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There's no such thing as a SpO_2 simulator

Why a primary calibration reference does not exist and how to properly measure SpO_2 accuracy

White Paper

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One of the most essential elements in medical equipment maintenance is functional testing, or in other words, verifying the competence of a device by applying it to another device that mimics the physiological signal of interest.

For the majority of devices, this simulation is a direct analog of the clinical signal. Simulators for the electrocardiograph (ECG) or for an electroencephalogram (EEG) provide voltage waveforms that mimic those parameters. Simulators for non-invasive blood pressure provide a pneumatic pressure signal identical to the blood pressure waveform found in an artery. Invasive blood pressure, temperature, and cardiac output simulators produce varying patterns of resistance or impedance to mimic the output of a strain gauge or a thermistor.

Simulation of oxygen saturation in humans, however, presents a challenge. A pulse oximeter uses two wavelengths of light: a red signal, which is partially absorbed by non-oxygenated hemoglobin, and an infra-red (IR) signal, which is partially absorbed by oxygenated hemoglobin in the patient's arterial blood.

At any level of oxygen saturation, the ratio of the pulsatile and non-pulsatile signals is derived for both wavelengths. The red ratio is then divided by the IR ratio (a "ratio of ratios") to produce a value (R) which correlates with the known oxygen saturation value to produce an "R-curve" unique to each manufacturer. At any value of R, the monitor's firmware "looks-up" and displays the percent oxygen saturation. Since the absorption waveform is pulsatile, the monitor also derives and displays the pulse rate.

Where does the "R-curve" come from?

Before market introduction, all prototype oxygen saturation monitors must be validated using in vivo testing as specified in Standard 80601-2-61 (2011) of the International Standards Organization (ISO). In a controlled desaturation study, volunteer subjects breathe a sequence of gas mixtures of decreasing oxygen content while connected to the prototype monitor. Arterial blood samples are taken from the subjects, and the saturation is measured by a co-oximeter in a clinical laboratory. As shown in Figure 1, the R-value derived in the monitor is plotted against each saturation value.

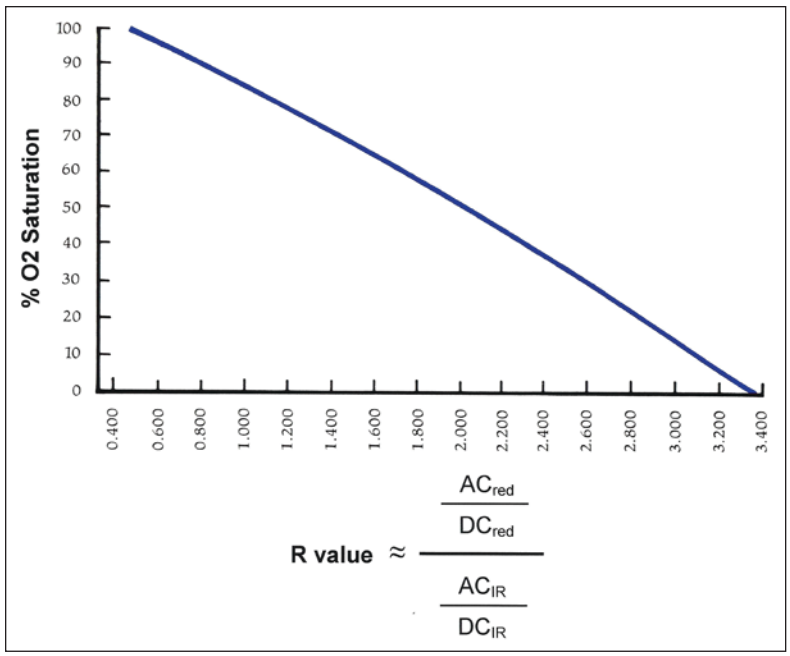

Figure 1. Example of an R-curve, correlating O_2 saturation with the R value.

The resulting R-curve is then integrated into the firmware of the monitor. The ISO standard prescribes the number of subjects, the saturation range, the laboratory analysis method, motion conditions, and varied perfusion levels. This validation method is also stipulated in the pre-market protocols of many regulatory agencies, such as the U.S. Food and Drug Administration's 510(k) guidelines.

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Why a primary calibration reference does not exist

Because pulse oximeters use the manufacturer-specific R-curve to derive and display saturation, we will never find a calibration pot or any other means to adjust the device against a primary reference. The only currently accepted primary reference is the in vivo study described above. Theoretically, a true simulator of oxygen saturation would require a pulsatile fluid loop which contains a hemoglobin-like substance transporting oxygen in various proportions. This theoretical simulator would need to vary the rate and volume of the fluid pulsations to mimic the pulse rates and perfusion levels, as well as provide several levels of optical transmission to represent various tissue densities. Motion artifact and interference from ambient lighting would also be needed. And to be marketable, the simulator would have to deal with the differences in the various manufacturer R-curves. This hypothetical test device would be impractical as a bench-top, production model. There are no simulators that independently verify the accuracy of a pulse oximeter.

How to properly measure SpO_2 accuracy

Annex FF of ISO Standard 80601-2-61 makes clear distinctions between the terms "simulator", "calibrator", and "functional tester". A calibrator would be a high-accuracy simulator, capable of electronic signals or optical responses identical to a human subject. By definition, a calibrator would also have to have accuracy much greater than the device under test, which is already typically 2 percent. Another annex of the standard requires the instruction manuals of pulse oximeter equipment to state that functional testers cannot in general be used to measure SpO_2 accuracy. Rather than being "primary standards" (or "gold standards") against which all monitors are calibrated, current pulse oximeter testers are "transfer standards" i.e. they are a reference of comparison validated against a another standard established previously. The U.S. FDA carefully defines this as "substantial equivalence" in its pre-market guidelines.

Since the introduction of the first commercial pulse oximeter in 1977, the objective performance verification of these monitors has been elusive. Healthcare technology personnel should bear in mind that a SpO_2 tester is a secondary standard which transfers equivalence from prior devices that have been validated before. The verb "simulate" means "to present a false appearance of", while the verb "emulate" means "to try to equal or excel". Other biomedical equipment testers may be simulators, but SpO_2 testers are, at best, emulators; they only approximate the physiology of a human subject.

All pulse oximeter testers currently on the market require the user to select the monitor manufacturer, or groups of manufacturers, in order to accommodate the manufacturer's R-curves. In addition to saturation and pulse rate, most testers offer user-selectable values of pulse amplitude, tissue transmittance, arrhythmias, motion artifact, and interference from power line frequencies. Many models also have pre-set combinations of clinically normal and abnormal values, and may allow the user to define custom values. All testers use either an electronic or optical interface with the unit under test. Some models offer both modes.

Electronic testers apply an electrical signal to the monitor through its sensor cable, without inclusion of the sensor. The user-selected electrical signal mimics various values of saturation and other variables. These units offer the option of testing the sensor (presumed to be a finger sensor) by verifying the continuity of the red and infrared LED's and that of the photodiode. Some models also test to confirm the photodiode's correct response to the two light signals.

In contrast to the electronic interface, optical testers provide a physical digit or "artificial finger" that includes a mechanical and/or opto-electronic element which allows variable transmission of the two light signals. (Figure 2.)

This type tests the entire monitor system (sensor, cable, and monitor) at once, which can save time when performance testing many units. As with the electronic types, these enable the user to select a range of values of saturation and other variables

and pre-sets, depending on the manufacturer. One vendor offers a set of calibrated fingers, or artificial digits with integrated dyes to allow transmission of light corresponding to a specific saturation.

Currently marketed SpO_2 testers offer a variety of functions, and the equipment technician must decide how thoroughly to test. Most SpO_2 monitors will be accurate at clinically "normal" values, but equipment technicians must detect when the monitor gives inaccurate values in the abnormal range, where clinicians must decide on clinical corrective action.

One widely promoted tester provides five preset combinations of saturation value, pulse rate, and pulse amplitude, where a unit like the SPOT Light SpO_2 functional tester by Fluke Biomedical enables independent selection of eight different saturations and pulse rates, three levels of light transmission, and the option of artifact from respiration and line frequencies. The SPOT Light also offers a selection of R-curves for eight different manufacturers, where another unit offers only three R-curves to cover all makers. With optical testers, precise positioning of the sensor probe on the digit can be problematic. Most units give an indication if the probe is placed incorrectly on the digit, but there is no indication of maximized signal strength. The SPOT Light includes an on-screen signal quality indicator to enable optimal placement of the probe, assuring consistent readings. The SPOT Light sets up in seconds to send SpO_2 saturation, heart rate, perfusion, transmission, artifact noise, and eight different manufactures custom R-curves to a pulse oximeter or patient monitor.

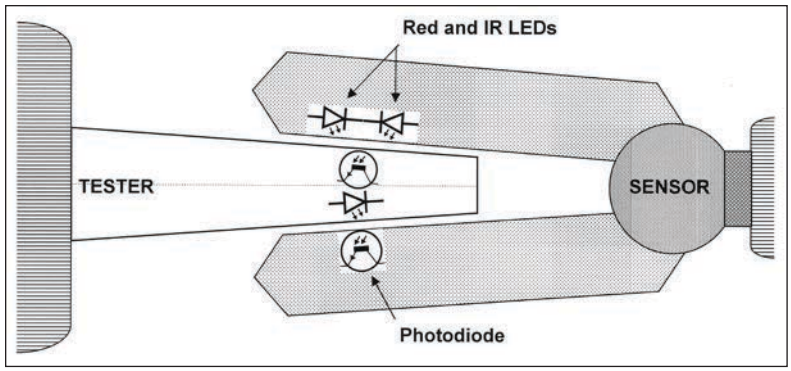

Figure 2. Testing finger using an LED and photodiode to interact with an SpO_2 sensor.

About the ProSim SPOT Light SpO_2 functional tester

Featuring an exclusive ergonomic design, the ProSim SPOT Light is the first comprehensive SpO_2 functional tester to come in a handheld and easy-to-use device. SPOT Light is lightweight and flexible with three custom presets specially-designed to make it the fastest and easiest-to-use device on the market today for pulse oximeter functional testing.

A helpful LCD display and three simple buttons make it effortless to rapidly change parameters and view each signal output sent to the pulse oximeter at a glance. An interchangeable, long-life battery ensures uninterrupted all-day operation without need to connect to a power supply.

To learn more about the SPOT Light SpO_2 Functional Tester Pulse Oximeter Analyzer, click here or visit www.flukebiomedical.com.

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About the author

Dennis J. McMahon, CBET-R, is a biomedical equipment technician with over forty years of medical technology experience. After earning a degree in Chemistry in the late '60s, he worked as an anesthesia technician at Harborview Medical Center until 1977. He certified as a biomedical technician in 1983, and attended service schools for a variety of clinical technology over the following three decades. Dennis currently instructs at North Seattle Community College and serves as the Education Chair for the Washington State Biomedical Association (WSBA).

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