CONFIRM Rx™ ICM
Model: DM3500

CONVENIENT. CONNECTED. CONTINUOUS.
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
- Shortness of breath
- Patients who are at risk for cardiac arrhythmias.
- Patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.
The Confirm Rx™ ICM is inserted under the skin in the left pectoral region. Common insertion locations are listed in the table below.

<table>
<thead>
<tr>
<th>Insertion Location</th>
<th>Mapping Recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>4th intercostal space, 45° relative to the sternum, along axis of the heart</td>
<td>No</td>
</tr>
<tr>
<td>4th intercostal space, parallel to the sternum</td>
<td>No</td>
</tr>
<tr>
<td>Anterolateral, inframammary between the 5th and 6th ribs</td>
<td>Yes</td>
</tr>
</tbody>
</table>
# CONFIRM Rx™ ICM SPECIFICATIONS

<table>
<thead>
<tr>
<th>SPECIFICATION</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>1.4 cc</td>
</tr>
<tr>
<td>Mass</td>
<td>3.0 g</td>
</tr>
<tr>
<td>Length</td>
<td>49 mm</td>
</tr>
<tr>
<td>Width</td>
<td>9.4 mm</td>
</tr>
<tr>
<td>Thickness</td>
<td>3.1 mm</td>
</tr>
<tr>
<td>Longevity</td>
<td>2 years</td>
</tr>
</tbody>
</table>

49 mm

9.4 mm

3.1 mm

[Image of the CONFIRM Rx™ ICM device with dimensions marked: 49 mm (Length), 9.4 mm (Width), 3.1 mm (Thickness).]
The Confirm Rx™ ICM is conditionally safe for use in the MRI environment when used according to instructions in the MRI Ready Monitor Systems manual.

### MRI CONDITIONAL

<table>
<thead>
<tr>
<th>Scan Parameters</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scanner Type</td>
<td>Horizontal Closed Bore</td>
</tr>
<tr>
<td>Magnet Strength</td>
<td>1.5 Tesla, Spatial Gradient ≤ 24 T/m maximum</td>
</tr>
<tr>
<td>RF Power (SAR)</td>
<td>Normal Operating Mode</td>
</tr>
<tr>
<td>Gradient Slew Rate</td>
<td>≤ 200 T/m/s</td>
</tr>
<tr>
<td>Spatial Field Gradient</td>
<td>≤ 24 T/m</td>
</tr>
<tr>
<td>Scan Region</td>
<td>Full Body</td>
</tr>
</tbody>
</table>
Confirm Rx ICM
Der erste Smartphone-kompatible ICM

Confirm Rx mit Bluetooth
Smartphone (iOS or Android)
Merlin.net™ PCN
Ihr Arrhythmie-Monitor wird heute Abend überprüft.

Achten Sie darauf, dass Ihr Mobilgerät eingeschaltet ist und sich in einem Abstand von nicht mehr als 1,5 Metern (5 ft.) befindet, wenn Sie schlafen gehen.

Symptome aufzeichnen

Verlauf  Hilfe  Mehr
Symptoms

What symptoms are you having?

- Fainting
- Dizziness
- Fluttering
- Shortness of breath
- Fast heart rate
- Other

Done
Transmission

Bluetooth® connection with ICM
Recording of episode
Sending of episode

Sending data to your clinic

During this time, keep your mobile device within 1.5 m (5 ft) of you.

Record Symptoms
Your cardiac monitor was checked today

Next automatic clinic transmission: Mar 15, 2017

When you go to bed, make sure your mobile device is on and within 1.5 m (5 ft) of you.
Manual and FAQ

FAQs
The myMerlin® for Confirm Rx™ app is used along with the St. Jude Medical Confirm Rx Insertable Cardiac Monitor. For simplicity, these FAQs use “myMerlin app” instead of “myMerlin for Confirm Rx app”.

In an emergency, do not use the app; call 911.

About myMerlin App
Getting Started
App Features
Troubleshooting

About myMerlin App
What does myMerlin app do?
Contact information:

ABC Care Clinic of LA
1234 Mockingbird Lane
Suite 12345
Los Angeles CA 90012 USA
(323) 555-1234

Remote Care Technical Support
For help, please call:
1-877-MY-MERLIN or
+1-877-696-3754
SUMMARY

- Confirm RX ICM: The new kid on the block
- Easy “injection” and programming
- Wireless transmission via Cell phone (the future!)
- Significance of subclinical AF? Remains to be determined… (true for all loop recorders)
USB BLUETOOTH® WIRELESS TECHNOLOGY ACCESSORY
MODEL: BLU1000

- Bluetooth® wireless technology enables communication between the cardiac monitor and the Merlin™ Patient Care System programmer
- Required for communicating with the Confirm Rx™ Insertable Cardiac Monitor
- Attaches to the Merlin™ Patient Care System programmer using an available USB port

RANGE: 2 m
INTERROGATING

NEW button to interrogate cardiac monitors

3 SECONDS

Bluetooth® wireless technology symbol indicates ICM communication status

STEP 1: Place magnet over device for 3 seconds

STEP 2: Touch Interrogate Monitors button
WIRELESS SECURITY MEASURES

- The ICM encrypts its wireless communication using AES-128 bit encryption and is designed to limit communications to only a single authenticated and paired myMerlin™ mobile app at any given time.

- The ICM uses a proprietary pairing protocol as an added control measure in addition to the pairing procedure specified in Bluetooth® wireless technology low energy protocols. 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 cardiac monitor denies access.

- The ICM uses an authorization protocol, which limits a paired mobile app's access based on clinician settings.

- The myMerlin™ mobile apps encrypt wireless communication to Merlin.net™ PCN through a secure TLS connection using SHA256 cryptographic protection.

- Merlin.net PCN is housed in a secured data center and is ISO27001:2013 certified. Access to patient data in Merlin.net PCN is restricted to authorized users as set by the clinic administrator. ICM data is encrypted using AES-128bit encryption.

- Merlin.net PCN is successfully certified through the EU-US Privacy Shield program to transfer patient information from the EU to the US.
AF DIAGNOSTICS

STORED EGMs
- AF Episode Entry

TREND & HISTOGRAMS
- AF Burden Trend – 30 or 31 Days
- Histogram - Mean Ventricular Rate
- Histogram - AF Episode Durations

OTHER STATISTICS
- Total AF Episodes
- Time Spent in AF since last cleared
- Most Recent Episode
- Highest Mean V Rate Episode
- Longest Episode
First study to evaluate performance of the SJM Confirm™ Implantable Cardiac Monitor to detect AF published in the Journal of Cardiovascular Electrophysiology in September 2016

- The European DETECT AF study was led by German physician Dr. Nölker
- The 90 patient study that compared the SJM Confirm™ implantable cardiac monitor to a holter monitor found:
  - SJM Confirm ICM can accurately detect AF episodes at least two minutes in length
  - SJM Confirm ICM had a sensitivity of 100%, out-performing the 96.1% sensitivity of other ICMs demonstrated in previous studies.
PREPARING FOR INSERTION
Interrogation & Initial Programming
CONFIRM Rx™ ICM CLINICIAN WORKFLOW

INITIAL INTERROGATION & PROGRAMMING

INSERT THE DEVICE

CHECK SENSING

CLOSE INCISION

ENROLL PATIENT IN MERLIN.NET™ PCN

PAIR ICM TO PATIENT’S MOBILE DEVICE
REASON FOR MONITORING

Reason for Monitoring is the ONLY required information to proceed.

- Syncope
- Palpitations
- Seizures
- Ventricular Tachycardia
- Suspected AF
- Post AF Ablation
- AF Management
- Cryptogenic Stroke
- Other

**STEP 3:** Enter Indication & Implant Date
STEP 4: Enter Patient Information

STEP 5: Enter Physician Information

STEP 6: Insert the device
Mapping is recommended if the insertion location is in the inframammary region. To determine the best location:

1. Set up the Merlin™ PCS or 12-lead ECG to view Lead I in the real-time display.
2. Place the Right Leg (RL) electrode on the torso and the Right Arm (RA) electrode and the Left Arm (LA) between the 5th and 6th ribs.
3. Print a real-time tracing and check the ECG for R-wave amplitude, and R-wave/T-wave ratio.
4. Note the best electrode configuration or use a skin marker to indicate the preferred electrode position before surgical prep.

**NOTE:** Place the conductive portion of the ECG pads 4 cm apart. This distance approximates the Confirm Rx™ ICM electrode spacing.
**MAX SENSITIVITY CONSIDERATIONS**

- **R-wave ≥ 0.45 mV**
  - NO
- **R-wave < 0.45 mV**
  - YES

**Use nominal Max Sensitivity (0.15 mV)**

**REMINDER**

If over-sensing occurs, increase Max Sensitivity until sensing is appropriate.

**CALCULATE**

\[
\frac{R\text{-wave Amplitude}}{3} \approx \text{Max Sensitivity}
\]

**EXAMPLE**

\[
\frac{0.31 \text{ mV}}{3} = 0.103 \text{ mV} \approx 0.10 \text{ mV}
\]

**Dynamic Range** | **Max Sensitivity (mV)**
---|---
±0.2 mV | 0.05, 0.075* and 0.1
±0.4 mV | 0.05, 0.075*, 0.1, 0.125, 0.15, 0.175 and 0.2
±0.8 mV (Nominal) | 0.075, 0.1, 0.125, 0.15 (Nominal), 0.175, 0.2, 0.225, 0.25, 0.3, 0.35 and 0.4
±1.6 mV | 0.15*, 0.175, 0.2, 0.225, 0.25, 0.3, 0.35, 0.4, 0.45, 0.5, 0.6, 0.7 and 0.8
CLEAR DIAGNOSTICS

PRESS BEFORE ENDING SESSION
DEVICE REPLACEMENT, EXPLANT & DISPOSAL

DEVICE REPLACEMENT
- Replace the device within one month of receiving a low battery alert, if necessary or desired.
- Replace the device immediately upon receiving a low battery alert if frequent EGMs are being stored and remotely transmitted.

EXPLANT AND DISPOSAL
- Interrogate the device and turn monitoring off before explanting
- Explant the device upon receiving an EOS alert.
- Return all explanted devices to Abbott.
- Never incinerate the device because of the potential for explosion. Explant the device before cremation.
EXPLANT TECHNIQUE

PROPER TECHNIQUE

IMPROPER TECHNIQUE