Providing Evidence to Guide Diagnosis

Enhanced sensing and detection

- New tracking threshold for reliable R-wave sensing*
- Classification by episode type
  - Bradycardia
  - Asystole
  - Ventricular Tachyarrhythmia
  - Fast Ventricular Tachyarrhythmia
- Noise reversion and overrange detection algorithms to limit false-positive episode detection

Ease of use from insertion to follow-up

- Leadless device with slim shape simplifies insertion
- MR Conditional** allows the ability to safely provide MR testing
- Medtronic CareLink® compatibility enables easy access to diagnostic data without an in-office clinic visit

Long-term monitoring capabilities

- Implantable for up to three years
- Designed to improve patient compliance – no wires or patches

Patient Assistant

Captures patient-activated episodes

ECG DATA STORAGE: TOTAL 49.5 MINUTES

Patient Activation – 22.5 minutes

6.5 min prior | 1 min post

Patient Activated

Up to 3 episodes

Automatic Activation – 27 minutes

End of episode

30 sec | 27 sec

Start of episode

Up to 27 episodes

* Reliable = Sensitivity of 98%, PPV of 99%

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

References

[1] Krahn AD, Klein GJ, Yee R, et al. Cost implications of testing strategy in patients with syncope (RAST). *J Am Coll Cardiol.* August 6, 2003;42(3):495-501.

[2] Kapoor WN. Diagnostic evaluation of syncope. *Am J Med.* January 1991;90(1):91-106.

[3] Krahn AD, Klein GJ, Yee R. Recurrent syncope. Experience with an implantable loop recorder. *Cardiol Clin.* May 1997;15(2):313-326.

[4] 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.

[5] 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.

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

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

[8] Linzer M, Yang EH, Estes NA 3rd, et al. 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.

Brief Statement

Indications

9528 Reveal® DX Insertable Cardiac Monitor

The Reveal DX 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.

9538 Reveal® Patient Assistant

The Reveal 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 DX 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

9528 Reveal DX Insertable Cardiac Monitor

Patients with the Reveal DX 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.

9538 Reveal Patient Assistant

Operation of the Model 9538 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

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Medtronic

Medtronic

Reveal® DX

INSERTABLE CARDIAC MONITOR

ALWAYS ON WATCH

Always on Watch

Reveal® DX Insertable Cardiac Monitor (ICM) captures the information you need to make informed decisions about your syncope patients who suffer from infrequent but recurrent episodes.[1] Due to the complex diagnosis of syncope, it's important to use the monitoring option that can provide clear information. With continuous monitoring for up to three years, Reveal DX overcomes the limitations commonly found with other testing options.

Compare Diagnostic Yields in Unexplained Syncope Patients

TEST/PROCEDURE	YIELD*
ECG	2-11%[2]
Holter Monitoring	2%[3]
External Loop Recorder	20%[1]
Reveal DX ICM	**43-88%[1,4,5]**
Tilt Table Test**	11-87%[6,7]
EP Study** without SHD***	11%[8]
EP Study** with SHD***	49%[6]

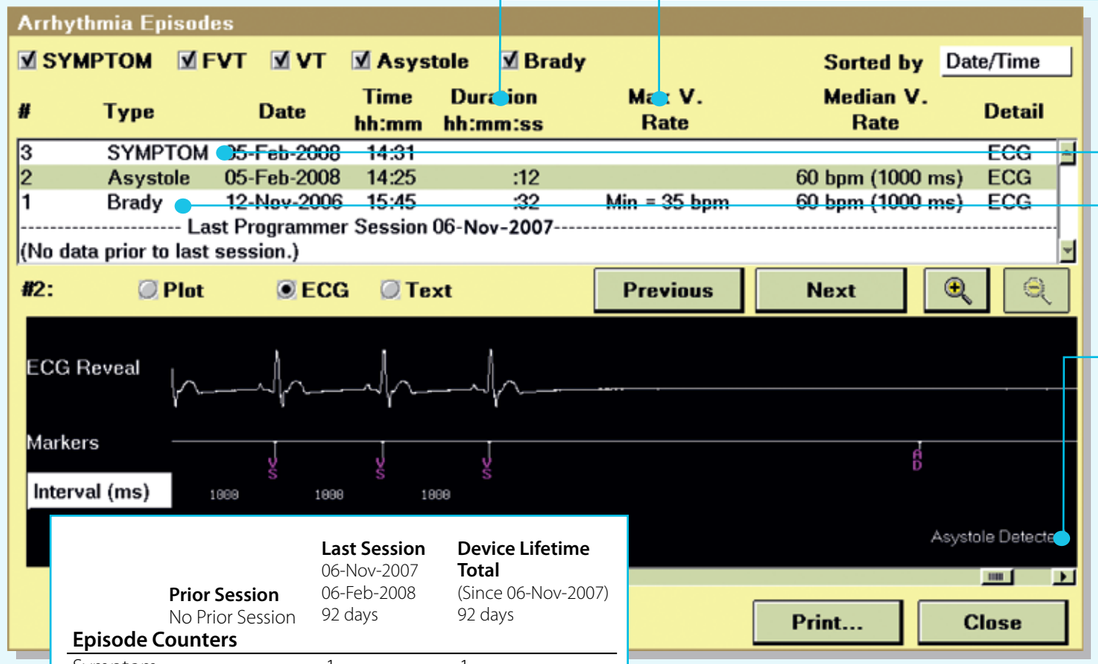
* Based on mean diagnosis time of 5.1 months[3]
** Provocative test
*** SHD structural or organic heart disease

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

Actual Size

To Reveal What You Can't See

Episode Log



	Prior Session	Last Session 06-Nov-2007	Device Lifetime Total (Since 06-Nov-2007)
	No Prior Session	06-Feb-2008	
		92 days	92 days
Episode Counters			
Symptom		1	1
FVT		0	0
VT		0	0
Asystole		1	1
Brady		1	1

Duration and ventricular rate of automatically detected episodes

Patient-activated (SYMPTOM) episode

Automatically detected episode

Arrhythmia classification

Episode Counters