



# Reveal XT™ and Reveal® DX Insertable Cardiac Monitors (ICMs)

REIMBURSEMENT GUIDE – 2009





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The coding suggestions and coverage guidelines in this guide do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third-party payers as to the correct form of billing or the amount that will be paid to providers of service.

# Reveal XT and Reveal DX Insertable Cardiac Monitors (ICMs)



This reimbursement guide is intended to assist in understanding payer coverage, coding, and payment associated with Reveal XT and DX Insertable Cardiac Monitors (ICMs). The guide includes a description of the devices and their benefits, commonly billed codes, and a related clinical bibliography. You may also call our Coding Hotline with reimbursement-related questions at 1 (866) 877-4102, option 1.

## What Are the Reveal XT and Reveal DX ICMs?

The Reveal XT and Reveal DX are small implantable medical devices that continuously monitor the heart's electrical activity/heart rhythms (i.e., subcutaneous electrocardiograms or ECGs) for up to 3 years. They can record both patient-activated events and automatically detected (auto-activated) events and store up to 49.5 minutes of ECG data (22.5 minutes of patient-activated episodes and 27 minutes of automatically-activated episodes).

The Reveal XT and Reveal DX ICM is a name change from our previous Reveal Plus insertable loop recorder (ILR). ICM better characterizes newer Reveal device functions and longer-term monitoring than previously available from Reveal Plus or arrhythmia monitoring by external event recorders that provide data over a short period (i.e., up to 30 days). However, please be aware that the new 2009 CPT<sup>1</sup> codes for monitoring implantable cardiac devices continue to classify Reveal XT and DX ICM devices as implantable loop recorders (ILRs).

Reveal XT and Reveal DX offer subcutaneous electrocardiograms and a new tracking threshold as well as noise reversion algorithms for improved auto-detection.<sup>2</sup> Specifically, the auto-activation feature may help to detect abnormal, asymptomatic heart rhythms and document an abnormal rhythm when the patient does not (or is unable to) activate the device.

Arrhythmias detected by the Reveal DX may be classified as bradyarrhythmia, asystole, or (fast) ventricular tachyarrhythmia. Arrhythmias detected by the Reveal XT may be classified as atrial tachyarrhythmia/atrial fibrillation (AT/AF), bradyarrhythmia, asystole, or (fast) ventricular tachyarrhythmia. The Reveal XT records other information about the patient, such as average heart rates, heart rate variability, and activity throughout the day.

Components include:

- The device – an implantable, single-use, programmable device that contains two electrodes on its surface for continuous monitoring of the patient's heart rhythm for up to three years.
- The Patient Assistant – a hand-held, battery-operated device that the patient uses to activate the recording function of the implanted cardiac monitor to store an event into the device's memory. The Patient Assistant for Reveal XT also has a query function which signals patients to call their physician or clinic when programmed arrhythmia detection or device criteria are met. The Patient Assistant communicates to the ICM through the patient's skin (via telemetry).
- Medtronic 2090 Programmer – A Medtronic programmer with Reveal XT and Reveal DX software is used and required to program and interrogate the devices at implant and during an in-office evaluation.
- Medtronic CareLink® Network – Patients with a Reveal device and enrolled in the CareLink® Network can remotely transmit stored data.

### Reveal XT Patient Assistant, Model 9539

**Query button:**

Patient presses button to determine if notification criteria are met.

**OK:**

Indicator illuminates when there are no recorded events (based on notification programming).

**Phone:**

Indicator illuminates when notification criteria are met. Patient should follow physician instructions.



Same functions as Reveal Patient Assistant Model 9538.

### Reveal Patient Assistant, Model 9538

**Record button:**

Patient presses button to record ECG with symptoms.

**Check mark:**

Indicator illuminates after successfully recording an event.

**Battery:**

Indicator illuminates when Patient Assistant battery is low.



## Functions

Clinicians may use the Reveal XT and Reveal DX in patients to help determine if patient symptoms are related to an abnormal cardiac rhythm and to uncover asymptomatic arrhythmias via auto detection.

Reveal XT and Reveal DX are similar in size and shape to their predecessor, Reveal Plus. However, the devices include expanded capabilities. The specific new features include:

- Increased longevity of up to 3 years (up to 2.5 times longer than Reveal Plus). This change was designed to increase the opportunity to capture an ECG and help determine the cause of patient symptoms.
- Improved sensing and detection, including the auto detection of ventricular tachyarrhythmia (VT) and fast ventricular tachyarrhythmias (FVT).
- MR Conditional – The Reveal XT and DX have been demonstrated to pose no known hazards in a specified MR environment. (Refer to the conditions of use specified in the Reveal XT and Reveal DX Clinician Manuals.)
- Compatible with Medtronic CareLink® Network – allows patients with a Reveal device to remotely transmit device data to a clinician.

Additionally, Reveal XT has the following new features:

- Atrial tachyarrhythmia detection capabilities for detecting symptomatic and asymptomatic AF
- Rhythm trending data, including up to 14 months of daily AT/AF burden and ventricular rate during AT/AF

Reveal XT monitoring with these features may help to:

- Detect the presence of AT/AF, including occurrence of asymptomatic episodes of AT/AF
- Monitor the patient's AT/AF burden to assess whether medical treatment is necessary or should be adjusted
- Monitor the patient's ventricular rhythm during atrial arrhythmia episodes to assess whether a rate control therapy is having the desired effect or needs to be adapted
- Record incidents of symptomatic events to correlate patient symptoms with cardiac rhythm and assist with differential diagnosis
- Continuously record other patient information that may help physician to assess the patient's condition, such as heart rate variability or patient activity

## How Are the Reveal XT and Reveal DX Implanted?

The implantation can be performed as a simple minimally invasive procedure. After the administration of local anesthesia, an incision (approximately 2 cm) is made, typically in the upper chest area. A subcutaneous pocket, approximately the size and shape of the device, is formed. The device is inserted into the pocket, sutured in place, and the incision is closed. Following the implant and prior to the closing of the incision, the device settings are programmed and the device is interrogated to verify signal strength, amplitude, and heart rhythm sensing. Explantation is recommended when the device is no longer clinically necessary or when the battery is depleted.

## Indications

Reveal XT (Model 9529) and Reveal DX (Model 9528) were cleared by the FDA for use in two groups of patients:

- Patients with clinical syndromes or situations at increased risk for cardiac arrhythmias
- Patients who experience transient symptoms such as dizziness, palpitation, syncope and chest pain, that may suggest a cardiac arrhythmia

The Reveal XT and Reveal DX 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 ICM:

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

<sup>†</sup> applicable only to the Reveal XT Patient Assistant Model 9539

## Reveal and Syncope

Current syncope testing methods are limited in terms of patient compliance, diagnostic yield, and the ability to capture infrequent events.

As noted in the chart:

- The diagnostic yield for a conventional ECG is very low and the short duration of the test makes it difficult to capture an arrhythmia.
- The effectiveness of **tilt table tests** depends on several factors, including patient selection and the use of provocative drugs. This is why there is a wide variation in the yield.
- **External loop recorders**, because of their short monitoring duration of 1-3 days and potential poor patient compliance, are most productive in motivated patients who experience relatively frequent syncope.
- **Reveal XT and Reveal DX** provide the longest duration for monitoring syncope as well as high diagnostic yields (43-88%)<sup>5,6</sup> compared to the conventional diagnostic methods listed.

## Conventional Diagnostic Methods

Test/Procedure	Yield*	Monitoring Duration
History and Physical Examination	49-85% <sup>3,4</sup>	NA
ECG	2-11% <sup>3</sup>	NA
Holter Monitoring	2% <sup>4</sup>	15 minutes
External Loop Recorder	20% <sup>4</sup>	1-3 days
Tilt Table	11-87% <sup>7,8</sup>	NA**
EP Study without <b>Structural Heart Disease</b> (SHD)	11% <sup>9</sup>	2-3 weeks
EP Study with SHD	49% <sup>7</sup>	NA**
<b>Reveal XT/ Reveal DX</b>	43-88% <sup>5,6</sup>	Up to 3 years

**Note:** Diagnostic yield is defined as the number of patients with diagnostically positive test results divided by the number of patients tested. Or, in the case of monitoring studies, the sum of true-positive and true-negative test results divided by the number of patients tested (Linzer M, Yang EH, Estes NA III, Wang P, Vorperian VR, Kapoor WN. Diagnosing syncope. Part 1: Value of history, physical examination, and electrocardiography. Clinical Efficacy Assessment Project of the American College of Physicians. *Ann Intern Med.* June 15, 1997;126(12):989-996).

\* Yield based on mean time to diagnosis of 5.1 months

\*\* Provocative test

# Reveal XT and Reveal DX Physician and Hospital Coding

## Physician and Hospital Coding

**For coding assistance or questions regarding reimbursement for Reveal XT and DX ICMs, call our Coding Hotline at 1 (866) 877-4102, option 1.**

The following codes may be helpful in billing for Reveal XT and Reveal DX ICM procedures. Please note that the new 2009 CPT codes for monitoring cardiac devices classify the Reveal XT and Reveal DX to be implantable loop recorders (ILRs), rather than implantable cardiac monitors (ICMs). These coding suggestions and coverage guidelines do not replace seeking coding advice from the payer and/or your own coding staff. The ultimate responsibility for correct coding lies with the provider of services. Please contact your local payer for interpretation of the appropriate codes to use for specific procedures. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other third-party payers as to the correct form of billing or the amount that will be paid to providers of service.

Procedure	CPT <sup>1</sup> /HCPCS* Code	CPT Code Description
Insertion	33282	Implantation of patient-activated cardiac event recorder (includes programming)
Removal	33284	Removal of an implantable, patient-activated cardiac event recorder
In Person Programming	93285	Programming device evaluation with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with physician analysis, review and report; implantable loop recorder system
In Person Interrogation	93291	Interrogation device evaluation (in person) with physician analysis, review and report, includes connection, recording and disconnection per patient encounter; implantable loop recorder system, including heart rhythm data derived analysis
Remote Interrogation Physician Analysis	93298 Not applicable to Hospital	Interrogation device evaluation(s), (remote) up to 30 days; implantable loop recorder system, including analysis of recorded heart rhythm data, physician analysis, review(s) and report(s)
Remote Interrogation Technical Service	93299	Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular monitor system or implantable loop recorder system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results
Device Code for Physician Office Implant	E0616* Non-Facility Only	Implantable cardiac event recorder with memory, activator and programmer
Device C-code	C1764* Hospital Only	Event recorder, cardiac (implantable) required when billing Medicare for an Outpatient implant.

\* Healthcare Common Procedure Coding System (HCPCS).

## Inpatient Hospital Coding

Procedure	ICD-9-CM Procedure Code	ICD-9-CM Procedure Code Description
Insertion	37.79	Revision or relocation of cardiac device pocket (includes implantation of ILR)
Removal	86.05	Incision with removal of foreign body or device from skin and subcutaneous tissue

## **Performing Reveal XT or Reveal DX Implants in a Physician's Office or Ambulatory Surgery Center (ASC)**

Providers should contact the applicable payer prior to performing a Reveal implant in the office or ASC setting. Sample letters to aid in contacting the payer can be obtained by contacting your Medtronic representative or by contacting the Medtronic Reimbursement Hotline. Based on historical data, Medicare device payment for in-office device implant procedures has been less than the cost of the device.

Non-Medicare device coverage depends on whether the office or ASC setting is an allowable site of service. Payment for office-based procedures may be made based on billing E0616 for the Reveal device, while ASC procedures are billed using CPT 33282. You should check with the individual payer for appropriate coverage and billing instructions. Ultimately, the decision to implant a Reveal device in the physician office or ASC setting rests with the provider of service.

# Coverage Status – Reveal for Unexplained Syncope

## **Use of Reveal XT and Reveal DX for Unexplained Syncope**

### **Coverage Status – Medicare**

Medicare coverage of Reveal implants for patients diagnosed with unexplained syncope (ICD-9-CM 780.2) is established. The majority of local coverage determination (LCD) policies that were issued for the insertable loop recorder (Reveal Plus) have been retired. As such, you may not find an active LCD when searching on a contractor's website. To access the most current information and determine whether an LCD is active, is retired, or was never issued, please log on to your Medicare contractor's website. In addition, you may wish to check the Medtronic website <http://www.medtronic.com/physician/reveal/reimbursement.html> or contact Medtronic at 1 (866) 877-4102, option 1. The LCD policies that were issued (and those still active) provide coverage for unexplained syncope (ICD-9-CM Diagnosis code 780.2).

Physicians are encouraged to contact their Contractor Medical Director (CMD) directly with any coverage- or billing-related questions.

### **Coverage Status – Non-Medicare**

Non-Medicare payer coverage is based on an individual's health plan certificate of benefits. Payer policies differ depending on the type of contract, and a number of other factors. As such, many non-Medicare payers have a process through which a provider or beneficiary can determine whether an item or service is covered. The process is typically referred to as a prior authorization or a predetermination request. Prior authorization requests may be obtained for physician services and for hospital services, depending on the payer policy. Contact the payers for instructions. Ask whether the process includes authorization for physician and hospital services. If separate authorizations are needed, find out what information is required to complete the requests. You may want to involve the hospital pre-admission staff to assist in submitting a prior authorization for the hospital services.

# Coverage Status – Reveal XT for Arrhythmia Monitoring

## Use of Reveal XT for Arrhythmia Monitoring

### Medicare

In the absence of a specific LCD or national coverage determination (NCD), Medicare coverage is governed by Section 1862. [42 U.S.C. 1395y] of the Social Security Act, which states, “(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services —

(1)(A) which, ... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

We encourage providers to contact their Contractor Medical Director to seek coverage clarification for the use of Reveal XT for detecting and monitoring arrhythmias.

### Medicare and Non-Medicare Payers

Payer coverage for implanting a Reveal XT device to monitor patients with diagnoses other than that of unexplained syncope has not been addressed by third-party payers. Providers should contact their payer directly to determine coverage.

### Resources

Several sample letter templates are available for use by contacting the Medtronic Coding Hotline at 1 (866) 877-4102, Option 1 or by contacting your Medtronic representative. You can reach your representative by calling 1 (800) 633-8766.

### Templates Available

- Sample Letter of Medical Necessity/Prior Authorization
- Sample Letter Requesting Coverage and Payment – Physician Office Setting
- Sample Letter for Submitting Practice Expense Information for Carrier Priced Claims Processing
- Sample Appeal Letter

# Selected Bibliography on Atrial Fibrillation

*Disease State Characteristics and Value of Long-Term Monitoring*

Note: All conclusions or statements are drawn directly from the cited clinical document.

Note: For customers interested in a syncope bibliography please contact your Medtronic representative.

## Incidence, Prevalence, and Risk Factors

### **Lloyd-Jones DM, Wang TJ, Leip EP, et al. Lifetime Risk for Development of Atrial Fibrillation: The Framingham Heart Study. *Circulation*. August 31, 2004;110(9):1042-1046.**

Conclusions: For men and women 40 years of age and older, the remaining lifetime risk for development of AF is approximately 1 in 4. Of note, lifetime risks for AF were similar in men and women at all ages. The high lifetime risk for AF that we report underscores the important public health burden posed by AF. With the aging of the population, the concomitant increased prevalence of predisposing factors, increased rates of cardiac surgical procedures, and improved survival after myocardial infarction and onset of CHF, the prevalence of AF is almost certain to increase in the coming decades.

### **Go AS, Hylek EM, Phillips KA, et al. Prevalence of Diagnosed Atrial Fibrillation in Adults National Implications for Rhythm Management and Stroke Prevention: the Anticoagulation Factors In Atrial Fibrillation (ATRIA) Study. *JAMA*. May 9, 2001; 285(18):2370-2375.**

Conclusions: Among the 1.89 million adult health plan members during the study period, the overall prevalence of diagnosed atrial fibrillation was 0.95%. The prevalence of atrial fibrillation was greater in men than in women overall (1.1% versus 0.8%) and in every age group. In women, the prevalence increased from 0.1% among those younger than 55 years to 9.1% among those 85 years or older. In men, the prevalence of atrial fibrillation ranged from 0.2% in those younger than 55 years to more than 11% among those 85 years or older.

### **Benjamin EJ, Wolf PA, D'Agostino RB, Silbershatz H, Kannel WB, Levy D. Impact of Atrial Fibrillation on the Risk of Death: The Framingham Heart Study. *Circulation*. September 8, 1998; 98(10):946-952.**

Conclusions: The clinical risk factors for AF include advancing age, diabetes, hypertension, congestive heart failure, rheumatic and nonrheumatic valve disease, and myocardial infarction. The echocardiographic risk factors for nonrheumatic AF include left atrial enlargement, increased left ventricular wall thickness, and reduced left ventricular fractional shortening.

## Asymptomatic AF

### **Flaker GC, Belew K, Beckman K, et al. Asymptomatic Atrial Fibrillation: Demographic Features and Prognostic Information from the Atrial Fibrillation Follow-Up Investigation of Rhythm Management (AFFIRM) Study. *Am Heart J*. April 2005;149(4):657-663.**

Conclusions: Determination of the frequency of AF is also confounded by the fact that patients have both symptomatic and asymptomatic episodes of AF. In symptomatic patients undergoing ambulatory monitoring, asymptomatic episodes outnumber symptomatic episodes by a 12:1 ratio. Previous studies have shown that approximately 25-30% of patients presenting with strokes have AF that was not previously recognized.

### **Strickberger SA, Ip J, Saksena S, Curry K, Behnson TD, Ziegler PD. Relationship between Atrial Tachyarrhythmias and Symptoms. *Heart Rhythm*. February 2005;2(2):125-131.**

Conclusions: The major finding of this study is that in patients with symptomatic bradycardia, a history of atrial fibrillation, and an indication for permanent pacing, symptoms perceived to be related to atrial fibrillation often are not associated with an atrial tachyarrhythmia. In this study, almost 95% of documented atrial tachyarrhythmia episodes were asymptomatic, and symptoms attributed to atrial fibrillation were associated with atrial tachyarrhythmias only approximately 15% of the time. Furthermore, 45% of patients who reported symptoms that they associated with atrial fibrillation did not have a documented atrial tachyarrhythmia coincident with their symptoms.

**Nieuwlaat R, Capucci A, Camm AJ, et al, for the European Heart Survey Investigators. Atrial Fibrillation Management: A Prospective Survey in ESC Member Countries: The Euro Heart Survey on Atrial Fibrillation. *Eur Heart J*. November 2005;26(22):2422-2434.**

Conclusions: In a study with patients who recently had received devices with long-term monitoring functions, more than 50% of the patients showed unsuspected paroxysmal AF.

**Roche F, Gaspoz JM, Da Costa A, et al. Frequent and Prolonged Asymptomatic Episodes of Paroxysmal Atrial Fibrillation Revealed by Automatic Long-Term Event Recorders in Patients with a Negative 24-Hour Holter. *PACE*. November 2002;25(11):1587-1593.**

Conclusions: A study by Roche 2002, estimated that 55% of patients who were asymptomatic would have remained undiagnosed without continuous monitoring. In this same study, it was shown that standard 24-hour monitoring would have missed 44% of PAF patients.

**Hindricks G, Piorkowski C, Tanner H, et al. Perception of Atrial Fibrillation before and after Radiofrequency Catheter Ablation Relevance of Asymptomatic Arrhythmia Recurrence. *Circulation*. July 19, 2005;112(3):307-313.**

Conclusions: In this prospective study, 114 patients with at least three documented AF episodes together with corresponding symptoms and an ineffective trial of at least one antiarrhythmic drug were selected for RF ablation. A continuous, 7-day, Holter session was recorded before ablation, right after ablation, and after 3, 6, and 12 months of follow-up. In 52 patients (57%), both symptomatic and asymptomatic episodes were recorded, whereas in five patients (5%), all documented AF episodes were asymptomatic. After ablation, the percentage of patients with only asymptomatic AF recurrences increased to 37% ( $P < 0.05$ ) at the 6-month follow-up. Even in patients presenting with highly symptomatic AF, asymptomatic episodes may occur and significantly increase after catheter ablation. A symptom-only-based follow-up would substantially overestimate the success rate.

### Limitations of Short-Term Monitoring

**Jabaudon D, Sztajzel J, Sievert K, Landis T, Sztajzel R. Usefulness of Ambulatory 7-Day ECG Monitoring for the Detection of Atrial Fibrillation and Flutter after Acute Stroke and Transient Ischemic Attack. *Stroke*. July 2004;35(7):1647-1651.**

Conclusions: In the present study, AF was detected in 22 of 149 patients with acute stroke or TIA, accounting for 50% (22/44) of all cardioembolic strokes. Standard ECG identified this arrhythmia in 6.7% of the patients, in about half of the cases at admission (5/11 patients), and in the remaining cases within the first 5 days. Holter disclosed AF in an additional 5% of the patients presenting a normal standard ECG. Finally, ELR allowed further detection of this arrhythmia in 5.7% of the patients, thus identifying AF in 1 of 18 patients having a normal standard ECG and Holter. The calculated risk of AF in this study was 16.9%.

In addition, patients with TIA, having no residual deficit, may be reluctant to wear the ELR device for 7 days, whereas outpatient appointments may be difficult to organize for severely impaired patients, as illustrated by the 73% compliance rate for ELR.

**Israel CW, Grönfeld G, Ehrlich JR, Li YG, Hohnloser SH. Long-Term Risk of Recurrent Atrial Fibrillation As Documented by an Implantable Monitoring Device. *JACC*. January 7, 2004;43(1):47-52.**

Conclusions: In 51 (46%) of 110 patients, AF was documented by the resting ECG during follow-up, whereas device interrogation revealed episodes of AF in 97 patients. In 57 patients (59% of patients with device-detected AF episodes and 52% of the total patient group), asymptomatic AF recurrence was detected in at least one follow-up period solely by the implanted monitoring device.

This prospective long-term follow-up study demonstrates that AF recurrences of > 48-hour duration are asymptomatic in more than one-third of patients with a history of paroxysmal or persistent AF. Moreover, in 16% of patients with a history of AF, recurrences of > 48-hour duration develop even after documentation of freedom from AF for three months or longer. These observations demonstrate that the success rates of maintaining continuous SR in patients with a history of AF are often grossly overestimated.

**Vasamreddy CR, Dalal D, Dong J, et al. Symptomatic and Asymptomatic Atrial Fibrillation in Patients Undergoing Radiofrequency Catheter Ablation. *J Cardiovasc Electrophysiol*. February 2006;17(2):134-139.**

Conclusions: This is the first study reporting the outcomes of mobile cardiac telemetry monitoring (CardioNet) following catheter ablation of AF. Even though the intense monitoring protocol enabled us to monitor patients closely post-ablation and to better account for both symptomatic and asymptomatic AF, compliance with protocol was a major limitation of this study. In the current study, only 53% of the study participants were able to complete the study protocol. During this period, each patient was asked to transmit electrocardiogram tracing for 1 minute four times a day. The adherence rate to these scheduled transmissions was only 42%.

**Montenero AS, Quayyum A, Franciosa P, et al. Implantable Loop Recorders: A Novel Method to Judge Patient Perception of Atrial Fibrillation. Preliminary Results from a Pilot Study. *J Interv Card Electrophysiol.* June 2004;10(3):211-220.**

Conclusion: The implantable loop recorder may be a helpful tool in monitoring patients undergoing ablation. Dedicated AF detection characteristics could give additional value to the device.

## AF, Stroke, and Mortality

**Benjamin EJ, Wolf PA, D'Agostino RB, Silbershatz, Kannel WB, Levy D. Impact of Atrial Fibrillation on the Risk of Death: The Framingham Heart Study. *Circulation.* September 8, 1998; 98(10):946-952.**

Conclusions: In subjects from the original cohort of the Framingham Heart Study, AF was associated with a 1.5- to 1.9-fold mortality risk after adjustment for the preexisting cardiovascular conditions with which AF was related. The decreased survival seen with AF was present in men and women and across a wide range of ages.

**Wolf PA, Abbott RD, Kannel WB, et al. Atrial Fibrillation As an Independent Risk Factor for Stroke: The Framingham Study. *Stroke.* August 1991; 22(8):983-988.**

Compared with subjects free of these conditions, the age-adjusted incidence of stroke was more than doubled in the presence of coronary heart disease ( $p < 0.001$ ) and more than trebled in the presence of hypertension ( $p < 0.001$ ). There was a more than fourfold excess of stroke in subjects with cardiac failure ( $p < 0.001$ ) and a near fivefold excess when atrial fibrillation was present ( $p < 0.001$ ). In persons with coronary heart disease or cardiac failure, atrial fibrillation doubled the stroke risk in men and trebled the risk in women. With increasing age, the effects of hypertension, coronary heart disease, and cardiac failure on the risk of stroke became progressively weaker ( $p < 0.05$ ). Advancing age, however, did not reduce the significant impact of atrial fibrillation.

**Sherman DG, Kim SG, Boop BS, et al. Occurrence and Characteristics of Stroke Events in the Atrial Fibrillation Follow-Up Investigation of Sinus Rhythm Management (AFFIRM) Study. *Arch Intern Med.* May 23, 2005;165(10):1185-1191.**

Conclusions: Stroke attributable to AF increases with advancing age, from 1.5% for those aged between 50 and 59 years to 23.5% for those between 80 and 89 years. The annual risk of stroke in patients with nonvalvular AF not taking warfarin sodium is 3-5% (2 to 7 times that of people without AF), and AF is thought to be responsible for 15% of thromboembolic strokes.

**Lin HJ, Wolf PA, Benjamin EJ, Belanger AJ, D'Agostino RB. Newly Diagnosed Atrial Fibrillation and Acute Stroke: The Framingham Study. *Stroke.* September 1995;26(9):1527-1530.**

Conclusions: It is not an uncommon clinical situation that AF is documented for the first time at the time of hospital admission for stroke. When atrial fibrillation (AF) is first documented at the time of onset of acute stroke, it is difficult to establish a temporal relationship between AF and stroke. Did AF precede and precipitate the stroke, or did the arrhythmia appear as a result of stroke? Ninety-two percent (24/26) of subjects presenting with newly discovered AF at the time of acute stroke continued to have this rhythm disturbance in a chronic or paroxysmal form. In only two subjects (8%) was the arrhythmia short-lived and nonrecurrent. These follow-up data suggest that in most instances AF was probably the precipitant rather than the consequence of stroke.

**Page RL, Tilsch TW, Connolly SJ, et al. Asymptomatic or "Silent" Atrial Fibrillation: Frequency in Untreated Patients and Patients Receiving Azimilide. *Circulation.* March 4, 2003;107(8):1141-1145.**

Conclusions: In the Framingham study, an early report demonstrated that among patients with stroke associated with atrial fibrillation, the arrhythmia was newly diagnosed in 24%. A subsequent report from Framingham showed newly diagnosed atrial fibrillation on admission in 18% of patients with atrial fibrillation-related stroke and subsequent diagnosis of paroxysmal atrial fibrillation within 14 days in another 4.4%.

**Capucci A, Santini M, Padeletti L, et al. Monitored Atrial Fibrillation Duration Predicts Arterial Embolic Events in Patients Suffering from Bradycardia and Atrial Fibrillation Implanted with Antitachycardia Pacemakers. *JACC*. November 15, 2005;46(10):1913-1920.**

Conclusion: Our results show that, in a population of pacemaker patients suffering from AF, device-detected AF recurrences longer than one day are independently associated with embolic events. The risk of embolism, adjusted for known risk factors, was 3.1 times increased (95% CI 1.1 to 10.5,  $p = 0.044$ ) in patients with device-detected atrial fibrillation episodes longer than one day during follow-up.

### **AF As an Underlying Factor in Stroke of Unknown Etiology (Cryptogenic Stroke)**

**Ionita CC, Xavier AR, Kirmani JF, Dash S, Divani AA, Qureshi AI. What Proportion of Stroke Is Not Explained by Classic Risk Factors? *Preventive Cardiology*. Winter 2005;8(1):41-46.**

Conclusions: Two thirds of strokes are explained by identifiable risk factors. Age, hypertension, and nonvalvular atrial fibrillation are by far the most frequent and well documented ones. In spite of a thorough diagnostic evaluation, 30% of strokes remain cryptogenic, i.e., no specific cause is identified and the classic risk factors are not present.

**Jabaudon D, Sztajzel J, Sievert K, Landis T, Sztajzel R. Usefulness of Ambulatory 7-Day ECG Monitoring for the Detection of Atrial Fibrillation and Flutter after Acute Stroke and Transient Ischemic Attack. *Stroke*. July 2004;35(7):1647-1651.**

Conclusions: In the present study, AF was detected in 22 of 149 patients with acute stroke or TIA, accounting for 50% (22/44) of all cardioembolic strokes. Standard ECG identified this arrhythmia in 6.7% of the patients, in about half of the cases at admission (5/11 patients), and in the remaining cases within the first 5 days. Holter disclosed AF in an additional 5% of the patients presenting a normal standard ECG. Finally, ELR allowed further detection of this arrhythmia in 5.7% of the patients, thus identifying AF in 1 of 18 patients having a normal standard ECG and Holter. The calculated risk of AF in this study was 16.9%.

**Tayal AH, Tian M, Kelly KM, et al. Atrial Fibrillation Detected by Mobile Cardiac Outpatient Telemetry in Cryptogenic TIA or Stroke. *Neurology*. November 18, 2008;71(21):1696-1701.**

Conclusions: There is a high rate of atrial fibrillation (AF) detection by Mobile Outpatient Telemetry (21 days) in patients with cryptogenic TIA/stroke that may be related to extended monitoring duration, patient selection, and inclusion of all new onset AF episodes. Brief AF episodes (< 30 seconds) may be biomarkers of more prolonged and clinically-significant AF.

**Liao J, Khalid Z, Scallan C, Morillo C, O'Donnell M. Noninvasive Cardiac Monitoring for Detecting Paroxysmal Atrial Fibrillation or Flutter after Acute Ischemic Stroke: A Systematic Review. *Stroke*. November 2007;38(11):2935-2940.**

Conclusions: Screening consecutive patients with ischemic stroke with routine Holter monitoring will identify new atrial fibrillation/flutter in approximately 1 in 20 patients. Although based on limited data, extended duration of monitoring may improve the detection rate. Further research is required before definitive recommendations can be made.

## References

- <sup>1</sup> Current Procedural Terminology (CPT®) is copyright 2008 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative causes, or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use.
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## Brief Statement

### 2090 Programmer

Prior to use, refer to the Programmer Reference Guide as well as the appropriate programmer software and implantable device technical manuals for more information related to specific implantable device models. Programming should be attempted only by appropriately trained personnel after careful study of the technical manual for the implantable device and after careful determination of appropriate parameter values based on the patient's condition and pacing system used.

*See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential 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 this device to sale by or on the order of a physician.

## 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).*

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