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Sensor Calibration Verifies Accuracy

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FDA regulations for medical devices require manufacturers to develop and monitor production practices to ensure that the end device conforms to its specifications. Medical devices that rely on one or more embedded sensors not only need testing, but also sensor calibration. A calibration program is a major part of this quality system to verify the accuracy and precision of measurements. Walt describes the techniques, tools, and equipment used to calibrate a disposable medical device.

Digital circuits can be subject to pass/fail testing. However, sensors require precise testing or calibration to be accurate. Calibration ensures that different individual devices give the same result. Sensors needing calibration include temperature, pressure, acceleration, strain, displacement, blood pressure, oxygen saturation, and blood glucose.

Medical devices must meet FDA regulations regarding device traceability and validation. The calibration process must ensure traceable measurements where the start and end of a calibration chain can be followed. Disposable devices add another constraint because the cost must be kept low without sacrificing accuracy and traceability.

The following discussion explains how the temperature and pressure sensors in a disposable catheter met accuracy requirements while maintaining low cost and meeting FDA requirements for traceability to the National Institute of Standards and Technology (NIST).

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Achieving accuracy in temperature and pressure measurements

Depending on the required accuracy of the sensor, calibration may be simple or complex. A sensor that meets the accuracy requirements according to a manufacturer data sheet may only need to be tested to show that it is functioning, if the manufacturer is qualified by the device manufacturer's quality system. The pressure sensor in the catheter fell into this category.

A sensor that nearly meets the accuracy requirements may only need a single-point calibration to remove the offset error. For many sensors the largest error is the offset. A single-point calibration can significantly improve accuracy.

A less accurate sensor or a more demanding application may need a two-point calibration to remove offset and gain errors. Calibration requires subjecting the sensor to two different levels of temperature, pressure, or whatever is being calibrated, usually near the extremes of the range. For a temperature sensor, there is a time delay to reach a stable temperature, which adds cost to the calibration. This type of calibration is often impractical for a disposable device.

A sensor that is far from meeting the accuracy requirements or one that is very nonlinear may need to be calibrated at multiple points to compensate for offset, gain, and linearity errors. This is rarely done on disposable devices.

When a device is calibrated, the results must be used to modify the device output. Sometimes a potentiometer is turned to set the calibration. Potentiometers are subject to change with temperature, vibration, and aging. More often, the calibration is stored in nonvolatile memory on the device. A processor reads the calibration and adjusts the readings. Storage in nonvolatile memory lends itself well to low-cost disposable devices with automated calibration.

Meeting FDA traceability requires NIST traceable calibration and tracking of devices by serial number, which is common for devices in other fields besides medical devices. The record-keeping requirements are more stringent for medical devices, and automated calibration can efficiently generate the electronic records used by the record-keeping system.

Calibrating a disposable catheter

Voler Systems built a tester for disposable catheters (Figure 1) that required calibration of the temperature and pressure sensors as well as functional tests. It was critical that the catheter temperature and pressure sensors were verified to meet accuracy specifications to assure that the catheter was safe and accurate for the operating temperature range of -80 °C to +37 °C.

The catheter used thermocouples to measure temperature. Thermocouples, although very common, are one of the most difficult sensors to use. They need a separate "cold junction sensor", which gives a reference temperature, since the thermocouple itself only reports temperature relative to where its wires are connected. Thermocouples are nonlinear and have an output of only a few microvolts per °C, requiring high gain.
In modern digital systems the linearization is easily performed with a processor using a calculation or lookup table. The high-gain amplifier and the cold junction sensor each add errors that need to be considered in the calibration.

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In this case the thermocouple calibration needed to be more precise than a one-point calibration. The thermocouples were calibrated at +37 °C. With a one-point calibration, an offset is added to all temperature readings. However, in this case the offset could actually increase the error at -80 °C. So it was important to not apply any offset at -80 °C.

This was done with a calculation. It was assumed there was no error at -80 °C, which was used as the second point in a two-point calibration without actually making a measurement at -80 °C. The result is an offset at +37 °C and no offset at -80 °C. Between these extremes, the offset decreases linearly from a maximum at +37 °C to no offset at -80 °C.

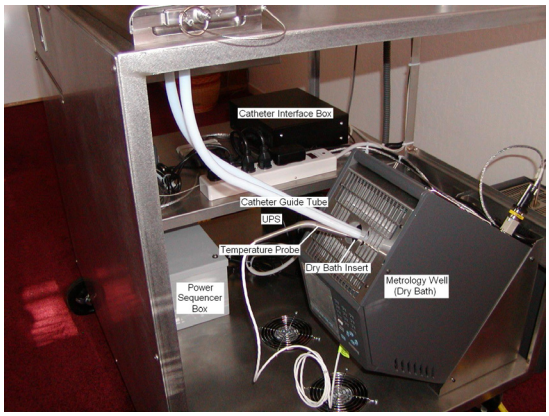

Figure 1 | A Catheter is calibrated in an air bath (metrology well on the right) using a custom-designed guide tube.

The test system used a commercial dry bath metrology well for temperature calibration, as placing the catheter into water could increase the bio-burden, making it difficult to sterilize. The calibration was made traceable to NIST by calibrating two temperature probes: one in the metrology well and another that measured the cold junction temperature near the catheter handle.

Voler Systems built a tester for disposable catheters (Figure 1) that required calibration of the temperature and pressure sensors as well as functional tests. It was critical that the catheter temperature and pressure sensors were verified to meet accuracy specifications to assure that the catheter was safe and accurate for the operating temperature range of -80 °C to +37 °C.

REQUIRED ACCURACY			
Temperature		Pressure	
±2.0 °C at +37 °C		±1.1% of full scale	
±5.0 °C at -80 °C			
ERROR SOURCES			
Temperature		Pressure	
Sensor – all errors at +37 °C	0.5 °C	Sensor – all errors	0.9%
Sensor – all errors at -80 °C	1.9 °C	ADC offset	0.003%
Amplifier offset	0.7 °C	ADC gain	0.046%
Amplifier gain	0.75 °C	ADC resolution	0.0015%
Cold junction sensor offset	0.5 °C	Total error	0.95%
Cold junction sensor gain	0.25 °C		
Cold junction gradient	0.5 °C		
Cold junction amp offset	0.00 °C		
Cold junction amp gain	0.02 °C		
ADC offset	0.00 °C		
ADC gain	0.15 °C		
ADC resolution	0.00 °C		
Total error at +37 °C	3.37 °C		
Total error at -80 °C	4.77 °C		

Table 1 | Error calculation without calibration. Including all error sources. By calibrating two temperature sensors, the system could be maintained traceable to NIST, meeting the FDA requirements for traceability. The pressure sensors did not need to be calibrated.

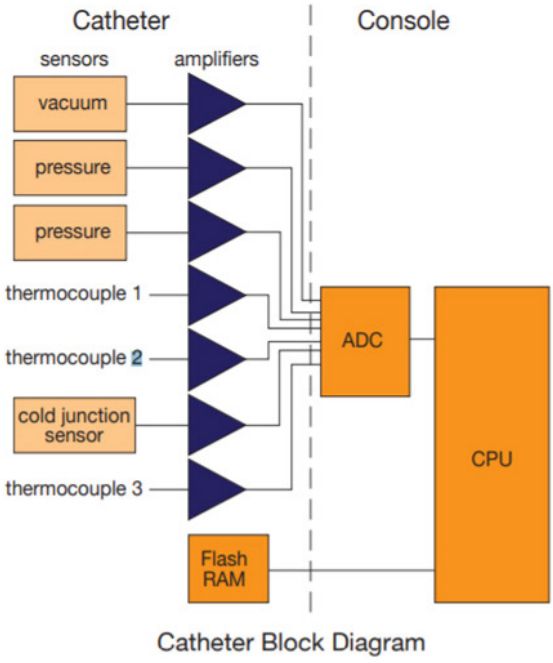

Figure 2 | The electronics that contribute to errors are in both the catheter and the console to which it connects.

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Some of the errors in the table are in the console that the catheter plugs into (see figure 2). Since catheters must be interchangeable with any console, the console errors cannot be removed by calibrating the catheter. Since the console is not disposable, the electronics in it were designed to have very small errors, and almost all the error was in the catheter.

The pressure sensors met the accuracy requirements according to vendor specifications, and the electronics added little to this error. The vendor was going to be approved through the manufacturer's quality system, so it was deemed sufficient to check the pressure sensors' outputs at atmospheric pressure, without applying a calibrated pressure or performing a calibration. Because the pressure sensors are absolute devices, one point was sufficient to verify the pressure sensors were working accurately.

Some of the errors in Table 1 were in the console that the catheter plugs into (see Figure 2). Catheters must be interchangeable with any console, so the console errors could not be removed by calibrating the catheter. Because the console is not disposable, the electronics in it were designed to have very small errors, and almost all the errors were in the catheter.

The settling time for the temperature calibration proved to be a major consideration. In the calibration bath the thermocouples stabilized rapidly in about 30 seconds. The cold junction sensor, located in the handle of the catheter, stabilized more slowly, taking 10 minutes. The long stabilization was caused by the electronics in the handle heating the cold junction sensor. The electronics dissipated only a few milliwatts, but that was enough to create a temperature change of more than a degree after power was applied to the catheter.

Because calibration could not be done with the catheter disassembled, there was no choice but to wait for 10 minutes for the catheters to stabilize. The calibration system was designed to hold two to four catheters simultaneously. The power was applied to all of them at once, so up to four catheters stabilized in 10 minutes, yielding a test time just longer than 2.5 minutes per catheter, which was acceptable. Once the temperature was stable, the entire automatic calibration process took about 2 seconds.

The calibration of the thermocouples was repeatable to ±0.05 °C including all error sources. By calibrating two temperature sensors, the system could be maintained traceable to NIST, meeting the FDA requirements for traceability. The pressure sensors did not need to be calibrated.

Ensuring traceable measurements

In the real world, all measurements are subject to some error. Calibration must achieve the accuracy required with high reliability and repeatability. Calibration of disposable devices is challenging due to accuracy and cost trade-offs. Medical devices must also meet government regulations regarding device traceability and validation. The calibration process must ensure traceable measurements where the start and end of a calibration chain can be followed.

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About Walt Maclay

Mr. Walt Maclay, President and founder of Strawberry Tree inc, dba Voler Systems, one of the top electronic design firms in Silicon Valley, is committed to delivering quality electronic products on time and on budget. It provides design, development, risk assessment, and verification of new devices for medical, consumer, and industrial applications. Voler is particularly experienced in designing wearable and IoT devices, using its skill with sensors and wireless technology. The company has developed hundreds of products including medical devices, wearable devices, home health, products for the aging, and other medical, consumer, and industrial devices.

Mr. Maclay is recognized as a domain expert in Silicon Valley technical consulting associations. He has spoken at dozens of events on sensors, wearable devices, wireless communication, security for medical devices, and low power design. In 2019 he wrote Highly Successful Engineering Design Projects, a book about project management available from Amazon. From 2008 to 2010 he was President of the Professional and Technical Consultants Association (PATCA). He is a senior life member of the Institute of Electrical and Electronic Engineers (IEEE) and a member of the Consultants Network of Silicon Valley. He has been an instructor at Foothill College in the Product Realization Certificate Program, teaching successful new product introduction skills. He has applied his outstanding leadership to many multidisciplinary teams that have delivered quality electronic devices. Mr. Maclay holds a BSEE degree in Electrical Engineering from Syracuse University.

Mr. Maclay is active in helping technology startup companies. He has participated in angel investor groups and has advised dozens of startup companies on technical and funding issues. He has mentored startups at Techstars and Cleantech Open. He is a reviewer for NSF SBIR grants. As founder of his own company, he has dealt with issues of funding, product development, marketing, sales, and finance, giving him the experience to advise others. Voler Systems is a member of a technology consortium, the Product Realization Group, which provides all the services to introduce new technology products. Mr. Maclay started and led two forums for CEOs of small companies to discuss issues of importance to them.

Voler clients, from early stage startups to large established corporations, are delighted with the quality and service they have received. Past clients include Alexza Pharmaceuticals, Applied Materials, BAE Systems, Boeing, Boston Scientific, Intel, JDS Uniphase, Life Technologies, Lockheed Martin, Maxon Lift, Merck, NASA Ames, Northrop Grumman, Orbital Sciences, Puget Sound Naval Shipyard, Radiant Medical, Rain Bird, Sandia Labs, Siemens, Spectra Physics, St. Jude Medical, Stanford University, Teikoku Pharma, Teradyne, Thoratec, the University of California at Davis, Zosano Pharma, and hundreds of others.

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