

References

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- ² Verma A, Champagne J, Sapp J, et al. Discerning the Incidence of Symptomatic and Asymptomatic Episodes of Atrial Fibrillation Before and After Catheter Ablation (DISCERN AF): a prospective, multicenter study. *JAMA Intern Med*. January 28, 2013;173(2):149-156.
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- ⁴ Kapa S, Epstein AE, Callans DJ, et al. Assessing arrhythmia burden after catheter ablation of atrial fibrillation using an implantable loop recorder: the ABACUS study. *J Cardiovasc Electrophysiol*. August 2013;24(8):875-881.
- ⁵ Sinha S. The Impact of Atrial Fibrillation: Paroxysmal Atrial Fibrillation: Diagnosis, Progression, and Stroke Risk. *MedPageToday*. Available at: <https://archive.li/DU7LI>. Accessed February 25, 2019.
- ⁶ Mascarenhas DA, Farooq MU, Ziegler PD, Kantharia BK. Role of insertable cardiac monitors in anticoagulation therapy in patients with atrial fibrillation at high risk of bleeding. *Europace*. June 2016;18(6):799-806.
- ⁷ Passman R, Bernstein RA. New Appraisal of Atrial Fibrillation Burden and Stroke Prevention. *Stroke*. February 2016;47(2):570-576.

Brief Statment

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.

- ⁸ Bakhai A, Darius H, De Caterina R, et al. Characteristics and outcomes of atrial fibrillation patients with or without specific symptoms. *Eur Heart J Qual Care Clin Outcomes*. October 1, 2016;2(4):299-305.
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- ¹⁰ Calkins H, Hindricks G, Cappato R, et al. 2017 HRS/EHRA/ECAS/APHS/SOLACE expert consensus statement on catheter and surgical ablation of atrial fibrillation. *Europace*. January 1, 2018;20(1):e1-e160.
- ¹¹ Pürerfellner H, Sanders P, Sarkar S, et al. Adapting detection sensitivity based on evidence of irregular sinus arrhythmia to improve atrial fibrillation detection in insertable cardiac monitors. *Europace*. November 1, 2018;20(FI_3):f321-f328.
- ¹² Passman RS, Rogers JD, Sarkar S, et al. Development and validation of a dual sensing scheme to improve accuracy of bradycardia and pause detection in an insertable cardiac monitor. *Heart Rhythm*. July 2017;14(7):1016-1023.
- ¹³ TruRhythm Detection Algorithms. Medtronic data on file, 2017.
- ¹⁴ Reference the Reveal LINQ ICM Clinician Manual for usage parameters.

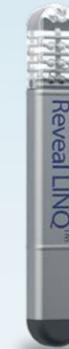
Potential Complications

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.

LONG-TERM MONITORING FOR AF MANAGEMENT



Reveal LINQ™
Insertable Cardiac Monitoring System



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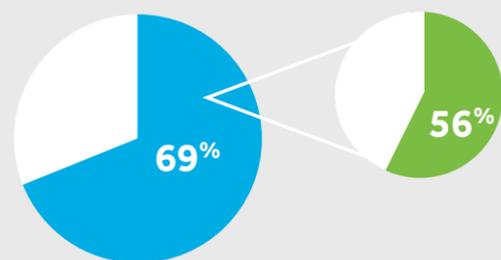
Medtronic

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CONTINUOUS CARDIAC MONITORING FOR YOUR AF PATIENTS

Build a diagnostic picture by continuously monitoring AF burden, heart rate variability, and daily activity with Reveal LINQ insertable cardiac monitor (ICM).

Reveal LINQ ICM provides physicians with **longitudinal data** to objectively determine both asymptomatic and symptomatic AF. This data results in the measure of true AF burden and accurate characterization of the AF type to effectively guide therapy decisions.^{1,2}



69%

of patients had at least one AF recurrence³

56%

of the recurrent AF being asymptomatic²

Based on clinical evidence.

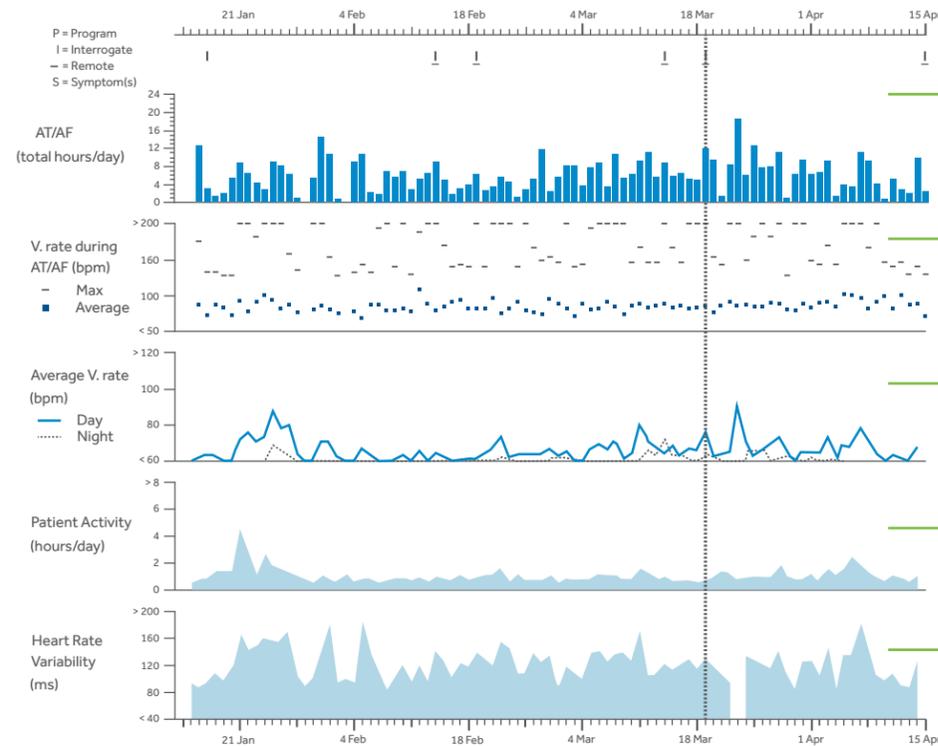
CONTINUOUS
CARDIAC MONITORING
LEADS TO MORE
ACTIONABLE EVENTS THAN
CONVENTIONAL MONITORING.⁴

Actual size



DATA-DRIVEN DECISIONS

Cardiac Compass™ report — 90-day view



AT/AF total time per day

This trend data is based on a count of 2-minute periods when an AT/AF episode is detected or in progress.

Ventricular rate during AT/AF

The daily average ventricular rate is derived from the number of ventricular beats during AT/AF episodes and the total time in AT/AF for that day.

Average ventricular rate

The average day and night heart rates are derived from the sum and number of R-R intervals during the periods defined as "day" and "night."

Patient activity

The sum of patient activity in hours per day

Heart rate variability

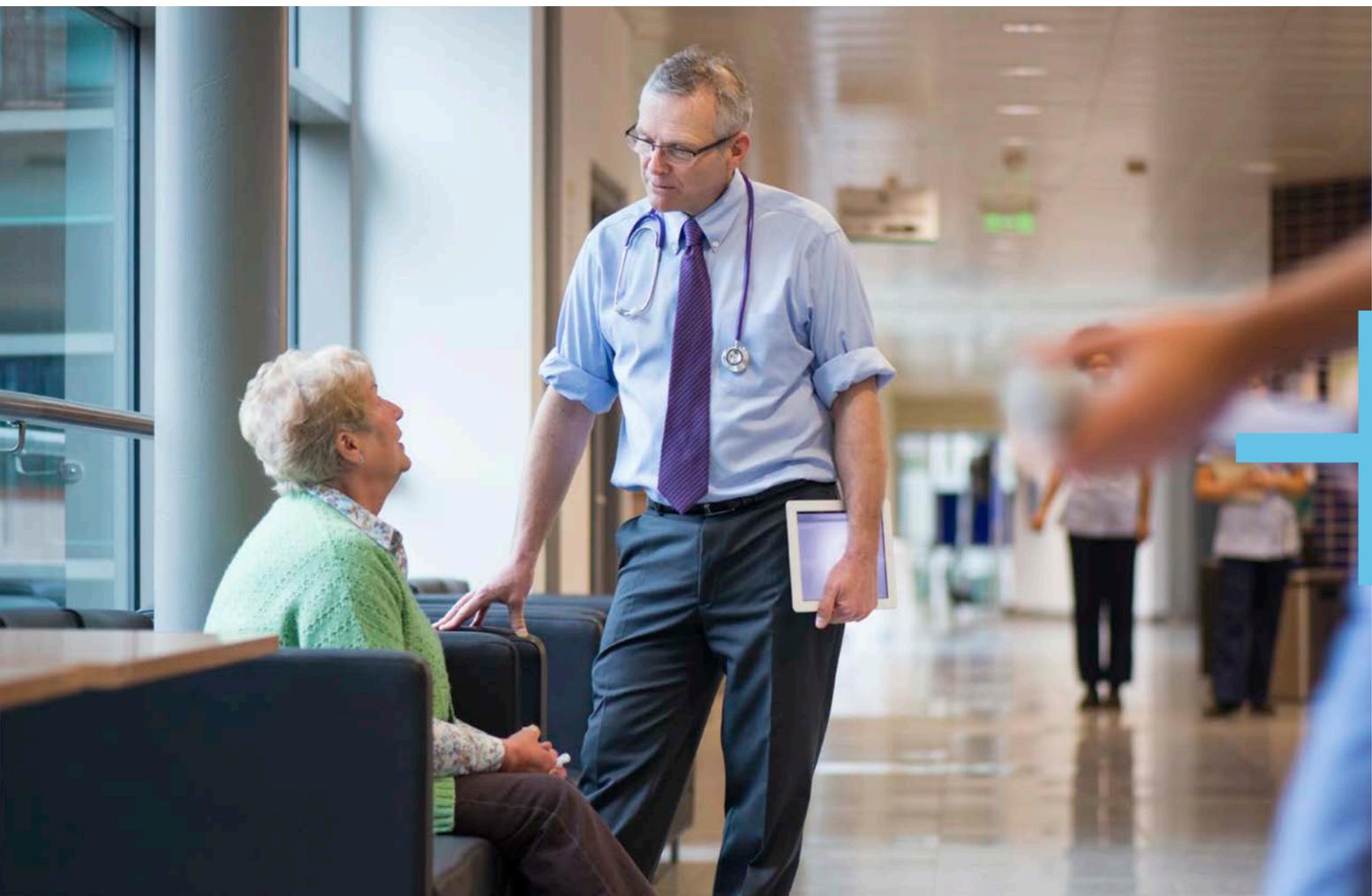
Median ventricular interval calculated every 5 minutes.

CareAlert™ notifications

Allow for customization by clinic and/or individual patient

- AF of any duration
- AF burden
- Ventricular rate
- Symptom + Auto Detect
- Ventricular rate during AF burden

Medtronic CareAlert™ notifications are not intended to be used as the sole basis for making decisions about patient medical care.



Reveal LINQ ICM allows physicians to continually monitor **the ongoing change in AF burden** so that treatment can be initiated or changed on a timely basis.⁵⁻⁷

ARRHYTHMIA MANAGEMENT ALLOWS FOR:



- Case planning guidance
- Symptom-rhythm correlation
- Assessment of drug therapy
- Objective measurement of AF burden
- Determination of therapy success (e.g., post-AF ablation cardioversion)

ARE YOU MONITORING HIGH-RISK PATIENTS LONG ENOUGH?

69%

of patients had at least one AF recurrence³

3X

increase in asymptomatic episodes post-ablation²

56%

of recurrent AF is asymptomatic²

Patients with asymptomatic episodes are at equal risk for stroke as symptomatic patients⁸

HRS AF ABLATION GUIDELINES:

- Prior to undergoing a catheter ablation procedure, it is important to **confirm that a patient's symptoms result from AF** and to determine whether a patient has **paroxysmal or persistent AF**. This is of importance as the ablation technique, procedure outcome, and anticoagulation strategies employed ... may be impacted by the **accurate characterization of the AF type and burden.**⁹
- Patients in whom discontinuation of systemic anticoagulation is being considered should consider undergoing **continuous ECG monitoring** to screen for asymptomatic AF/AFL/AT.¹⁰

INDUSTRY-LEADING TRURHYTHM™ DETECTION

Our newest detection algorithms streamline episode review without sacrificing sensitivity.

Exclusive smart detection algorithms that streamline data



INTELLIGENT

Smart filtering algorithm improves detection accuracy for Brady & Pause.



ACTIONABLE

Streamlined episodes & report updates simplify data review.



EXCLUSIVE ALGORITHMS

significantly reduce false positives while preserving sensitivity.^{11,12}



99.7%

Highest published AF detection accuracy on the market streamlines data review¹³

3 YEARS¹⁴

Up to 3-year longevity for long-term monitoring

MRI CONDITIONAL¹⁴

Safe for MRI at 1.5 and 3.0T even on the same day of insertion*

*Reveal LINQ has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Please see the Reveal™ ICM clinician manual or MRI technical manual for more details.