

PHYSIOTEL DIGITAL BATTERY PASSIVATION

BACKGROUND

All PhysioTel™ Digital Implants are powered by lithium batteries. Lithium batteries offer many advantages including high energy density and a low self-discharge rate. These advantages come with a price, as all lithium batteries are affected by a phenomenon known as passivation. Passivation serves to reduce the extent that the battery will discharge on its own when the device is turned off. However, passivation that builds up over time can temporarily lower the battery voltage when the implant is enabled after a long dormant period. Depending on the extent of passivation, the start-up sequence of the implant may be delayed temporarily until the battery passivation has been removed by the circuitry.

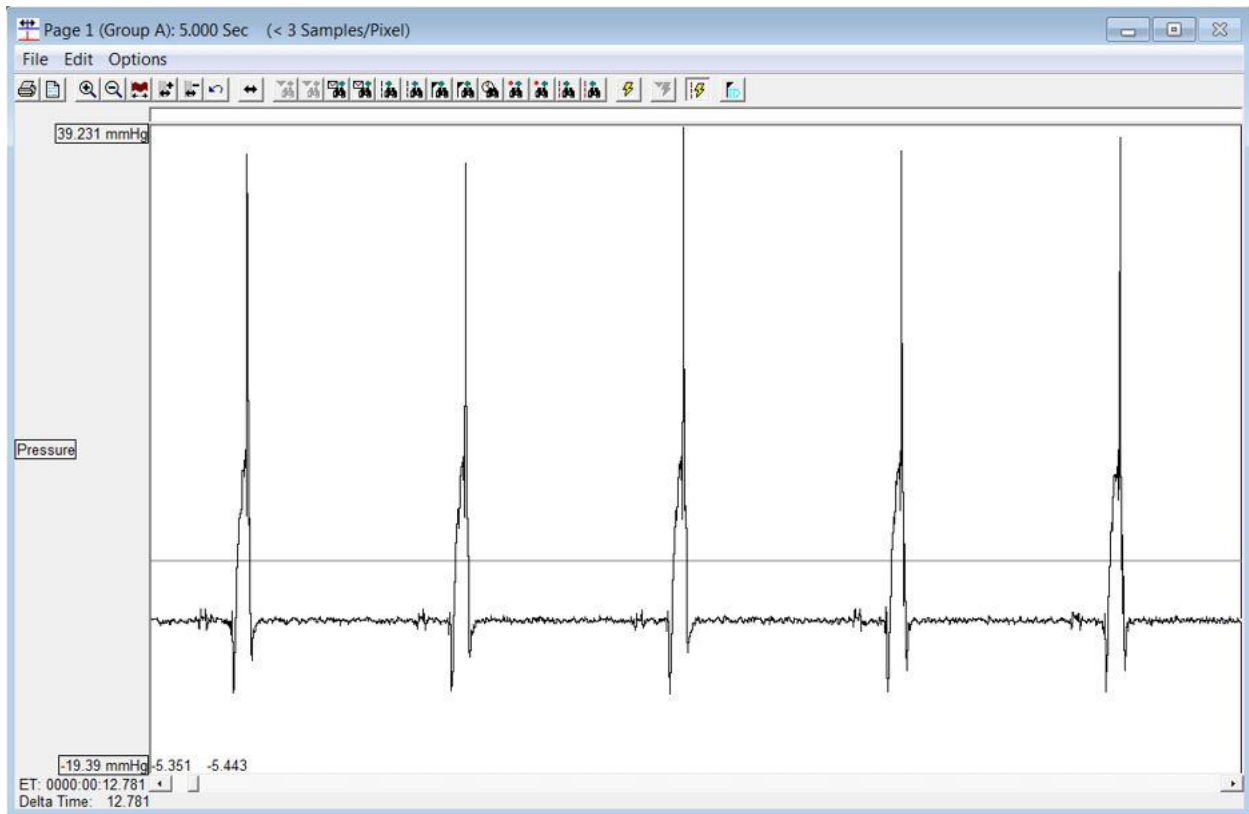
DSI seasons all lithium batteries upon receipt. Measures such as the seasoning process, tests performed during manufacturing, and on-time during surgery work together to burn off the accumulated passivation and allow the implants to function as intended during a study. Despite these preventative measures, the passivation layer will reform after a period of time in the off state, and it will form quicker if stored at higher temperatures or when implanted.

POSSIBLE EFFECTS ON IMPLANTS

Depending on how long an implant has remained in the shipping mode, two types of passivation effects might be observed. A very high amount of passivation can reduce the battery voltage enough so that the start-up sequence of the implant will be repeated until the battery passivation has been sufficiently reduced, which can take 30 seconds to several minutes. DSI's Power-On-Detector (POD) is useful in identifying whether the start-up sequence of the implant is being repeated because of battery passivation. The POD will emit a beep sound for as long as any implant within range is burning off battery passivation (by repeating the start-up sequence). When the beep sound stops, the implant will join the system as usual. This is how the POD will behave with Physiotel Digital implants manufactured after July 1, 2018. With Physiotel Digital implants manufactured before this date, the POD may not give a beep indication when the implant is restarting because of high passivation, but the outcome will be the same: the passivation will burn off and the implant will join the system.

A more moderate amount of passivation will allow a rapid start-up, but will show up for a short while as small "spikes" in the pressure signal, spaced 1 second apart. These spikes can be as high as 50mmHg but will reduce in amplitude and finally go away as the passivation is burned off, with no user intervention required. Once the implants join the system, placing them in active mode will reduce the passivation faster than if they were left in stand-by mode.

An example of what they may look like is shown below.



Note: 1 second spikes might be observed on biopotential channels while in the sterile pack or when not yet implanted. These are not from passivation but are an expected result of the high-gain biopotential amplifiers picking up very small voltages from the environment or from the antenna. Once the leads are implanted the biopotential spikes from environmental noise will go away.

RECOMMENDED ACTIONS

Passivation is a useful battery property that extends the lifetime of the implant. The effects on implant start-up or on pressure waveforms are easily dealt with by turning the implants on and starting the collection of data 30 minutes to an hour before starting your study. The same early start of data collection is recommended prior to taking a pressure offset measurement.