SUMMARY

This article provides information regarding the operation and interpretation of **Event Counters** and **Histograms** available in ALTRUA®, INSIGNIA®, PULSAR® MAX II, and DISCOVERY® II pacemakers.

Products Referenced
All referenced Boston Scientific Pulse Generators and the ZOOM® LATITUDE® Programming System.

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the full instructions for use found at: www.bsci.com/ifu.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

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

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Pacemaker Counter and Histogram Operation and Interpretation

The **Event Counters** feature in Boston Scientific pacemakers feature counts and records, and display a variety of data, including the total number of paced and sensed events. The **Histograms** feature displays a graphical representation of the counter data and provides the amount of time that the device has spent pacing and sensing at various rates. **Event Counters** and **Histograms** are available by selecting Therapy History on the ZOOM® LATITUDE® Programmer.

Event Counters

The **Paced and Sensed Event Counters** (Figure 1) record the number of intrinsic and paced events that occur during an event recording period. This period begins with the last time the Counters were reset by the clinician and ends when the data set is retrieved from the pacemaker during a telemetry session.

Three sets of event counters are available for review (Figure 2) by pressing the Paced and Sensed Details icon (Figure 1):

1. Atrial-only events
2. Ventricular-only events
3. Combination Atrial-Ventricular (A-V) events

NOTE: *These data are provided as both a percentage of the total events and a total count since the last reset.*

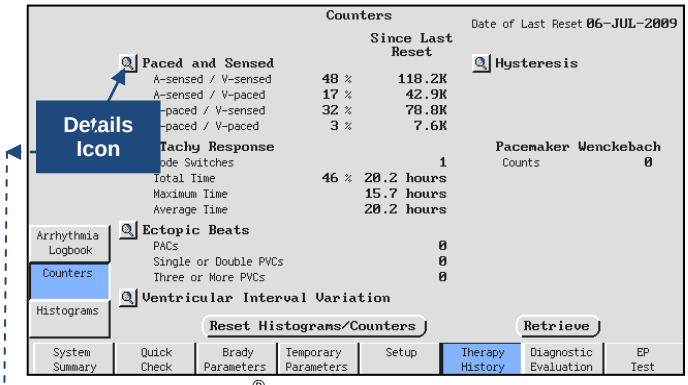


Figure 1. ALTRUA® Event Counters

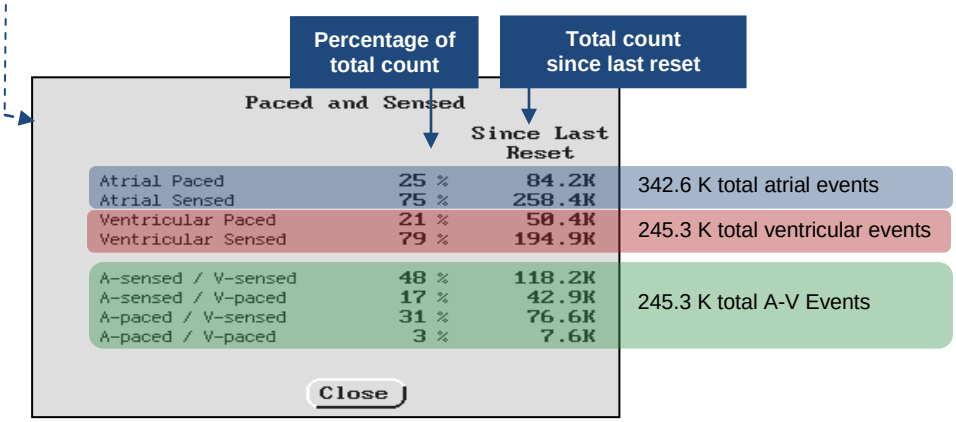


Figure 2. Detailed ALTRUA® Paced and Sensed Event Counters

Events Counted

The events that are counted are:

- **Atrial-only events:** Counted from the atrial channel and assigned to either the paced or sensed bin.
- **Ventricular-only events:** Counted from the ventricular channel and assigned to either the paced or sensed bin.
- **Combination A-V events:** Counted from the ventricular channel, and then categorized in the following sequence based upon the preceding atrial event:
    1. The ventricular event is designated as either paced or sensed.
    2. The atrial event immediately preceding the ventricular event is classified as either paced or sensed.
    3. The overall A-V combination is assigned to one of four possible A-V pace/sense bins (Figure 2).

Comparing Counter Data

When evaluating counter data, the following should be considered:

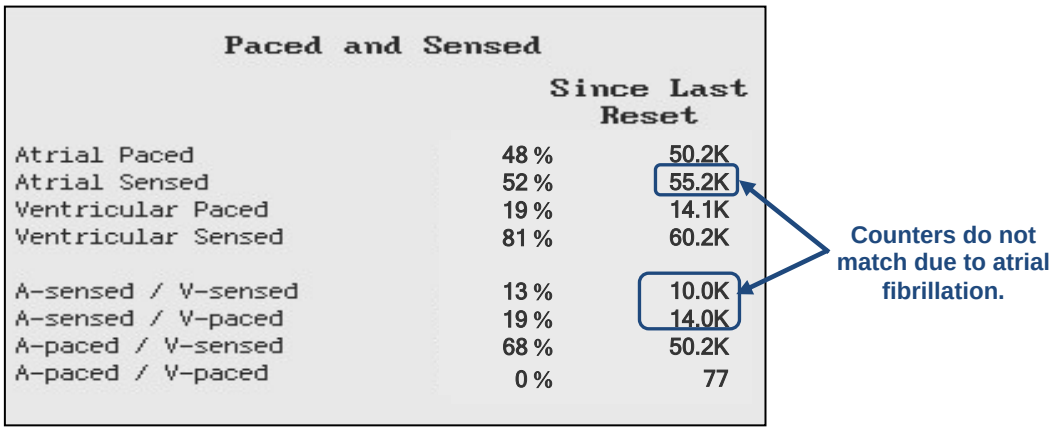
- The total of the combination A-V event counters will always match the total of the ventricular-only event counters as both are counted from the same ventricular events (Figure 2).
- The total of the combination A-V event counters will not match the total of the atrial-only event counters unless there is perfect 1:1 A-V conduction in dual-chamber mode. In this scenario, every ventricular event is preceded by one and only one atrial event, resulting in matching counters.
- Occasionally, the total of the combination A-V event counters will not match the total of the atrial-only counters (Figure 2) because the atrium and the ventricle often work independently of each other. Examples of common situations resulting in dissociation of the counters include:
    - Atrial arrhythmias (more than one atrial event for each ventricular event)
    - Ventricular arrhythmias (more than one ventricular event for each atrial event)
      NOTE: *PVCs are not included in the ventricular pace/sense counters; they have their own counters.*
    - Device programming to a single-chamber mode—AAI(R) or VVI(R)

Table 1 contains examples of counter results that may be observed in the clinical setting.

Table 1. Examples of Counter Results in Various Programmed Modes

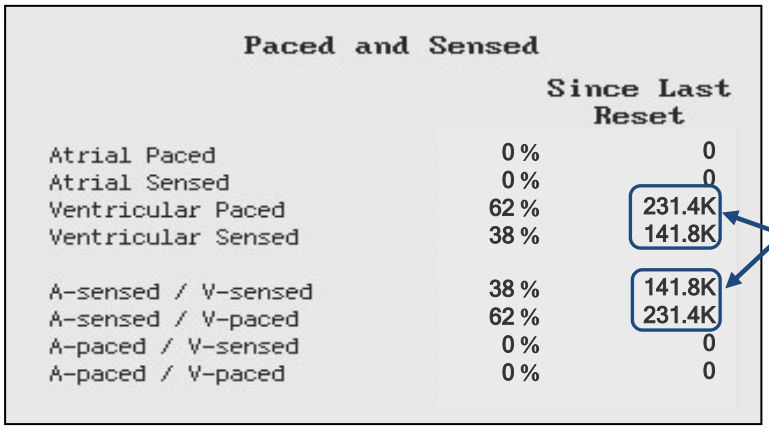
Example 1	A dual-chamber device programmed to DDI(R) mode in a patient with frequent atrial fibrillation

A large number of atrial-sensed events are recorded as a result of the patient's atrial fibrillation. These data are not represented in the combination A-V event counters since those counters only recognizes the single atrial event immediately preceding the associated ventricular event.



Example 2	A dual-chamber device programmed to VVI(R) mode

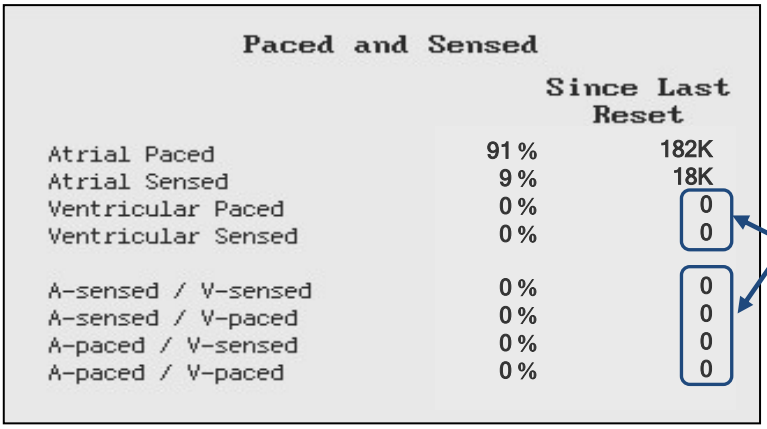
While the device is operating in VVI mode, even though a lack of atrial sensing prevents classification of combination A-V events, the A-V event counters are populated. This occurs because both V and AV counters count ventricular-only events. By default, the ventricular events are considered to have been preceded by atrial sensed events and are classified accordingly, even though no atrial data have been collected. Nevertheless, both totals are **fully accurate**. In addition, note that the totals are also equal.



In VVI mode, the V counters match the Combination A-V counters since the source data are the same.

Example 3	A dual-chamber device programmed to AAI(R) mode

While the device is operating in AAI mode, the A-V event counters are not populated, because they count ventricular activity.



V counters and Combination A-V counters are not populated (i.e., set at "0") when the device is programmed to AAI Mode.

Histograms

Histograms provide a graphical representation of the atrial and ventricular paced and sensed events collected during the recording period. This information may facilitate diagnostic interpretation of cardiac activity.

Events are sorted into rate bins on the Histograms, with two different options for displaying the data, **AV Histograms** and **Pace/Sense Histograms**.

A-V Histograms show the type of ventricular events (paced or sensed) that follow atrial activity (Figure 3). The maximum Y-axis scale value (50% or 100%) is automatically determined by the maximum value in either the Ventricular Paced/ Ventricular Sensed bins (displayed on the Pace/Sense Histograms) or the Atrial Paced VP/VS bins (displayed on the **A-V Histograms**).

Pace/Sense Histograms show atrial paced and sensed events and ventricular paced and sensed events (Figure 4). The maximum Y-axis scale value (50% or 100%) is automatically determined by the maximum value in any of the Atrial or Ventricular bins (displayed on the **Pace/Sense Histograms**).

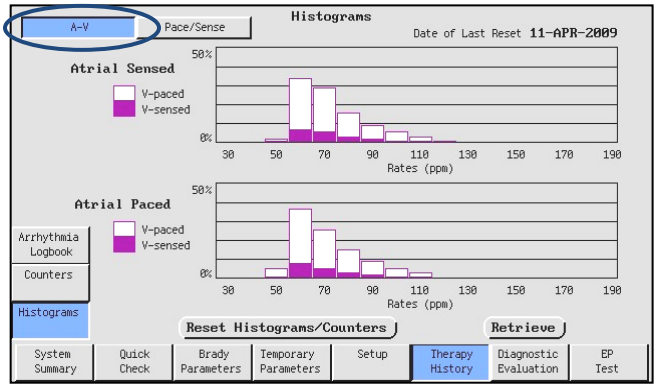


Figure 3. ALTRUA® A-V Histograms

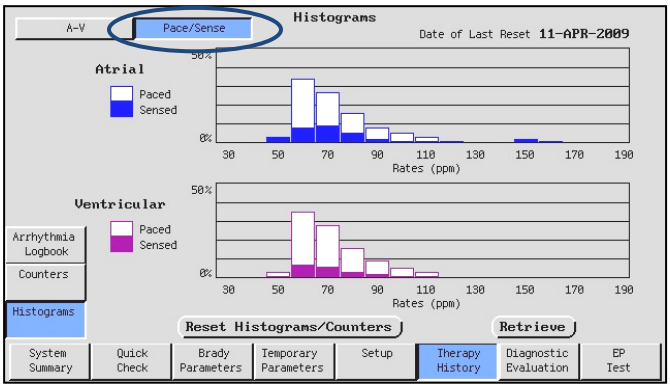


Figure 4. ALTRUA® Pace/Sense Histograms

When the A-V Histograms are printed, sometimes an Atrial Sensed histogram bar that extends beyond the chart boundaries (Figure 5) is present. This will occur **only if**:

- The highest value of Ventricular Paced/Ventricular Sensed or Atrial Paced VP/VS events at any given rate is less than 50%, setting the maximum Y-axis scale value to 50% (rather than 100%), **AND**
- Atrial sensed VP/VS events occurred with a frequency greater than 50% at any given rate. Because this value is greater than the set Y-axis scale value of 50%, the histogram bar will appear above the previously scaled Y-axis.

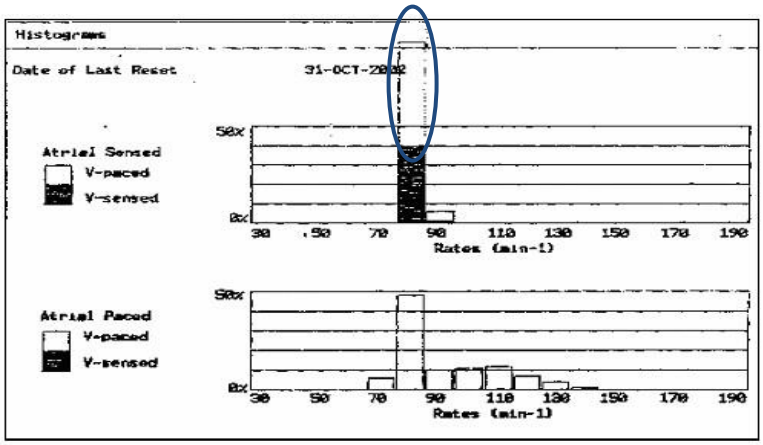


Figure 5. A-V Histograms Printout

In this situation, the printed histogram differs from the histogram displayed on the programmer in the following manner:

- Programmer screen: the bar noted above is automatically truncated and does not extend beyond the top of the grid.
- Printout: the actual pacing percentage will be displayed, by going beyond 50%. Counters will also display the actual pacing percentage. Also, the bar will extend beyond the top of the grid as shown in Figure 5.

NOTE: *This Y-axis scaling will not occur with the* ***Pace/Sense Histograms*** *because scale selection is based solely on a single maximum count (not on combinations).*

ALTRUA® and INSIGNIA® Pacing Systems from Boston Scientific

Indications

Pacemaker indications include: symptomatic paroxysmal or permanent second- or third-degree AV block; symptomatic bilateral bundle branch block; symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders; bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Pacemakers' dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual-chamber modes are specifically indicated for: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm.

Contraindications

Pacemakers are contraindicated for the following patients under the circumstances listed: patients with unipolar pacing leads or in MV mode with an implanted ICD because it may cause unwanted delivery or inhibition of ICD therapy; use of the MV sensor in patients with only unipolar leads, because a bipolar lead is required in either the atrium or the ventricle for MV detection (INSIGNIA® Plus, ALTRUA® 20/40); MV mode in patients with both unipolar atrial and ventricular leads (INSIGNIA® Ultra, ALTRUA® 60); single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias, which might trigger ventricular pacing; dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias; asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. For single use only-do not resterilize devices. Inappropriate sustained high-rate pacing occurred in the PULSAR™ MAX clinical study in 5 out of 130 patients with MV ON, 4 to 14 days after implant. If sustained high-rate pacing could be of concern, consider programming a reduced Max Sensor Rate or MV to Passive. These programming recommendations are intended to assure that MV calibration is evaluated and, if necessary, recalibrated (4 →ON) when the patient and pacing system have stabilized post implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred.

Precautions

For specific information on precautions, refer to the following sections of the product labeling: MV sensor calibration at implant; clinical considerations; sterilization, storage and handling; lead evaluation and connection; implantation; programming and pacemaker operation; MV initialization; environmental and medical therapy hazards; elevated pressure; explanted pacemakers. Advise patients to avoid sources of electric or magnetic interference (EMI). If the pacemaker inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of the EMI, moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation.

Potential Adverse Events

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure related, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev. R)

ZOOM® LATITUDE® Programming System from Boston Scientific

Intended Use

The Model 3120 Programmer/Recorder/Monitor (PRM) is intended to be used as a complete system to communicate with Guidant or Boston Scientific implantable pulse generators. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the System Guide for the Guidant or Boston Scientific pulse generator being interrogated.

Contraindications

The Model 3120 PRM is contraindicated for use with any pulse generator other than a Guidant or Boston Scientific device. For contraindications for use related to the Guidant or Boston Scientific pulse generator, refer to the System Guide for the Guidant or Boston Scientific pulse generator being interrogated.

Warnings

There are no warnings associated with this programming system.

Precautions

For specific information on precautions, read the following sections of the product labeling: General, Preparation for Use, Maintenance and Handling.

Adverse Effects

None known.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse effects. Rx only. (Rev. E)