References

[1] Krahn AD, Klein GJ, Yee R, Norris C. Final results from a pilot study with an implantable loop recorder to determine the etiology of syncope in patients with negative noninvasive and invasive testing. *Am J Cardiol.* July 1, 1998;82(1):117-119.

[2] Krahn AD, Klein GJ, Yee R, Takle-Newhouse T, Norris C. Use of an extended monitoring strategy in patients with problematic syncope. Reveal Investigators. *Circulation.* January 26, 1999;99(3):406-410.

[3] Krahn AD, Klein GJ, Yee R, Hoch JS, Skanes AC. Cost implications of testing strategy in patients with syncope: randomized assessment of syncope trial. *JACC.* August 6, 2003;42(3):495-501.

[4] Kapoor WN. Evaluation and outcome of patients with syncope. *Medicine (Baltimore).* May 1990;69(3):160-175.

[5] Kapoor WN. Evaluation and management of the patient with syncope. *JAMA.* November 11, 1992;268(18):2553-2560.

[6] Linzer M, Yang EH, Estes NA III, Wang P, Vorperian VR, Kapoor WN. Diagnosing syncope. Part 2: Unexplained syncope. Clinical Efficacy Assessment Project of the American College of Physicians. *Ann Intern Med.* July 1, 1997;127(1):76-86.

* Accurate = true daily burden > 10 minutes: AF burden accurate in 92% of patients. True daily burden ≤ 10 minutes: absence of AF appropriately detected in 96% of patients.

** Reveal XT has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Please see Reveal XT clinician manual for more details.

Brief Statement

Indications

9529 Reveal XT™ Insertable Cardiac Monitor

The Reveal XT 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

9539 Reveal XT Patient Assistant

The Reveal XT Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates one or more of the data management features in the Reveal Insertable Cardiac Monitor:

- To verify whether the implanted device has detected a suspected arrhythmia or device related event
- To initiate recording of cardiac event data in the implanted device memory

Contraindications

There are no known contraindications for the implant of the Reveal XT 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

9529 Reveal XT Insertable Cardiac Monitor

Patients with the Reveal XT 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. MRI scans should be performed only in a specified MR environment under specified conditions as described in the device manual.

9539 Reveal XT Patient Assistant

Operation of the Model 9539 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.

www.medtronic.com

World Headquarters
Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Medtronic USA, Inc.
Toll-free: 1 (800) 328-2518
(24-hour technical support for physicians and medical professionals)

Medtronic

Reveal XT™

INSERTABLE CARDIAC MONITOR

Providing Comprehensive Arrhythmia Monitoring with AF Detection and Diagnostic Data

Medtronic

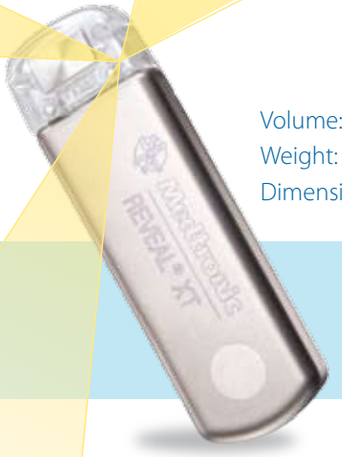
Always on Watch

Reveal XT™ Insertable Cardiac Monitor (ICM) captures the ECG you need to make informed decisions about your syncope patients and those who experience transient symptoms that may suggest a cardiac arrhythmia.† Due to the complexity in diagnosing these patients, it's important to use the monitoring option that can provide clear information. With continuous ECG monitoring for up to three years, Reveal XT overcomes the limitations commonly found with other testing options.

Compare Diagnostic Yields in Unexplained Syncope Patients

TEST/PROCEDURE	YIELD*
ECG	2-11%[1]
Holter Monitoring	2%[2]
External Loop Recorder	20%[3]
Reveal XT ICM	**43-88%[1-3]**
Tilt Table Test**	11-87%[4,5]
EP Study** without SHD***	11%[6]
EP Study** with SHD***	49%[4]

* Based on mean diagnosis time of 5.1 months[2]
** Provocative test
*** SHD structural or organic heart disease



Volume: 9 cc
Weight: 15 g
Dimensions: 62 x 19 x 8 mm

Actual Size

† For more information regarding reimbursement, please contact your local Medtronic representative. In the United States, contractors have established Medicare coverage of Reveal XT implants for patients diagnosed with unexplained fainting. Coverage to monitor patients with diagnoses other than unexplained syncope has not been addressed by Medicare contractors. Providers with questions should contact their contractor.

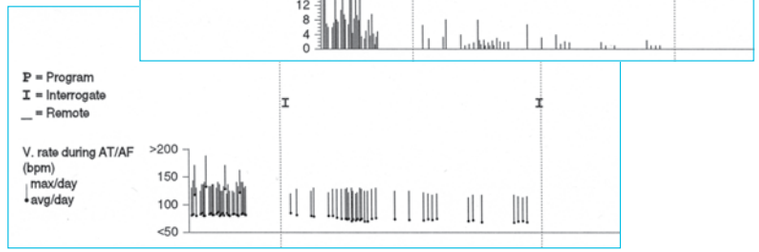
Providing Comprehensive
Arrhythmia Monitoring

Advanced Auto Detection Algorithms

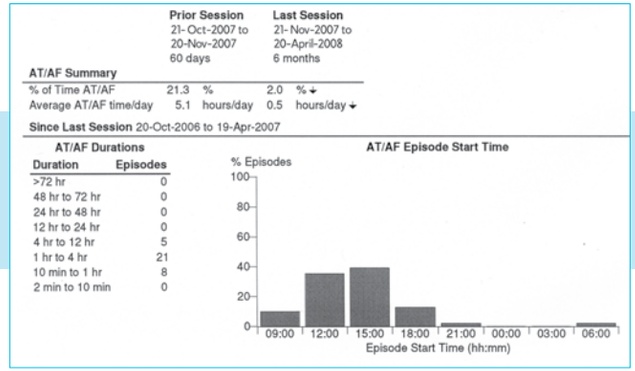
- Classifications by Rhythm Type:
  - Atrial tachyarrhythmia/atrial fibrillation (AT/AF)
  - Ventricular tachyarrhythmia (VT)
  - Fast ventricular tachyarrhythmia (FVT)
  - Bradyarrhythmias
  - Asystole
- Includes Exclusive AF Detection Algorithm, Which May:
  - Detect the presence of AT/AF, including asymptomatic episodes
  - Monitor AT/AF burden to assess if medical treatment is necessary
  - Monitor ventricular rhythm during atrial arrhythmia episodes to assess if rate control therapy is having the desired effect or needs to be adapted

Complete Diagnostics

Cardiac Compass® Trends: 14 months of rhythm data including accurate daily AF burden measurement,* ventricular rate during AT/AF, heart rate variability, and average day and night rates



AT/AF Summary: Provides duration and episode start time details

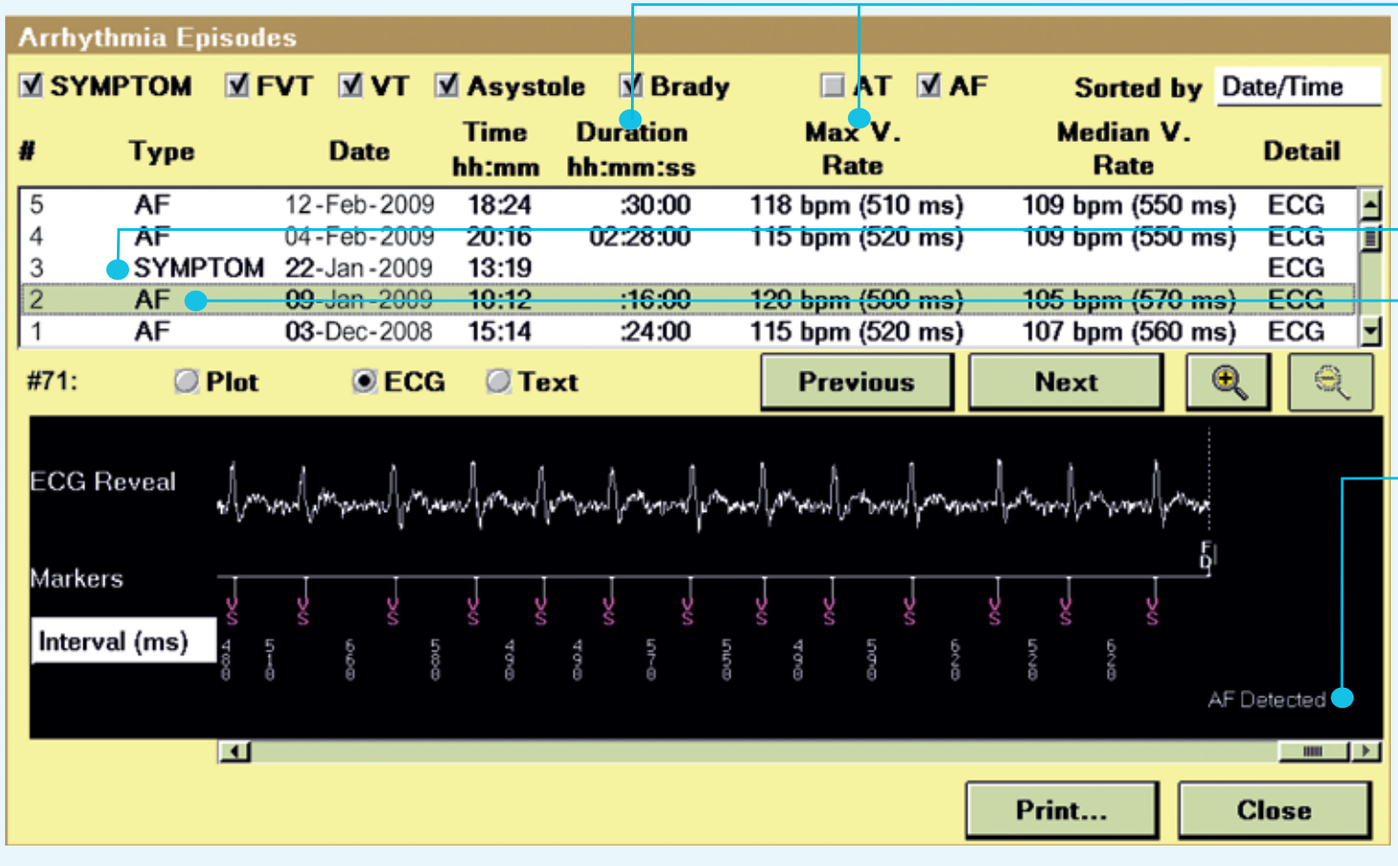


Revealing the Data You Need to Make Informed Decisions

Patient Assistant

The Record button captures patient-activated (SYMPTOM) episodes. The Query button is programmed per physician identified criteria to enable status notifications.

Episode Log



Duration and ventricular rate of automatically detected episodes

Patient-activated (SYMPTOM) episode

Automatically detected episode

Arrhythmia classification

Ease of Use

From Insertion

- Reveal Vector Check confirms insertion positioning
- Leadless device with slim shape simplifies insertion

To Follow-Up

- Straightforward user interface allows for quick follow-ups
- Episode log allows data sorting and viewing by rhythm type
- ECG storage includes prioritization to streamline arrhythmia identification

Convenient Care

Medtronic CareLink® Compatible

- Easy access to diagnostic data without an in-office clinic visit – optimizes scheduling and treatment
- Data may be transmitted immediately after patient-marked event or at scheduled intervals

MR Conditional

Reveal XT combines long-term monitoring with the ability to safely provide MRI testing.**

Establish the Symptom-Rhythm Correlation

ECG Data Storage (Total 49.5 minutes) –
Captured via Patient Assistant or automatically