INSERTABLE CARDIAC MONITOR

Confirm Rx™

Insertable Cardiac Monitor
Model DM3500

The Confirm Rx™ Insertable Cardiac Monitor (ICM) with SharpSense™ technology is designed to detect arrhythmias and wirelessly transmit data to the Merlin.net™ Patient Care Network (PCN) for the following patients:

- Patients who experience symptoms that may be cardiac-related.
- Patients who are at risk for abnormal cardiac rhythms.
- Patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF.

Product Highlights

Device

- SharpSense technology improves the detection of AF, Bradycardia and Pause, with high relative sensitivity.
- Electrogram (EGM) scatterplots to easily identify relationships between variables.
- The slim design allows a simple insertion procedure requiring minimal time and resources. Not noticeable after insertion in most patients.
- Intuitive one-touch programming on the Merlin™ Patient Care System (PCS).
- Patient-activated and auto-activated triggers for EGM storage.
- Programmable data storage options to ensure capture of significant events while reducing the risk of missing unexpected events.
- Proven Abbott Sense*Ability*™ sensing algorithm feature designed to allow accurate sensing over a wide range of signals.
- Device is 1.5 Tesla (T) and 3T MR Conditional.

Mobile App and Connectivity

- Bluetooth® wireless technology between ICM and myMerlin™ Mobile App, which patients can download onto their smartphone device. No need for a separate bedside transmitter or patient activator.
- ICM continuously monitors rhythm and myMerlin Mobile App proactively transmits data per schedule and alerts set by the clinic.
- The myMerlin Mobile App features integrated activator functionality, which allows patients to privately record and transmit EGMs during symptoms.
- App notifications inform patients of daily device checks and scheduled transmissions to promote remote monitoring adherence without burdening the clinic.
- 35+ languages available on the myMerlin Mobile App to engage patients and provide a personalized experience.
- Abbott mobile transmitters are available for patients without their own compatible mobile device.

Ordering Information

Contents: ICM device, insertion tool, and incision tool

MODEL NUMBER	DESCRIPTION	DIMENSIONS (H x L x T, MM)	WEIGHT (G)	VOLUME (CM^3)	LONGEVITY
DM3500	Confirm Rx™ ICM	49 x 9.4 x 3.1	3.0	1.4	2 years

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PHYSICAL SPECIFICATIONS	
Model Number	DM3500
Device Coating	Parylene
Telemetry	Bluetooth®

PARAMETER SPECIFICATIONS	
Parameter	**Settings**
Nominal Settings	
Sense Refractory Period	250 ms
Sensing	On post initial reason for monitoring programming (Off in shelf life)
Sensitivity	0.125 mV
Programmable Settings	
Sense Refractory Period	125-400 ms in increments of 25 ms
Sensing	0.075 - 0.25 in increments of 0.025 mV and 0.30 to 0.40 in increments of 0.05 mV
AF	
EGM Storage	On; Off
AF Duration	0.5, 1, 2, 6, 10, 20, 30, 60 min
AF Burden Alert	Off, 30 min, 1, 3, 6, 9, 12, 24 hrs
AF Continuous Episode Alert	Off, 10, 20, 30, 60, 180 min
Ventricular Rate during AF Alert Rate Threshold Total Time	 Off, 90 – 150, 175, 200 bpm 1, 3, 6, 9, 12 hrs
Tachy	
EGM Storage	On; Off
Rate	120 – 250 bpm in increments of 5 bpm
Duration	8-24 intervals in increments of 1; 25-50 intervals in increments of 5
Sudden Onset % Delta	On; Off 4-86% in increments of 2
Bigeminy Qualifier	On; Off
Brady	
EGM Storage	On; Off
Rate	30, 40, 50 bpm
Pause	
EGM Storage	On; Off
Duration	2, 3, 4, 5, 6, 7, 8 sec
Diagnostics	
Reason for Monitoring Selection	Syncope, Palpitations, Seizures, Ventricular Tachycardia, Suspected AF, Post AF Ablation, AF Management, Cryptogenic Stroke, Other
Total EGM Storage	60 min
Symptom EGM Duration	Pre-Trigger: 4, 6, 8, 10, 12, 14 min Post-Trigger: 30, 40, 50, 60 sec
Device Detected EGM Duration AF Pre- and Post-Trigger Other Pre- and Post-Trigger (Tachy, Brady, Pause)	 10, 20, 30, 60, 90 and 120 sec 10, 20, 30, 40, 50 and 60 sec
Heart Rate Histogram	Yes
AF Diagnostics	Yes
AF Burden Trend	Yes
Other Features	
Episodal Diagnostics	Yes
Activity Inhibits Auto Detection	On; Off
Noise Response Inhibits Auto Detection	Yes
Patient Trigger	Yes
Remote Monitoring	myMerlin App via Bluetooth® wireless technology
Patient Activator	myMerlin App via Bluetooth® wireless technology

Longevity provided under the following usage scenarios

- *Average of 1 auto-detected episode per day*
- *Average of 1 patient-activated symptom episode per month*
- *Up to 6 month shelf storage time*

Note: At a maximum shelf storage time of 18 months, longevity is reduced by approximately 5 months.

Security Measures

- The ICM encrypts its wireless communication and patient health information (PHI) data both at rest and in-transit from ICM to the myMerlin™ Mobile App and Merlin.net™ Patient Care Network (PCN). All data is encrypted using Advanced Encryption Standard (AES) 128-bit encryption with a secure 1.2 Transport Layer Security (TLS) connection.
- AES 128-bit encryption is designed to limit communication to only a single authenticated and paired app transmitter at any given time.
- The ICM uses the pairing procedure specified in Bluetooth® wireless technology low energy protocols and a proprietary pairing protocol as an added security measure. Pairing requests are authenticated using certificate-based public key cryptography authentication.
- The ICM creates a unique 128-bit key for the paired mobile app and verifies it at the onset of every communication. If the unique key is not verified, the monitor denies access.
- The ICM uses an authorization protocol, which limits a paired mobile app's access.
- Firmware upgrades for the ICM are cryptographically authenticated before installation.
- The Merlin.net Patient Care Network (PCN) is housed in a secured data center and is ISO27001:2013 certified. Access to patient data in the Merlin.net PCN is restricted to authorized users as set by the clinic administrator.

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications for Use: The Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms that may be cardiac-related such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias such as bradycardia, tachycardia, and sinus pauses. The Confirm Rx ICM is also indicated for patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF. The Confirm Rx ICM is intended to be inserted subcutaneously in the left pectoral region, also described as the left anterior chest wall. The Confirm Rx ICM has not been specifically tested for pediatric use.

Intended Use: The Confirm Rx ICM is intended to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms, as indicated.

Contraindications: There are no known contraindications for the insertion of the Confirm Rx ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

Potential Adverse Events: Possible adverse events (in alphabetical order) associated with the device, include the following: allergic reaction, bleeding, chronic nerve damage, erosion, excessive fibrotic tissue growth, extrusion, formation of hematomas or cysts, infection, keloid formation and migration.

Refer to the User's Manual for detailed indications for use, contraindications, warnings, precautions and potential adverse events.

Abbott
15900 Valley View Court, Sylmar, CA 91342
Tel: +1 818 362 6822
Abbott.com

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