

SUMMARY

INSIGNIA® and ALTRUA® pacemakers include an Automatic Capture feature in the ventricle. This algorithm automatically measures the ventricular pacing threshold and adjusts the pacing output to 0.5 V above the measured threshold. Following each ventricular pacing output, capture is automatically verified by the pacemaker on a beat-to-beat basis via sensing of the evoked response.

Products Referenced

INSIGNIA® and ALTRUA® pacemakers

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation and indications for use, reference the appropriate product labeling.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator

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Automatic Capture

To successfully stimulate the heart, pacemaker output energy (amplitude and pulse width) must be programmed above the stimulation (or pacing) threshold. Traditionally, to determine the stimulation threshold, a manual pacing threshold test is performed by reducing the pulse amplitude while maintaining a constant pulse width. The pacemaker amplitude is then programmed to a suitable value based on the measured stimulation threshold plus a safety margin.

Automatic Capture – Overview

Certain INSIGNIA® and ALTRUA® pacemaker models include a ventricular Automatic Capture algorithm. Automatic Capture automatically measures the ventricular pacing threshold and adjusts the pacing amplitude to 0.5 V above the measured threshold. Following each regular ventricular pacing output (i.e., non-backup safety), capture is automatically verified by the pacemaker on a beat-to-beat basis via sensing of the evoked response.

Rather than manually initiating a ventricular pacing threshold test, and then programming the appropriate parameters, Automatic Capture automatically runs a threshold test and then uses the lowest pacing amplitude required to ensure capture. If the pacing threshold fluctuates, Automatic Capture will automatically adjust and will provide back-up safety paces as needed on a beat-to-beat basis.

Overall pacemaker longevity can be influenced by parameter settings. Use of Automatic Capture may extend longevity performance by minimizing voltage output. A comparison of longevity projections in BSC pacemakers with manual energy programming to BSC pacemakers using Automatic Capture shows a projected longevity gain of up to fifteen¹ percent or more when used over a device's lifetime, that is, if Automatic Capture is programmed at or shortly after pacemaker implantation.²

Automatic Capture – Programming and Algorithm

Automatic Capture can be selected in the ventricle by choosing AUTO from the Ventricular Amplitude parameter options. Programming the ventricular amplitude to AUTO will automatically adjust the ventricular Pulse Width to 0.4 ms and set the ventricular voltage output to an initial value of 3.5 V. Before entering beat-to-beat capture verification mode, Automatic Capture must first successfully measure the ventricular threshold. This measurement can be made through a commanded test, or it will be performed automatically after the programming session is completed.

Commanded Test

An automatic threshold measurement can be commanded via the Threshold Test screen. When the ventricular auto threshold measurement is successfully completed, Automatic Capture will enter its beat-to-beat capture verification mode. **NOTE:** *An evoked response indicates capture. To view the Evoked Response EGM during the test, select the V-ER option to the right of the EGM display (Figure 1).*

Automatic Ambulatory Threshold Test

If a commanded threshold test is not performed, the algorithm will automatically try to measure the ventricular threshold within 10 minutes after the programming session is completed (See Table 1).

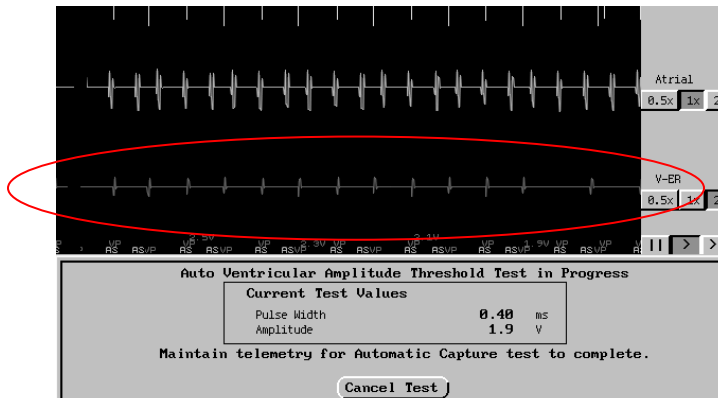


Figure 1. Evoked Response Channel – Auto Ventricular Amplitude Threshold Test

Table 1. Modes of Automatic Capture and Mode Algorithm

Mode	Mode Description / Mode Algorithm
Beat-to-Beat	<p>Automatic Capture is monitoring every pace. If capture is not seen, a backup safety pace is issued.</p> <ul style="list-style-type: none"> ▪ This mode is entered upon successful initialization and threshold measurement. ▪ Ventricular pacing amplitude = measured threshold + 0.5 V ▪ Ventricular pulse width = 0.4 ms (nonprogrammable) ▪ For each V pace, the device checks for an evoked response <ul style="list-style-type: none"> ○ If there is an evoked response, beat-to-beat mode continues. ○ If Loss of Capture (LOC) occurs, the device delivers a backup safety pace within 100 ms of the primary ventricular pulse in the ventricular channel at 1.5 V greater than the previously measured threshold (minimum of 3.5 V and a maximum of 4.5 V). ○ If LOC occurs in 2 of 4 cardiac cycles, the device delivers a backup safety pace in the ventricular channel at 1.5 V greater than previously measured threshold (up to 4.5 V) and Confirmed Loss of Capture (C-LOC) is declared. <ul style="list-style-type: none"> ▪ If C-LOC occurs, an Ambulatory Ventricular Automatic Threshold Test is performed (see next Mode).
Ambulatory Ventricular Automatic Threshold Test	<p>A threshold test is occurring.</p> <ul style="list-style-type: none"> ▪ The pacemaker performs an Ambulatory Ventricular Automatic Threshold Test by starting at a voltage of 3.5 V and stepping down. <ul style="list-style-type: none"> ○ If the test is successfully completed (i.e., threshold is successfully measured), the device will return to beat-to-beat mode, applying the new threshold. ○ If the test cannot be successfully completed (i.e., no loss of capture is detected after decrementing to lowest output of 0.1 V) or if the measured threshold is greater than 3.0 V, the device will enter Retry Mode (see next Mode). <p>NOTES:</p> <ul style="list-style-type: none"> ▪ The pacemaker will initiate a Ambulatory Ventricular Automatic Threshold Test every 21 hours or upon C-LOC. ▪ During the Automatic Threshold Test, some parameters will be temporarily changed to help ensure a successful measurement.³ ▪ The test may be delayed or terminated mid-test if telemetry is initiated/occurring, a magnet is applied, or A-Tachy Response ATR is initiated/exited during the scheduled Ambulatory Ventricular Automatic Threshold Test.
Retry	<p>Retry Mode is entered when Automatic Capture is active, and the device is operating in beat-to-beat mode and is unable to confirm capture due to reasons such as loss of capture or due to signal/noise issues.</p> <ul style="list-style-type: none"> ▪ Retry pacing amplitudes will be at 2X previous measured threshold (minimum of 3.5 V and maximum of 5.0 V). ▪ Automatic Capture will attempt to measure the ventricular threshold. If successful, Automatic Capture will return to the beat-to-beat mode. <p>NOTE: Automatic Capture will re-attempt the threshold measurement based upon the reason the pacemaker entered Retry. For example, if the reason was noise detected on the evoked response channel or on the ventricular sense amplifier, the threshold test is attempted every hour. If the reason was inadequate evoked response signal, threshold not found at lowest pacing amplitude, or threshold > 3.0 V, the threshold test is attempted every 21 hours.</p> <ul style="list-style-type: none"> ▪ Automatic Capture will continually operate in the Retry Mode (with a minimum ventricular output of 3.5 V and a maximum of 5.0 V) until it successfully determines a ventricular pacing threshold. <p>For devices that are in Retry Mode (and corresponding higher amplitude) on a frequent basis, the clinician may choose to turn Automatic Capture Off by programming the ventricular amplitude to a fixed voltage setting.</p>

Reviewing Automatic Capture Activity

The System Summary (Figure 2) and Daily Measurements (Figure 3) screens summarize the Automatic Capture activity.

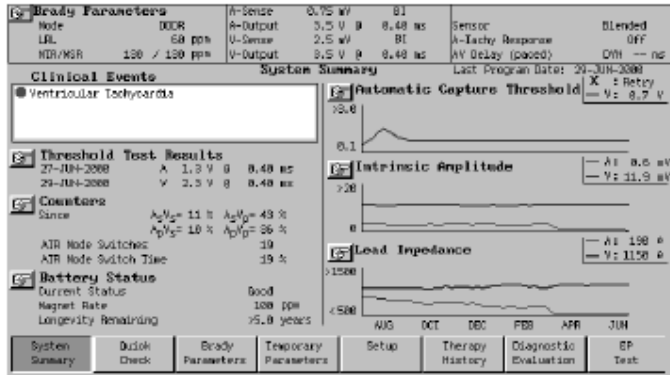


Figure 2. System Summary Screen

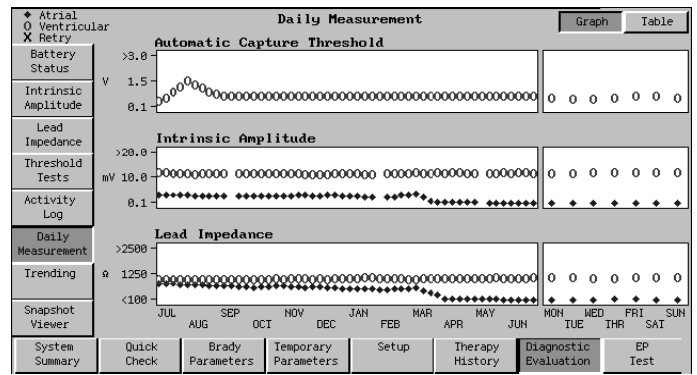


Figure 3. Daily Measurements Screen

Automatic Capture and Elective Replacement Time (ERT) Operation

When the pacemaker reaches ERT, device replacement should be scheduled. Beat-to-beat Automatic Capture is automatically disabled and ventricular amplitude is fixed at twice the last measured threshold, but not greater than 5.0 volts and not less than 3.5 volts. A battery status indicator of ERT is a permanent state and cannot be returned to ERN or GOOD by manually decreasing amplitude. As the battery continues to deplete, the device will reach End-of-Life (EOL) three months after ERT.

Note that the pacemaker continually evaluates current programmed parameters and pacing conditions, and positions replacement indicators to ensure a full three-month replacement window between ERT and EOL. Therefore, reducing the programmed ventricular amplitude after ERT is reached will not change the battery status and will not increase the duration of the replacement window.

NOTES:

- *Automatic Capture is intended for ventricular use only. Do not program Amplitude to AUTO for single-chamber devices implanted in the atrium.*
- *If Automatic Capture has been programmed, it is suspended for the duration of magnet application. During magnet application, the amplitude is set at the most recent automatic capture amplitude value (threshold + 0.5 V).*

¹ALTRUA 60, 750 Ohms, 0.4 ms Pulse Width, 60 ppm, 3.5 V in atrium, ventricular threshold of 0.5 volts, 100% paced.

²Boston Scientific Corporation: System Guide, ALTRUA™ 60 Multiprogrammable Pacemakers Models S601, S602, S603, S605, S606, St. Paul, MN: Boston Scientific Corporation, 2009; Reference Tables ii. Available online at www.bsci.com/ifu.

³Boston Scientific Corporation: System Guide, ALTRUA™ 60 Multiprogrammable Pacemakers Models S601, S602, S603, S605, S606, St. Paul, MN: Boston Scientific Corporation, 2009; Section 6-16. Available online at www.bsci.com/ifu.