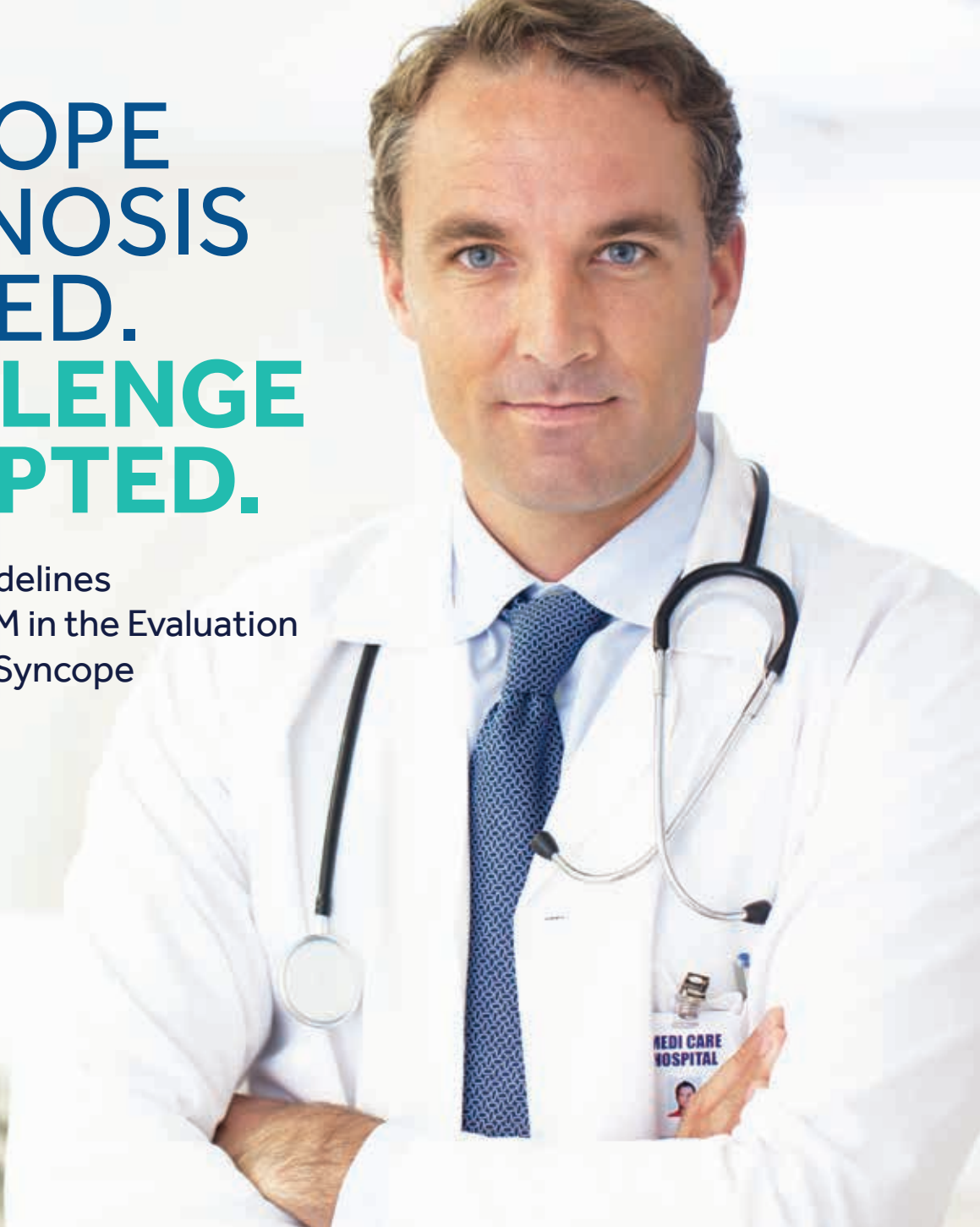


# SYNCOPE DIAGNOSIS NEEDED. CHALLENGE ACCEPTED.

ESC & NICE Guidelines  
Recommend ICM in the Evaluation  
of Unexplained Syncope



Actual size

**Reveal LINQ™**  
Insertable Cardiac  
Monitoring System

**Medtronic**

# GETTING ANSWERS IS URGENT

## CARDIAC SYNCOPES IS DEADLY

Cardiac syncope can be a predictor of sudden cardiac death.<sup>1</sup>

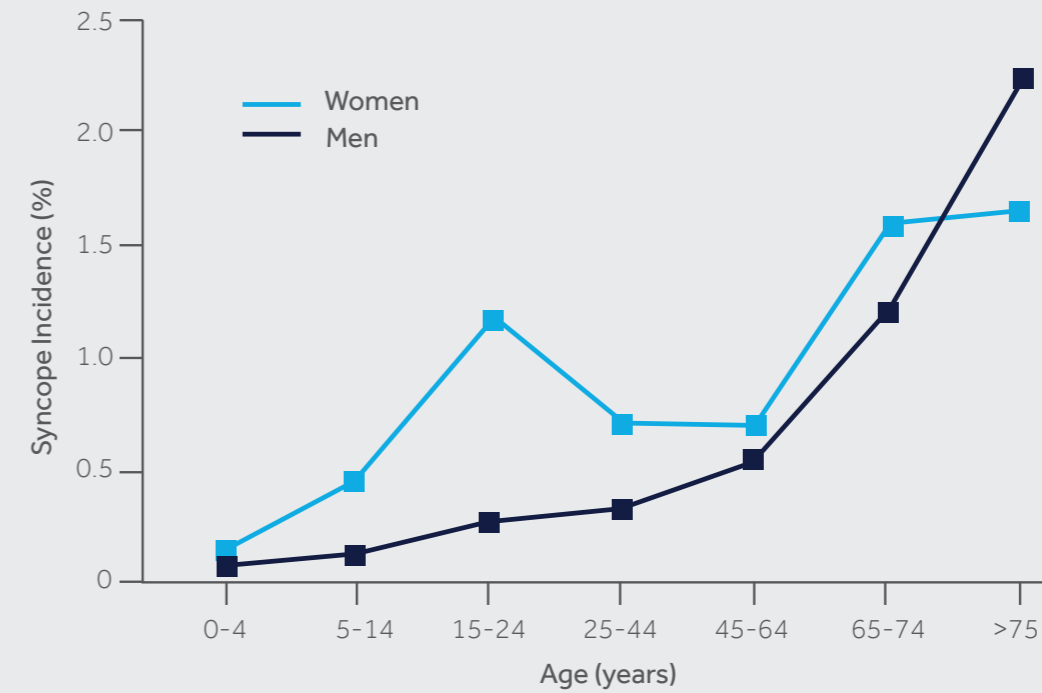
**2X**  
increased risk of death<sup>2</sup>

**> 10%**  
mortality rate at six months<sup>2</sup>



# UNDIAGNOSED SYNCOPES A GROWING CHALLENGE TO THE HEALTHCARE SYSTEM

Prevalence of Syncope Based on Age and Sex of Patients<sup>6,7</sup>



**50%**

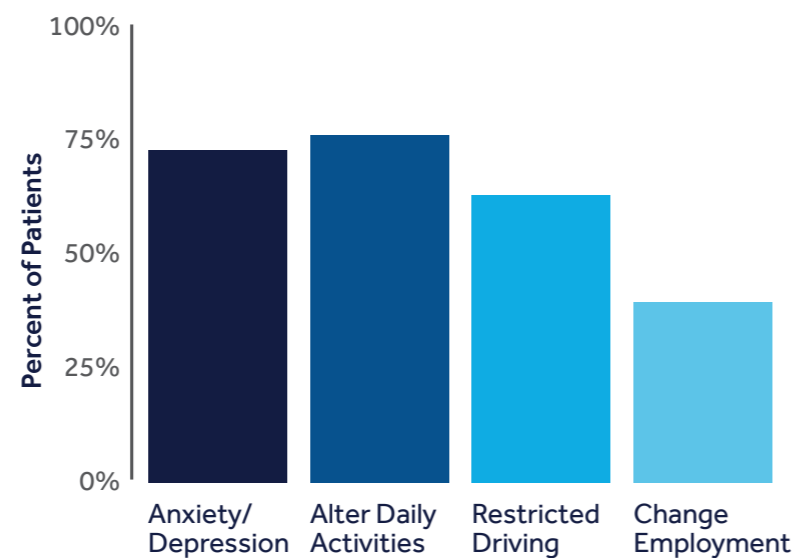
of patients admitted to hospital for syncope-related events are > 75 years of age.<sup>6</sup>

**~20%**

of cardiovascular syncope in patients older than 70 appears as falls.<sup>8</sup>

## LIVING WITHOUT A DIAGNOSIS COMPROMISES QUALITY OF LIFE<sup>3-5</sup>

- 1.4X increased risk of occupational accidents<sup>5</sup>
- 2X increased risk of loss of employment<sup>5</sup>



With an increasingly older population, syncope ED visits, admissions, and injury will continue to rise.<sup>9</sup>

## PATIENTS REMAIN UNDIAGNOSED

Syncope accounts for **1-3%** of emergency room visits<sup>10,11</sup>

**32%** of those ER patients are hospitalized<sup>12</sup>

HALF OF PATIENTS ADMITTED TO THE HOSPITAL LEAVE WITHOUT A DIAGNOSIS<sup>13</sup>

# ESC GUIDELINES

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

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

ESC 2018 Guidelines Recommendation<sup>14</sup>

COR	LOE	RECOMMENDATION
I	A	<b>UPGRADED:</b> 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	<b>NEW:</b> 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

## CHOOSE THE RIGHT TESTS FOR THE RIGHT PATIENT

Guidelines recommend choosing a diagnostic test based on high arrhythmia risk and frequency of symptoms.

**88%**

of patients who are guideline-eligible for an ICM are over-tested with other modalities before being offered an ICM/ILR.<sup>15</sup>

# A MULTIDISCIPLINARY TEAM APPROACH TO IMPROVE SYNCOPES CARE

## Structured Care Pathway

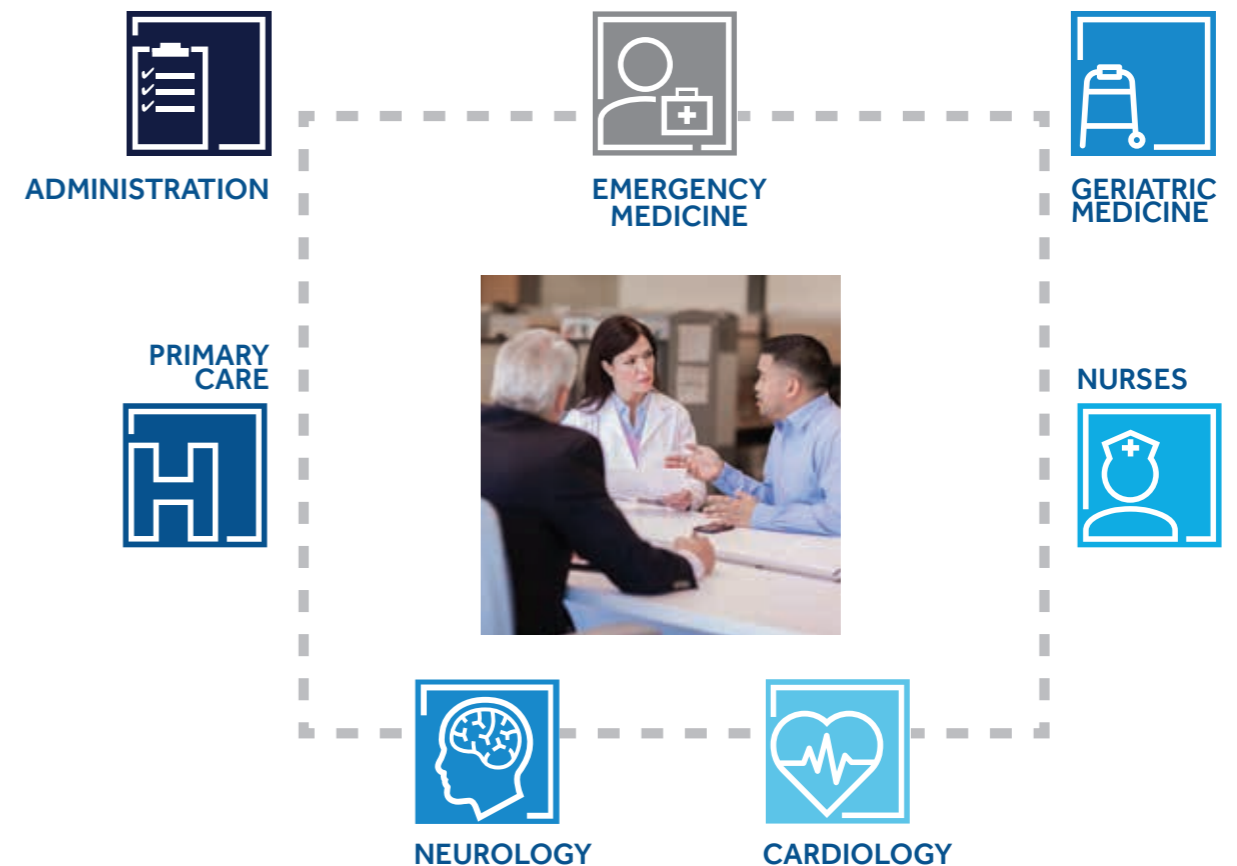
Structured care pathways "offer safe and effective alternatives to [hospital] admission."<sup>14</sup>

## Multidisciplinary Approach

Cardiology, emergency and internal medicine, neurology, geriatric[s], and nursing cover aspects of [syncope] management.<sup>14</sup>

## Syncope Unit Implementation

Consensus shows that a dedicated [syncope] service affords better management "from risk stratification to diagnosis, therapy, and follow-up."<sup>14</sup>





# REVEAL LINQ ICM: A COST-EFFECTIVE DIAGNOSTIC TOOL



## SUPERIOR DIAGNOSTIC YIELD

Clinical evidence overwhelmingly supports ICM for recurrent syncope



### Recurrent syncope is costly

**£5,713** Average cost per patient of all additional syncope hospitalizations<sup>16</sup>

**£5,617** Average cost of injury due to fall (with likely syncopal cause)<sup>16</sup>

**£1,613** Average overuse cost per patient when utilizing low-yield diagnostic tests.<sup>17</sup>

"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<sup>14</sup>

**3.6X**

more likely to reach a diagnosis with ICM vs. standard of care<sup>14</sup>

2018 ESC Guidelines  
Meta-analysis of  
5 randomized clinical trials

**44%**

ICM diagnostic yield<sup>31</sup>

2017 Meta-analysis of  
49 studies  
4,381 patients\*

vs. standard of care **5-20%**<sup>†20-23</sup>

### Avoid hospitalizations, injury, and costs with earlier ICM insertion

**60%**  
reduction in hospitalizations for patients with an ICM<sup>18</sup>

**67%**  
reduction in cost with fewer tests, fewer hospital days<sup>19</sup>

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

# PATIENTS PREFER REVEAL LINQ™ ICM

Over External Wearable Monitors<sup>24</sup>

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



# CARDIAC MONITORING UP TO 3 YEARS

## 20%

of syncope diagnosed with Reveal™ ICMs occurred after 2 years<sup>26</sup>

THE LONGER YOU LOOK, THE MORE YOU FIND



Actual size

The world's smallest insertable cardiac monitor

## SIMPLE

Insertion procedure is minimally invasive and brief

## CONVENIENT

100% of patients found Reveal LINQ ICM did not limit their activities of daily living<sup>24</sup>

## 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\*

"[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."<sup>†25</sup>

—Reveal LINQ Patient

"It ... was, for me, a peace of mind thing, knowing that, if anything happens, they can capture it."<sup>†25</sup>

—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."<sup>†25</sup>

—Reveal LINQ Patient

# INDUSTRY-LEADING TRURHYTHM™ DETECTION

	Reduction in false detects*	Relative sensitivity*
BRADY	↓ 95% <sup>27</sup>	98.3% <sup>27</sup>
PAUSE	↓ 47% <sup>27</sup>	99.4% <sup>27</sup>
AF <sup>†</sup>	↓ 49% <sup>27</sup>	99.1% <sup>27</sup>

\*Compared to the Reveal LINQ ICM without TruRhythm Detection  
<sup>†</sup>In known AF patients



## EXCLUSIVE ALGORITHMS

significantly reduce false positives while preserving sensitivity.<sup>28,29</sup>



## INTELLIGENT

Smart filtering algorithm improves detection accuracy for Brady and Pause.



## ACTIONABLE

Streamlined episodes and report updates simplify data review.

\*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.

<sup>†</sup>Patient outcomes may vary.

## References

- <sup>1</sup> R. Brugada, et al. (eds), Clinical Approach to Sudden Cardiac Death Syndromes, London: Springer-Verlag; 2010.
- <sup>2</sup> Soteriades ES, Evans JC, Larson MG, et al. Incidence and prognosis of syncope. *N Engl J Med*. September 19. 2002;347(12):878-885.
- <sup>3</sup> 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.
- <sup>4</sup> 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.
- <sup>5</sup> 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).
- <sup>6</sup> Wieling W, Ganzeboom KS, Saul JP. Reflex syncope in children and adolescents. *Heart*. September 2004;90(9):1094-1100.
- <sup>7</sup> Campbell AJ, Reinken J, Allan BC, Martinez GS. Falls in old age: a study of frequency and related clinical factors. *Age Ageing*. November 1981;10(4):264-270.
- <sup>8</sup> Andrea Ungar. Fall prevention in the elderly. *Clin Cases Miner Bone Metab*. 2013 May-Aug; 10(2): 91–95.
- <sup>9</sup> Ganzeboom KS, Mairuhu G, Reitsma JB, Linzer M, Wieling W, van Dijk N. Lifetime cumulative incidence of syncope in the general population: a study of 549 Dutch subjects aged 35-60 years. *J Cardiovasc Electrophysiol*. November 2006;17(11):1172-1176.
- <sup>10</sup> Probst MA, Kanzaria HK, Gbedemah M, Richardson LD, Sun BC. National trends in resource utilization associated with ED visits for syncope. *Am J Emerg Med*. August 2015;33(8):998-1001.
- <sup>11</sup> Day SC, Cook EF, Funkenstein H, Goldman L. Evaluation and outcome of emergency room patients with transient loss of consciousness. *Am J Med*. July 1982;73(1):15-23.
- <sup>12</sup> Sun BC, Emond JA, Camargo CA Jr. Characteristics and admission patterns of patients presenting with syncope to U.S. emergency departments, 1992-2000. *Acad Emerg Med*. October 2004;11(10):1029-1034.
- <sup>13</sup> 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.
- <sup>14</sup> Brignole M, Moya A, de Lange FJ, et al. 2018 ESC Guidelines for the diagnosis and management of syncope. *Eur Heart J*. June 1, 2018;39(21):1883-1948.
- <sup>15</sup> 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.
- <sup>16</sup> Wolff C, Petkar S. Long term clinical and economic burden of recurrent unexplained syncope and the real world effectiveness of implantable cardiac monitors in England, 2016 ESC abstract.
- <sup>17</sup> Edvardsson N, Frykman V, van Mechelen 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.
- <sup>18</sup> 2016 Abstract on UK Hospital Episode Statistics for 12,002 syncope patients.
- <sup>19</sup> 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.
- <sup>20</sup> 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.
- <sup>21</sup> 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.
- <sup>22</sup> 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.
- <sup>23</sup> 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.
- <sup>24</sup> Reveal LINQ Usability Study. Medtronic data on file. 2013.
- <sup>25</sup> Research on file.
- <sup>26</sup> 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.
- <sup>27</sup> TruRhythm™ Detection Algorithms. Medtronic data on file. 2017.
- <sup>28</sup> 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.
- <sup>29</sup> 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.
- <sup>30</sup> Reference the Reveal LINQ ICM Clinician Manual for usage parameters.
- <sup>31</sup> 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.
- <sup>32</sup> 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.
- <sup>33</sup> 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.
- <sup>34</sup> 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.
- <sup>35</sup> 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.
- <sup>36</sup> CM Competitive Comparison Guide. Medtronic data on file. 2017.
- <sup>37</sup> Medtronic Reveal Publications. Medtronic data on file. 2016.

See the device manual for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan™ device, see the MRI SureScan™ technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at [www.medtronic.eu](http://www.medtronic.eu).

For applicable products, consult instructions for use on manuals.medtronic.com. 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.

Medtronic and the Medtronic logo are trademarks of Medtronic.  
™Third party brands are trademarks of their respective owners.  
All other brands are trademarks of a Medtronic company.

# DIAGNOSIS NEEDED. CHALLENGE ACCEPTED.

ESC Guidelines Recommend ICM in the  
Evaluation of Unexplained Syncope

## CHOOSE REVEAL LINQ™ ICM FOR PATIENTS

with high arrhythmia risk  
or recurrent symptoms  
> 30 days apart

ICM Delivers  
Superior  
Diagnostic Yield  
That Leads to  
Treatment



Reveal LINQ™ ICM  
up to 3 years<sup>30</sup>

## 20 YEARS OF ICM LEADERSHIP & INNOVATION

- The most effective diagnostic tool for infrequent, unexplained syncope<sup>13,22,23,31-35</sup>
- Unmatched detection accuracy<sup>36</sup>
- The most studied and validated ICM, with over 500 publications<sup>37</sup>

## Medtronic

### Europe

Medtronic International Trading Sàrl.  
Route du Molliau 31  
Case postale  
CH-1131 Tolochenaz  
www.medtronic.eu  
Tel: +41 0 21 802 70 00  
Fax: +41 0 21 802 79 00

[medtronic.eu](http://medtronic.eu)

### United Kingdom/Ireland

Medtronic Limited  
Building 9  
Croxley Green Business Park  
Hatters Lane  
Watford  
Herts WD18 8WW  
www.medtronic.co.uk  
Tel: +44 0 1923 212213  
Fax: +44 0 1923 241004

UC201807848cEE © Medtronic 2020.  
All Rights Reserved.