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Pulse Oximetry Analyzer

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White Paper

Introduction

The principal function of a patient simulator is to provide very reproducible and predictable signals that represent those obtained from patients. With pulse oximeters, the key signals are the red and infrared (IR) photoplethysmograms (PPG) that otherwise come from shining light across a patient's blood-perfused tissue bed. For hospital biomedical engineers, the simulator offers a reliable and reproducible tool for functionally testing systems to ensure they are performing as they have been designed to operate, and to help troubleshoot systems that may be malfunctioning. For manufacturers, the simulator is a useful bench top signal source for use in development, and can be used to verify some of the system's designs and/or claimed specifications—particularly in the corners of performance-space that patients can, though perhaps less commonly, exhibit. In some cases, these test results may be acceptable in regulatory submissions as a substitute for clinical data.

Background—how does pulse oximetry function?

Pulse oximeters shine red and IR light from, most commonly, a pair of light emitting diodes (LEDs) into a blood-perfused tissue bed, and detect a portion of the re-emitted light a short distance away—typically on an opposite side of a finger, toe, ear, or at an adjacent location along a skin surface. Once per heartbeat, during the higher blood pressure systolic period, an incremental amount of light-absorbing hemoglobin (in the arterial blood) enters the local tissue, causing a little less light to reach the photodetector. During the lower pressure diastolic period, this arterial blood drains from the tissue through the capillary bed and veins and flows back towards the heart, restoring the local hemoglobin content—and transmitted light signals—to their previous levels. The resulting cycling light signals (i.e., the PPG) appear quite similar to an inverted blood pressure waveform. The red and IR modulation amplitudes* (ac/dc, as shown in Figure 1) depend on: the amount of incremental blood volume that cycles in the tissue on a beat-by-beat basis, the concentration of hemoglobin in the blood and, importantly for pulse oximetry, the SaO_2 level. This SaO_2-dependence is a result of oxygenated and deoxygenated hemoglobin absorbing red and IR light differently† , with the ratio of red-to infrared modulation levels (*R*-value) following a curve similar to the one depicted in Figure 2. Optical interactions between the pulse oximeter sensor and the underlying bulk tissues at the target sensor site also influence the curve's specific behavior. Manufacturers characterize this relationship empirically during the development of their systems, thus calibrating the system's displayed estimates of patient SaO_2, i.e., the SpO_2 readings.

* "Modulation amplitude" or "level", "pulse amplitude", and "perfusion level" are commonly used and equivalent terms in pulse oximetry for describing the relative ac-to-dc amplitude of cardiac-induced pulses in the PPG signal.

† Stronger light absorption by pulsing arterial blood decreases detected dc signals, but increases the ac/dc modulation amplitude. At low O_2 saturation, blood absorbs more of the red than IR light.

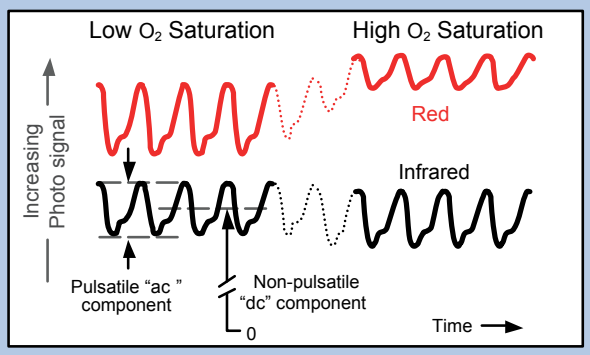

Figure 1. Arterial blood pulsing in tissues modulates the amount of transmitted sensor light. The relative impact to red and IR photo signals depends on the amount of oxygenated and deoxygenated hemoglobin present (i.e., the SaO_2). At high O_2 saturation, the red modulation (=ac/dc) is about half the size of the IR. At low O_2 saturation, because deoxygenated hemoglobin strongly absorbs visible and red light, the red light level falls but modulation becomes larger. (Not drawn to scale.)

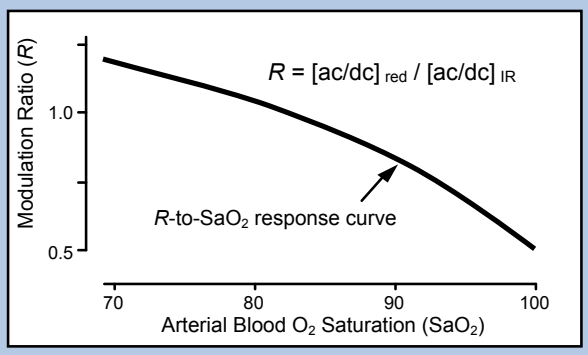

Figure 2. The modulation ratio, or *R*-value, is computed from the detected red and infrared signals and follows the SaO_2 of the underlying blood in the tissue. This relationship, shown by the black curve in the figure, depends also on the sensor's specific optical characteristics and their interaction with the tissue. Manufacturers characterize the precise relationship for their systems empirically, using it to properly translate real time measured *R*-values into units of %SpO_2.

Pulse oximeters can be exposed to a wide range of patient physio-optical signal conditions:

- Transparent to opaque tissues (e.g., a pediatric finger compared to a darkly pigmented neonate's foot, resulting in high and low dc light levels, respectively),
- Very strong to weak perfusion levels (e.g., dilated and very warm hands compared to peripherally vasoconstricted and cold hands, exhibiting high and low ac/dc levels, respectively), and
- A wide span of SaO_2 levels (<70–100 %) and heart rates (<40–250 bpm).

Accordingly, in order to provide accurate and reliable SpO_2 and pulse rate readings over the full range of clinical settings and patient populations, the pulse oximeter's sensor designs, electronics, and software algorithms need to be engineered to track the detected red and IR light levels' relative modulations accurately over a wide range of signal conditions.

Signal simulation

The ProSim SPOT SpO_2 Test Module delivers programmed PPG signals to a tested pulse oximeter, appearing to the oximeter as if it was connected to a patient. After first detecting the intensities and timing characteristics of the attached oximeter sensor's emitted red and IR LED light, the ProSim adds simulated cardiac pulse-like waveforms (such as those depicted in Figure 1) to the respective channels that mimic the modulation amplitude, *R*-value, and heart beat behavior of patients under a variety of monitoring conditions. These combined signals are then used to drive a set of LEDs that artificially illuminate the sensor's photodetector, thus emulating the photo-signals that would otherwise be observed by the monitor with a sensor attached to a patient's finger.

Specific SpO_2 values are simulated by generating a pulse-like IR signal at the desired perfusion level, and a red pulse signal scaled by the corresponding *R*-value from the *R*-to-SaO_2 response curve for a given manufacturer's design (Figure 2). These curves are typically manufacturer specific and, in some cases, sensor design dependent. To ensure unbiased SpO_2 readings, select the tested device manufacturer's name on the ProSim and use the proper type of sensor. If the manufacturer's name is not listed or proper sensor available, see the section below regarding generating response curves.

While testing a pulse oximeter on one's own finger can quickly answer whether a pulse oximeter is *generally* working, it cannot reveal limitations or functional issues that appear under more challenging patient conditions such as opaque tissues and weak perfusion levels. The ProSim has been designed to test pulse oximeters under both nominal and challenging conditions, with settings to cover a wide range of light transmission and perfusion levels. Furthermore, because the sensor is used as the interface between the pulse oximeter and the simulator, the ProSim can functionally test the complete system: the monitor, cabling, connectors, sensor light emitters and photodetector.

Applications and examples

Generating an *R*-to-SpO_2 response curve for an unlisted manufacturer

Several calibration curves have been incorporated into the ProSim that align the SpO_2 settings of the simulator with the *R*–to–SpO_2 relationships found within several manufacturers' products (provided the proper corresponding sensor is used). For unlisted manufacturers, SpO_2 readings may not agree with the ProSim setting; typically the discrepancy becomes increasingly more pronounced as SpO_2 settings progress below 90 %. There are two ways to accommodate a lack of available manufacturer preset:

1. Create an SpO_2 translation chart. Choose one of the manufacturers listed on the ProSim SpO_2 menu (labeled as "Type:") and make a note of the one selected. Using a target monitor known to be functioning properly, create a data table with one row or column listing a range of selected ProSim SpO_2 settings (such as 100 %, 95 %, 90 %, etc.) and a second for listing the resulting SpO_2 values displayed on the target monitor. Future testing of the target and equivalent monitors should provide the same SpO_2 readings as observed initially (± 1 %, per accuracy specifications). Table 1 below provides an example that comes from using a manufacturer preset that does not correspond to the device being tested:

Table 1. Example SpO_2 reading translation chart

(ProSim SpO_2 e.g., Type: Nonin)	97 %	90 %	85 %	80 %	75 %	70 %	65 %	60 %
Device under test	97 %	90 %	85 %	78 %	69 %	59 %	50 %	40 %

2. Create a custom response curve. Connect a computer to the ProSim and use the "Create new SpO_2 *R*-curve" wizard supplied with the simulator or available from Fluke. Following the instructions outlined in the step–by–step wizard, begin by attaching the pulse oximeter and sensor to the ProSim SpO_2 interface and ensure the computer, simulator, and pulse oximeter are tuned on. Users have a choice of generating curves with Low (10 % SpO_2 steps), Medium (5 % steps), or High (1 % steps) resolution, and can select the SpO_2 span for the curve, e.g., 30 % – 100 % SpO_2. For Low and Medium resolution curves, the ProSim linearly interpolates the *R*–values for intermediate SpO_2 settings. In the next step, and for each of the target SpO_2 values across the span, you will be instructed to adjust the simulated *R*–value using the wizard's large up or down arrows until the monitor's displayed SpO_2 agrees with the Target SpO_2. Once this is completed, you will have an opportunity to provide or update a name for the *R*–curve and save it to your computer. The last step uploads the *R*–curve to the ProSim and adds it to the menu of available choices.

Testing for standards and regulatory compliance

Patient simulators have been recognized by regulatory bodies and in international standards as acceptable for use in testing and validating device performance in several areas.[1, 2, 3] This is particularly useful for required testing under conditions not routinely observed in human subjects, or in extreme environmental conditions. Specifically, patient simulators are acceptable for generating signals to verify/validate device performance of, or for:

- SpO_2 accuracy at low perfusion levels[1]
- Pulse rate accuracy under normal and low perfusion conditions[1, 2, 3]
- Proper SpO_2 and PR data communication in a multi–parameter system, if the oximetry component is identical to an original equipment manufacturer's (OEM) previously–cleared system, in lieu of *in vivo* studies[1]
- Supplying a continuous signal for testing probe wiring faults[2, 3]
- Supplying a continuous signal for electromagnetic immunity testing[2, 3]

Provided the methods used are properly described in test reports, the simulator may also be appropriate for use in validating display values, outputs and indicators locally or over a remote network.[1] Patient simulators including the ProSim, are not, however, an appropriate substitute for clinical testing *in vivo* for the purpose of verifying or validating SpO_2 reading accuracy in comparison to blood SaO_2.[†] In all cases, users should ensure testing is consistent with the most recent published Standards and refer to the specific requirements and procedures outlined by the Governing Bodies.

[†] The ProSim and other simulators are unable to sufficiently reproduce the light absorption and scattering interactions between the sensor's optics and blood perfused tissues, nor their influence on how the resulting *R*–value corresponds to SaO_2. Accordingly, the FDA[1] and International Standards[2, 3] recognize only clinical study measurements for validating SpO_2 accuracy, and explicitly exclude functional testers and patient simulators for this purpose.

Summary

Pulse oximetry measures SpO_2 and pulse rate by shining red and IR light across a blood perfused tissue. The ProSim SPOT SpO_2 Test Module, interfacing with the oximeter through its sensor, emulates SpO_2 signal conditions over a wide range of patient characteristics, providing reproducible and predictable signals for a variety of testing applications which can't be achieved by using a clinical engineer's finger or many other patient simulators.

References

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About the author:

Paul D. Mannheimer, Ph.D., is a biomedical engineer/physicist with more than 25 years experience in technology development, clinical and laboratory research, and product design in the fields of pulse oximetry, patient monitoring, and optoelectronic and fiber optic components. He is a published author of numerous peer-reviewed research studies, abstracts, and white-papers, and inventor with many issued U.S. patents. Dr. Mannheimer has been an active member and designated expert with the U.S. and International Standards Committees responsible for developing the pulse oximetry standards ISO 9919 and ISO 80601-2-61. Having spent much of his career with Nellcor/Covidien where he was a Sr. Technical Fellow, he continues his work in medical technology as an independent consultant.

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