SYNCOPE DIAGNOSIS NEEDED. CHALLENGE ACCEPTED.

ACC/AHA/HRS & ESC Guidelines Recommend ICM in the Evaluation of Unexplained Syncope

Actual size

Reveal LINQ™
Insertable Cardiac Monitoring

Medtronic

DIAGNOSING UNEXPLAINED SYNCOPE **IS CHALLENGING**

HALF OF PATIENTS ADMITTED TO THE HOSPITAL FOR SYNCOPE LEAVE WITHOUT A DIAGNOSIS[1]

An average of 251,000 people are hospitalized for syncope every year.[2]

PATIENTS NEED **ANSWERS**

3
specialists visited on average[3]

13
inconclusive tests*[3]

*Median number

1 in 4
undergo more than 20 tests[4]

GETTING ANSWERS **IS URGENT**

CARDIAC SYNCOPE **IS DEADLY**

Cardiac syncope can be a predictor of sudden cardiac death.[5]

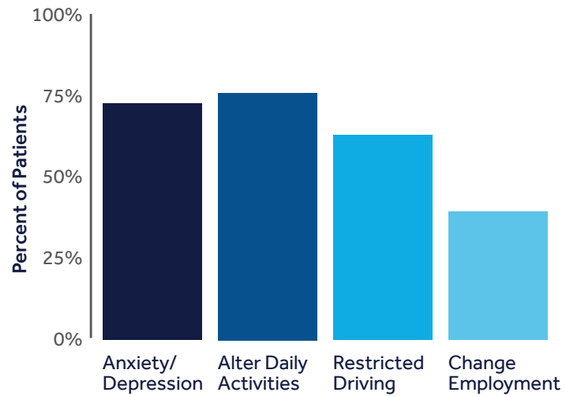
2X
increased risk of death[6]

>10%
mortality rate at six months[6]

36%
suffer significant trauma[3]

Visit Medtronic.com/Syncope to hear William's story

LIVING WITHOUT A DIAGNOSIS **COMPROMISES QUALITY OF LIFE**[7-9]



- 1.4X increased risk of **occupational accidents**[9]
- 2X increased risk of **loss of employment**[9]

ACC/AHA/HRS & ESC GUIDELINES

Recommend Cardiac Monitoring with Reveal LINQ™ ICM Early in the Evaluation of Syncope

Reveal LINQ is recommended for patients with infrequent symptoms > 30 days apart

ACC/AHA/HRS 2017 Guidelines Recommendation[10]

COR	LOE	RECOMMENDATION
I	NA	If the initial evaluation (history, physical exam, ECG) is unclear and a cardiac cause is suspected, cardiac monitoring is recommended.
I	C-EO	The choice of a specific cardiac monitor should be determined on the basis of the frequency and nature of syncope events.
IIa	B-R	To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an ICM can be useful.

COR — Class of Recommendation LOE — Level of Evidence

ICM is the only ambulatory monitor with a Class I recommendation for syncope

ESC 2018 Guidelines Recommendation[11]

COR	LOE	RECOMMENDATION
I	A	**UPGRADED:** ICMs upgraded to Class I/Level A recommendation — the strongest level of clinical evidence — for early monitoring in low-risk patients and after workup of high-risk patients.
IIb	B	**NEW:** ICMs added as a Class II/Level B recommendation to diagnose unexplained falls and unconfirmed epilepsy
IIa	B	ICMs should be considered in patients with suspected or certain reflex syncope presenting with frequent or several syncopal episodes.

COR — Class of Recommendation LOE — Level of Evidence

Holter monitor and tilt testing downgraded from Class I to Class II recommendation

CONTINUE MONITORING. GET TO THE ANSWER.

If initial monitoring is non-diagnostic, keep looking with Reveal LINQ ICM.

88% of patients who are guideline-eligible for an ICM/ILR are over-tested with other modalities before being offered an ICM/ILR.[4]

↑ Over-testing **increases cost** with no improvement to diagnostic yield.[4]

Reveal LINQ™ ICM **up to 3 years**[12]

SUPERIOR DIAGNOSTIC YIELD

Clinical evidence overwhelmingly supports ICM for infrequent syncope

PATIENTS WITH LONG-TERM MONITORING GET ANSWERS

3.6x
more likely to reach a diagnosis with ICM vs. standard of care

2018 ESC Guidelines
Meta-analysis of
5 randomized clinical trials[11]

44%
ICM diagnostic yield[13]

2017 Meta-analysis of
49 studies
4,381 patients†

vs. standard of care **5–20%***[14-17]

*Range for ICM in the same studies was 42-52%.
†84% of the 4,381 patients in the studies were reported to have been tested with a Reveal™ ICM.

EARLIER ICM USE SAVES PATIENTS MONEY

Multiple studies show cost savings with ICM compared to conventional testing due to fewer tests and hospital admissions.[14,17-19]

REVEAL LINQ ICM BROADLY COVERED

Medicare and private payers cover inpatient and outpatient Reveal LINQ ICM insertions.*

REVEAL LINQ GUIDES TREATMENT DECISIONS

78%
of Reveal™ ICM patients with syncope recurrence received a differential diagnosis (PICTURE Study)[3]

82%
of Reveal ICM guided diagnoses led to treatment[3]

IMPROVED QOL
in ICM patients with syncope[16,20]

SIGNIFICANT REDUCTION
in syncope burden with therapies guided by ICM diagnosis[21]

*Please see coverage guide in Medtronic Reimbursement App for specific coverage information by provider.

"Holter monitoring in syncope is inexpensive in terms of setup costs, but expensive in terms of cost per diagnosis."

–ESC 2018 Syncope Guidelines Task Force[11]

PATIENTS PREFER REVEAL LINQ™ ICM

Over External Wearable Monitors[22]

Continuous, automatic cardiac monitoring and patient-activated symptom marking to correlate symptoms to cardiac rhythms

SIMPLE
Insertion procedure is minimally invasive and brief

CONVENIENT
100% of patients found Reveal LINQ ICM did not limit their activities of daily living[22]

ULTRA-DISCREET
Not visible in most patients

MRI CONDITIONAL
Safe for MRI at 1.5 and 3.0T even on the same day of insertion*

*Reveal LINQ has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Please see the Reveal ICM clinician manual or MRI technical manual for more details.

"[If I'd known about it,] I wouldn't have requested it — I would have demanded that be done. I was tired of not having any answers." [23,†]
—Reveal LINQ Patient

"It . . . was, for me, a peace of mind thing, knowing that, if anything happens, they can capture it."[23,†]
—Reveal LINQ Patient

"It's easier than the portable monitors. . . . I had a very bad accident because I passed out . . . so I was very ready to do anything to make sure that I don't have another serious accident. . . . I . . . was glad to have a monitor that I don't have to have around my neck all the time."[23,†]
—Reveal LINQ Patient

†Patient outcomes may vary.

CARDIAC MONITORING UP TO 3 YEARS

20%

of syncope diagnosed with Reveal ICMs occurred after 2 years[24]

THE LONGER YOU LOOK, THE MORE YOU FIND

Actual size

The world's smallest insertable cardiac monitor

INDUSTRY-LEADING TRURHYTHM™ DETECTION

	Reduction in false detects*	Relative sensitivity*
BRADY	↓ 95%	98.3%
PAUSE	↓ 47%	99.4%

*Compared with the Reveal LINQ ICM without TruRhythm Detection

EXCLUSIVE ALGORITHMS
significantly **reduce false positives while preserving sensitivity.**[25,26]

INTELLIGENT
Smart Filtering algorithm improves detection accuracy for Brady & Pause.

ACTIONABLE
Streamlined Episodes & Report Updates simplify data review.

References

[1] Mendu ML, McAvay G, Lampert R, Stoehr J, Tinetti ME. Yield of diagnostic tests in evaluating syncopal episodes in older patients. *Arch Intern Med*. July 27, 2009;169(14):1299-1305.
[2] Data obtained from CDC National Hospital Ambulatory Medical Care Survey (NHAMCS) from the years 2008-2014.
[3] Edvardsson N, Frykman V, van Mechelin R, et al. Use of an implantable loop recorder to increase the diagnostic yield in unexplained syncope: results from the PICTURE registry. *Europace*. February 2011;13(2):262-269.
[4] Edvardsson N, Wolff C, Tsintzos S, Rieger G, Linker NJ. Costs of unstructured investigation of unexplained syncope: insights from a micro-costing analysis of the observational PICTURE registry. *Europace*. July 2015;17(7):1141-1148.
[5] R. Brugada, et al. (eds), Clinical Approach to Sudden Cardiac Death Syndromes, London: Springer-Verlag; 2010.
[6] Soteriades ES, Evans JC, Larson MG, et al. Incidence and prognosis of syncope. *N Engl J Med*. September 19, 2002;347(12):878-885.
[7] Linzer M, Pontinen M, Gold DT, Divine GW, Felder A, Brooks WB. Impairment of physical and psychosocial function in recurrent syncope. *J Clin Epidemiol*. 1991;44(10):1037-1043.
[8] Linzer M, Gold DT, Pontinen M, Divine GW, Felder A, Brooks WB. Recurrent syncope as a chronic disease: preliminary validation of a disease-specific measure of functional impairment. *J Gen Intern Med*. April 1994;9(4):181-186.
[9] Numé AK, Kragholm K, Carlson N, et al. Syncope and Its Impact on Occupational Accidents and Employment. *Circ Cardiovasc Qual Outcomes*. April 2017;10(4).
[10] Shen WK, Sheldon RS, Benditt DG, et al. 2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines, and the Heart Rhythm Society. *J Am Coll Cardiol*. August 1, 2017;70(5):e39-e110.
[11] Brignole M, Moya A, de Lange FJ, et al. 2018 ESC Guidelines for the diagnosis and management of syncope. *Eur Heart J*. Published online March 19, 2018.
[12] Reference the Reveal LINQ ICM Clinician Manual for usage parameters.
[13] Solbiati M, Casazza G, Dipaola F, et al. The diagnostic yield of implantable loop recorders in unexplained syncope: A systematic review and meta-analysis. *Int J Cardiol*. March 15, 2017;231:170-176.
[14] Farwell DJ, Freemantle N, Sulke AN. Use of implantable loop recorders in the diagnosis and management of syncope. *Eur Heart J*. July 2004;25(14):1257-1263.
[15] Krahn AD, Klein, GJ, Yee R, Skanes AC. Randomized assessment of syncope trial: conventional diagnostic testing versus a prolonged monitoring strategy. *Circulation*. July 3, 2001;104(1):46-51.
[16] Podoleanu C, DaCosta A, Defaye P, et al. Early use of an implantable loop recorder in syncope evaluation: a randomized study in the context of the French healthcare system (FRESH study). *Arch Cardiovasc Dis*. October 2014;107(10):546-552.
[17] Krahn AD, Klein GJ, Yee R, Hoch JS, Skanes AC. Cost implications of testing strategy in patients with syncope: randomized assessment of syncope trial. *J Am Coll Cardiol*. August 6, 2003;42(3):495-501.
[18] Davis S, Westby M, Pitcher D, Petkar S. Insertable loop recorders are cost-effective when used to investigate transient loss of consciousness which is either suspected to be arrhythmic or remains unexplained. *Europace*. March 2012;14(3):402-409.
[19] Providência R, Candeias R, Morais C, et al. Financial impact of adopting implantable loop recorder diagnostic for unexplained syncope compared with conventional diagnostic pathway in Portugal. *BMC Cardiovasc Disord*. May 6, 2014;14:63.
[20] Farwell DJ, Freemantle N, Sulke N. The clinical impact of implantable loop recorders in patients with syncope. *Eur Heart J*. February 2006;27(3):351-356.
[21] Sulke N, Sugihara C, Hong P, Patel N, Freemantle N. The benefit of a remotely monitored implantable loop recorder as a first line investigation in unexplained syncope: the EaSyAS II trial. *Europace*. June 2016;18(6):912-918.
[22] Reveal LINQ Usability Study. Medtronic data on file. 2013.
[23] Research on file.
[24] 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.
[25] Pürerfellner H, Sanders P, Sarkar S, et al. Adapting detection sensitivity based on evidence of irregular sinus arrhythmia to improve atrial fibrillation detection in insertable cardiac monitors. *Europace*. Published online October 3, 2017.
[26] Passman RS, Rogers JD, Sarkar S, et al. Development and validation of a dual sensing scheme to improve accuracy of bradycardia and pause detection in an insertable cardiac monitor. *Heart Rhythm*. July 2017;14(7):1016-1023.
[27] Da Costa A, Defaye P, Romeyer-Bouchard C, et al. Clinical impact of the implantable loop recorder in patients with isolated syncope, bundle branch block and negative workup: A randomized multicenter prospective study. *Arch Cardiovasc Dis*. March 2013;106(3):146-154.
[28] Linzer M, Yang EH, Estes NA 3rd, Wang P, Vorperian VR, Kapoor WN. Diagnosing syncope. Part 2: Unexplained syncope. Clinical Efficacy Assessment Project of the American College of Physicians. *Ann Intern Med*. July 1, 1997;127(1):76-86.
[29] Krahn AD, Klein GJ, Yee R, Takle-Newhouse T, Norris C. Use of an extended monitoring strategy in patients with problematic syncope. Reveal Investigators. *Circulation*. January 26, 1999;99(3):406-410.
[30] ICM Competitive Comparison Guide. Medtronic data on file. 2017.
[31] Medtronic Reveal Publications. Medtronic data on file. 2016.

Indications, Safety, and Warnings

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 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

Consult instructions for use at this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat Reader® with the browser.

Important Reminder: This information is intended only for users in markets where Medtronic products and therapies are approved or available for use as indicated within the respective product manuals. Content on specific Medtronic products and therapies is not intended for users in markets that do not have authorization for use.

Reveal LINQ™ LNQ11 Insertable Cardiac Monitor and Patient Assistant

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 specifically been 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 and 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.

Medtronic MyCareLink™ Patient Monitor, Medtronic CareLink™ Network, and CareLink™ Mobile Application

Intended Use

The Medtronic MyCareLink patient monitor and CareLink network are indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manual. The CareLink mobile application is intended to provide current CareLink network customers access to CareLink network data via a mobile device for their convenience. The CareLink mobile application is not replacing the full workstation, but can be used to review patient data when a physician does not have access to a workstation. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician. CareLink network availability and mobile device accessibility may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. Mobile device access to the Internet is required and subject to coverage availability. Standard text message rates apply.

Contraindications

There are no known contraindications.

Warnings and Precautions

The MyCareLink patient monitor must only be used for interrogating compatible Medtronic implantable devices.

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 these devices to sale by or on the order of a physician.

DIAGNOSIS NEEDED. CHALLENGE ACCEPTED.

ACC/AHA/HRS & ESC Guidelines Recommend ICM in the Evaluation of Unexplained Syncope

CHOOSE REVEAL LINQ™ ICM FOR PATIENTS WITH SYMPTOMS > 30 DAYS APART

ICM Delivers Superior Diagnostic Yield for infrequent syncope compared to conventional testing[15,16,27]

Reveal LINQ™ ICM
up to 3 years[12]

20 YEARS OF ICM LEADERSHIP & INNOVATION

- The most effective diagnostic tool for infrequent, unexplained syncope[1,13,15,16,20,27-29]
- Unmatched detection accuracy[30]
- The most studied and validated ICM, with over 500 publications[31]

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

Medtronic