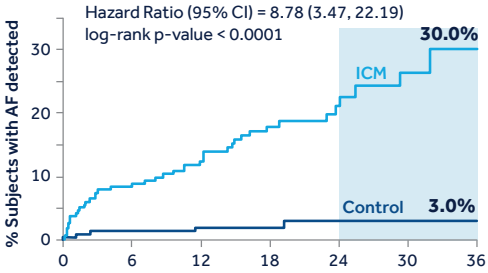
COMPARISON GUIDE

Reveal LINQ™ ICM vs. Confirm Rx™ ICM

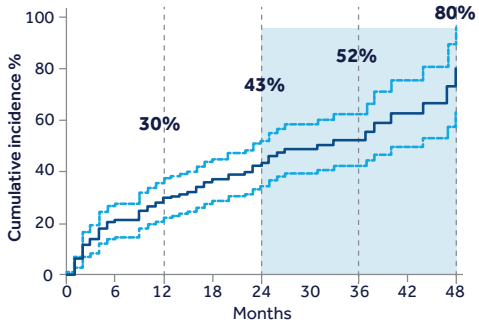
Attributes	Medtronic Reveal LINQ™ ICM	Abbott Confirm Rx™ ICM	Potential Clinical Impact
Battery	3 years[1]	2 years[2]	**Patient Diagnosis** Confirm Rx™ customers may miss diagnosis in 30% of Cryptogenic Stroke patients & 20% + Syncope patients after year 2.[3,4]
AF Episode *PPV*	95.3%[5]	60.7%[6,7]	**Data Burden** Confirm Rx™ customers may experience 8X more false positives[5,7]
AF Duration *Sensitivity*	98.9%[5]	83.8%[6,7]	**AF Episodes** Confirm Rx™ customers may miss AF detection with lower sensitivity[5,7]
Home Monitoring	Wireless connection to MyCareLink™ patient monitor	Bluetooth® connection to a personal mobile device or mobile transmitter[2]	
Transmission Range	2 m from ICM[1]	1.5 m from ICM[8]	
Size & Procedure	1.2 cc with insertion toolkit provided[1]	1.4 cc with insertion toolkit provided[2]	
MRI	1.5T & 3T[9]	1.5T[2]	
Published Evidence	500+ published articles & abstracts[10]	<20 published articles & abstracts[11]	
Long-term Monitoring Resources	Reveal LINQ™ clinic education & workflows, Reveal LINQ℠ Monitoring Service & Reveal LINQ™ Mobile Manager	Not yet available — new workflows required	

Longevity: ICM Time to Diagnosis[3,4]

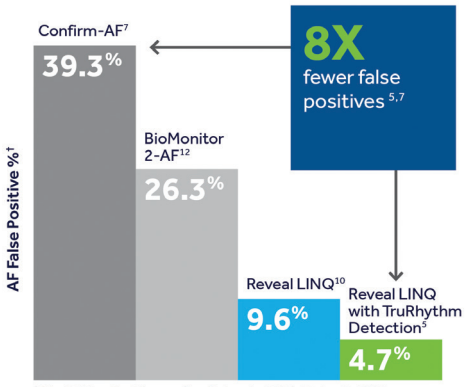
30%+ Cryptogenic Stroke AF diagnoses occur after 2 years[3]



20%+ Syncope diagnoses occur after 2 years[4]



AF Accuracy: False Positive%[5,7,10,12]



†% of False Positives = (1 – Episode PPV). Episode PPV may vary (gross, patient average).

Reveal LINQ™ System delivers:

- Industry-leading performance with the **world's most accurate ICM**[5,7]
- Clinically proven performance with **500+ published articles & abstracts**[10]
- System of exclusive solutions to **streamline workflow**

Disclaimer: A controlled, head-to-head study evaluating the comparative performance of these devices has not been done.

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References

[1] Reveal LINQ™ ICM LNQ11 Clinician Manual. 2017.
[2] Confirm Rx™ Insertable Cardiac Monitor U.S. Champ Document. 2017
[3] Sanna T, Diener HC, Passman RS, et al. Cryptogenic stroke and underlying atrial fibrillation. *N Engl J Med*. June 26, 2014;370(26):2478-2486.
[4] Furukawa T, Maggi R, Bertolone C, Fontana D, Brignole M. Additional diagnostic value of very prolonged observation by implantable loop recorder in patients with unexplained syncope. *J Cardiovasc Electrophysiol*. January 2012;23(1):67-71.
[5] TruRhythm™ Detection Algorithms. Medtronic data on file. 2017.
[6] Confirm Rx™ ICM DM3500 FDA Clearance Letter 2017.
[7] Nölker G., Mayer J., Boldt LH, et al. Performance of an Implantable Cardiac Monitor to Detect Atrial Fibrillation: Results of the DETECT AF Study, *J Cardiovasc Electrophysiol*. 2016;27(12):1403-1410.
[8] Confirm™ Rx MyMerlin App Demo.
[9] Reveal LINQ ICM LNQ11 MRI Procedural Information. 2017.
[10] Medtronic Reveal™ Publications. Medtronic data on file. 2016.
[11] St. Jude Confirm™ Publications. Medtronic data on file, 2017.
[12] Biotronik BioMonitor 2 Technical Manual. 2017.

If you are located in the United States, please refer to the brief statement below to review applicable indications, safety, and warning information. See the **device manual** for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-763-514-4000 and/or consult the Medtronic website at medtronic.com.

If you are located outside the United States, see the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.com.

www.medtronic.com/manuals

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Brief Statement
Reveal LINQ™ LNQ11 Insertable Cardiac Monitor and Patient Assistant
Indications: Reveal LINQ™ LNQ11 Insertable Cardiac Monitor: The Reveal LINQ insertable cardiac monitor is an implantable patient-activated and automatically-activated monitoring system that records subcutaneous ECG and is indicated in the following cases: patients with clinical syndromes or situations at increased risk of cardiac arrhythmias; patients who experience transient symptoms such as dizziness, palpitation, syncope, and chest pain, that may suggest a cardiac arrhythmia. This device has not been specifically tested for pediatric use. **Patient Assistant:** The Patient Assistant is intended for unsupervised patient use away from a hospital or clinic. The Patient Assistant activates the data management feature in the Reveal™ insertable cardiac monitor to initiate recording of cardiac event data in the implanted device memory. **Contraindications:** There are no known contraindications for the implant of the Reveal LINQ insertable cardiac monitor. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated. **Warnings/Precautions: Reveal LINQ LNQ11 Insertable Cardiac Monitor:** Patients with the Reveal LINQ insertable cardiac monitor should avoid sources of diathermy, high sources of radiation, electrosurgical cautery, external defibrillation, lithotripsy, therapeutic ultrasound, and radiofrequency ablation to avoid electrical reset of the device, and/or inappropriate sensing as described in the Medical procedure and EMI precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ MRI Technical Manual. **Patient Assistant:** Operation of the Patient Assistant near sources of electromagnetic interference, such as cellular phones, computer monitors, etc., may adversely affect the performance of this device. **Potential Complications:** Potential complications include, but are not limited to, device rejection phenomena (including local tissue reaction), device migration, infection, and erosion through the skin. See the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com. **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

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