2017 ACC/AHA/HRS SYNCOPE GUIDELINES

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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

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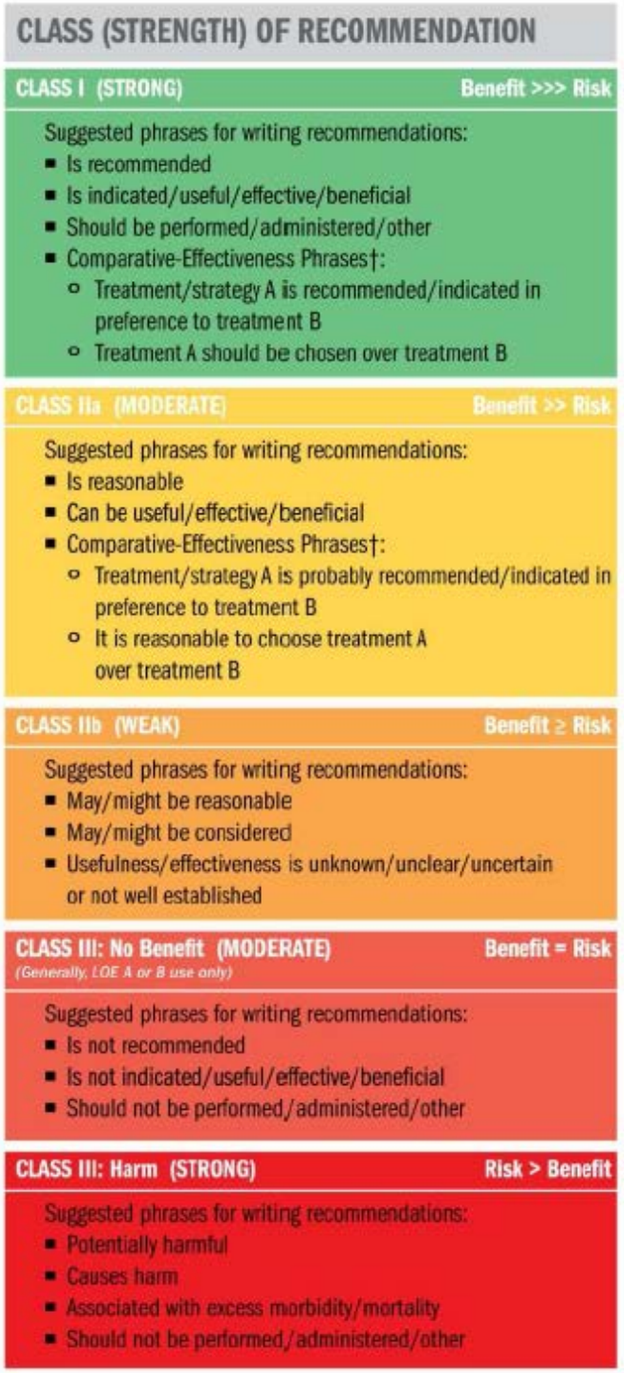
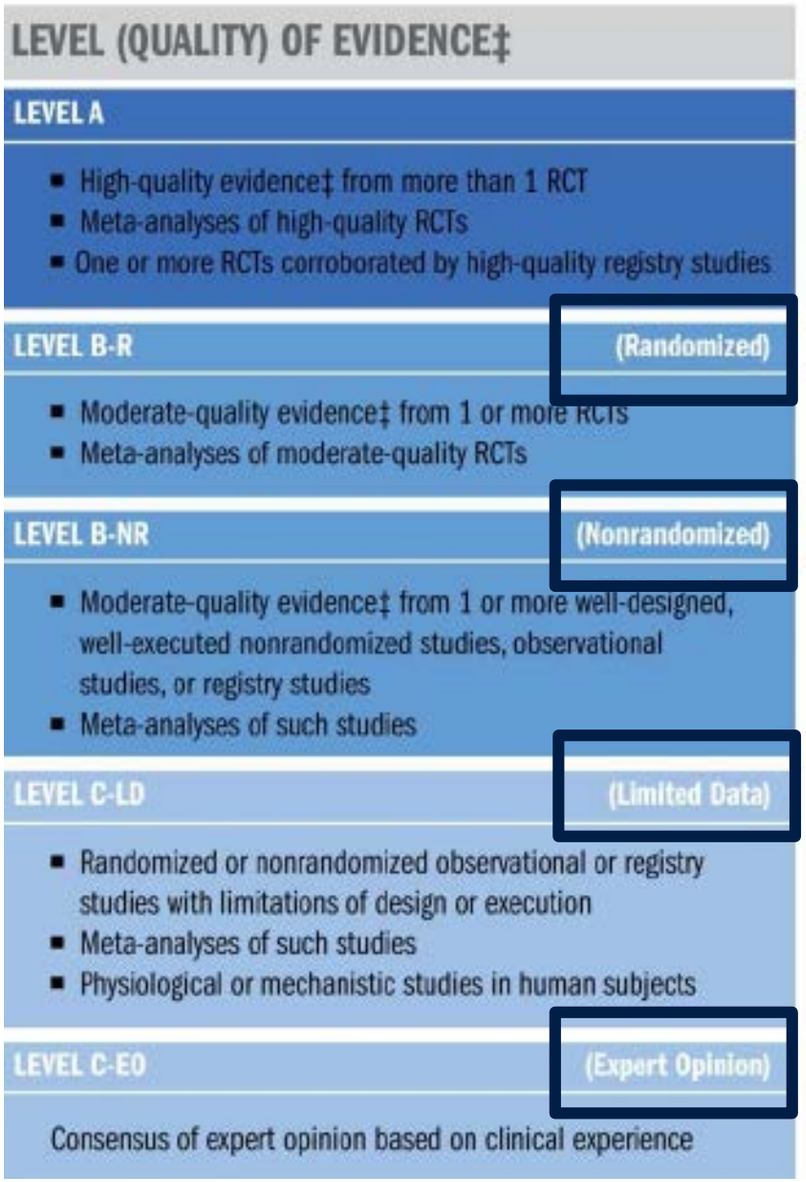
Source: Shen WK, et al.. J Am Coll Cardiol. 2017. DOI: 10.1016/j.jacc.2017.03.003.

EVIDENCE LEVEL DEFINITIONS – NEW DESCRIPTORS





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.

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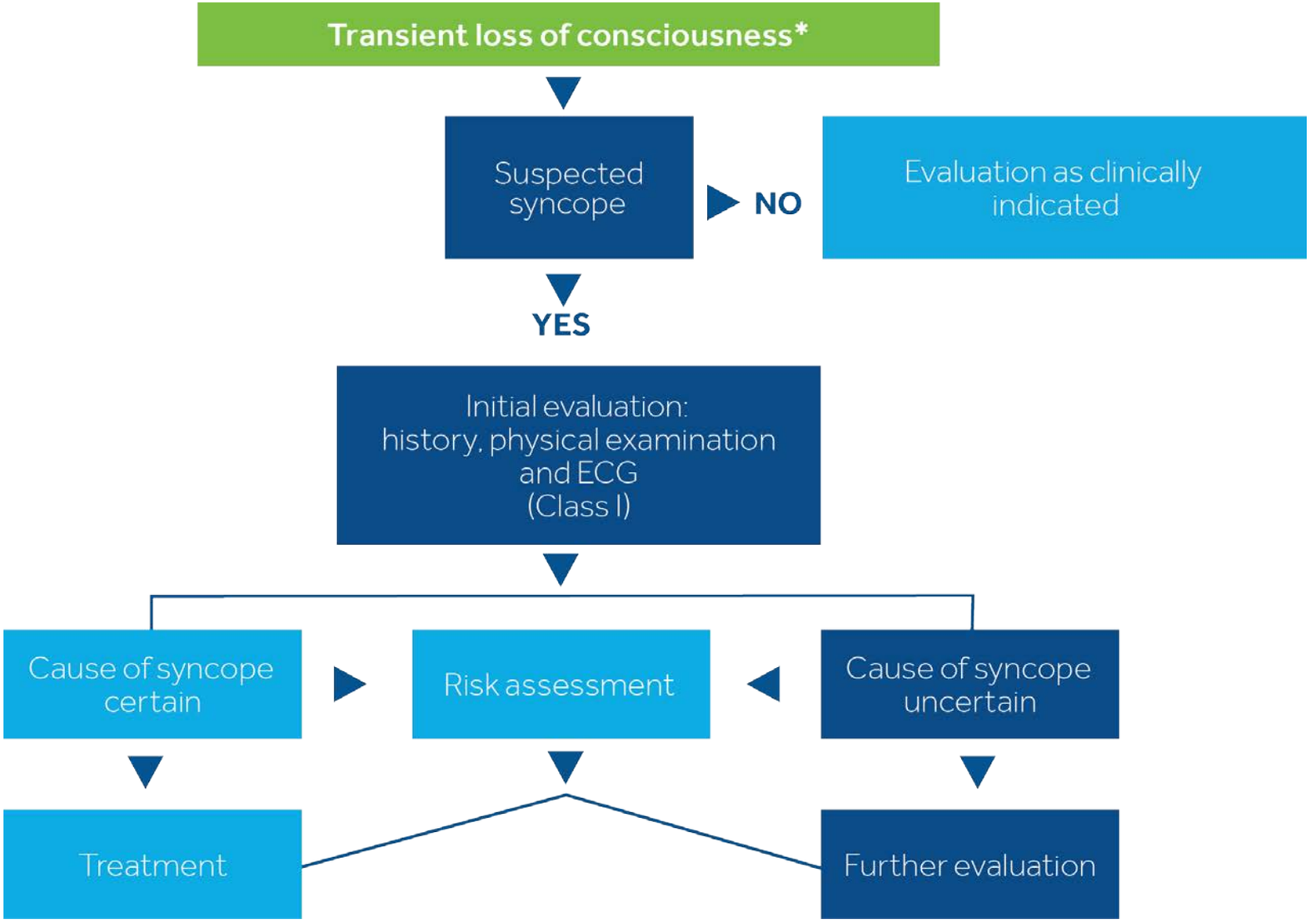
SYNCOPE INITIAL EVALUATION



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

CHARACTERISTICS IDENTIYING 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

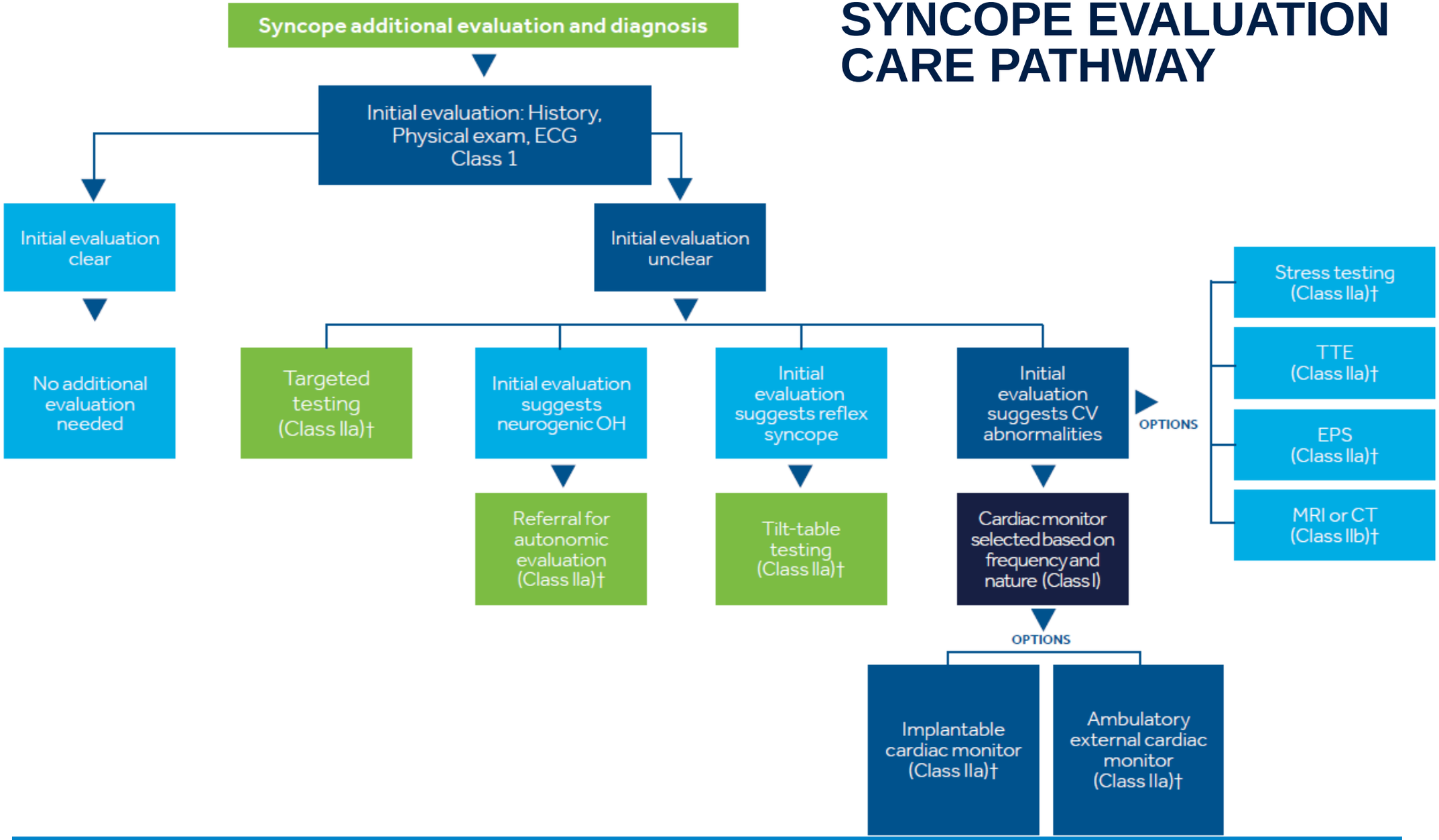
- Older age (>60yr)
- Male Sex
- Absence of nausea/vomiting before syncope
- Ventricular arrhythmias detected
- Cancer
- Structural heart disease
- Heart failure
- Cerebrovascular disease
- Diabetes mellitus
- High CHADS2 score
- Abnormal ECG
- Low GFR (kidney function)

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

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

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CARDIAC MONITORING RECOMMENDATIONS

Class	LOE	Recommendation
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
IIa	B-NR	To evaluate selected ambulatory patients with syncope of suspected arrhythmic etiology, the following external cardiac monitoring approaches can be useful: 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**

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.

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Class I	Cardiac Monitor Selection	Class IIa
recommendation for cardiac monitoring in patients suspected of cardiac cause for syncope		recommendation for both external and insertable cardiac monitors
Patient selection strategies and risk stratification should increase physician awareness and confidence to use ICMs in syncope patients	Based on specific criteria: ▪ Frequency of symptoms ▪ Patient characteristics ▪ Nature of syncope events	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

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

CLEAR DEFINITIONS FOR SYNCOPE-RELATED TERMS (CONTINUED)

Term	Definition/Comments
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 SEEQ™ MOBILE CARDIAC TELEMETRY SYSTEM

Indications

The Medtronic SEEQ Mobile Cardiac Telemetry (MCT) System is intended to continuously measure, record, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (e.g., atrial fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias, and conduction disorders. The SEEQ MCT System monitors, derives, and displays: ECG, Heart Rate.

Contraindications

- Patients with known allergies or hypersensitivities to adhesives or hydrogel
- Patients with potentially life-threatening arrhythmias, or who require inpatient/hospital monitoring

Warnings and Precautions

- Do not reapply the Wearable Sensor (it is meant for one-time use)
- For a complete list of precautions, please refer to the Instructions for Use document

See the device manual for detailed information regarding the indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1 (800) 328-2518 and/or consult Medtronic's website at www.medtronic.com.

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

The SEEQ™ MCT System and the Medtronic Monitoring Center are provided by Medtronic Monitoring Inc., a wholly owned subsidiary of Medtronic.

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 Medtronic's website at www.medtronic.com.

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BRIEF STATEMENT

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 Medtronic's website at www.medtronic.com.

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

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