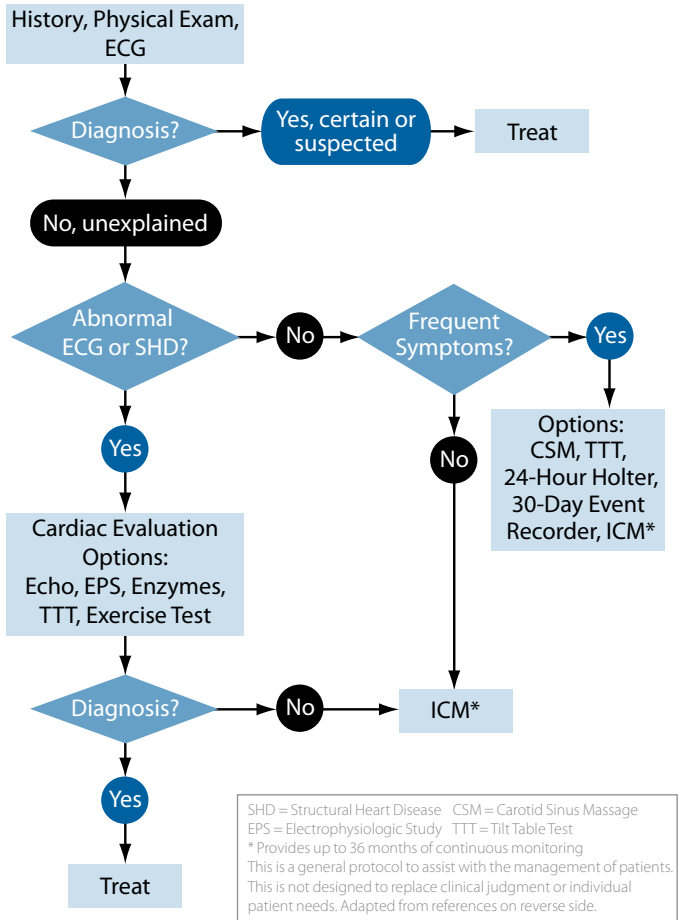


# SYNCOPE EVALUATION

## ROLE OF THE INSERTABLE CARDIAC MONITOR (ICM)



The Reveal® DX and Reveal XT™ are implantable patient-activated and automatically activated monitoring systems that record subcutaneous ECG and are indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia. These symptoms include, but are not limited to, dizziness, palpitations, syncope, and chest pain.

#### Flowchart adapted from:

Olshansky B. Syncope: Overview and approach to management. In: Grubb B and Olshansky B. eds. *Syncope: Mechanisms and Management*. 2nd ed. Malden, MA: Blackwell Futura; 2005:1-46.

Krahn AD, Klein GJ, Yee R, Skanes AC. The use of monitoring strategies in patients with unexplained syncope – role of the external and implantable loop recorder. *Clin Auton Res*. October 2004;14(Suppl 1):55-61.

Raviele A, Alboni P, Sutton D, Kenny RA. Initial evaluation of the syncope patient. In: Benditt D, Blanc J-J, Brignole M, Sutton R, eds. *The Evaluation and Treatment of Syncope*. Elmsford, NY: Futura. 2003:38-45.

Strickberger SA, Benson DW, Biaggioni I, et al. AHA/ACCF Scientific Statement on the evaluation of syncope: from the American Heart Association Councils on Clinical Cardiology, Cardiovascular Nursing, Cardiovascular Disease in the Young, and Stroke, and the Quality of Care and Outcomes Research Interdisciplinary Working Group; and the American College of Cardiology Foundation: in collaboration with the Heart Rhythm Society: endorsed by the American Autonomic Society. *Circulation*. January 17, 2006;113(2):316-327.

Brignole M, Alboni P, Benditt DG, et al. Guidelines on management (diagnosis and treatment) of syncope – update 2004. *Europace*. November 2004;6(6):467-537.

Kaufmann H, Wieling W. Syncope: a clinically guided diagnostic algorithm. *Clin Auton Res*. October 2004;14 (Suppl 1):87-90.

#### Brief Statement

##### Indications: 9529 Reveal XT™ and 9528 Reveal™ DX Insertable Cardiac Monitors

The Reveal XT and Reveal DX Insertable Cardiac Monitors are implantable patient-activated and automatically activated monitoring systems that record subcutaneous ECG and are 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™ and 9538 Reveal™ Patient Assistants

The Reveal XT and Reveal Patient Assistants are 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. (Model 9539 only)
- 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 or Reveal DX Insertable Cardiac Monitors. 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 and 9528 Reveal DX Insertable Cardiac Monitors

Patients with the Reveal XT or 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.

##### 9539 Reveal XT and 9538 Reveal Patient Assistants

Operation of the Model 9539 or 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](http://www.medtronic.com).

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.

[www.medtronic.com](http://www.medtronic.com)

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