EBR SYSTEMS

Alternative Echo Protocol with Reduced Power Settings

Important information for patients with WiSE® Cardiac Resynchronization Therapy (CRT) System implant

Introduction

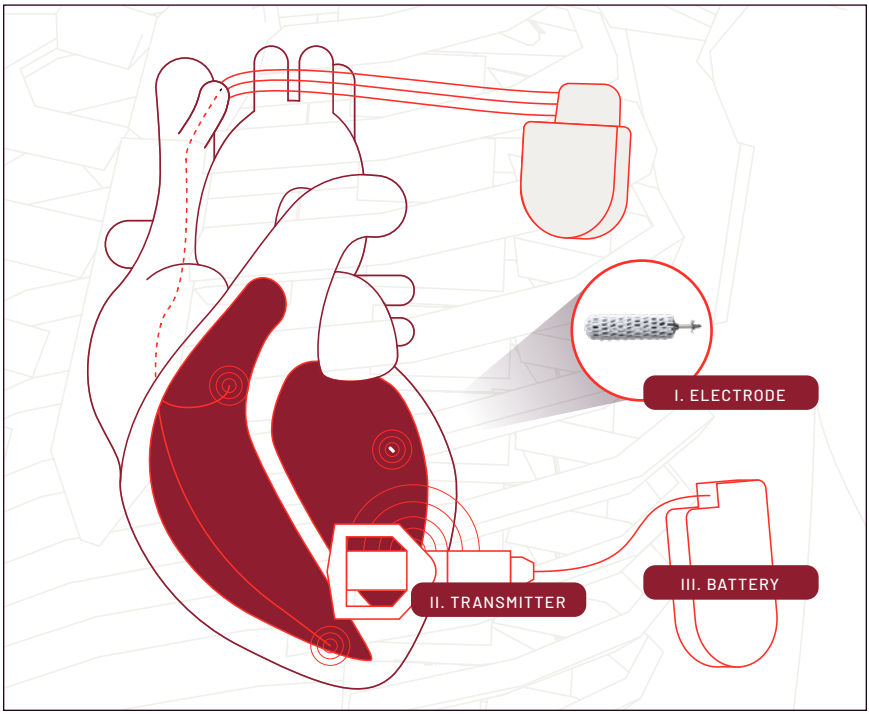
This document provides essential instructions when caring for patients with the WiSE CRT System, which comprises of:

I. **Electrode:** An endocardial implant, the Electrode, converts ultrasound into electrical energy to pace to the left ventricle.

II. **Transmitter:** Implanted in the lower left chest area, between the ribs, it ultrasonically powers the Electrode.

III. **Battery:** Implanted subcutaneously on the left mid axillary line; it powers the Transmitter.

The WiSE technology utilizes ultrasonic energy to power its Electrode, enabling its leadless and ultra-compact design, for endocardial implantation in the left ventricle.

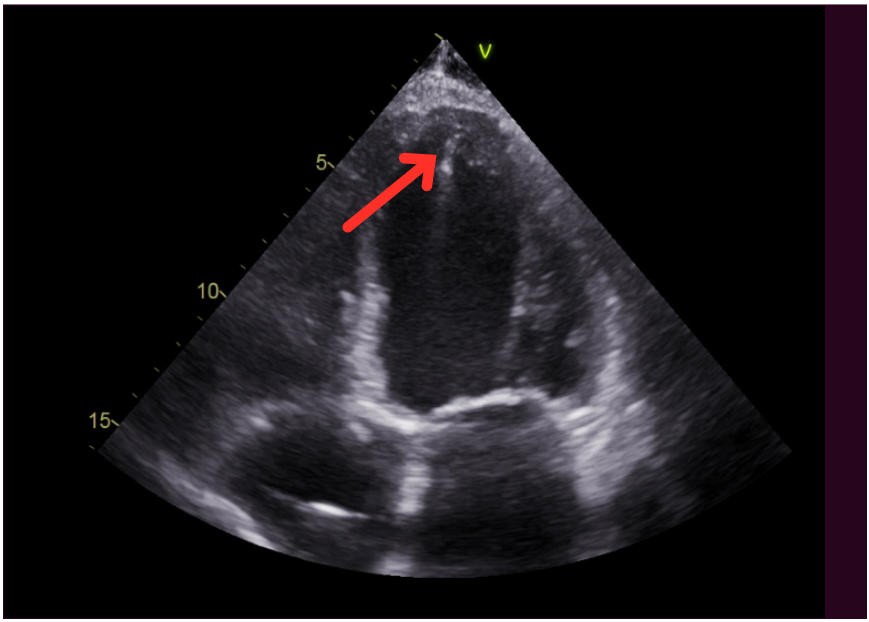


Overview

The WiSE CRT System patients are implanted with an ultrasound-sensitive medical device. In rare instances, the ultrasound imaging probe has the potential for the electrode to convert the ultrasound energy into extra stimuli.

Safe use of transthoracic ultrasound requires the patient to be **monitored at all times** by an ECG and an external defibrillator to be available. The WiSE electrode is generally not sensitive to routine ultrasound imaging. However, in rare circumstances extra stimulation has been associated with:

- Apical or near-apical Electrode implant (image below)
- Echo imaging from apical views



An example image of an apical Electrode implant (arrow) imaged from the apical window is shown above.

Guidance when performing a standard echo protocol with continuous ECG monitoring:

STEP 1	**If Electrode is in an apical position or if there is a sudden irregular heart rhythm**  Immediately remove probe from patient and continue to Step 2.
STEP 2	Decrease transmit power (MI) to the lowest setting.
STEP 3	Start imaging and gradually increase transmit power until adequate image quality is achieved. **If extra pacing stimulation occurs**  Immediately remove probe from patient and continue to Step 4.
STEP 4	Determine if contrast study should be performed per hospital protocol. If yes, use echocardiography contrast protocol with the **lowest MI settings possible.**

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WARRANTY INFORMATION

For complete warranty information, call EBR Systems, Inc. at (408) 720-1906.

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