Confirm Rx™

Model DM3500
Insertable Cardiac Monitor

Abbott's 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 transient symptoms that may suggest a cardiac arrhythmia
- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- 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
- Small size (~ 1.4 cc) with slim profile
- Simple insertion procedure requiring minimal time and resources
- Intuitive one-touch programming on the Merlin™ Patient Care System
- Remote monitoring ready
- 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
- 1.5 T MR Conditional

Mobile App and Connectivity

- Bluetooth® wireless technology between ICM and myMerlin™ app, which patients can download onto their mobile device. No need for a separate bedside transmitter or patient activator
- ICM continuously monitors rhythm and myMerlin app proactively transmits data per schedule and alerts set by the clinic
- App features integrated activator functionality, allowing patients to privately record and transmit EGMs during symptoms. No separate activator hardware required
- Notifications inform patients of daily device checks and scheduled transmissions to promote remote monitoring adherence without burdening the clinic
- App available in 35+ languages to engage patients and provide a personalized experience
- Transmissions are sent to the Merlin.net PCN, providing clinicians with data and reports
- Abbott mobile transmitters are available for patients without their own compatible mobile device*

Ordering Information

Confirm Rx ICM

NAME	MODEL NUMBER	DESCRIPTION	MRI STATUS	X-RAY ID MODEL CODE
Confirm Rx ICM	DM3500	Insertable cardiac monitor	1.5 T MR Conditional	CC

Indications: The Confirm Rx™ ICM is indicated for the monitoring and diagnostic evaluation of patients who experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for cardiac arrhythmias. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation. The Confirm Rx ICM has not been specifically tested for pediatric use.

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.

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, contraindications, warnings, precautions and potential adverse events.

Additional Information: Clinicians must log onto Merlin.net™ Patient Care Network to view transmissions from patients' Confirm Rx ICM. On Merlin.net PCN they can configure transmission schedules and enable or disable features on a patient's myMerlin™ for Confirm Rx ICM mobile app. Review of transmissions is dependent on the clinician and may not happen immediately following delivery of such transmissions.

Limitations*: Patients may use their own Apple‡ or Android‡ mobile device to transmit information from their Confirm Rx ICM using the myMerlin™ for Confirm Rx™ mobile app. To do so the device must be powered on, app must be installed, Bluetooth® wireless technology enabled and data coverage (cellular or WiFi‡) available. The myMerlin™ for Confirm Rx mobile app provides periodic patient monitoring based on clinician configured settings. Data is resent if the transmission was not sent successfully. However, there are many internal and external factors that can hinder, delay, or prevent acquisition and delivery of ICM and patient information as intended by the clinician. These factors include: patient environment, data services, mobile device operating system and settings, ICM memory capacity, clinic environment, schedule/configuration changes, or data processing.

An Abbott mobile transmitter is available for patients without their own compatible mobile device.

Product Specifications

PHYSICAL SPECIFICATIONS

Model	DM3500
Volume	1.4 cc
Length	49 mm
Width	9.4 mm
Thickness	3.1 mm
Weight	3.0 g
PARAMETER	**SETTINGS**

Features	
Longevity	2 years†
Detection Sampling Rate	512 Hz
Patient Trigger	Yes
Symptom Alert	Off
	On (All Symptoms)
	On (with Detection)
Remote Monitoring	myMerlin™ app via Bluetooth® wireless technology
Patient Activator	myMerlin app via Bluetooth® wireless technology
Tachycardia Trigger and Alert	Yes
Bradycardia Trigger and Alert	Yes
Pause Trigger and Alert	Yes
AF Trigger and Alert	Yes
Programmable AF Episode Duration	30 seconds, 1, 2, 6, 10, 20, 30, 60 minutes
AF Burden Alert	Off, 30 minutes, 1, 3, 6, 9, 12, 24 hours
AF Continuous Episode Alert	Off, 1, 2, 6, 10, 20, 30, 60, 180 minutes
Ventricular Rate during AF Alert	Off
	90–150, 175, 200 bpm
	1, 3, 6, 9, 12 hours
Activity Inhibits Auto Detection	Programmable, On or Off
Noise Response Inhibits Auto Detection	Yes

Diagnostics	
Episodal Diagnostics	Yes
Total EGM Storage	60 minutes
Symptom EGM Duration	Pre-trigger — 4, 6, 8, 10, 12, 14 minutes
	Post-trigger — 30, 40, 50, 60 seconds
Auto Detected EGM Duration	AF Pre- and Post-trigger — 10, 20, 30, 40, 50, 60 and 120 sec
	Other (Tachy, Brady, Pause) Pre- and Post-trigger — 10, 20, 30, 40, 50 and 60 sec
EGM Sampling Rate	128 Hz
Heart Rate Histogram	Yes
AF Diagnostics	Yes
AF Burden Trend	Yes

†Two years under the following usage scenarios:
- Average of one auto-detected episode per day
- Average of one patient-activated symptom per month
- Up to six-month shelf storage time

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

Security Measures

- The ICM encrypts its wireless communication using Advanced Encryption Standard (AES) 128-bit encryption and is designed to limit communications to only a single authenticated and paired myMerlin™ app 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 cloud-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 based on clinician settings

- The myMerlin™ app encrypts wireless communication to the Merlin.net™ Patient Care Network (PCN) through a secure Transport Layer Security connection using SHA256 cryptographic protection

- The Merlin.net 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. ICM data is encrypted using AES 128-bit encryption

- The Merlin.net PCN is successfully certified through the EU-U.S. Privacy Shield program to transfer patient information from the EU to the U.S.

Abbott