitor's ability to collect information about the patient's heart and can reduce the amount of data available for the clinic to analyze. By following simple guidelines included in this section, the patient may avoid data collection problems related to electrical interference. Any effects of electromagnetic energy fields on the heart monitor data will stop when the patient moves away from the source of the electromagnetic energy field.

The following information is also provided to the patient in the Reveal LINQ patient manual. The cardiology nurse or doctor may want to review this information with the Reveal LINQ patient. If you have any questions or concerns about EMI, contact a Medtronic representative.

1.3.1 General guidelines for patients

Area restrictions – Before entering an area where signs are posted prohibiting persons with an implanted cardiac device, such as a pacemaker, ICD, or cardiac monitor, consult with your doctor.

Proper grounding of electrical items – To avoid interference from electrical current that may leak from improperly grounded electrical items and pass through the body, observe the following precautions:

- Make sure that all electrical items are properly wired and grounded.
- Make sure that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

1.3.2 Wireless communication devices

Wireless communication devices include transmitters that can affect cardiac devices. When you use wireless communication devices, keep them at least 15 cm (6 in) away from your cardiac device. The following items are examples of such devices:

- Handheld cellular, mobile, or cordless telephones (wireless telephones); two-way pagers; personal digital assistants (PDAs); smartphones; and mobile email devices
- Wireless-enabled devices such as laptop, notebook, or tablet computers; network routers; MP3 players; e-readers; gaming consoles; televisions; DVD players; and headsets
- Remote keyless entry and remote car starter devices

Using wireless telephones – Cardiac devices have been tested with many types of wireless telephone technologies to ensure that they operate correctly while a wireless phone is in use. Keep a cardiac device at least 15 cm (6 in) away from the antenna of a handheld wireless telephone (for example, by holding the telephone to the ear farthest away from the cardiac device). Do not carry the telephone in a pocket over the device or in a shoulder bag near the device.

1.3.3 Household and hobby items with motors and other items that cause EMI

Household and hobby items that have motors or that generate electromagnetic energy fields could interfere with a cardiac device. Keep a cardiac device at least 15 cm (6 in) away from the following items:

- Handheld kitchen appliances, such as electric mixers
- Sewing machines and sergers
- Personal care items, such as corded handheld hair dryers, corded electric shavers, electric or ultrasonic toothbrushes (base charger), or back massagers
- Remote controller of radio-controlled toys
- Two-way walkie-talkies (less than 3 W)

The following sections describe some household and hobby items that require special precautions:

Induction cook tops – An induction cook top uses an alternating magnetic field to generate heat. Keep a cardiac device at least 60 cm (24 in) away from the heating zone when the induction cook top is turned on.

Electronic body fat scale – Using this type of scale can affect the data stored in the cardiac device.

UPS (uninterruptable power source) up to 200 amperes – Keep a cardiac device at least 30 cm (12 in) away from a UPS. If the UPS is operating by battery source, keep a cardiac device at least 45 cm (18 in) away.

Electronic pet fences or invisible fences – Keep a cardiac device at least 30 cm (12 in) away from the buried wire and the indoor antenna of electronic pet fences or invisible fences.

Home-use electric kilns – Keep a cardiac device at least 60 cm (24 in) away from home-use electric kilns.

Handheld metal detectors – Keep a cardiac device at least 60 cm (24 in) away from the detector end.

Boat motors – Keep a cardiac device at least 30 cm (12 in) away from electric trolling motors or gasoline-powered boat motors.

Portable electric generators up to 20 kW – Keep a cardiac device at least 30 cm (12 in) away from portable electric generators.

1.3.4 Home power tools

Most home power tools should not affect cardiac devices. Consider the following common-sense guidelines:

- Keep all equipment in good working order to avoid electrical shock.
- Be certain that plug-in tools are properly grounded (or double insulated). Using a ground fault interrupter outlet is a good safety measure (this inexpensive device prevents a sustained electrical shock).

Some home power tools could affect cardiac device operation. Consider the following guidelines to reduce the possibility of interference:

Electric yard and hand-held power tools (plug-in and cordless) – Keep a cardiac device at least 15 cm (6 in) away from such tools.

Soldering guns and demagnetizers – Keep a cardiac device at least 30 cm (12 in) away from these tools.

Gasoline-powered tools and gasoline-powered yard equipment – Keep a cardiac device at least 30 cm (12 in) away from components of the ignition system. Turn off the motor before making adjustments.

Car engine repair – Turn off car engines before making any adjustments. When the engine is running, keep a cardiac device at least 30 cm (12 in) away from components of the ignition system.

1.3.5 Industrial equipment

After recovering from the Reveal LINQ insertion procedure, you likely will be able to return to work, to school, or to your daily routine. However, if you will be using or working near high-voltage equipment, sources of high electrical current, magnetic fields, or other EMI sources that may affect device operation, consult with your doctor. You may need to avoid using, or working near, the following types of industrial equipment:

- Electric furnaces used in the manufacturing of steel
- Induction heating equipment and induction furnaces, such as kilns
- Industrial magnets or large magnets, such as those used in surface grinding and electromagnetic cranes
- Dielectric heaters used in industry to heat plastic and dry glue in furniture manufacturing
- Electric arc and resistance welding equipment
- Broadcasting antennas of AM, FM, shortwave radio, and TV stations
- Microwave transmitters. Note that microwave ovens are unlikely to affect cardiac devices
- Power plants, large generators, and transmission lines. Note that lower voltage distribution lines for homes and businesses are unlikely to affect cardiac devices.

1.3.6 Radio transmitters

Determining a safe distance between the antenna of a radio transmitter and a cardiac device depends on many factors such as transmitter power, frequency, and the antenna type. If the transmitter power is high or if the antenna cannot be directed away from a cardiac device, you may need to stay farther away from the antenna. Refer to the following guidelines for different types of radio transmitters:

Two-way radio transmitter (less than 3 W) – Keep a cardiac device at least 15 cm (6 in) away from the antenna.

Portable transmitter (3 to 15 W) – Keep a cardiac device at least 30 cm (12 in) away from the antenna.

Commercial and government vehicle-mounted transmitters (15 to 30 W) – Keep a cardiac device at least 60 cm (24 in) away from the antenna.

Other transmitters (125 to 250 W) – Keep a cardiac device at least 2.75 m (9 ft) away from the antenna. For transmission power levels higher than 250 W, contact a Medtronic representative for more information.

1.3.7 Security systems

When passing through security systems, follow these precautions:

Electronic antitheft systems, such as in a store or a library, and point-of-entry control systems, such as gates or readers that include radio frequency identification equipment – These systems should not affect a cardiac device, but, as a precaution, do not linger near or lean against such systems. Simply walk through these systems at a normal pace.

Airport, courthouse, and jail security systems – Given the short duration of security screening, it is unlikely that metal detectors (walk-through archways and handheld wands) and full body imaging scanners (also called millimeter wave scanners and three-dimensional imaging scanners) in airports, courthouses, and jails will affect a cardiac device. When encountering these security systems, follow these guidelines:

- Always carry your cardiac device ID card. If a cardiac device sets off a metal detector or security system, show your ID card to the security operator.
- Minimize the risk of temporary interference with your cardiac device while going through the security screening process by not touching metal surfaces around any screening equipment.
- Do not stop or linger in a walk-through archway; simply walk through the archway at a normal pace.
- If a handheld wand is used, ask the security operator not to hold it over or wave it back and forth over your cardiac device.
- If you have concerns about security screening methods, show your cardiac device ID card to the security operator, request alternative screening, and then follow the security operator's instructions.



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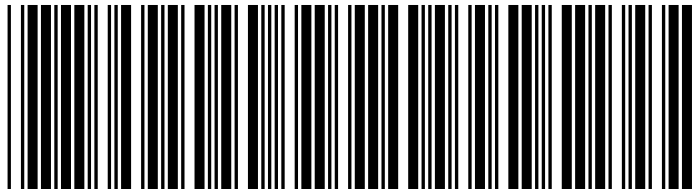
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