The commonly used method for zeroing/calibration of a fluid-filled pressure measurement device is typically done by simultaneously collecting readings from the device under calibration and from a known calibrated reference, while the pressure applied to these devices is varied over the range of interest. (See the figure below.)

For each new pressure applied to the transducers, a data pair is collected: $P_{\text{reference}}$, $P_{\text{device}}$

Varying the pressure source over range yields a data vector (array) of paired pressure readings from the transducers.

$P_{\text{reference}1}$, $P_{\text{device}1}$

$P_{\text{reference}2}$, $P_{\text{device}2}$

$P_{\text{reference}N-1}$, $P_{\text{device}N-1}$

$P_{\text{reference}N}$, $P_{\text{device}N}$

Next, a least squares fit is applied to the array of paired data (regressed) to determine the functional relationship between the device under calibration and the known reference. The figure below shows a plot of the data and the effect of fitting a line to the data array.

For example, assume that linear regression was used. The regression yields the factors (gain and offset) needed to correct future readings from the device:

$P_{\text{calibrated}} = m \cdot P_{\text{device}} + b$

$m = \text{gain (slope)}$

$b = \text{offset}$
The automatic in-vivo calibration process of the MAQUET fiber-optic Intra-Aortic Balloon (IAB) used by the Intra-Aortic Balloon Pump (IABP) System CS300 is essentially identical to that described above in the background section. This section details the method.

It is important to explain the term “shuttle gas”. Shuttle gas refers to the fixed volume of helium gas which is “shuttled” back and forth into the IAB balloon to cause inflation and deflation. The CS300 console contains a factory calibrated pressure transducer, which monitors the shuttle gas pressure in the IAB pneumatic circuit (“shuttle gas transducer”). This transducer is used in all of the CS300's operating states: Standby, Assist, and Autofill. As will be explained below, it is also used during the auto-calibration process. The figure below shows the locations of the shuttle gas and fiber optic pressure transducers.

CS300 CONSOLE

The CS300 IABP, and its predicate device, the CS100, have an automatic process (“Autofill process”) which completely purges the “old helium” from the shuttle gas pneumatic circuit and then replaces it with a known volume of fresh helium. This process maintains the volume and purity of the shuttle gas, i.e., it replaces the gas lost due to diffusion of helium.

Autofills occur at startup and every two hours thereafter. During the Autofill process, pumping is briefly suspended then readings from the transducer are used to monitor the helium removal and replacement process.

In the CS300 IABP, the Auto-calibration process has been integrated into the system’s Autofill process. During the calibration phase of the Autofill process, the shuttle gas transducer provides reference measurements of patient blood pressure for use by the calibration process. Since it is located in the CS300’s pneumatic circuit, the shuttle gas transducer cannot measure patient blood pressure directly, i.e., it has no direct contact with patient blood. Therefore, measurement of patient blood pressure is accomplished via indirect means. This is achieved by “under-inflation” of the IAB while shuttle gas pressure is monitored.

When the IAB balloon is under-inflated, its membrane walls are flaccid, therefore it cannot support a pressure difference. As a consequence, shuttle gas pressure continuously changes to match (equal) patient blood pressure. To elaborate on this concept, consider these two examples:

**When a patient’s blood pressure increases**, it attempts to collapse the balloon (the IAB’s volume decreases). Decreasing the balloon volume causes the pressure within the balloon to increase. Balloon collapse ceases when pressure equilibrium occurs, i.e., the decrease in balloon volume results in a pressure inside the balloon which is equal to the pressure outside the balloon.
Similarly, if a patient’s blood pressure decreases, the balloon volume increases until the pressure inside the balloon equilibrates with a patient’s blood pressure. Consequently, the shuttle gas pressure waveform matches the patient’s blood pressure waveform.

The figure below shows examples of the waveforms from the fiber-optic transducer and the shuttle gas transducer.

IAB under-inflation is achieved by this process: Assist is suspended (IAB is deflated). Next, a predetermined amount of shuttle gas is removed from the pneumatic circuit (part of the autofill “purge process). Then, the IAB is “inflated”. However, because of the helium removal, the IAB only partially inflates, i.e., by design, it inflates to a target volume of 10 cc (A fully inflated adult IAB inflates to 40 cc). While the IAB is under-inflated, calibration data is collected for 6 seconds, and then the IAB is returned to its fully deflated state. Then, the purge and fill process completes, and assist resumes. The overall process of helium purge, calibration and replacement requires 16 seconds.

As in the “generic” calibration case, the collected data consists of simultaneous readings from the “reference transducer” and the device. The figure below illustrates this concept.

The patient’s blood pressure is the source of test pressures. The IAB’s fiber-optic pressure transducer is the device to be calibrated, and the “shuttle gas transducer” is the reference pressure transducer.

As in the generic case, an array of pressure readings from the respective transducers is collected. Then regression is performed to determine the appropriate calibration correction factors, gain \( m \) and offset \( b \). After the calibration, these factors are used to continuously adjust the fiber-optic pressure transducer’s readings in “real-time”.

The auto-calibration process occurs at startup and every two hours thereafter. Consequently, all changes in transducer characteristics are corrected every two hours.

**NOTE:** Due to the in-vivo auto-calibration feature of the MAQUET fiber-optic IAB, it is not necessary to “balance” or “zero” the catheter outside the human body prior to the insertion!

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1 The shuttle gas transducer is calibrated using a digital manometer with an accuracy of 0.05% of full scale (NBS traceable). This accuracy includes the combined effects of temperature, linearity, repeatability, hysteresis and resolution. When all other systemic effects are considered, the tolerance on shuttle gas transducer calibration is 1.2%. This transducer is also periodically calibrated in accordance to a preventative maintenance schedule.