SYNCOPE DIAGNOSIS NEEDED.
CHALLENGE ACCEPTED.

ACC/AHA/HRS & ESC Guidelines Recommend ICM in the Evaluation of Unexplained Syncope
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.\(^2\)

CARDIAC SYNCOPE IS DEADLY

Cardiac syncope can be a predictor of sudden cardiac death.\(^3\)

2X increased risk of death\(^4\)

> 10% mortality rate at six months\(^5\)

PATIENTS NEED ANSWERS

An average of 251,000 people are hospitalized for syncope every year.\(^2\)

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\(^9\)

3 specialists visited on average\(^3\)

13 inconclusive tests*\(^3\)

1 in 4 undergo more than 20 tests*\(^3\)

1.4X increased risk of occupational accidents\(^9\)

2X increased risk of loss of employment\(^9\)

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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**

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>RECOMMENDATION</th>
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<tbody>
<tr>
<td>I</td>
<td>NA</td>
<td>If the initial evaluation (history, physical exam, ECG) is unclear and a cardiac cause is suspected, cardiac monitoring is recommended.</td>
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<tr>
<td>I</td>
<td>C-EO</td>
<td>The choice of a specific cardiac monitor should be determined on the basis of the frequency and nature of syncope events.</td>
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<tr>
<td>IIa</td>
<td>B-R</td>
<td>To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an ICM can be useful.</td>
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**ESC 2018 Guidelines Recommendation**

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<td>I</td>
<td>A</td>
<td><strong>UPGRADED:</strong> 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.</td>
</tr>
<tr>
<td>IIb</td>
<td>B</td>
<td><strong>NEW:</strong> ICMs added as a Class II/Level B recommendation to diagnose unexplained falls and unconfirmed epilepsy</td>
</tr>
<tr>
<td>IIa</td>
<td>B</td>
<td>ICMs should be considered in patients with suspected or certain reflex syncope presenting with frequent or several syncopal episodes.</td>
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COR — Class of Recommendation  LOE — Level of Evidence

**CONTINUE MONITORING. GET TO THE ANSWER.**

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

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

**NEW:** ICMs added as a Class II/Level B recommendation to diagnose unexplained falls and unconfirmed epilepsy

**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.

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

Over-testing increases cost with no improvement to diagnostic yield.

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

**Up to 3 years**
**SUPERIOR DIAGNOSTIC YIELD**
Clinical evidence overwhelmingly supports ICM for infrequent syncope

**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

**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 treatment³

**IMPROVED QOL in ICM patients with syncope**⁶,⁷

**SIGNIFICANT REDUCTION in syncope burden with therapies guided by ICM diagnosis**¹¹

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

2018 ESC Guidelines Meta-analysis of 5 randomized clinical trials¹¹

2017 Meta-analysis of 49 studies 4,381 patients¹

vs. standard of care 5–20%¹⁴-¹⁷

2018 ESC Guidelines Meta-analysis of 5 randomized clinical trials

I4-17

1.64% of the 4,381 patients in the studies were reported to have been tested with a Reveal™ ICM.

*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 Force¹¹
**INDUSTRY-LEADING TRURHYTHM™ DETECTION**

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<th>Reduction in false detects</th>
<th>Relative sensitivity</th>
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</thead>
<tbody>
<tr>
<td>BRADY</td>
<td>↓ 95%</td>
<td>98.3%</td>
</tr>
<tr>
<td>PAUSE</td>
<td>↓ 47%</td>
<td>99.4%</td>
</tr>
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"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." — Reveal LINQ Patient

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

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*Patient outcomes may vary.

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**SIMPLE**
Insertion procedure is minimally invasive and brief

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

**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.

*Compared with the Reveal LINQ ICM without Trurhythm Detection

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PATIENTS PREFER REVEAL LINQ™ ICM

Over External Wearable Monitors

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

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CARDIAC MONITORING UP TO 3 YEARS

20% of syncope diagnosed with Reveal ICMs occurred after 2 years

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THE LONGER YOU LOOK, THE MORE YOU FIND
References

2. Data obtained from CDC National Hospital Ambulatory Medical Care Survey (NHAMCS) from the years 2008-2014.
13. Davis S, Westby M, Pfeffer O, Petrus S. Insertable loop recorders are cost-effective when used to investigate transient loss of consciousness whereas it is either suspected to be arrhythmic or remains unexplained. Europace. March 2012;14(3):402-409.

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.

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 1-877-514-4000 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.

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 8.0 with the browser.

www.medtronic.com-Manuals

Patient Assistant

This device has not specifically been tested for pediatric use.

Patient Assistant

The 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 for the implant of the Reveal LINQ insertable cardiac monitor. However, the patient’s particular medical condition may dictate whether or not a substrate can be structurally implanted and therefore be tolerable.

Warnings and Precautions

Reveal LINQ ICD Insertable Cardiac Monitor

Patients with the Reveal LINQ insertable cardiac monitor should avoid sources of diathermy, high levels of radiation, electrocautery, 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 EER precautions manual. MRI scans should be performed only in a specified MR environment under specified conditions as described in the Reveal LINQ ICD™ 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.
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

Reveal LINQ™ ICM up to 3 years

20 YEARS OF ICM LEADERSHIP & INNOVATION

- The most effective diagnostic tool for infrequent, unexplained syncope
- Unmatched detection accuracy
- The most studied and validated ICM, with over 500 publications

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