PRINCIPLES OF OPERATION

PULSE OXIMETRY SUBSYSTEM

The monitor is based on the principles of spectrophotometry and plethysmography. It includes an electro-optical sensor and a microprocessor-based monitor.The sensor has two low-voltage light-emitting diodes (LEDs) as light sources and one photodiode as a photodetector.One LED emits red light (nominal 660nm) and the other emits infrared (nominal 920nm).When the light from the LEDs passes through the sensor site,part of it is absorbed.The photodetector measures the light that passes through,which indicates red and infrared absorption.
With each heartbeat,a pulse of oxygenated arterial blood flows to the sensor site.Oxygenated hemoglobin differs from deoxygenated hemoglobin in its relative red and infrared absorption,and the monitor measures red and infrared absorption to determine the percentage of functional hemoglobin that is saturated with oxygen.
Light absorption that is measured when pulsatile blood is not present reflects absorption by tissue and nonpulsatile blood-absorption that does not change substantially during the pulse. This is analogous to the reference measurement of a spectrophotometer. Absorption is also measured when pulsatile, arterial blood is in the tissue. The monitor then corrects this measurement for absorption when the pulsatile blood is not present. The ratio of the corrected absorption at each wavelength determines arterial oxygen saturation (SpO_2).

Automatic Calibration

The oximetry subsystem incorporates automatic calibration mechanisms. It is automatically calibrated each time it is turned on, at periodic intervals thereafter, and whenever a new sensor is connected. Also, the intensity of the sensor's LEDs is adjusted automatically to compensate for differences in tissue thickness.
Each sensor is calibrated when manufactured: the effective mean wavelength of the red LED is determined and eneoded into a calibration resistor in the sensor plug. The instrument's software reads this calibration resistor to determine the appropriate calibration coefficients for the measurements obtained by that sensor.

Functional versus Fractional Saturation :

Because the monitor measures functional SpO_2, it may produce measurements that differ from those of instruments that measurefractional SpO_2. Functional SpO_2 is oxygenated hemoglobin expressed as a percentage of the hemoglobin that is capable of transporting oxygen. Because the monitor uses two wavelengths, it measures oxygenated and deoxygenated hemoglobin, yielding functional SpO_2. It does not detect dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin.
In contrast, some laboratory instruments such as the Instrumentation Laboratory 282 CO-Oximeter report fractional SpO_2-oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, whether or not that hemoglobin is available for oxygen transport. Measured dysfunctional hemoglobins are included.
Consequently to compare this monitor's measurements directly with those of another instrument, that other instrument must measure functional SpO_2. If it measures fractional SpO_2,those measurements can be converted using the following equation:

$$\text{functional saturation} \quad \text{fractional saturation} \times \frac{100}{100-(\%\ \text{carboxyhaemoglobin}+\%\ \text{methaemoglobin})}$$

Design History

The original idea came from Teledyne in 1996.

UDT were approached by Teledyne as they had been manufacturing Pulse Oximeter probes for original manufacturers for many years.

Datascope, Criticatre, Massimo were some of the largest.

In November 1996 the clip was designed in presence of E. Avila. J. Moore Teledyne & J S Lamb

and time table set

Jan 1997 Final design.

April UDT to confirm the final design

April 15th prototypes to be available May 1st release the product

May 14th Product launch

May 30th European Sales seminar product launch in Europe

January 1997 meeting : As UDT had historically manufactured many types of probes and had access to many types of LED' they were using close tolerance LED's which meant they did not need coding resistors in Nellcor and Ohmeda probes.

However they were not aware that both the Ohmeda and Nellcor instruments required resistors to work.

D. Lamb & JS Lamb were present and over night had the effect proved in the UK by S. Hardaker.

April Teledyne withdrew from project

Viamed could not manufacture and UDT did not want to be nominated manufacturer.

MCI became involved as nominated USA manufacturer

July discussions on product progress.

No problem with UDT quality (ISO9000)

The procedure for a new probe is based on the ability to dis assemble any probe, evaluate the components especially the LED's and using standard parts reverse engineer the product.

Calculations

The probes were originally designed by Teledyne Analytical USA.

Teledyne is an ISO 9001 certified company which has been manufacturing for the Medical devices market for many years.

Original manufacturers probes were reversed engineered and "re-designed" using the same materials and specifications.

The design drawings were then used by UDT who have been a manufacturer of several types of pulse oximeter probes for several original probe manufacturers for many years. UDT is possibly the third largest manufacturer of pulse oximeter probes in the world today.

The above has enabled the compatible probes to be designed and manufactured to exacting standards by companies with a proven history of medical device design and manufacture.

In order to improve accuracy and tracking between the original manufacturers probe and the Teledyne compatible generic the use of generic diodes was not allowed.

Each manufacturers probe had the diodes examined for wavelength and output and the compatible uses matched diodes and detectors. This becomes apparent in the electronic testing.

There are a limited number of diodes being used by the original manufacturers and this has allowed a colour coding system to be introduced into the probe for easy identification.

All the probes use the same method of mounting and assembly.

All new probes are designed by the reverse engineering method.