TruRhythm™ Detection
Inside Reveal LINQ™ ICM

NEW INTELLIGENCE INSIDE.

TruRhythm™ Algorithms

How new algorithms were developed
Medtronic analyzed over 50,000 real-world ECGs from the CareLink™ network data warehouse. This manual adjudication revealed that the most common false positives were for Brady, Pause, and Atrial Fibrillation (AF). Medtronic scientists and engineers enhanced the detection algorithms inside the Reveal LINQ™ ICM to significantly reduce false detects, while maintaining high relative sensitivity. A validation dataset of ECGs was then processed through the new TruRhythm™ algorithms to measure the reductions in false detects.

Brady and Pause algorithms
Medtronic employs a *smart filtering* algorithm with a new 2nd sensing filter that analyzes rhythms for possible undersensing of PVCs or small-amplitude R waves. This 2nd smart filter works with the current sensing scheme and identifies PVCs or small R waves to reject false Pause and Brady episodes, resulting in 95% less false Brady episodes, and 47% fewer false Pause episodes.

AF algorithm
A new self-learning algorithm learns a patient's daily rhythm, and adapts its detection threshold automatically based on the patient's history of P-wave evidence. This tailored detection improves AF discrimination in patients with sick sinus syndrome and PACs, resulting in 49% fewer false AF episodes.

5th generation AF detection algorithm
The new *self-learning* AF algorithm is the 5th generation innovation in AF detection in Reveal™ ICMs.

2009	1st Generation	**Reveal™ XT ICM** Industry's 1st AF detection algorithm based on R-wave variability
2011	2nd & 3rd Generations	**Reveal™ XT ICM with FullView™ Software** New AF discriminators for noise and ectopy rejection
2014	4th Generation	**Reveal LINQ™ ICM** New AF algorithm with P-Sense discriminator
2017	5th Generation	**TruRhythm™ Detection inside Reveal LINQ™** New Self-Learning AF algorithm significantly reduces false episodes

TruRhythm™ Performance

Significant reduction in false episodes, while maintaining relative sensitivity*†

	Reduction in false detects*,1	Relative sensitivity†,1
Brady	↓ 95%	98.3%
Pause	↓ 47%	99.4%
AF**	↓ 49%	99.1%

*Compared with the Reveal LINQ™ ICM without TruRhythm™ Detection
†Relative Sensitivity compared with the Reveal LINQ™ ICM without TruRhythm™ Detection
**In known AF patients

TruRhythm™ AF detection algorithm maintains high sensitivity, with improved accuracy and streamlined episodes*

	Reveal LINQ™ ICM *without* TruRhythm™ Detection	Reveal LINQ™ ICM *with* TruRhythm™ Detection1
AF Duration Sensitivity†,** (gross)	98.9%	98.9%
AF Duration Specificity** (gross)	99.5%	99.8%
AF Episode Sensitivity† (patient average)	99.8%	99.7%
AF Episode PPV (patient average)	90.4%	95.3%

* Compared with the Reveal LINQ™ ICM without TruRhythm™ Detection
† Relative Sensitivity compared with the Reveal LINQ™ ICM without TruRhythm™ Detection
** AF Duration Sensitivity and Specificity show AF Burden Accuracy

Medtronic

Reference

[1] TruRhythm™ Detection Algorithms. Medtronic data on file. 2017.

Indications, Safety, and Warnings

If you are located in the United States, please refer to the brief statement(s) below to review applicable indications, safety, and warning information. 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 1-763-514-4000 and/or consult the Medtronic website at medtronic.com.

If you are located outside the United States, see the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.com.

www.medtronic.com/manuals

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

Brief Statement

Reveal LINQ™ Insertable Cardiac Monitor

Indications: The Reveal LINQ insertable cardiac monitor (ICM) 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

The device has not been tested specifically for pediatric use.

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

Warnings/Precautions: Patients with the Reveal LINQ ICM 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.

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

See the device manuals 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 the Medtronic website at medtronic.com.

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

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