

Implant Battery Voltage Assessment and End of Life

June 21, 2019

DSI is proud to offer and stands behind our implant battery life warranties. This warranty is determined based on implant battery capacity and the implant's published warranty is based on an expected worst-case capacity scenario. We also acknowledge customers often use our implants beyond our warranted battery life. This document explains recommendations on how to monitor battery voltage and determine the battery cutoff voltage after which physiologic data should not be trusted. This cutoff is referred to as the implant's End-of-Life (EOL) voltage.

| Implant | End of Life Voltage |
|---------------------------|---------------------|
| L series | 2.80 V |
| M series | 3.20 V |
| HD-S02, HD-X02, and HD-XG | 1.50 V |
| Other HD implants | 1.55 V |

Due to compromised accuracy of physiologic data when the battery voltage falls below a model-specific EOL threshold voltage, the battery voltage must be monitored if the device is to be used past the warranty battery life. Ponemah acquisition software reports the implant battery voltage of L series, M series and HD series devices, but there are slight differences in how the battery voltage is measured and in how Ponemah manages a low battery voltage. Note Ponemah estimates the number of days left in the battery for all three implant types, however, the battery voltage is not used in arriving at that estimate. Because the starting capacity of the battery cannot be precisely known, the reserve capacity of the battery life is reached, cannot be predicted.

Battery Resistance

<u>PhysioTel Digital:</u> DSI implant designs include measures to maintain the accuracy of physiologic data despite changes in battery voltage. Extreme voltage changes can occur when the PhysioTel Digital implant battery experiences high internal resistance, which typically occurs for one of two reasons:

- <u>Passivation resistance:</u> PhysioTel Digital implants use lithium batteries which exhibit
 passivation if unused for a period of time. Passivation is a property which extends the life of the
 implant, since without battery passivation the unused batteries would experience much higher
 self-discharge during shipment, while waiting to be implanted, or during a study while the device
 is in shipping mode. Passivation is a temporary phenomenon and will naturally burn off after the
 implant is activated. Burning off passivation typically takes less than 10 minutes, but it is DSI's
 recommendation to turn on implants 30 min 1 hr prior to data acquisition to allow time for
 passivation burn-off.
- 2) <u>End-of-Life resistance:</u> As the end of the battery's useful life approaches (near EOL), the battery voltage will drop because of electrochemical effects, while at the same time the internal battery resistance will increase. The effects of high internal resistance will manifest similarly to those observed with a passivated battery; the difference being passivation resistance effects will fade

away over time, while EOL resistance effects will steadily worsen as the battery continues depleting after reaching EOL.

<u>PhysioTel HD:</u> implants use a battery with different chemistry, therefore internal battery resistance effects are insignificant.

Battery Voltage Measurement in PhysioTel Digital Implants

There are slight differences in the way each PhysioTel Digital implant type manages battery voltage reporting, due to their unique designs. The M series reports a battery voltage which ignores the effect of temporary passivation and will reflect the most positive battery voltage. The L series devices reports a battery voltage which includes the temporary passivation effects and will reflect the lowest voltage. The difference between these two reporting techniques are illustrated below.

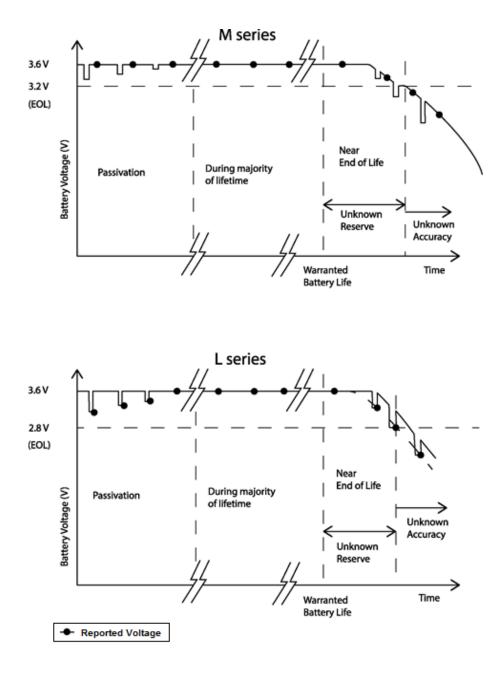


Figure 1. M series battery voltage will not track the passivated voltage, since it reflects the most positive battery voltage. L series battery voltage *will* reflect the passivation in the battery voltage readings, since it reflects the lowest battery voltage. The L series battery voltage will start low in a passivated battery, then increase as the passivation is removed.

Ponemah v6.X Response to L series and M series EOL Voltages

For PhysioTel Digital implants, Ponemah v6.X displays the current battery voltage in the *Sampling Control* dialog. When the measured voltage drops below the corresponding EOL voltage for the device, the displayed battery voltage is shaded with yellow highlighting. **The EOL thresholds for PhysioTel Digital implants** are:

L series: 2.8 V M series: 3.2 V

| 📴 Samplir | ng Con | trol | | | | | | | |
|--------------|--------|--------------|-------------------------|---------|--------|-----------------|-----------------|--------|--|
| All | Sche | dule 1 So | chedule 2 Notifications | | | | | | |
| ▼ Save Video | | | | | | | | | |
| | | <u>State</u> | Subject Name 🗸 | Species | Camera | Battery On Time | Battery Voltage | Alarms | |
| Contin | uous | Stop | o All Continuous | | | | | | |
| | | Sampling | 861102 | H | | | 3.585 V | | |
| | | | | | | | | | |
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Figure 2. Displays a M11 implant voltage as 3.585 V in the Sampling Control dialog.

Plotting Battery Voltage in Ponemah Review

The user can plot the battery voltage in Ponemah Review if the battery voltage channel was enabled during acquisition. This will allow verification that the battery voltage was above the EOL threshold voltage during acquisition.

| PhysioTel Digital Hardware Configuration 2.0.1 | 8108.5, Copyright © Data Sciences International 1996-2018 | phases in the second seco |
|--|---|--|
| Configuration | Implant Details | 0 |
| ▲ CLC Configuration ▲ ○ 1008391 ▶ ● 861102 | Implant Name: 861102 Enabled: Ødel: Model: M11 SN: 861102 Frequency: Frequency: F1-C1 Activation Date: 6/102 Frequency: F1-C1 Activation Date: 6/102 Frequency: F1-C1 Activation Date: 5/18/2016 Battery: J.62V Freesure ECG Temperature ************************************ | Current Mode: Standby Turn Implant Off Inactive Channels: Accelerometer X Accelerometer Y Accelerometer Z Battery Life Remaining Signal Strength Battery Days Remaining Signal Strength Battery Days Remaining |
| Apply Templates | Add or remove channel(s), change the name, or turn the imp | lant off. |

Figure 3. Enable Battery Voltage by moving from Inactive to Active in the *Implant Details* page, accessible by clicking on the implant in the Configuration Tree, located in the *PhysioTel Digital (CLC) Configuration* page, accessible from *Hardware* in the main Ponemah menu.

In addition, battery voltages below the EOL threshold can be marked as "bad" using the *Noise* tab in the *RAW Analysis Attributes* for the Battery Voltage channel. If the **Minimum Signal Value** is set to 2.8 (for L series) or 3.2 (for M series), the battery voltage waveform will be marked as bad when the measurement falls below the entered voltage:

| RAW Analysis Attributes (1011450 Battery | , Input 5) | x |
|---|---|--------------------------|
| Std Attrib Adv Attrib1 Noise Marks | Typical Values Additional Channels | ОК |
| Enable Noise Detection Enable Dropout Detection Minimum Signal Value 3.2 V Maximum Signal Value 4 V Min Good Data Time 10 s | Enabled Enabled -1000 V 1000 V 10 s | Cancel Apply Print |
| | | |

After applying bad data marks to the battery voltage channel, it is necessary to merge the bad data marks with other physiologic channels. In Ponemah Review, click "Actions", then click "Merge Bad Data Marks."

Ponemah v5.X Response to L series and M series EOL Voltages

By default, Ponemah v5.X cannot store the battery voltage or plot the battery voltage waveform. During an acquisition, the current battery voltage is displayed in the *Implant Status* dialog, and when the voltage drops below the corresponding threshold voltage for L series (2.8V) or M series (3.2V), the color of battery voltage text displayed turns from black to red. If you are interested in saving implant voltage, for the purposes of graphing in Ponemah Review, please contact DSI to learn more.

Ponemah v6.X Response to HD series EOL Voltages

Ponemah v6.X responds to HD battery voltages below threshold in a manner similar to that described above for the PhysioTel Digital implants. The *Sampling Control* dialog will display the battery voltage text highlighted in yellow. In addition, the *Notifications* tab will flash an exclamation point to indicate an error entry (related to the low voltage) has been added to the *Experiment Log*. The **EOL threshold voltages used for HD series implants** are:

1.50 V for HD-S02, HD-X02 and HD-XG 1.55 V for all other HD implants If the battery channel is enabled while acquiring data, the battery voltage may be plotted to verify that the battery voltage was above the EOL threshold during acquisition. Battery voltages lower than the EOL threshold can be marked as "bad" using the *Noise* tab in the *RAW Analysis Attributes* for the Battery Voltage channel. If the **Minimum Signal Value** is set to 1.50 (for HD-S02, HD-X02 and HD-XG) or to 1.55 (for all other HD series implants) the battery voltage waveform will be marked as bad when the measurement falls below the entered voltage.

Ponemah v5.X Response to HD series EOL Voltages

Ponemah v5.X can record HD battery voltage, but a warning message may be received at the start of acquisition that battery voltage must be sampled at a 50Hz sample rate. Since only one secondary sample rate is allowed, the user must change the secondary sample rate to 50Hz. Please note, the Autoconfigure Protocol feature will change the secondary sample rate back to 10Hz

Please contact DSI's Technical Support team if you have additional questions: support@datasci.com