INSERTABLE CARDIAC MONITOR

# Assert-IQ™

Insertable Cardiac Monitor
Model DM5000, DM5300, DM5500





The Assert-IQ™ Insertable Cardiac Monitor (ICM) 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

- The slim design allows a simple insertion procedure requiring minimal time and resources. Not noticeable after insertion in most patients.
- Longest lasting Bluetooth® ICM, with full functionality and no compromises with features.[1-6]
- Advanced algorithms reduce false detections by 98.7% for AF and Pause while maintaining 97.7% of true events.[7-9]
- Key Episode technology sets Abbott's Assert-IQ ICM apart from others by allowing clinicians the ability to see all episodes, or 3 Key Episodes depending on the needs of the patient or clinic.[10]
- Clear, crisp EGMs allow for improved visualization of P-waves, which could lead to faster care decisions for your patients.[11]
- Remote Programming allows clinicians to adjust the settings of the connected device, optimize performance, and limit unnecessary alerts or transmissions – all without requiring the patient to visit the clinic.
- With IQ Insights, clinicians can make data-driven decisions faster and more confidently. Additional sensors on the device capture these exciting new diagnostics:
  - Leading premature ventricular contraction (PVC) detection algorithm that offers the ability to capture consecutive events including couplets and triplets.[12]
  - Body Position & Posture at episode onset enables you to assess other patient factors while adjudicating episodes.
  - The only ICM that tracks elevated heart rate with and without activity.[1-6]
  - AF Burden, trending, and more.
- 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.
- Advanced Bluetooth® technology checks in every 20 seconds with the device, ensuring data is captured, encrypted, and transferred to the Merlin.net PCN quickly and easily.
- 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 |
|---|---|---|---|---|---|
| DM5000 | Assert-IQ™ ICM 3 | 46.5 x 9.4 x 3.1 | 2.9 | 1.2 | 3 years |
| DM5300 | Assert-IQ™ ICM 3+ | 46.5 x 9.4 x 3.1 | 2.9 | 1.2 | 3 years |
| DM5500 | Assert-IQ™ ICM EL+ | 49 x 9.4 x 4.4 | 3.7 | 1.9 | 6 years |

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| PHYSICAL SPECIFICATIONS | |
|---|---|
| Model Number | DM5500, DM5300, DM5000 |
| Device Coating | Parylene |
| Raised Header Electrode Surface Area | 37 $mm^2$ |
| 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 | 0.05-0.3 mV in increments of 0.025 mV |
| **AF** | |
| EGM Storage | On; Off |
| AF Sensitivity | Least, Less, Balanced, More |
| AF Duration | 30 sec, 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, 1, 2, 6, 10, 20, 30, 60, 180 min |
| Ventricular Rate during AF Alert<br>Rate Threshold<br>Total Time | On; Off<br>90, 100, 110, 120, 130, 140, 150, 175, 200 bpm<br>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<br>% Delta | On; Off<br>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 |
| PVC Burden® | On; Off |
| Activity Trends | On; Off |
| Posture at Episode Onset* | On; Off |
| Total EGM Storage | 60 min |
| Symptom EGM Duration | Pre-Trigger: 4, 6, 7, 10, 12, 14 min<br>Post-Trigger: 30, 40, 50, 60 sec |
| Device Detected EGM Duration<br>AF Pre- and Post-Trigger<br>Other Pre- and Post-Trigger (Tachy, Brady, Pause) | <br>10, 20, 30, 60, 90, 120 sec<br><br>10, 20, 30, 40, 50, 60 sec |
| Heart Rate Histogram | Yes |
| AF Diagnostics | Yes |
| AF Burden Trend | Yes |
| **Other Features** | |
| Patient Trigger | Yes |
| Remote Monitoring | myMerlin App via Bluetooth® wireless technology |
| Remote Programming* | Merlin.net Patient Care Network (PCN) |

Longevity provided under the following usage scenarios:
- Average of 1 auto-detected episode per day
- Average 1 patient-activated symptom episode per month
- Up to 6 month shelf storage time

# 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.
- Remote programming commands created by an authorized clinician are cryptographically authenticated by the ICM.
- 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.

**REFERENCES**

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8. Afzal MR, Gopinathannair R, Manyam H, et al. Development and Evaluation of A New Algorithm Enhancement to Improve Specificity of Pause Detection in an Insertable Cardiac Monitor. Presented at Heart Rhythm Society (HRS); San Francisco, USA; 2022.
9. Data on File. Abbott - Report SJM-CFM-0919-0163.
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11. Shehata MM, Nair DG, Qu F, et al. Insertable Cardiac Monitor P-wave Visibility in a New Clinical Report. Presented at Asia Pacific Heart Rhythm Society (APHRS); Bangkok Thailand; 2022.
12. Manyam H, Afzal MR, Gopinathannair R, et al. Evaluation of A Novel Premature Ventricular Contraction Detection Algorithm in An Insertable Cardiac Monitor. Presented at Heart Rhythm Society (HRS); San Francisco, USA; 2022.

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

**Intended Use:** The Assert-IQ 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 by detecting arrhythmias and transmitting data for review.

**Contraindications:** There are no known contraindications for the insertion of the Assert-IQ 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.

*Indicates available on DM5300/DM5500



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