# Jot Dx™

Insertable Cardiac Monitor
Model DM4500

The Jot Dx™ 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.

Jot Dx ICM utilizes the key episode feature on Merlin.net PCN to reduce monitoring burden. This includes the ability to toggle the feature on or off at facility or patient level.

## Product Highlights

### Device

- The slim design allows a simple insertion procedure requiring minimal time and resources. Not noticeable after insertion in most patients.
- SharpSense™ technology improves the detection of AF, Bradycardia and Pause, with high relative sensitivity.
- Electrogram (EGM) scatterplots to easily identify relationships between variables.
- Intuitive one-touch programming on the Merlin™ Patient Care System.
- Remote monitoring ready.

- Patient-activated and auto-activated triggers for EGM storage.
- Proven SenseAbility™ 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.
- App features integrated activator functionality, allowing patients to privately record and transmit EGMs during symptoms. No separate activator hardware required.
- 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.
- 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

Contents: ICM device, insertion tool, and incision tool

| MODEL NUMBER | DESCRIPTION | DIMENSIONS (H × W × T, MM) | WEIGHT (G) | VOLUME (CM³) | LONGETIVITY |
|---|---|---|---|---|---|
| DM4500 | Jot Dx ICM | 49 x 9.4 x 3.1 | 3.0 | 1.4 | 2 years |

## Product Specifications

| PHYSICAL SPECIFICATIONS | |
| --- | --- |
| Model Number | DM4500 |
| Device Coating | Parylene |
| X-Ray ID Model Code | CC |
| Telemetry | Bluetooth® |

| FEATURES | |
| --- | --- |
| **Parameter** | **Settings** |
| Patient Trigger | Yes |
| Symptom Alert | Off<br>On (All Symptoms)<br>On (with Detection) |
| Remote Monitoring | myMerlin™ mobile app via Bluetooth® wireless technology |
| Patient Activator | myMerlin mobile 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 min |
| AF Burden Alert | Off, 30 minutes, 1, 3, 6, 9, 12, 24 hrs |
| AF Continuous Episode Alert | Off, 10, 20, 30, 60, 180 min |
| Ventricular Rate during | Off |
| AF Alert | Rate Threshold: 90, 100, 110, 120, 130, 140, 150, 175, 200 bpm<br>Total Time: 1, 3, 6, 9, 12 hrs |
| Activity Inhibits Auto Detection | Programmable; On or Off |
| Noise Response Inhibits Auto Detection | Yes |

| DIAGNOSTICS | |
| --- | --- |
| **Parameter** | **Settings** |
| Episodal Diagnostics | Yes |
| Total EGM Storage | 60 min |
| Symptom EGM Duration | Pre-trigger — 4, 6, 8, 10, 12, 14 min<br>Post-trigger — 30, 40, 50, 60 sec |
| Auto Detected EGM Duration | AF Pre- and Post-trigger — 10, 20, 30, 60, 90, 120 sec<br>Other (Tachy, Brady, Pause) Pre- and Post-trigger — 10, 20, 30, 40, 50, 60 sec |
| Heart Rate Histogram | Yes |
| AF Diagnostics | Yes |
| AF Burden Trend | Yes |

Longevity provided the following usage scenarios:
- Average of one auto-detected episode per day
- Average of one patient-activated symptom episode 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 and patient health information (PHI) data both at rest and in-transit from the ICM to the myMerlin™ Mobile App and Merlin.net™ PCN. All data is encrypted using Advanced Encryption Standard (AES).

- 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 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:** Jot Dx™ 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. Jot Dx™ ICM is also indicated for patients who have been previously diagnosed with atrial fibrillation (AF) or who are susceptible to developing AF. Jot Dx™ ICM is intended to be inserted subcutaneously in the left pectoral region, also described as the left anterior chest wall. Jot Dx™ ICM has not been specifically tested for pediatric use.

**Intended Use:** Abbott ICMs are intended to help physicians and clinicians monitor, diagnose and document the heart rhythm in patients who are susceptible to cardiac arrhythmias and unexplained symptoms by detecting arrhythmias and transmitting data for review.

**Contraindications:** There are no known contraindications for the insertion of Jot Dx™ 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.

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

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