

Evaluating Pacemaker Battery Status

BACKGROUND INFORMATION

Unlike Boston Scientific defibrillators, Boston Scientific pacemakers do not include a beeper to indicate replacement time. Therefore, proper follow-up and battery status management are vital to ensure pacing therapy remains available as the device nears end of life.

Boston Scientific pacemakers provide several methods for ongoing evaluation of pacemaker battery status. This article is intended to provide customers with a better understanding of these methods of battery status evaluation.

CRT-P: Cardiac Resynchronization Therapy- Pacemaker
 PDM: Pulsar, Discovery, Meridian
 PDII: Pulsar Max II, Discovery II

CRM PRODUCTS REFERENCED*

PULSAR® MAX, DISCOVERY®, MERIDIAN®, PULSAR MAX II, DISCOVERY II, INSIGNIA®, CONTAK RENEWAL TR® CONTAK RENEWAL TR 2

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

CRM CONTACT INFORMATION

Technical Services – U.S.
 1.800.CARDIAC (227.3422)
Tech.Services@bsci.com

Technical Services – Europe
 +32 2 416 7222
eurtechservice@bsci.com

LATITUDE Clinician Support
 1.800.CARDIAC (227.3422)
latitude@bsci.com

Patient Services
 1.866.484.3268 – U.S. and Canada
 001.651.582.4000 – International

Pacemaker battery status can be evaluated by viewing the **Battery Status** screen following device interrogation with a programmer. The **Battery Status** screen provides four corresponding methods of evaluating current battery status:

- Battery Status Gauge
- Battery Status Indicator
- Magnet Rate
- Longevity Remaining*

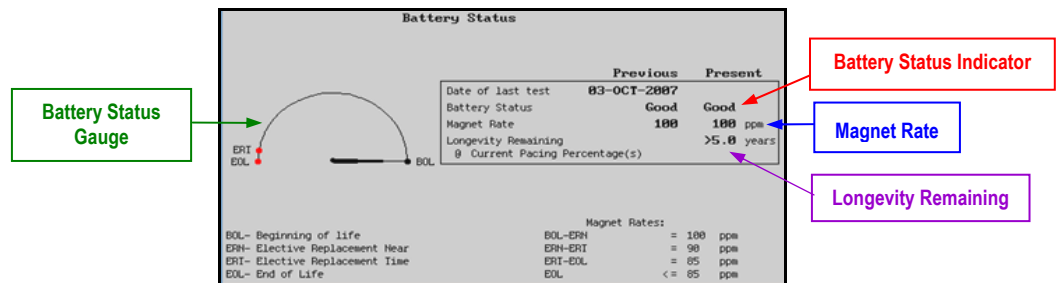


Figure 1. INSIGNIA® Battery Status screen.

Battery Status Gauge

The Battery Status gauge is a graphical representation of battery status. Gauge position is determined by Amplitude, Pulse Width, Mode, Rate, and Lead Impedance. Nine positions are utilized on the gauge: 100% (BOL), 75%, 50%, 40%, 30%, 20%, 10%, 0% (ERT and EOL). Although the dial may indicate any of the nine positions, **BOL, ERT, and EOL are the three positions labeled on the gauge** (Figure 2).

The gauge rounds up to the nearest position to indicate the percentage battery status remaining. For example, if the battery status is determined to be 15%, the dial on the gauge will be at the 20% position. Similarly, if 76% is calculated to be remaining, the dial will be at BOL, or 100%. The gauge position is updated any time programming changes are performed to the Amplitude, Pulse Width, Mode, and/or Rate.

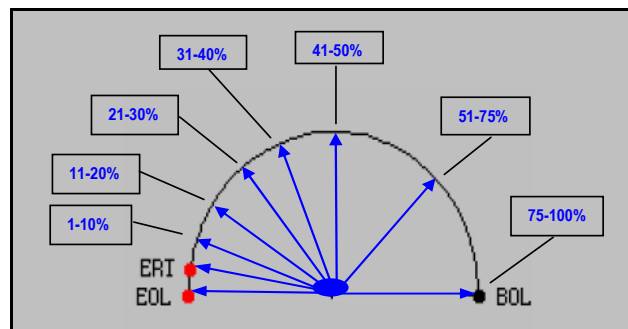


Figure 2. Battery Status Gauge positions.

Longevity Remaining

The Longevity Remaining for all pacemakers is an approximation dependant upon the same parameters as the Battery Status Gauge: Amplitude, Pulse Width, Mode, Rate, and Lead Impedance. The time 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 performed to the Amplitude, Pulse Width, Mode, and/or Rate.

*Longevity Remaining is available in the INSIGNIA, PULSAR MAX® II, and DISCOVERY® II pacemakers and CONTAK RENEWAL TR® and CONTAK RENEWAL TR 2 CRT-P devices.

[†]CONTAK RENEWAL TR and CONTAK RENEWAL TR 2 CRT-P devices display Longevity Remaining from > 8.5 years to < 0.5 years.

INSIGNIA pacemakers and CONTAK RENEWAL TR/ TR-2 CRT-P devices

The Longevity Remaining is estimated using the average pacing percentages of the last 30 days at the programmed device settings and the most recent lead impedance measurement. If the pacing percentage increases, the time remaining may be less than the number displayed. If the pacing percentage decreases, the time remaining may be more.

PULSAR MAX-II and DISCOVERY II pacemakers

The Longevity Remaining is estimated using 100% pacing at the programmed device settings and the most recent lead impedance measurement.

Battery Status Indicator

Four battery status indicators are used to characterize current battery status: GOOD, Elective Replacement Near (ERN), Elective Replacement Time (ERT) and End of Life (EOL). Each indicator corresponds with a magnet rate.

Table 1. Battery status Indicators, Associated Magnet Rates and Corresponding Functionality and Patient Follow-up

Indicator	Magnet Rate	Device Functionality	Patient Follow-up
GOOD	100 ppm	<ul style="list-style-type: none"> ▪ All device features are available. 	<ul style="list-style-type: none"> ▪ Normal follow-up schedule per individual clinic guidelines.
ERN* (Elective Replacement Near)	90 ppm	<ul style="list-style-type: none"> ▪ All device features remain available. ▪ Not a permanent indicator; may revert to GOOD if pacing demands are decreased or programming changes are made. 	<ul style="list-style-type: none"> ▪ Approximately one year remaining. ▪ Intensified follow-up is recommended.
ERT (Elective Replacement Time)	85 ppm	<ul style="list-style-type: none"> ▪ Mode will change to a nonadaptive-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* ▪ The ERT indicator is a permanent state. Even with decreased pacing demands or programming changes, the device will not revert back to ERN or GOOD. 	<ul style="list-style-type: none"> ▪ Schedule pacemaker replacement.
EOL (End of Life)	≤ 85 ppm	<ul style="list-style-type: none"> ▪ Three months after ERT, as the battery continues to deplete, the device will reach EOL. ▪ 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 features will be disabled: <ul style="list-style-type: none"> • Dual-chamber • Rate Smoothing • Safety Switch‡ • Hysteresis • Threshold test • Histograms • Lead impedance measurements • P & R wave measurements • Arrhythmia logbook • Event Counters • Temporary parameters • Quick Check 	<ul style="list-style-type: none"> ▪ Replace the pacemaker as pacing and telemetry are no longer guaranteed.

*Only available with INSIGNIA pacemakers.
†Only available with INSIGNIA Ultra pacemakers. Ventricular output is fixed at twice the last measured threshold (but not > 5.0 V or < 3.5 V).
‡Only available with PULSAR, PULSAR II, and INSIGNIA pacemakers.

Magnet Rate

The Magnet Rate displayed on the **Battery Status** screen of the programmer is based solely on the Battery Status Gauge position. When a programmer is not available, magnet application will provide a valuable method for evaluating battery status as the pacing rate elicited with magnet application will correspond with a battery status indicator (Table 1).