

2017
ACC/AHA/HRS
SYNCOPE
GUIDELINES



Medtronic
Further, Together

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

Developed in Collaboration With the American College of Emergency Physicians and Society for Academic Emergency Medicine

Endorsed by the Pediatric and Congenital Electrophysiology Society

WRITING COMMITTEE MEMBERS

Win-Kuang Shen, MD, FACC, FAHA, FHRS, Chair†

Robert S. Sheldon, MD, PhD, FHRS, Vice Chair

David G. Benditt, MD, FACC, FHRS*‡

Mitchell I Cohen, MD, FACC, FHRS ‡

Daniel E. Forman, MD, FACC, FAHA ‡

Zachary D. Goldberger, MD, MS, FACC, FAHA, FHRS ‡

Blair P. Grubb, MD, FACC §

Mohamed H. Hamdan, MD, MBA, FACC, FHRS ‡

Andrew D. Krahn, MD, FHRS*§

Mark S. Link, MD, FACC‡

Brian Olshansky, MD, FACC, FAHA, FHRS ‡

Satish R. Raj, MD, MSc, FACC, FHRS*§

Roopinder Kaur Sandu, MD, MPH ‡

Dan Sorajja, MD ‡

Benjamin C. Sun, MD, MPP, FACEP ||

Clyde W. Yancy, MD, MSc, FACC, FAHA ‡

Source: Shen WK, et al. *J Am Coll Cardiol*. 2017. DOI: 10.1016/j.jacc.2017.03.003.

EVIDENCE LEVEL DEFINITIONS – NEW DESCRIPTORS

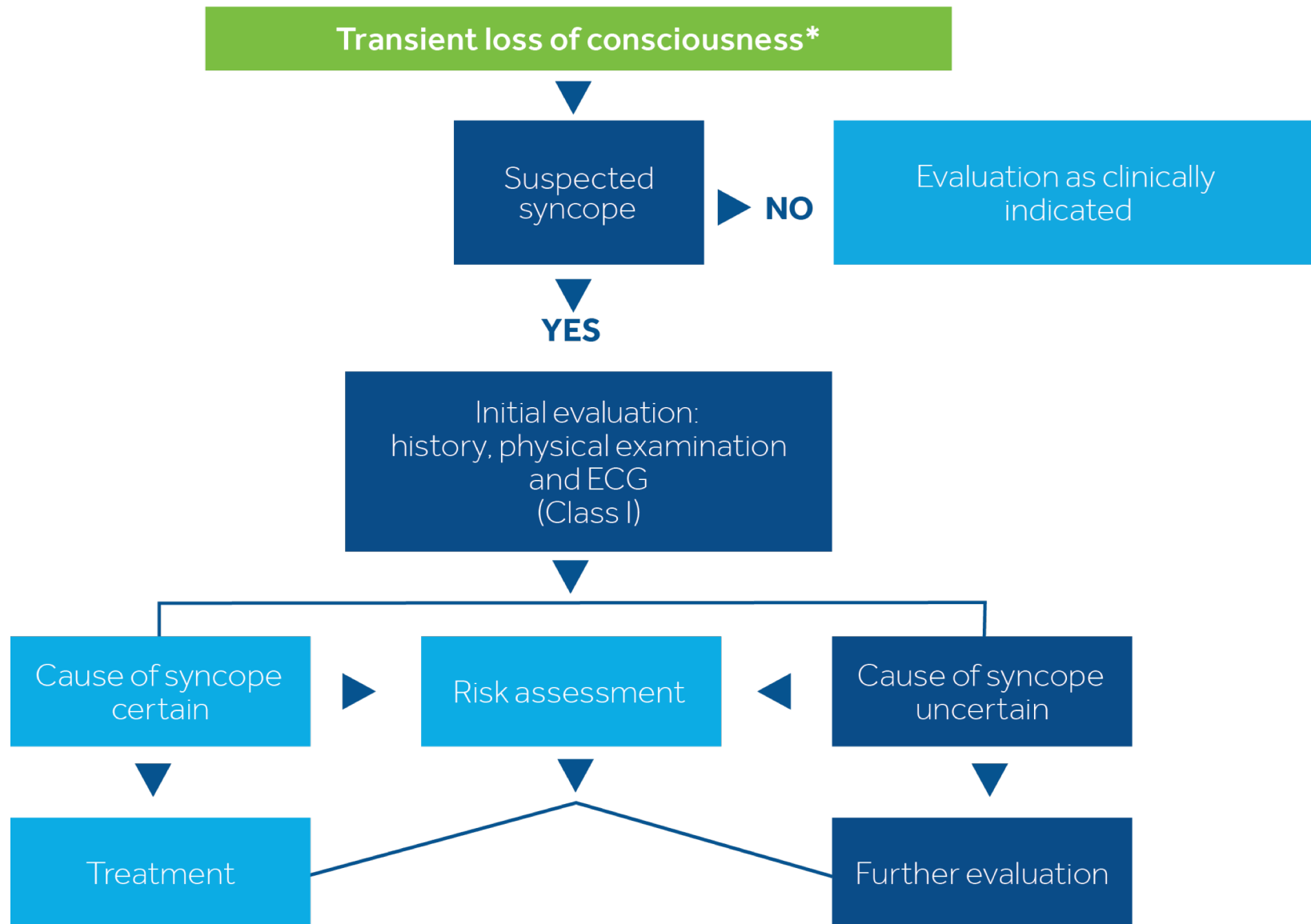
CLASS (STRENGTH) OF RECOMMENDATION	
CLASS I (STRONG)	Benefit >>> Risk
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> ■ Is recommended ■ Is indicated/useful/effective/beneficial ■ Should be performed/administered/other ■ Comparative-Effectiveness Phrases†: <ul style="list-style-type: none"> ○ Treatment/strategy A is recommended/indicated in preference to treatment B ○ Treatment A should be chosen over treatment B 	
CLASS IIa (MODERATE)	Benefit >> Risk
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> ■ Is reasonable ■ Can be useful/effective/beneficial ■ Comparative-Effectiveness Phrases†: <ul style="list-style-type: none"> ○ Treatment/strategy A is probably recommended/indicated in preference to treatment B ○ It is reasonable to choose treatment A over treatment B 	
CLASS IIb (WEAK)	Benefit ≥ Risk
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> ■ May/might be reasonable ■ May/might be considered ■ Usefulness/effectiveness is unknown/unclear/uncertain or not well established 	
CLASS III: No Benefit (MODERATE)	Benefit = Risk
<i>(Generally, LOE A or B use only)</i>	
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> ■ Is not recommended ■ Is not indicated/useful/effective/beneficial ■ Should not be performed/administered/other 	
CLASS III: Harm (STRONG)	Risk > Benefit
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> ■ Potentially harmful ■ Causes harm ■ Associated with excess morbidity/mortality ■ Should not be performed/administered/other 	

LEVEL (QUALITY) OF EVIDENCE‡	
LEVEL A	
<ul style="list-style-type: none"> ■ High-quality evidence‡ from more than 1 RCT ■ Meta-analyses of high-quality RCTs ■ One or more RCTs corroborated by high-quality registry studies 	
LEVEL B-R	(Randomized)
<ul style="list-style-type: none"> ■ Moderate-quality evidence‡ from 1 or more RCTs ■ Meta-analyses of moderate-quality RCTs 	
LEVEL B-NR	(Nonrandomized)
<ul style="list-style-type: none"> ■ Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies ■ Meta-analyses of such studies 	
LEVEL C-LD	(Limited Data)
<ul style="list-style-type: none"> ■ Randomized or nonrandomized observational or registry studies with limitations of design or execution ■ Meta-analyses of such studies ■ Physiological or mechanistic studies in human subjects 	
LEVEL C-EO	(Expert Opinion)
Consensus of expert opinion based on clinical experience	

Note: types of clinical data qualify level of evidence
•i.e. “randomized”/ “non randomized”

Source: Shen WK, et al. *J Am Coll Cardiol.* 2017. DOI: 10.1016/j.jacc.2017.03.003.

SYNCOPE INITIAL EVALUATION



Source: Shen WK, et al. *J Am Coll Cardiol.* 2017. DOI: 10.1016/j.jacc.2017.03.003.

CHARACTERISTICS IDENTIFYING PATIENTS MOST LIKELY TO BE ASSOCIATED WITH A CARDIAC CAUSE

Class	LOE	Recommendation
I	B-NR	Evaluation of the cause and assessment for the short- and long-term morbidity and mortality risk of Syncope are recommended

Historical Characteristics Associated with Increased Probability of Cardiac Causes of Syncope

- Older age (>60yr)
- Male Sex
- Presence of ischemic heart disease, structural heart disease, previous arrhythmias, or reduced ventricular function
- Brief (palpitations) or no symptoms prior to loss of consciousness
- Occurs with exertion
- Occurs in supine position
- Low number of events (1 or 2)
- Abnormal cardiac examination
- Family history of inheritable conditions or premature SCD (<50 yr of age)
- Presence of known congenital heart disease

Source: Shen WK, et al. *J Am Coll Cardiol.* 2017. DOI: 10.1016/j.jacc.2017.03.003.

CHARACTERIZING RISK SCORE OF SYNCOPAL PATIENTS

Class	LOE	Recommendation
I	B-NR	Evaluation of the cause and assessment for the short- and long-term morbidity and mortality risk of syncope are recommended

Short-term (<30 d) risk factors

- Older age (>60yr)
- Male Sex
- Palpitations or no symptoms prior to loss of consciousness
- Occurs with exertion
- Structural heart disease
- Heart failure
- Cerebrovascular disease
- Family history of SCD
- Trauma
- Bleeding evidence
- Persistent abnormal vitals/ECG
- Positive troponin

Long-term (>30d) risk factors

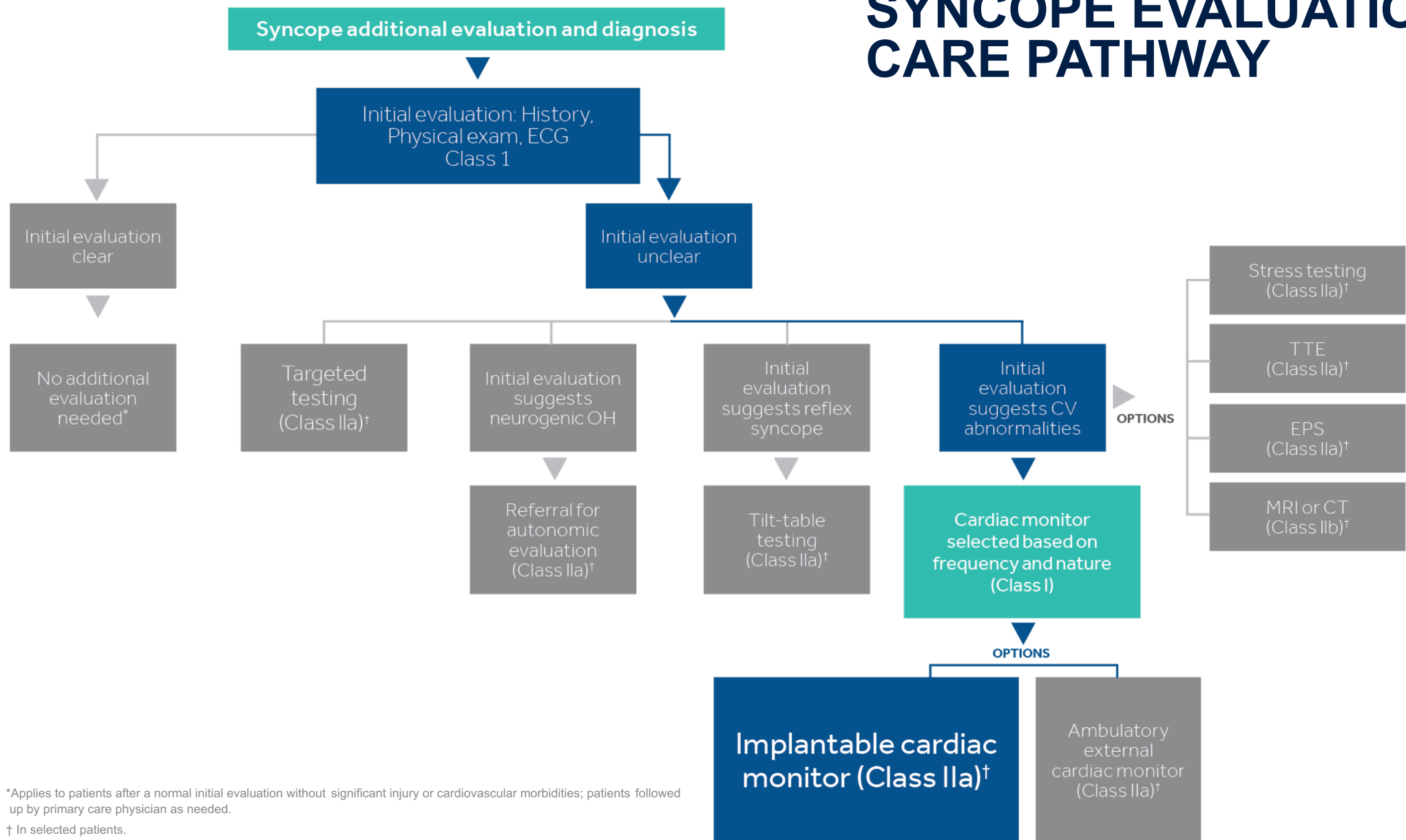
- Older age (>60yr)
- Male Sex
- Absence of nausea/vomiting before syncope
- Ventricular arrhythmias detected
- Cancer
- Structural heart disease
- Heart failure
- Cerebrovascular disease
- Diabetes mellitus
- High CHADS2 score
- Abnormal ECG
- Low GFR (kidney function)

IIb	B-NR	Use of risk stratification scores may be reasonable in the management of patients with syncope
-----	------	--

High-risk patients should be considered for cardiac monitoring early in evaluation

Source: Shen WK, et al. *J Am Coll Cardiol.* 2017. DOI: 10.1016/j.jacc.2017.03.003.

SYNCOPE EVALUATION CARE PATHWAY



- After initial evaluation and if cardiac cause is suspected, cardiac monitoring should be performed – Class I Recommendation
- ICMs should be placed in all patients with infrequent symptoms

CARDIAC MONITORING RECOMMENDATIONS

Class	LOE	Recommendation
I	C-EO	The choice of a specific cardiac monitor should be determined on the basis of the <u>frequency</u> and <u>nature</u> of syncope events.
Ila	B-R	To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, an ICM can be useful
Ila	B-NR	To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, the following external cardiac monitoring approaches can be useful: <ol style="list-style-type: none"> 1. Holter monitor 2. Transtelephonic monitor 3. External loop recorder 4. Patch recorder 5. Mobile cardiac outpatient telemetry

- Cardiac monitoring is necessary
- Patient selection is based on frequency of symptoms, likelihood of arrhythmic cause and patient characteristics
- Randomized clinical trials demonstrate the value of ICM monitoring in syncope patients

Source: Shen WK, et al.. *J Am Coll Cardiol*. 2017. DOI: 10.1016/j.jacc.2017.03.003.

MONITORING SELECTION CRITERIA

THE RIGHT DEVICE FOR THE RIGHT PATIENT

Holter Monitors



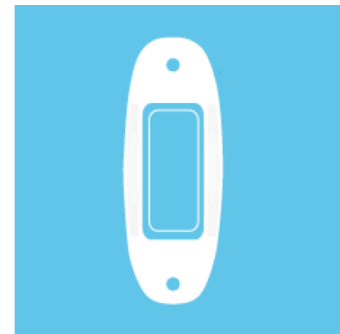
Extended Holters



External Loop Recorders



Mobile Cardiac Telemetry



Insertable Cardiac Monitors



Duration

24 – 48 hrs

2-14 days

Up to 1 month

≤3 years

Patient Selection

Daily, symptoms

Weekly symptoms

Monthly symptoms
(some up to 6 wks)

Monthly, symptoms

Recurrent, infrequent symptoms that present > 30 days apart

Diagnostic choice should be based on frequency of symptoms and nature of syncope events.

Source: Shen WK, et al.. *J Am Coll Cardiol.* 2017. DOI: 10.1016/j.jacc.2017.03.003.

Class I

recommendation for cardiac monitoring in patients suspected of cardiac cause for syncope

Patient selection strategies and risk stratification should increase physician awareness and confidence to use ICMs in syncope patients

Cardiac Monitor Selection

Based on specific criteria:

- Frequency of symptoms
- Patient characteristics
- Nature of syncope events

Class IIa

recommendation for both external and insertable cardiac monitors

Randomized clinical evidence supports use of ICMs in syncope patients

Medtronic's portfolio of cardiac diagnostic monitors meets the span of recommended cardiac monitoring options per the Syncope Guidelines

Source: Shen WK, et al.. *J Am Coll Cardiol*. 2017. DOI: 10.1016/j.jacc.2017.03.003.

CLEAR DEFINITIONS FOR SYNCOPE-RELATED TERMS

Term	Definition/Comments
Syncope	A symptom that presents with an abrupt, transient, complete loss of consciousness, associated with inability to maintain postural tone, with rapid and spontaneous recovery. The presumed mechanism is cerebral hypoperfusion. There should not be clinical features of other nonsyncope causes of loss of consciousness, such as seizure, antecedent head trauma, or apparent loss of consciousness (i.e., pseudosyncope)
Loss of consciousness	A cognitive state in which one lacks awareness of oneself and one's situation, with an inability to respond to stimuli.
Transient Loss of consciousness	Self-limited loss of consciousness can be divided into syncope and nonsyncope conditions. Nonsyncope conditions include but are not limited to seizures, hypoglycemia, metabolic conditions, drug or alcohol intoxication, and concussion due to head trauma. The underlying mechanism of syncope is presumed to be cerebral hypoperfusion, whereas nonsyncope conditions are attributed to different mechanisms.
Presyncope (near-syncope)	The symptoms before syncope. These symptoms could include extreme lightheadedness; visual sensations, such as "tunnel vision" or "graying out"; and variable degrees of altered consciousness without complete loss of consciousness. Presyncope could progress to syncope, or it could abort without syncope
Unexplained syncope (syncope of undetermined etiology)	Syncope for which a cause is undetermined after an initial evaluation that is deemed appropriate by the experienced healthcare provider. The initial evaluation includes but is not limited to a thorough history, physical examination, and ECG.
Cardiac (cardiovascular) Syncope	Syncope caused by bradycardia, tachycardia, or hypotension due to low cardiac index, blood flow obstruction, vasodilatation, or acute vascular dissection
Noncardiac syncope	Syncope due to noncardiac causes which include reflex syncope, OH, volume depletion, dehydration, and blood loss
Reflex (neurally mediated) syncope	Syncope due to a reflex that causes vasodilation, bradycardia, or both.
Carotid sinus syndrome	Reflex syncope associated with carotid sinus hypersensitivity (30). Carotid sinus hypersensitivity is present when a pause ≥ 3 s and/or a decrease of systolic pressure ≥ 50 mm Hg occurs upon stimulation of the carotid sinus. It occurs more frequently in older patients. Carotid sinus hypersensitivity can be associated with varying degrees of symptoms. Carotid sinus syndrome is defined when syncope occurs in the presence of carotid sinus hypersensitivity.

Source: Shen WK, et al.. *J Am Coll Cardiol*. 2017. DOI: 10.1016/j.jacc.2017.03.003.

BRIEF STATEMENT

MEDTRONIC 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 tested specifically 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 www.medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

BRIEF STATEMENT, cont'd

MEDTRONIC MYCARELINK™ PATIENT MONITOR, MEDTRONIC CARELINK™ NETWORK AND CARELINK™ MOBILE APPLICATION

The Medtronic MyCareLink Patient Monitor and the Medtronic CareLink Network are indicated for use in the transfer of patient data from Medtronic implantable cardiac devices. These products are not a substitute for appropriate medical attention in the event of an emergency. Data availability and alert notifications are subject to Internet connectivity and access, and service availability. The MyCareLink Patient Monitor must be on and in range of the device. Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care.

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 www.medtronic.com.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

UC201711645a EN ©2018 Medtronic.
Minneapolis, MN. All Rights Reserved.
07/2018

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

medtronic.com