SYNCOPE DIAGNOSIS GUIDANCE

2018 European Society of Cardiology (ESC) Guidelines for the Diagnosis and Management of Syncope

PROLONGED MONITORING RECOMMENDATIONS

- **Certain diagnosis/mechanism**
  - Treat appropriately

- **Uncertain diagnosis/mechanism**
  - **T-LOC suspected syncope**
    - **Syncope**
      - High risk, arrhythmia likely
        - **In-hospital monitoring (CLASS II)**
          - **ILR (CLASS II)**
            - If negative
              - **ILR (CLASS II)**
      - Low risk, arrhythmia likely and recurrent episodes
        - **ELR (CLASS IIa)**
      - Low risk, reflex likely and need for specific therapy
        - **ILR (CLASS IIa)**
      - Low risk and rare episodes
        - **Not indicated**

- **T-LOC non-syncopal**
  - **Unconfirmed epilepsy**
  - **Unexplained falls**
  - **ILR (CLASS IIb)**

ESC Syncope Guidelines now updated with stronger recommendation for insertable cardiac monitors (ILRs):

- ILRs upgraded to Class I/Level A recommendation — the strongest level of clinical evidence
- ILRs added as a Class II/Level B recommendation to diagnose unexplained falls and unconfirmed epilepsy
- Holter monitor and tilt testing revised from Class I to Class II recommendation
RECOMMENDATIONS FOR CARDIAC MONITORING

<table>
<thead>
<tr>
<th>RECOMMENDATION</th>
<th>COR</th>
<th>LOE</th>
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<td>ILR is indicated in an early phase of evaluation in patients with recurrent syncope of uncertain origin, absence of high-risk criteria, and a high likelihood of recurrence within the battery life of the device (175, 176, 181–184, 202).</td>
<td>I</td>
<td>A</td>
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<td>ILR is indicated in patients with high-risk criteria in whom a comprehensive evaluation did not demonstrate a cause of syncope or lead to a specific treatment (174, 180, 187, 188, 195).</td>
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<td>ILR should be considered in patients with suspected or certain reflex syncope presenting with frequent or severe syncopal episodes (184–186).</td>
<td>IIa</td>
<td>B</td>
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<td>ILR may be considered in patients in whom epilepsy was suspected but the treatment has proven ineffective (137, 189–191).</td>
<td>IIb</td>
<td>B</td>
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<tr>
<td>ILR may be considered in patients with unexplained falls (191–194).</td>
<td>IIb</td>
<td>B</td>
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COR — Class of Recommendation
LOE — Level of Evidence

Reference

Reveal LINQ™ 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/Precautions: Reveal LINQ 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.

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

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.