

Checking the Accuracy of Pressure Implants

Reliable and accurate data points are essential in order to ensure that the results of your research project will be meaningful. When data points are collected automatically using electronic instrumentation, it is important to have a reliable means of determining if the values being recorded are accurate.

When measuring blood pressure telemetrically, it is essential to verify that the measurements are accurate, since a small percentage of these devices exhibit a significant long-term drift. Verification can be done in a variety of ways, including pressure chambers, arterial cannulation, comparison to a mercury manometer, etc. Arterial cannulation is normally used only if it is necessary to check the accuracy of the device at a time other than at implantation or explantation. For most protocols, this is not necessary. Since those devices that exhibit long-term drift almost always drift toward lower pressure, validation of accuracy at implantation and explantation can provide a simple and reliable method for assuring that the measurements obtained during the course of the study are accurate. The following procedure will determine if the pressure implant is reading zero prior to implantation or if there is a deviation (zero offset).

Checking accuracy prior to implantation

All DSI implants are carefully calibrated and tested prior to being shipped to the customer. However, DSI strongly recommends that all pressure devices be checked again immediately prior to surgery. The following protocol will allow you to verify that the pressure implant is functioning normally prior to surgical placement in an animal.

Upon arrival, each implant and shipping package should be examined thoroughly for any obvious signs of damage. If the devices will be stored, ensure they are turned off to avoid battery depletion. To check offset, turn the implantation approximately 1-4 hours prior to surgery. This will allow the electronics time to stabilize.

Just prior to surgery, the implant should be placed on its assigned receiver in the sterile pack. It is very important that the catheter tip be level with the body of the implant. If the catheter is above or below the level of the implant body, the measured values will be affected by this "head pressure" and will not be accurate. Usually, if the implant is checked while it is still in the sterile pack, the unit is held in the proper position for zero offset. For devices manufactured within the first month, this value should be within ± 3 mmHg of zero to comply with manufacturer specifications. Devices older than three months may experience a larger offset. If desired, a hard copy of the trace can be made and be printed. This should be kept with the lab data for the project as verification of initial accuracy.

Another accuracy verification option is to collect the pressure "waveform" or offset in the same way you would sample from the animal. This procedure will save the pressure offset data in the same file with the animal's data, permanently associating the offset value to the animal.

If your experimental protocol or quality standards (such as FDA or GLP) require that implant accuracy be checked more thoroughly, we recommend placing the transmitter in a chamber that can be pressurized using a mercury manometer and verifying the accuracy of the device at several pressures (e.g., 100, 200, and 300 mmHg). Such a chamber can be fabricated by your mechanical shop. If the value of offset is outside ± 3 mmHg, contact DSI's Technical Staff for further instructions.

If your implants have been on the shelf for an extended period of time and they have an unacceptable zero offset, it may be possible to adjust calibration values to compensate for the offset. If you are routinely experiencing offsets prior to implantation greater than ± 1.5 mmHg, your ambient pressure monitor (APR-1) may require calibration. Contact DSI for assistance.

Checking accuracy at explantation

It is also valuable to check the zero offset of the implant at the end of the experiment. If the device was accurate prior to implantation and at explantation, it is safe to assume that the measurements were accurate throughout the experiment.

To do a post-implant offset, the transmitter should be carefully removed from the animal. If it is necessary to cut the catheter, the procedure should **ONLY** be done using a new scalpel blade at a 45-degree angle to the catheter, while cutting away from the transmitter body. The catheter should be cut at no less than 3cm from the body of the transmitter. Using scissors to cut the catheter may damage the sensor. **If you plan on reusing the device, do not cut the catheter.**

Gently clean the catheter to remove any blood or tissue debris from the tip. It is essential that the temperature of the implant be stable while the offset is checked. This can be done by leaving the implant at room temperature for 1 to 2 hours or by placing it in a beaker of 37 degrees Celsius water immediately upon removal from the animal. The water in the beaker should be just barely deep enough to cover the body of the implant to avoid any effect of head pressure on the offset measurement. Once the temperature of the implant has stabilized, the device should be placed on its receiver and the value recorded as described above.

The following procedure will allow you to verify that the pressure implant is functioning normally prior to surgical placement in an animal. These directions are for use with the Ponemah software.

Pressure Offset Procedure

1. Make sure each implant is setup and assigned to a receiver in the OpenART configuration. Refer to the OpenART manual for this procedure under "Getting Started".
2. In Ponemah, setup the protocol file as normal. For the BP and/or LVP channels, add the NPMN derived parameters. Start an acquisition.
3. Look at the BP and/or LVP pressure channels and measure the distance the signals are from 0mmHg. In Ponemah, you can refer to the NPMN parameter.
4. Continue the acquisition. Record the offset value on the Lab Sheet provided in the OpenART manual (Appendix D).
5. While acquiring, refer to How to Enter a Pressure Offset Value to continue.

How to Enter the Pressure Offset Value

When using Ponemah with Open ART, there are a few different methods for entering in a pressure offset value for BP or LVP signals. These methods depend greatly upon the version of the BP and LVP analysis modules being used. Pick one that suits your software version or preferences as they will all perform the same function.

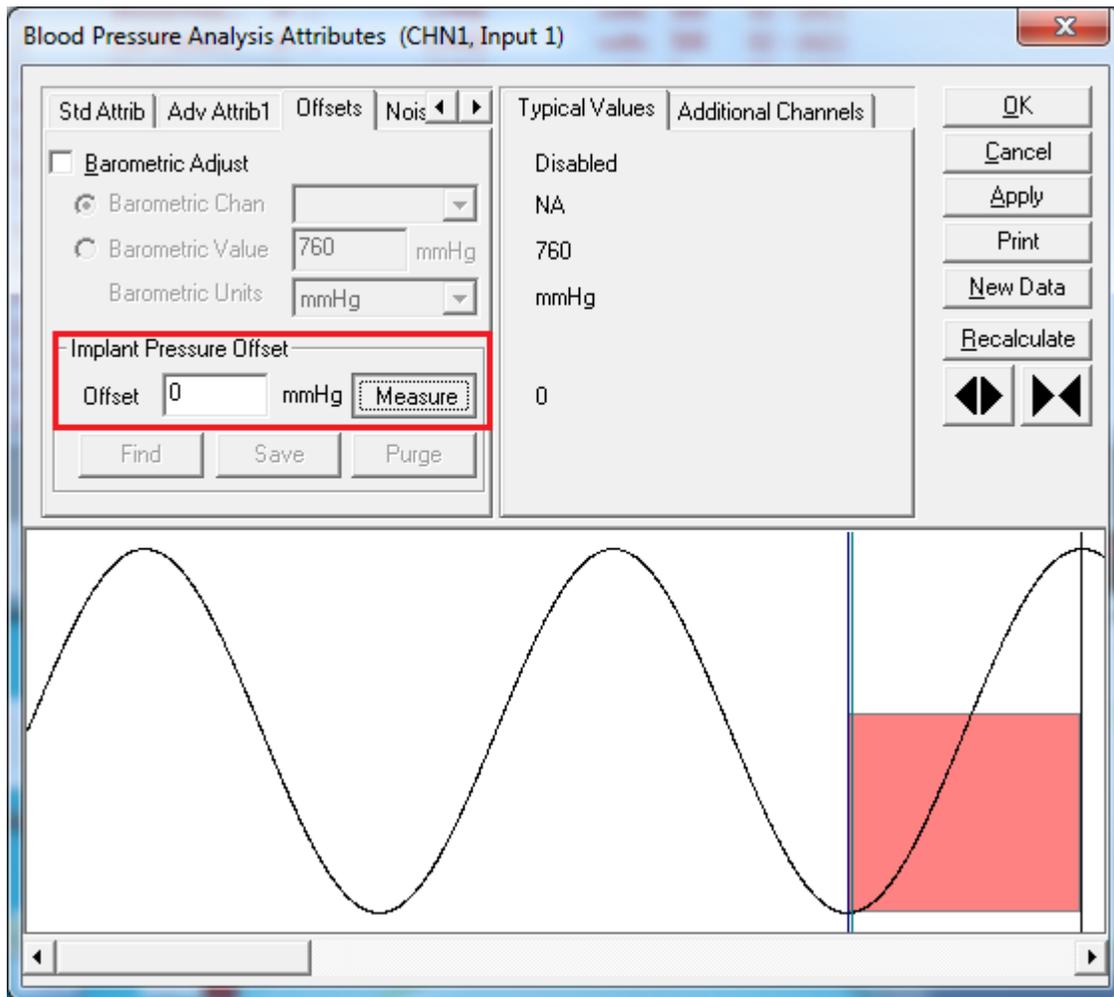


Figure 1: Offset Measure

Ponemah 5.0 BP Analysis Module – Have Ponemah Measure the Offset

1. While running the offset acquisition, go to the Status window in the main Ponemah window. Double-click on the BP channel to bring up the BP Analysis Attributes.
2. In the BP Analysis Attributes window, go to the Offsets tab. At the bottom there is a text box for the offset. Click the 'Measure' button next to it (Figure 1), and Ponemah will automatically input the offset. The offset can also be manually entered here instead.

Earlier Ponemah Versions of BP Analysis Module – Manually Enter the Offset in Analysis Attributes

1. While running the offset acquisition, go to the Status window in the main Ponemah window. Double-click on the BP channel to bring up the BP Analysis Attributes.
2. In the BP Analysis Attributes window, go to the Offsets tab. At the bottom there is a text box for the offset. Manually enter the offset (refer to Figure 1) that was recorded onto the lab sheet earlier.

Earlier Ponemah Versions of BP Analysis Module – Alternate Method, Manually Enter the Offset in OpenART

1. After recording the offset onto the lab sheet, stop the acquisition.
2. Go to Hardware -> Edit DSI Setup to open the OpenART configuration.
3. Expand the corresponding DSI implant in the OpenART configuration and right-click on the Pressure channel. Select 'Properties'.
4. In the Properties window for the pressure channel, go to the 'Advanced' tab.
5. Under the Advanced tab, enter the offset value recorded earlier into the offset row and click OK. See Figure 2.

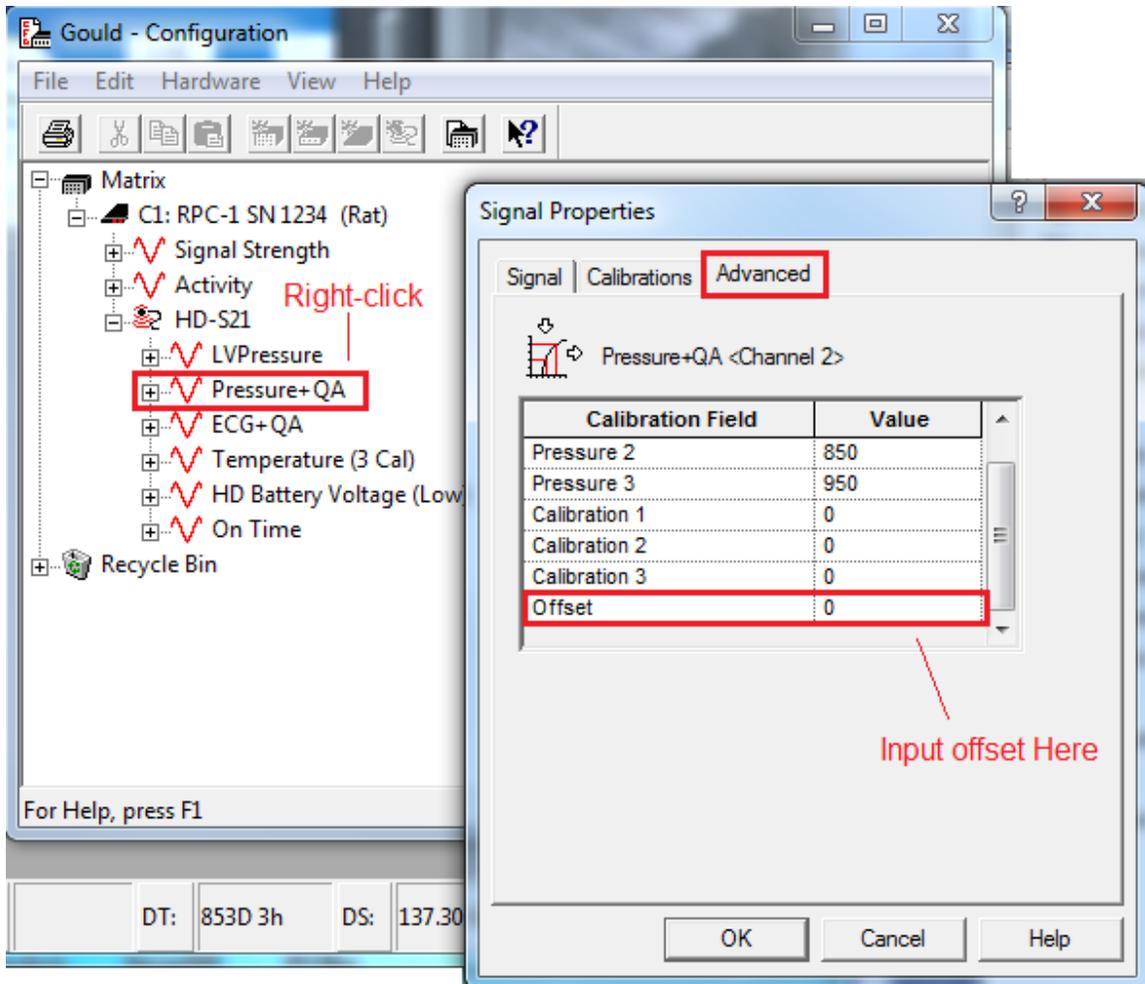


Figure 2: BP Offset in OpenART

Ponemah 5.0 LVP Analysis Module – Manually Enter the Offset in Analysis Attributes

1. While running the offset acquisition, go to the Status window in the main Ponemah window. Double-click on the LVP channel to bring up the LVP Analysis Attributes.
2. In the LVP Analysis Attributes window, go to the Adv Attrib1 tab. At the bottom there is a text box for the offset. Manually enter the offset (refer to Figure 3) that was recorded onto the lab sheet earlier.

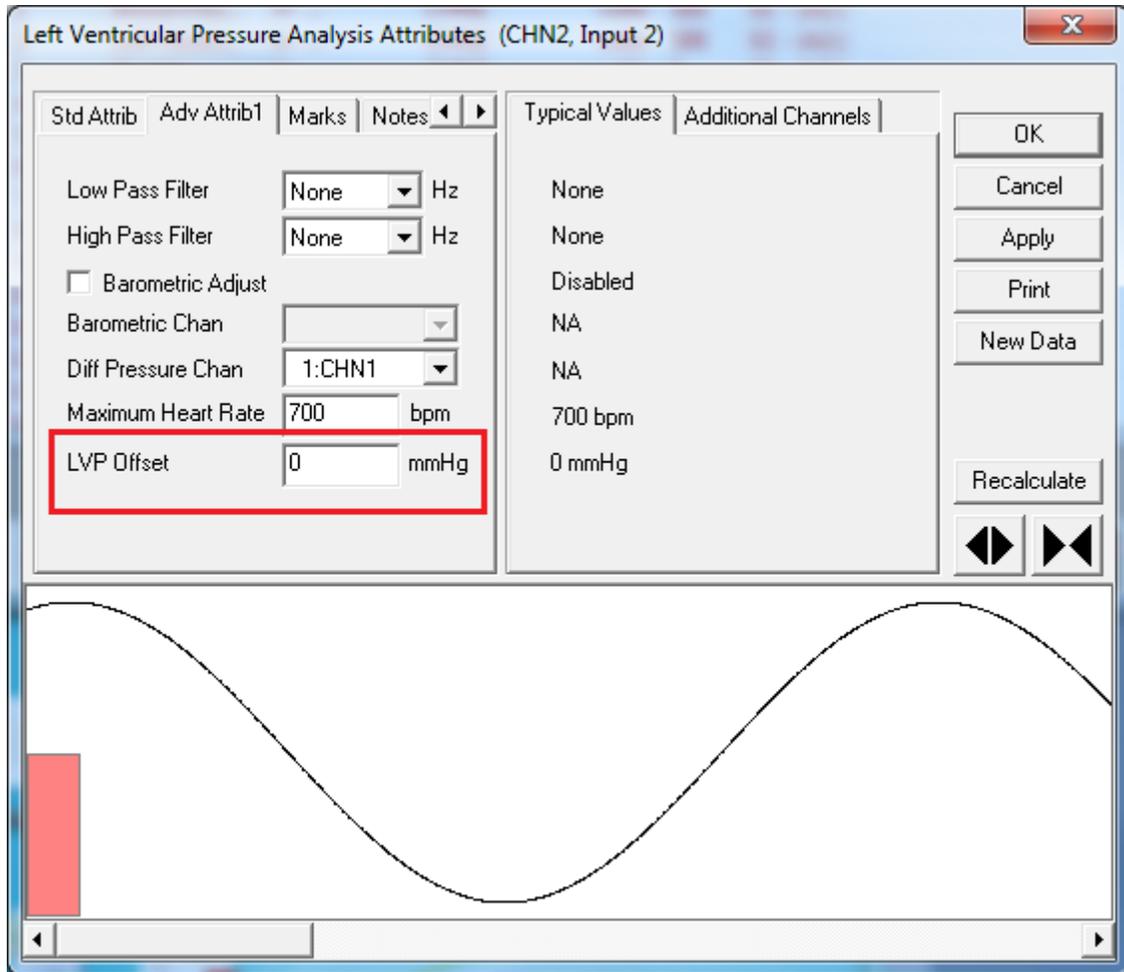


Figure 3: LVP Manual Offset

Earlier Ponemah Versions of LVP Analysis Module – Alternate Method, Manually Enter the Offset in OpenART

1. After recording the offset onto the lab sheet, stop the acquisition.
2. Go to Hardware -> Edit DSI Setup to open the OpenART configuration.
3. Expand the corresponding DSI implant in the OpenART configuration and right-click on the LVPPressure channel. Select 'Properties'.
4. In the Properties window for the pressure channel, go to the 'Advanced' tab.
5. Under the Advanced tab, enter the offset recorded earlier into the offset row and click OK. See Figure 4.

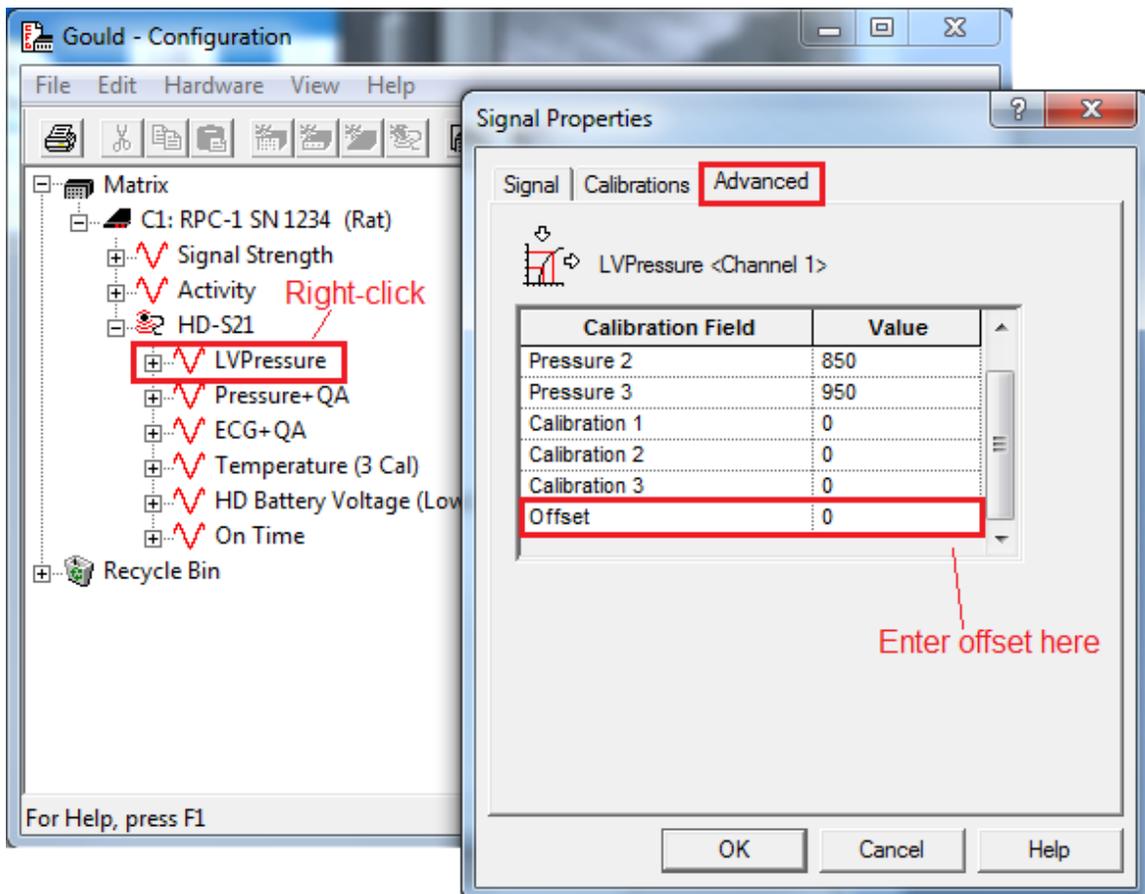


Figure 4: LVP Manual Offset in OpenART