



Stellar Telemetry: For Measuring Physiological Parameters

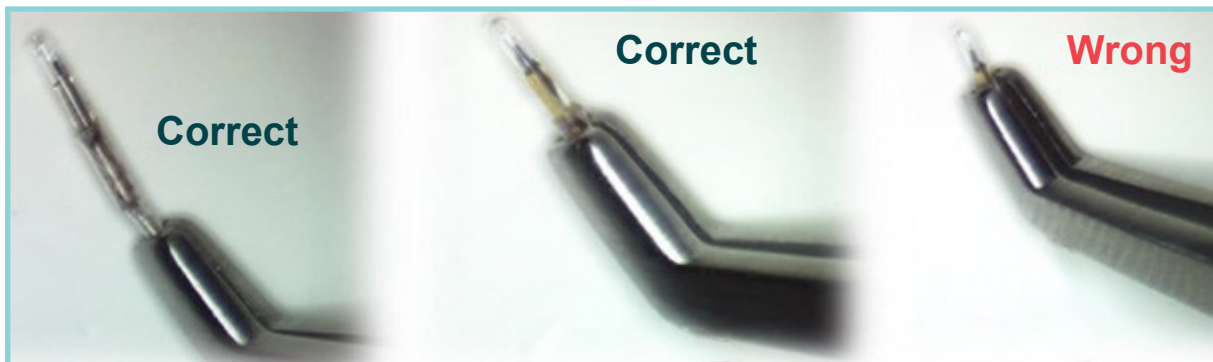
Handling, Checking Offset, and Re-use of Stellar Pressure Catheters

Background

Stellar pressure catheters incorporate a solid-state pressure sensor located at the tip of the catheter and provide high-fidelity pressure measurements. The sensor is encased in a thin-walled glass tube that is sealed at the end and has a sensing window on the side of the catheter. This document addresses several considerations intended to optimize the use, accuracy, and longevity of the pressure measurements.

Handling of the Catheters

The glass tip is fragile and should be handled carefully. The catheter should only be held with a cannulation forceps by gripping behind the glass portion of the tip. The length of the pressure catheter consists of wires encased in a silicone tubing and is designed to be robust. However, the catheters should be routed to minimize the possibility of kinking or excessive stretching.



Checking Zero Offset

The pressure sensors are pre-calibrated at the factory, including temperature compensation to minimize the pressure change often observed with changes in temperature. Each device includes a .set settings file (typically on a provided USB drive) that includes the pressure calibration values (slope and offset).

The Stellar pressure sensors measure absolute pressure, which must be corrected by barometric pressure to provide relative pressure in standard units of mmHg. The Stellar receiver includes an integrated barometric pressure sensor that is constantly monitored in the host software (Notocord-hem or Biopac AcqKnowledge). The software subtracts barometric pressure from the implant pressure readings as data are collected to provide an accurate relative pressure measurement.

It is important to be aware that most pressure sensors can and do drift over time. Pressure drift can occur when stored on a shelf or while implanted, although most pressure drift occurs while implanted due to the fluid environment. It is strongly recommended that pressure offsets are checked both prior to implantation and following explantation (if there is still battery life available).

Best practice is to explant while the implant is still functioning so that the pressure offset can be recorded and the data corrected as necessary. The battery voltage at the time of explant should also be recorded as the pressure offset will be impacted by sharp drops in battery voltage at the

Pressure offsets should be measured as follows	
1.	Remove the magnet from the implant if a magnet is currently in place.
2.	Start collecting data to allow the implant battery voltage to stabilize. For example, schedule recordings for 30 seconds every minute for 5 minutes for memory implants, or continuously for 5 minutes for real-time implants, and watch for any noticeable changes in pressure measurements.
3.	<p>Ideally warm the implant to near body temperature (37 degrees C). We recommend hydrating the implants in warm saline prior to surgery, so this would be an ideal time to record pressure offsets.</p> <p>A. Keep in mind that water depth will contribute to the measured pressure offset. One inch of water is equivalent to about 1.9mmHg.</p>
4.	<p>Check the measured pressure in the software by one of the following methods (see the corresponding QuickStart guide for software details):</p> <p>A. Notocord with memory implants</p> <ul style="list-style-type: none"> i. Configure the implants and a sampling protocol and start sampling from the Notocord-hem software OR ii. Use the Peek option for the pressure channel in the STE10 or STE30 module <p>B. Biopac with memory implants</p> <ul style="list-style-type: none"> i. Configure the implants and a sampling protocol and start sampling from the Biopac AcqKnowledge software. <p>C. Notocord with real-time continuous implants</p> <ul style="list-style-type: none"> i. Configure the implants in the Stellar Commander software and use the “Start Animal Units” function to turn the implants on. ii. Load the Stellar Commander configuration into the Notocord STE20 module and start data acquisition. Monitor the pressure signal in the CTD60 display.

Following are some guidelines relating to observed pressure offsets for new/unused implants

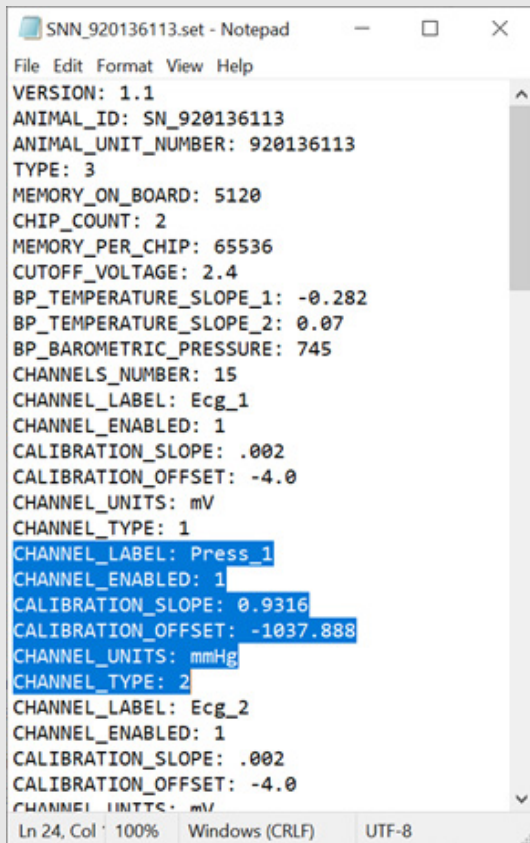
1.	Pressure offsets within +/-5mmHg are normal. In most cases the implants can be used with no further action. If your studies require a higher level of absolute accuracy, the pressure calibration offset value can be changed in the .set file associated with the implant (see below). Before making these small changes, we recommend checking the pressure offset at/near body temperature (around 37 degrees Celsius).
2.	For pressure offsets exceeding +/-5mmHg, but less than +/-10mmHg, we recommend adjusting the pressure offset calibration value in the .set file associated with the implant.
3.	For pressure offsets exceeding +/-10mmHg, we recommend that you contact TSE technical support to confirm the measurements and discuss options to resolve the error.

Correcting Pressure Offsets through Implant Settings Files

Note that used implants may have higher pressure offsets and we recommend **ALWAYS** checking the pressure offset and making necessary corrections to the settings files prior to implantation. Corrections to the .set files can be done by TSE to minimize the chance of errors. If you prefer to make the corrections yourself, the following procedure should be followed:

1.	Make a backup of each .set file to be modified, for example in a subfolder called Original Settings.
2.	Open the .set file for the corresponding serial number in Notepad or other text editor.
3.	Find the section in the .set file corresponding to the pressure offset. If the implant has more than one pressure channel, make sure you match the offset with the proper channel.
4.	Adjust the offset by subtracting the measured offset from the CALIBRATION_OFFSET. For example, if the measured offset is +6mmHg, subtract 6 from -1037.888 in the settings file below for a modified offset of -1043.888.

5. Save the new .set file and load the new file into the Notocord or Biopac software (memory implants) or into the Stellar Commander software (real-time continuous implants). Verify that the offset is now very close to zero using the steps in the “Checking Zero Offset” section above.



```
SNN_920136113.set - Notepad
File Edit Format View Help
VERSION: 1.1
ANIMAL_ID: SN_920136113
ANIMAL_UNIT_NUMBER: 920136113
TYPE: 3
MEMORY_ON_BOARD: 5120
CHIP_COUNT: 2
MEMORY_PER_CHIP: 65536
CUTOFF_VOLTAGE: 2.4
BP_TEMPERATURE_SLOPE_1: -0.282
BP_TEMPERATURE_SLOPE_2: 0.07
BP_BAROMETRIC_PRESSURE: 745
CHANNELS_NUMBER: 15
CHANNEL_LABEL: Ecg_1
CHANNEL_ENABLED: 1
CALIBRATION_SLOPE: .002
CALIBRATION_OFFSET: -4.0
CHANNEL_UNITS: mV
CHANNEL_TYPE: 1
CHANNEL_LABEL: Press_1
CHANNEL_ENABLED: 1
CALIBRATION_SLOPE: 0.9316
CALIBRATION_OFFSET: -1037.888
CHANNEL_UNITS: mmHg
CHANNEL_TYPE: 2
CHANNEL_LABEL: Ecg_2
CHANNEL_ENABLED: 1
CALIBRATION_SLOPE: .002
CALIBRATION_OFFSET: -4.0
CHANNEL_UNITS: mV
Ln 24, Col 1 100% Windows (CRLF) UTF-8
```

Correcting for drift between implantation and explantation

Pressure catheters are likely to drift more while they are in a humid or liquid environment. Pressure drift is not necessarily linear over time, but it is almost always in the same direction over time and the trend can be approximated with a linear fit. If you measure pressure offsets prior to implantation and after explantation, and the measured pressure signals are otherwise of good quality and pulse amplitude, you can calculate the trend and use your Biopac or Notocord software to correct the offset at a given point in time. TSE can provide an Excel spreadsheet to help with the calculation. The formula is as follows:

$$\text{Estimated offset} = (\text{explant offset} - \text{implant offset}) * (\text{measurement date} - \text{implant date}) / (\text{explant date} - \text{implant date})$$

Re-use of Implants with Pressure Catheters

Stellar pressure catheters can be re-used in multiple animals. This is most often done in rodents where typical studies are short in duration, and where there is more tolerance of risk of losing the pressure signal. TSE has a separate guide for explanting, cleaning, and re-sterilizing the catheters. Additional details relating to re-use of pressure catheters are presented here.

The following criteria should be considered before re-using a pressure catheter

1.	Is the glass tip of the catheter free from damage such as cracks in the glass?
2.	Is the length of the catheter to be inserted into an artery (or other pressure space) clean, smooth, and free from defects?
3.	Is the silicone gel/plug still in place in the pressure sensing window (typically on the side of the catheter near the tip)?
4.	<p>Is the implant still functional, and has adequate battery life to conduct another study?</p> <p>A. Battery voltage should be greater than 2.7 volts for XX implants B. Battery voltage should be greater than 3.4 volts for YY implants C. You should keep track of how much battery life has been used on previous studies based on your sampling protocol. Consult your sales representative or TSE technical support if you need details for expected battery life based on your sampling parameters.</p>
5.	<p>Is the pressure catheter still functional (sensor not blown, no broken wires)?</p> <p>A. A blown sensor or broken wire will typically result in a very high observed pressure offset with little or no response to applied pressure.</p>
6.	Has the zero offset been checked and corrected?
7.	<p>Is the risk of possible complications due to previous use acceptable?</p> <p>A. Related complications may include development of clots, thrombosis/fibrosis, moisture ingress, or general inflammation/rejection.</p>

If the answer to all of these is “yes”, then you can proceed with reuse of your Stellar implants.