

SUMMARY

Proper follow-up and battery status awareness are vital to ensure pacing therapy remains available as the device nears the end of its service life.

Boston Scientific INSIGNIA[®] and ALTRUA[™] pacemakers and programmers provide several tools to evaluate battery status. This article is intended to provide customers with a better understanding of battery status evaluation.

Products Referenced
INSIGNIA[®] and ALTRUA[™]
implantable 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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Battery Status Indicators for INSIGNIA[®] and ALTRUA[™] Pacemakers

Pacemaker battery status can be evaluated in two ways:

- A magnet may be positioned over the pacemaker. The resulting paced rate provides an indication of current battery status.
- The battery status can be viewed directly on the Battery Status screen following a device interrogation with a programmer.

Boston Scientific INSIGNIA and ALTRUA pacemakers automatically assess battery status every 11 hours. Upon initial interrogation or magnet application, the Battery Status is a reflection of the last battery evaluation performed by the pulse generator when operating under the programmed Amplitude, Pulse Width, Mode, Rate, and the weekly Lead Impedance average at that time. Note that subsequent parameter changes may alter battery status indicators.

Checking Battery Status with a Magnet

If a programmer is not available, battery status may be evaluated by applying a magnet and measuring the paced rate. If Magnet Response is programmed to **Async**, external application of a magnet of greater than 70 gauss (Figure 1) will elicit asynchronous pacing at a rate that corresponds to the pacemaker's current battery status. See Table 1.

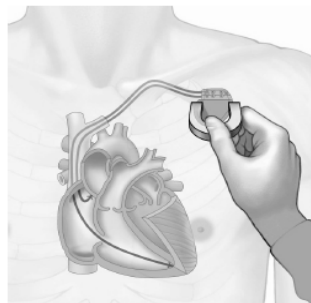


Figure 1. Magnet placement.

Table 1. Magnet Rate and Equivalent Battery Status

Magnet Rate	Battery Status	Patient Follow-up
100 ppm	GOOD	Normal follow-up schedule.
90 ppm	ERN (Displayed as GOOD on the Battery Status line)	Elective Replacement Near. Approximately one year or less remaining to ERT. Intensified follow-up is recommended.
85 ppm	ERT	Elective Replacement Time. Schedule replacement.
≤ 85 ppm	EOL	End of Life. Schedule replacement immediately. Pacing capture and telemetry are no longer guaranteed.

Checking Battery Status with a Programmer

Upon interrogation with a ZOOM LATITUDE programmer, battery status information may be viewed on the **Battery Status** screen (Figure 2). Four battery management tools are available:

Tools measured by the pacemaker

- Battery Status Indicator
- Magnet Rate

Tools estimated by the programmer

- Battery Status Gauge
- Longevity Remaining

Battery Status Indicator

The Battery Status Indicator is based on direct battery measurements performed by the pacemaker. Three indicators are used to characterize the current battery status: GOOD (greater than ERT on the Battery Status Gauge), Elective Replacement Time (ERT), and End of Life (EOL). Both current Battery Status and Battery Status for the previous test date are shown on the Battery Status screen and printed in the Battery Status report.

NOTE: *Elective Replacement Near (ERN), which is equal to a Magnet Rate of 90 ppm, indicates that intensified follow-up is recommended. However, ERN is a non-permanent/non-latching indicator and will not appear on the battery status line (GOOD will appear on the battery status line when Magnet Rate is 90 ppm).*

Magnet Rate

The Magnet Rate displayed on the programmer's Battery Status screen is determined by the pacemaker and corresponds to the asynchronous pacing rate that would be initiated if a magnet were to be applied:

- A Magnet Rate of 100 ppm indicates a normal follow-up schedule should be maintained.
- A Magnet Rate of 90 ppm is Elective Replacement Near (ERN). Intensified follow-up is recommended.
- A Magnet Rate of 85 ppm or less indicates pulse generator replacement should be scheduled.

Battery Status Gauge

The Battery Status Gauge is a graphical display of the programmer's estimate of current battery capacity remaining/status (Figure 3). Gauge position is representative of battery status when operating under the current programmed Amplitude, Pulse Width, Mode, Rate, and the most recent Lead Impedance measurement provided by the pacemaker. Nine steps are available on the gauge: 100% (BOL), 75%, 50%, 40%, 30%, 20%, 10%, ERT, and EOL. Labels are provided for three battery status positions - BOL (Beginning of Life), ERT (Elective Replacement Time), and EOL (End of Life). All battery status calculations are rounded up to the nearest available gauge position. For example, if the battery status is determined to be 15%, the gauge will point to the 20% position.

Longevity Remaining

The Longevity Remaining is an estimate prepared by the programmer that is dependent upon the same parameters as the Battery Status Gauge: programmed Amplitude, Pulse Width, Mode, Rate, and the most recent Lead Impedance measurement. In addition, the estimate uses the average pacing percentages of the last 30 days at the programmed device settings. Longevity Remaining is displayed from > 5.0 years to < 0.5 years in 0.5-year increments and will be updated any time programming changes are made or when a commanded lead impedance test completes.

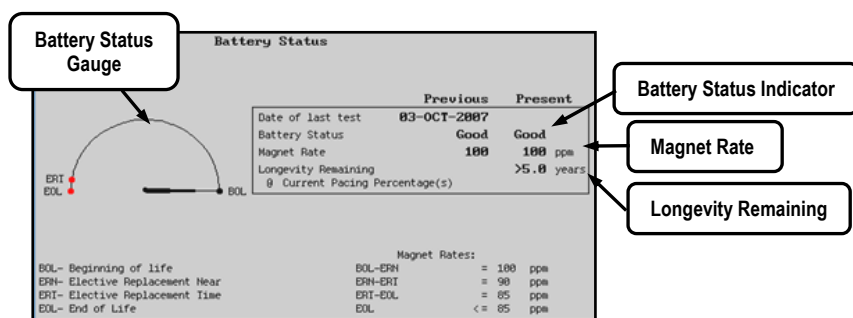


Figure 2. INSIGNIA® / ALTRUA™ Battery Status screen.

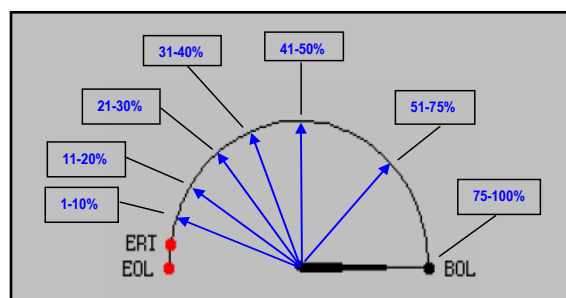


Figure 3. Battery Status Gauge positions.

Comparing Battery Status Tools

The **Battery Status Indicator** and **Magnet Rate** are based on direct battery measurements performed by the pacemaker. The pacemaker is scheduled to automatically assess these values every 11 hours and may require as many as five consecutive readings (approximately 55 hours) to reflect a battery status change from GOOD to ERT. Therefore, programming changes made during a follow-up session will not be reflected immediately in the Battery Status Indicator or Magnet Rate tools.

The **Longevity Remaining** and **Battery Gauge** tools are **estimates** provided by the programmer. Changing programmed parameter values or completing a commanded lead impedance test during a follow-up session will be **immediately** reflected in the Longevity Remaining and Battery Gauge estimates. However, because these four battery management tools are assessed on different schedules (pacemaker tools—every 11 hours, programmer tools—immediately upon parameter changes), they may not always align. For example, if the initial interrogation shows a Magnet Rate of 100 ppm (GOOD), but subsequent parameter changes cause the Longevity Remaining estimate to indicate less than 0.5 years remaining, consider deferring to the indicator which requires the most frequent patient follow-up.

The programmer can provide a printed report that includes present parameter values and pacemaker battery status. Consider printing a report at the end of a follow-up session, if a permanent record is desired.

The service life of INSIGNIA and ALTRUA pacemakers varies due to different battery capacities. Although battery capacity impacts overall device service life, the replacement indicators for all INSIGNIA and ALTRUA pacemakers will function the same regardless of battery capacity. Refer to the product user manual for battery capacity and longevity projections by pacemaker model.

Table 2. Summary of Battery Status Indicators, Magnet Rates, Device Functionality and Patient Follow-up

Battery Gauge	Battery Status	Magnet Rate	Device Functionality	Patient Follow-up
BOL Beginning of Life	GOOD	100 ppm	<ul style="list-style-type: none"> ▪ Expected battery status at implant. ▪ All device features are available. 	<ul style="list-style-type: none"> ▪ Normal implant and pre-discharge monitoring.
Gauge points between BOL and ERT	GOOD	100 ppm	<ul style="list-style-type: none"> ▪ Corresponds to a battery status gauge that is greater than ERT. ▪ All device features are available. 	<ul style="list-style-type: none"> ▪ Normal follow-up schedule per individual clinic guidelines.
	GOOD	90 ppm ERN	<ul style="list-style-type: none"> ▪ Elective Replacement Near ▪ ERN is not a permanent/latching indicator, and will not appear on the battery status line (GOOD will appear). A Magnet Rate of 90ppm may revert to 100ppm with decreased pacing demands or programming changes. ▪ All device features remain available. 	<ul style="list-style-type: none"> ▪ Approximately one year or less remaining to ERT. ▪ Intensified follow-up is recommended.
ERT Elective Replacement Time	ERT	85 ppm	<ul style="list-style-type: none"> ▪ Mode will change to a non-adaptive-rate mode (i.e., DDDR to DDD, VVIR to VVI). ▪ The following features will be disabled: <ul style="list-style-type: none"> • Sensors • Trending • Event Markers • EP Test • Stored and Real-time EGMs • Beat-to-beat Autocapture* • Activity Log • Commanded Autothreshold ▪ The ERT indicator is a permanent state. Even with decreased pacing demands or programming changes, the device will not revert to ERN or GOOD. 	<ul style="list-style-type: none"> ▪ Schedule replacement. <p><i>NOTE: Unlike Boston Scientific defibrillators, Boston Scientific pacemakers do not include a beeper to indicate replacement time.</i></p>
EOL End of Life	EOL	≤ 85 ppm	<ul style="list-style-type: none"> ▪ Three months after ERT, as the battery continues to deplete, the device will reach EOL. ▪ EOL is a permanent state. Even with decreased pacing demands or programming changes, the device will not revert back to ERT, ERN or GOOD. ▪ Dual-chamber pacemakers will change modes to single-chamber operation (DDD and VDD to VVI). ▪ The lower rate limit will be lowered to 50 ppm and as the battery continues to deplete, the pacing amplitude will decrease. ▪ Telemetry is not guaranteed. ▪ The following additional features will be disabled: <ul style="list-style-type: none"> • Dual-chamber • Rate Smoothing • Threshold Test • Histograms • Lead impedance measurements • P & R wave measurements • Arrhythmia logbook • Event Counters • Temporary parameters • Quick Check 	<ul style="list-style-type: none"> ▪ Three months after ERT, the device will reach EOL. ▪ Schedule replacement immediately, as pacing capture and telemetry are no longer guaranteed.

*Available only with INSIGNIA Ultra, and ALTRUA 60 series pacemakers. Ventricular output is fixed at twice the last measured threshold (but not > 5.0 V or < 3.5 V).