

EVOLUTION OF THE CARDIAC MONITOR

Cardiac monitors have been used for years to help physicians determine if patients are experiencing irregular heartbeats (arrhythmias) that are causing recurrent fainting, palpitations, unexplained stroke, or atrial fibrillation. Over time, these devices have grown smaller—and smarter—and the latest devices are revolutionizing the world of cardiac monitoring.

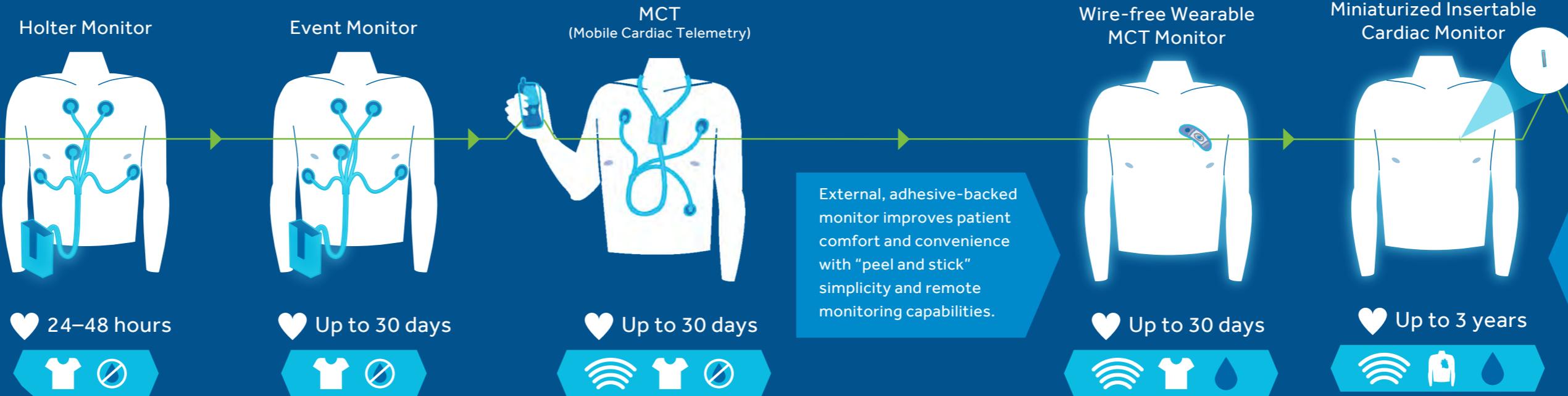


Reveal LINQ™
Insertable Cardiac Monitor

Cardiac monitors have evolved from large, wired, external devices to small and simple, yet powerful, systems that monitor a patient's heartbeat for up to three years,¹ without the bulk and inconvenience of traditional devices.

KEY

-  = Duration of use
-  = Not water resistant
-  = Water resistant
-  = Worn externally
-  = Worn internally
-  = Device automatically transmits data to physicians via wireless connectivity



External, adhesive-backed monitor improves patient comfort and convenience with "peel and stick" simplicity and remote monitoring capabilities.

Nearly invisible on most patients; approximately 1/3 the size of an AAA battery and safe for use in an MRI setting.

1. Reference the Reveal LINQ ICM Clinician Manual for usage parameters.

Brief Statement: REVEAL LINQ™ LNQ11 Insertable Cardiac Monitor and Patient Assistant

Indications

REVEAL LINQ™ LNQ11 Insertable Cardiac Monitor

The Reveal LINQ Insertable Cardiac Monitor is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases:

- patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain, that may suggest a cardiac arrhythmia.

This device has not been specifically tested for pediatric use.

Patient Assistant

The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal Insertable Cardiac Monitor to initiate recording of cardiac event data in the implanted device memory.

Contraindications

There are no known contraindications for the implant of the Reveal LINQ Insertable Cardiac Monitor. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

Warnings/Precautions

REVEAL LINQ™ LNQ11 Insertable Cardiac Monitor

Patients with the Reveal LINQ Insertable Cardiac Monitor should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the Medical procedure and EMI precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ MRI Technical Manual.

Patient Assistant

Operation of the Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device.

Potential Complications

Potential complications include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin.

See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult Medtronic's website at www.medtronic.com.

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

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physicians and medical professionals)

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