

Smiths Medical PM, Inc.

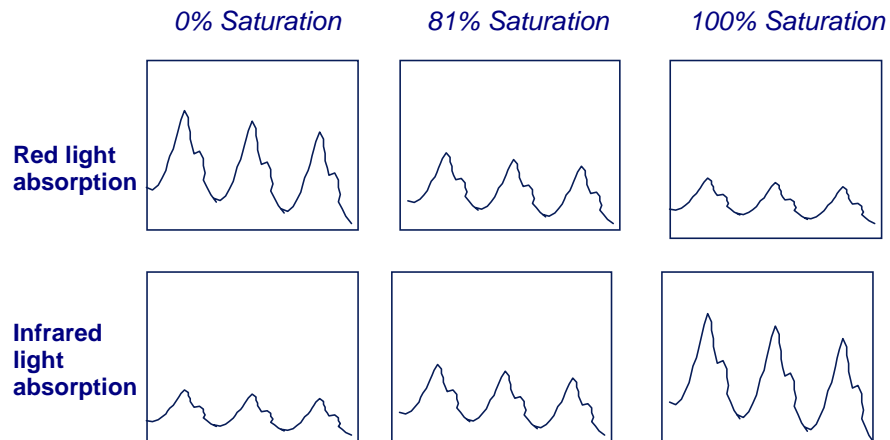
How can SpO₂ readings differ from manufacturer to manufacturer?

Principle

Pulse oximetry combines the principles of optical plethysmography and spectrophotometry to determine arterial oxygen saturation values. Optical plethysmography uses light absorbance technology to reproduce waveforms produced by pulsating blood. Spectrophotometry uses various wavelengths of light to perform quantitative measurements about light absorption through given substances.

Technology

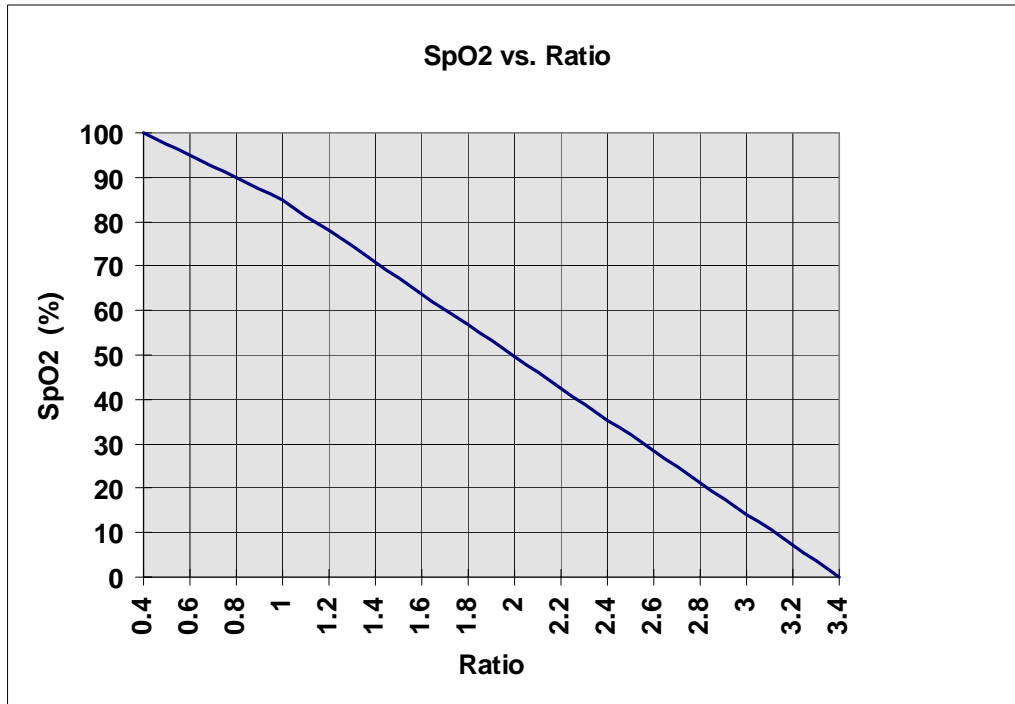
Two wavelengths of light are passed through body tissue via light emitting diodes (LED) to a photodetector. The two LEDs are red light and infrared light. These two LEDs are chosen because light absorption varies with the oxygen concentration of hemoglobin in both the red (660nm) and infrared (890-940nm) light. The pulse amplitudes of the red and infrared signals are detected and measured to produce a Ratio value.



The red light amplitude (AC red) is divided by the infrared light pulse amplitude (AC ir) to form the intermediate value called **Ratio**.

$$\text{Ratio} = \frac{AC_{RED} / DC_{RED}}{AC_{IR} / DC_{IR}}$$

Ratio is used as the input to a “lookup table” function in the pulse oximeter. The SpO_2 value is the result of the “lookup” function.



SpO₂ Computation

Each manufacturer uses a unique calibration curve. A calibration curve is an algorithm that is empirically derived as a result of data obtained from desaturation studies. It relates light transmittance to oxygen saturation mathematically. Each pulse oximetry manufacturer develops its own proprietary calibration curve; no two are alike.

Desaturation studies consist of recording data from many human test subjects at different levels of saturation or desaturation. Measured arterial blood saturations and SpO_2 readings are obtained and recorded at each level of desaturation. Desaturation is induced by having the subjects breathe a hypoxic gas mixture. This process is repeated over and over with many different test subjects. The data is then plotted on a graph. A proprietary calibration curve is developed by making the best fit of the SpO_2 data against the measured data within accuracy specifications.

Accuracy Specifications

The industry standard for pulse oximetry accuracy specifications is ± 2 digits. This specification is usually equal to ± 1 standard deviation of 68% of the test population; 1 standard deviation above and below the line of identity on a graph relating true to measured values. Therefore any two pulse oximeters, regardless of manufacturer, can display different SpO_2 readings and still be accurate. Some manufacturer's SpO_2 readings are higher than an actual measured SaO_2 , some are lower and some read the same, but they are all within ± 2 digit specifications.

Below is an example of three different manufacturer's SpO₂ readings compared to the actual arterial blood saturation measured with a laboratory co-oximeter. All three manufacturer's readings are considered accurate because they are within said specifications. Remember, a higher reading does not necessarily equal a more accurate reading, as demonstrated with the 100% SpO₂ below. It is not possible to be 100% oxygen saturated due to the normal anatomical ventilation to perfusion mismatches of the human body, yet pulse oximeters read 100% and are considered accurate.

Manufacturer 1	Manufacturer 2	Manufacturer 3	Co-Oximeter
<i>SpO₂ 96%</i>	<i>SpO₂ 98%</i>	<i>SpO₂ 100%</i>	<i>SaO₂ 98%</i>
<i>-2 %</i>	<i>0</i>	<i>+2 %</i>	<i>Measured (actual)</i>

Summary

Each pulse oximetry manufacturer uses various wavelength LEDs which will affect the Ratio obtained. The calibration curve is empirically derived from dynamic data that contains many variables. Manufacturers adjust their proprietary calibration curve in order to meet a specification range. Based on this information, it is understandable how an SpO₂ reading can vary from manufacturer to manufacturer and still be accurate.

Sources

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