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SpO2 Simulators – When Accuracy Matters!

SaO2 is the reading of oxygen saturation from arterial blood analysis. This method is invasive and analyzes the concentration of oxygen in the blood with a co-oximeter.

SpO2 is a method for the reading of saturation of peripheral oxygen. SpO2 readings have the benefit of being continuous and non-invasive.

The SpO2 value is an estimate of the SaO2 value.

Pulse Oximeter Manufacturers Challenge

The pulse oximeter includes a sensor with a red LED, an infrared LED, and a photodiode. The SpO2 sensor is connected to a SpO2 monitor via a cable. The challenge for Pulse Oximeter Manufacturers is to be able to display an acceptable / accurate SpO2 value on their monitors and ensure the same reading will be seen on several different monitors of the same model knowing that a very tiny change of wavelength of the LEDs in the sensor results in the display of very different SpO2 readings.

For this purpose, on the hardware side, specific research on high quality LEDs is done. The wavelength of the LEDs used on the same model of sensor is supposed to be exactly the same and the quantity of light emitted should be the same over the time. On the software side, specific calibration curves (algorithms) are developed and programmed for the monitors. A specific algorithm, the “R-curve” is made for a couple of sensor and monitor models in order to accurately calculate arterial oxygen saturation.

Pulse Oximeter Premarket Notifications Submissions

Before Pulse Oximeters can be introduced in different markets, the unit needs to comply with ISO 80601-2 -61:2017. This ISO standard applies for new equipment and for significant modifications on existing equipment. It describes the tests to perform in order to verify the basic safety and essential performance of Pulse Oximeter equipment.

For the USA, a Guidance for Industry and FDA staff : Pulse Oximeters – Premarket Notification Submissions is available on the Internet for reading. It recommends to conduct the Oximeter performance test as described in ISO 80601.

For that purpose, “in vivo” tests need to be performed. Volunteers are connected to the prototype of the SpO2 monitor, breathing gas mixtures with decreasing Oxygen concentrations. The reading of SpO2 values on the monitor are compared with the SaO2. The R-curve (or algorithm) is then established that way.

Then, if successful, ISO 80601-2-61:2017 asks for the final labelling of the device to include:

- SpO2 accuracy specification in the SpO2 range of 70% to 100%
- Pulse Rate accuracy
- Alarm limits and range
- and other requirements...

Pulse Oximeters in the Market

Pulse oximetry is a monitored vital sign. As a result, pulse oximeters should be carefully treated and tracked during its lifetime in the hospital.

If the test procedures described in ISO 80601-2-61:2017 don't apply anymore after the product has been already approved and introduced in the market, then attention needs to be taken in performing Preventive Maintenance (PM).

Most of the main Manufacturers specify in their PM procedures to check the accuracy of the monitor's SpO2 readings using a SpO2 functional tester. These procedures ask the Biomedical Engineers and Technicians to proceed with the following tests:

- Simulate SpO2 values (in the range of 70% to 100%)
- Check the desaturation alarm
- Check the readings on the monitor

Readings should be within the tolerance of ± 2% or ± 3%, depending of the Manufacturer as shown below:

SpO2 Simulation	97%	93%	90%	80%	70%
SpO2 Limit	95% to 99%	91% to 95%	88% to 92%	78% to 82%	67% to 73%
SpO2 Reading					
Pass / Fail					

Even more critical is the monitoring of SpO2 for Neonate babies.
The Royal Children's Hospital Melbourne stated in an article:

"*Oxygen saturation should be targeted within the range of 91-95% when receiving oxygen therapy, in both pre-term and term neonates. Monitoring alarm limits for all neonates receiving oxygen therapy should be set with a lower limit of 89% and an upper limit of 95%*".

In these examples, we can see that for a simulation, the low and high acceptable limits are very close to each other and require the use of an accurate SpO2 functional tester.

Here we reach the point about the choice of the SpO2 tester that can be used for such tests with the question:

Is your SpO2 tester accurate enough to test SpO2 monitors?

First, we must consider that the accuracy of SpO2 monitors is typically 2% in the range of 70% to 100%, and sometimes 3% for low saturation signals or Neonate modes. Its not dependent on the SpO2 technology used in the monitor and sensor, this is specified under ISO 80601-2-61. A product that does not meet the requirements will not be allowed onto the market.

Second, it is necessary to realise that the accuracy of the readings on a SpO2 monitor is the accuracy of the SpO2 tester added to the accuracy of the Device Under Test (DUT).

Third, it is obvious that the testing device should be, at least, equal in accuracy or even better than the Spo2 monitor it is supposed to test. There is no sense in testing a SpO2 monitor with a SpO2 functional tester that is less accurate than the Spo2 monitor itself!

Real life example:

You would like to test a low SpO2 value (85%) or a patient desaturation alarm on a SpO2 monitor. Imagine the SpO2 simulation accuracy of your SpO2 tester is as follows:

For simulation between 81% and 90%, the accuracy of simulation is the selected value +/- 5 counts + Specified accuracy of the DUT

For our example, asking a 85% SpO2 simulation, we potentially can obtain the possible readings on the monitor:

- Low Value : 85% minus 5 % minus 2% gives a minimum reading of 78%
- High Value : 85% plus 5 % plus 2% gives a Maximum reading of 92%

Using such functional tester, an 85% SpO2 simulation can result in a displayed value between 78% and 92%.

Knowing that the monitor manufacturer specifies (as our example above) that the reading should be the value simulated +/- 2, then the question is:

Would you take the responsibility to say the test has passed ?

It is obvious that such a tester can not be used for testing SpO2 monitors simply because it is not accurate enough.

Better solutions do exist……

Datrend SpO2 test solutions

At Datrend, accuracy matters, and we offer 2 models of SpO2 tester, both with 1% accuracy:

vPad-O2 *(part of vPad-A1)*

Oxitest Plus 7

Images not to scale.

The specified accuracy of these SpO2 testers are:

- **Oxitest** : ± 1% at specified SpO2 pre-sets for simulations between 55% and 100%
- **vPad-O2** : ± 1 count + specified accuracy of the DUT for simulations between 30% and 100%

Both SpO2 testers from Datrend are 1% accurate and so can be used for testing SpO2 monitors which are typically 2% accurate.

The vPad-O2 has many features that will help you to perform accurate tests on SpO2 monitors :

- Selectable manufacturer and Model type
- Unlimited R-Curve data, user selectable, pre-programmed and user programmable
- SpO2 values from 30 - 100% at 1% accuracy
- Masimo Rainbow compatible
- And much more…

The Oxitest Plus7, our value range simulator, is just as accurate at 1% and offers :

- 118 verified R-curves
- SpO2 values from 55 - 100% at 1% accuracy
- Unique Nellcor sensor R-curve code reader – the tester auto sets the R curve for Nellcor sensors
- And much more…

The vPad-O2 is future proof. The engineer can program a new R-curve for new SpO2 monitors or a new type of sensor for an older monitor. The vPad O2 is just part of the vPad-A1 multiparameter patient simulator.

The vPad-O2 and Oxitest do have lots of unique features that will help you perform the best tests possible on SpO2 monitors.

To learn more about the Oxitest and vPad-O2, please visit the Datrend web site at www.datrend.com or Sales@Datrend.com.

References:

- Guidance for Industry and FDA staff: Pulse Oximeters – Premarket Notification Submissions [510k]
- International Standards Organization, ISO 80601-2-61:2017 Medical Electrical Equipment – Particular requirements for the basic safety and essential performance of Pulse Oximeter equipment
- Nellcor: Technology overview of the Nellcor Oximax Pulse Oximetry System
- The Royal Children's Hospital Melbourne: Oxygen saturation SpO2 level targeting in neonates

