

Assert-IQ™ ICM

DM5000, DM5300, DM5500



Compatible with myMerlin™ Mobile App

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.¹⁻⁷
- Advanced algorithms reduce false detections by 98.7% for AF and Pause while maintaining 97.7% of true events.⁸⁻¹⁰
- Key Episode technology sets 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.¹¹
- Clear, crisp EGMs allow for improved visualization of P-waves, which could lead to faster care decisions for your patients.¹²
- 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.¹³
 - 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.¹⁻⁷
- 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 (CC)	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



PHYSICAL SPECIFICATIONS

Model Number	DM5500, DM5300, DM5000
Device Coating	Parylene
Raised Header Electrode Surface Area	37 mm ² (double-sided)
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	On; Off
Rate Threshold	90; 100; 110; 120; 130; 140; 150; 175; 200 bpm
Total Time	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
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 Post-Trigger: 30; 40; 50; 60 sec
Device Detected EGM Duration	
AF Pre- and Post-Trigger	10; 20; 30; 60; 90; 120 sec
Other Pre- and Post-Trigger (Tachy, Brady, Pause)	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™ 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.

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Assert-IQ™ ICM

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.

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

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