

Equipment Package: Pulse Oximeter

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Equipment Packet Contents:

This packet contains information about the operation, maintenance, and repair of pulse oximeters.

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1. Operation and Use of Pulse Oximeters

Featured in this Section:

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Wikipedia. "Pulse Oximeter." *Wikipedia*, p. 1-4. Retrieved from:
https://en.wikipedia.org/wiki/Pulse_oximetry

Chapter 4.14 Pulse Oximeters

Brief Introduction to Pulse Oximeters

Function

A pulse oximeter is a device that non-invasively monitors the oxygen saturation of a patient's blood. It measures the amount of oxygen in a patient's arterial blood during operations and diagnosis. This level of oxygen, or 'oxygen saturation' is often referred to as SpO_2 , measured in %, and this is displayed on the pulse oximeter. A pulse oximeter also displays pulse rate.

How it works

The coloured substance in blood, haemoglobin, is carrier of oxygen and the absorption of light by haemoglobin varies with the amount of oxygenation. Two different kinds of light (one visible, one invisible) are directed through the skin from one side of a probe, and the amount transmitted is measured on the other side. The machine converts the ratio of transmission of the two kinds of light into a % oxygenation. Pulse oximeter probes can be mounted on the finger or ear lobe.



Pulse oximeter

A **pulse oximeter** is a medical device that indirectly measures the oxygen saturation of a patient's blood (as opposed to measuring oxygen saturation directly through a blood sample) and changes in blood volume in the skin, producing a photoplethysmograph. It is often attached to a medical monitor so staff can see a patient's oxygenation at all times. Most monitors also display the heart rate. Portable, battery-operated pulse oximeters are also available for home blood-oxygen monitoring. The original oximeter was made by Milliken in the 1940s.^[1] The precursor to today's modern pulse oximeter was developed in 1972, by Aoyagi at Nihon Kohden using the ratio of red to infrared light absorption of pulsating components at the measuring site. It was commercialized by Biox in 1981. The device did not see wide adoption in the United States until the late 1980s.

Function

A blood-oxygen monitor displays the percentage of arterial hemoglobin in the oxyhemoglobin configuration. Acceptable normal ranges are from 95 to 100 percent, although values down to 90% are common. For a patient breathing room air, at not far above sea level, an estimate of arterial pO_2 can be made from the blood-oxygen monitor SpO_2 reading.

A pulse oximeter is a particularly convenient noninvasive measurement instrument. Typically it has a pair of small light-emitting diodes (LEDs) facing a photodiode through a translucent part of the patient's body, usually a fingertip or an earlobe. One LED is red, with wavelength of 660 nm, and the other is infrared, 905, 910, or 940 nm. Absorption at these wavelengths differs significantly between oxyhemoglobin and its deoxygenated form; therefore, the oxy/deoxyhemoglobin ratio can be calculated from the ratio of the absorption of the red and infrared light. The absorbance of oxyhemoglobin and deoxyhemoglobin is the same (isosbestic point) for the wavelengths of 590 and 805 nm; earlier oximeters used these wavelengths for correction for hemoglobin concentration.^[2]

The monitored signal bounces in time with the heart beat because the arterial blood vessels expand and contract with each heartbeat. By examining only the varying part of the absorption spectrum (essentially, subtracting minimum absorption from peak absorption), a monitor can ignore other tissues or nail polish, (though black nail polish tends to distort readings)^[3] and discern only the absorption caused by arterial blood. Thus, detecting a pulse is essential to the operation of a pulse oximeter and it will not function if there is none.



Typical measurement through the fingernail



A fingertip pulse oximeter with waveform



A handheld pulse oximeter

Advantages

A pulse oximeter is useful in any setting where a patient's oxygenation is unstable, including intensive care, operating, recovery, emergency and hospital ward settings, pilots in unpressurized aircraft, for assessment of any patient's oxygenation, and determining the effectiveness of or need for supplemental oxygen. Assessing a patient's need for oxygen is the most essential element to life; no human life thrives in the absence of oxygen (cellular or gross). Although a pulse oximeter is used to monitor oxygenation, it cannot determine the metabolism of oxygen, or the amount of oxygen being used by a patient. For this purpose, it is necessary to also measure carbon dioxide (CO₂) levels. It is possible that it can also be used to detect abnormalities in ventilation. However, the use of a pulse oximeter to detect hypoventilation is impaired with the use of supplemental oxygen, as it is only when patients breathe room air that abnormalities in respiratory function can be detected reliably with its use. Therefore, the routine administration of supplemental oxygen may be unwarranted if the patient is able to maintain adequate oxygenation in room air, since it can result in hypoventilation going undetected.

Because of their simplicity and speed, pulse oximeters are of critical importance in emergency medicine and are also very useful for patients with respiratory or cardiac problems, especially COPD, or for diagnosis of some sleep disorders such as apnea and hypopnea. Portable, battery operated pulse oximeters are useful for pilots operating in a non-pressurized aircraft above 10,000 feet (12,500 feet in the US)^[4] where supplemental oxygen is required. Prior to the oximeter's invention, many complicated blood tests needed to be performed. Portable pulse oximeters are also useful for mountain climbers and athletes whose oxygen levels may decrease at high altitudes or with exercise. Those using portable pulse oximeters are also making use of blood oxygen charting software. These charting methods provide print outs for the patients physician of blood oxygen and pulse, and reminders to check blood oxygen levels.

Limitations and Advancements

Oximetry is not a complete measure of respiratory sufficiency. A patient suffering from hypoventilation (poor gas exchange in the lungs) given 100% oxygen can have excellent blood oxygen levels while still suffering from respiratory acidosis due to excessive carbon dioxide.

It is also not a complete measure of circulatory sufficiency. If there is insufficient bloodflow or insufficient hemoglobin in the blood (anemia), tissues can suffer hypoxia despite high oxygen saturation in the blood that does arrive.

A higher level of methemoglobin will tend to cause a pulse oximeter to read closer to 85% regardless of the true level of oxygen saturation. It also should be noted that the inability of two-wavelength saturation level measurement devices to distinguish carboxyhemoglobin due to carbon monoxide poisoning from oxyhemoglobin must be taken into account when diagnosing a patient in emergency rescue, e.g., from a fire in an apartment. A Pulse CO-oximeter measures absorption at additional wavelengths to distinguish CO from O₂ and determines the blood oxygen saturation more reliably.

Appropriate fluid levels are vital to reducing postoperative risks and improving patient outcomes as fluid volumes that are too low (under hydration) or too high (over hydration) have been shown to decrease wound healing, increase risk of infection and cardiac complications.^[5]

Increasing usage

According to a report by Frost & Sullivan entitled *U.S. Pulse Oximetry Monitoring Equipment Market*, US sales of oximeters were worth \$201 million in 2006. The report estimated that oximeter sales in the US would increase to \$310 million annually by 2013.^[6]

In 2008, more than half of the major internationally-exporting medical equipment manufacturers in China were producers of pulse oximeters.^[7]

In June, 2009, video game company Nintendo announced an upcoming peripheral for the Wii console, dubbed the "Vitality Sensor," which consists of a pulse oximeter. This marks the onset of the use of this device for non-medical, entertainment purposes.^{[8] [9]}

See also

- Arterial blood gas
- Medical equipment
- Pulse oximetry
- Capnography, measuring of carbon dioxide (CO₂) in the respiratory gases
- Integrated Pulmonary Index

External links

- Principles of Pulse Oximetry Technology^[10]
- How Pulse Oximetry Works^[11]

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Pulse Oximeters

Operation and Use of Pulse Oximeters

Theory

This chapter covers the theory of operation for

- The monitor's oximetry function
- The circuit boards associated with the oximetry function: The MINX board and the MINX interface board
- The front panel interconnect board, the printer terminator board, and the power supply board
- The monitor's printing function.
- The circuit boards associated with the printing function: the printer connector board and the printer board.

The pulse oximeter determines a patient's arterial oxygen saturation and pulse rate. It measures the absorption of selected light wavelengths that are generated in a probe. The light passes through the tissue and is converted into an electronic signal by a photodetector (some light is absorbed by the tissue.) The electronic signal passes to the Signal processing section of the MINX board where it is amplified and processed. The light intensity information is converted into SaO₂ and pulse rate values.

NOTE: The SaO₂ read by oximeters and displayed on this monitor, is now referred to as SpO₂. This additional definition is now required because a two-wavelength instrument cannot measure the presence of dyshemoglobins or other pigments. The presence of appreciable amounts of these substances may result in erroneous readings.

Text

Developing World Healthcare Technology Laboratory. "Pulse Oximeters." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 1-161.

Pulse Oximeters

The functioning of the oximeter is based on the assumption that hemoglobin exists in two principle forms in the blood:

- Oxygenated (with O₂ molecules loosely bound) or HbO₂.
- Reduced (with no O₂ molecules bound) or Hb.

Arterial oxygen saturation (SaO₂) is defined as the ratio of oxygenated hemoglobin (HbO₂) to total hemoglobin [HbO₂ + Hb]:

$$SaO_2 = \frac{HbO_2}{HbO_2 + Hb} *$$

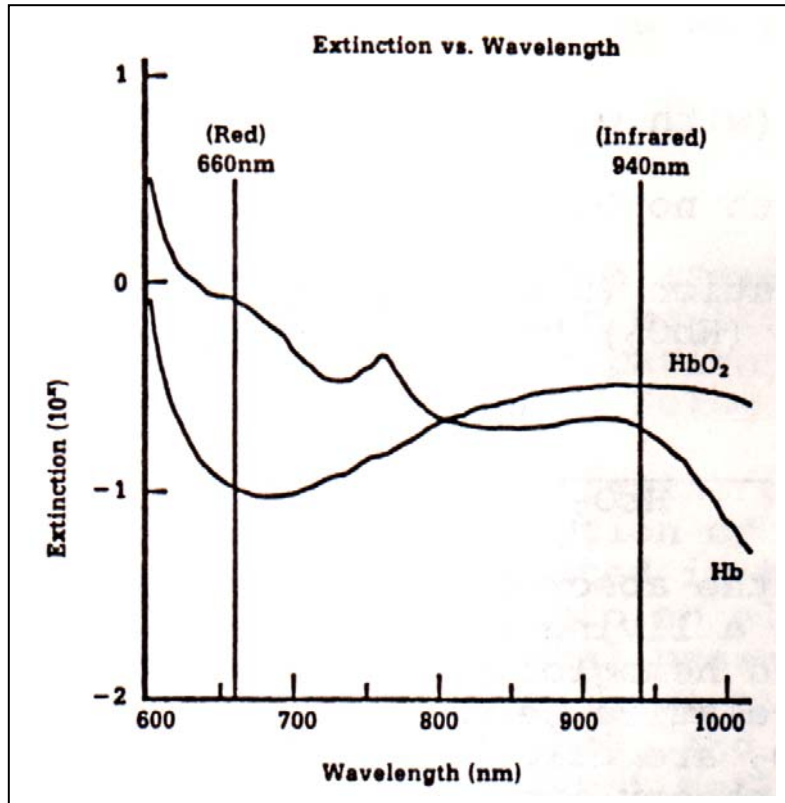
(*Interfering substances: Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substances that contain dyes, that change usual arterial pigmentation may cause erroneous readings.)

An oximeter measures the relative absorption of selected wavelengths of light passing through a living tissue sample. Since oxygenated hemoglobin and reduced hemoglobin absorb light as known functions of wavelengths, the relative percentage of these two constituents, and SaO₂ are calculated. The central problem in translating oximetry theory into a medical device is differentiating between the absorption due to oxygenated and reduced hemoglobin and the absorption due to all other tissue constituents.

The Ohmeda Biox 3700, for example, solves this problem with a patented two wavelength, pulsatile system. The pulsation of arterial blood flow present at a particular test site modulates the light the oximeter's probe detects. Since other fluids and tissues present at the test site generally do not pulsate, they do not modulate the light passing through the test site area. Therefore, the attenuation of light energy due to arterial blood flow can be detected, and isolated, thus providing the basis for the necessary calculations, by using the pulsatile portion of the incoming signal.

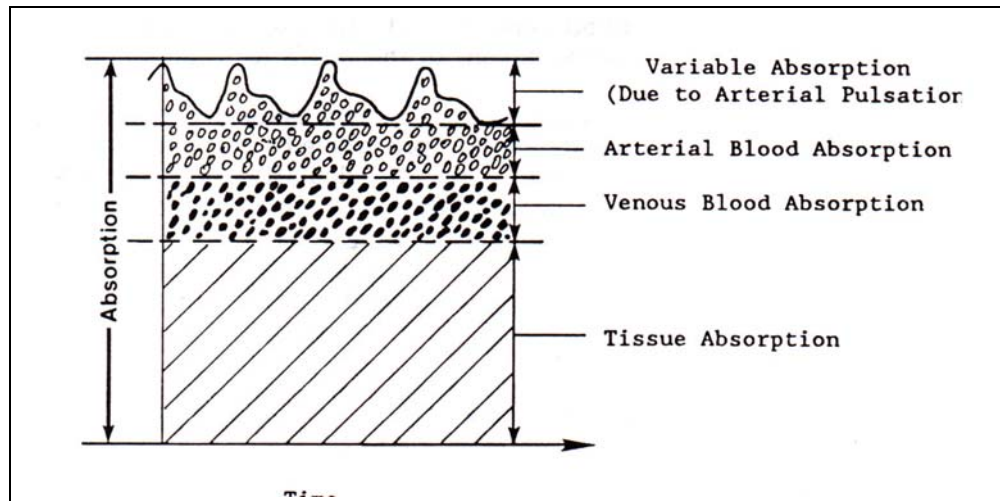
Two wavelengths of light, red and infrared, are utilized to gauge the presence of oxygenated and reduced hemoglobin.

Pulse Oximeters



EXTINCTION versus WAVELENGTH GRAPH

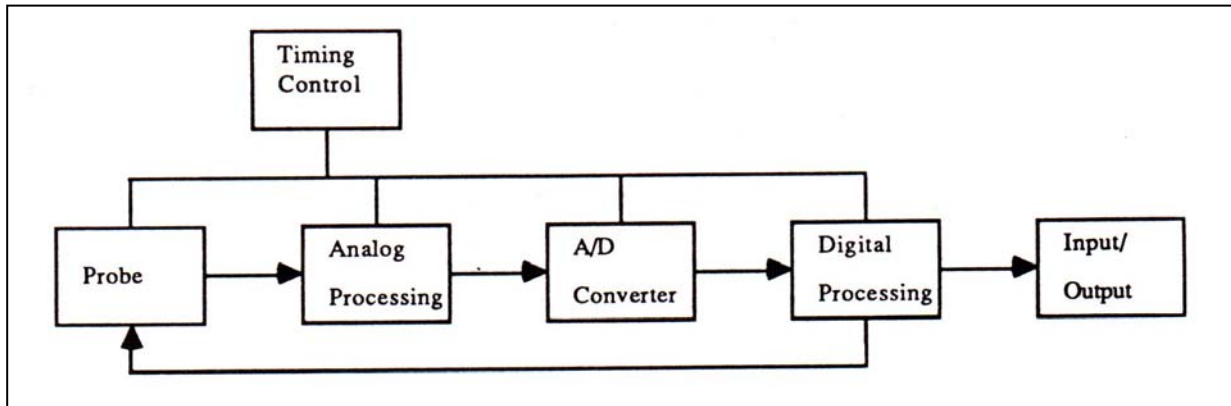
Oxygenated hemoglobin (HbO_2) and reduced hemoglobin (Hb) exhibit markedly different absorption (extinction) characteristics to red light @ 660 nm and infrared light @ 940 nm.



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Pulse Oximeters

The probe's photodetector converts the light, which is partially absorbed and modulated as it passes through the tissue sample, into an electronic signal. Since HbO₂ and Hb allow different amounts of light to reach the photodetector at the selected wavelengths, the electronic signal varies depending on which light source is "on" and the oxygenation of the arterial hemoglobin. The oximeter amplifies the electronic signals received. Analog and digital signal processing converts the light intensity information into SaO₂ and pulse rate values and displays them on the oximeter front panel.



Digital Processing

The microprocessor performs mathematical processes comparing the data from the red and infrared channels to each other. A ratio of the change in voltage in the red channel (ΔRED) to the change in voltage of the infrared channel (ΔIR) over some small interval of time is used to calculate SaO₂. This "instantaneous" oxygen saturation is calculated 30/25 (60/50 Hz) times per second.

A. From theory, oxygen saturation calculates as:

$$\text{SaO}_2 = K1R^2 + K2R + K3$$

Where $R = \frac{\Delta \text{RED}}{\Delta \text{IR}}$ and K1, K2, K3 are constants

where oxygen saturation at any point in time is a function of the change in the red channel divided by the change in the infrared channel.

The physical optical characteristics of hemoglobin are the basis of the calibration coefficients: K1, K2 and K3. The oximeter processes the instantaneous oxygen saturation values to produce the "average saturation values." The value appears on the oximeter's digital display.

One key digital processing function is to properly average the instantaneous oxygen saturation values. A running average gives a reasonable, but not excellent

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result. A weighted average of instantaneous values provides for a much more acceptable result. Perfusion at the test site and the current average saturation are the basis for the weight assigned to each instantaneous calculation. For example, movement at the probe site can create signal distortion, thus creating some erroneous instantaneous oxygen saturation values.

Since there are many saturation measurements per second, it is possible to discard bad values and the displayed saturation remains stable. The weighting function provides a stable reading, with low sensitivity to motion while retaining the capability of responding quickly to saturation changes. This running, weighted average uses data over a 6/3 seconds of data (Slow Mode/Fast Mode) and is updated every 0.67/0.33 seconds (Slow Mode/Fast Mode).

MODE	SAO ₂ AVERAGING PERIOD
Slow	12 seconds
Normal	6 seconds
Fast	3 seconds

A DEFAULT PARAMETER refers to a Volume Level or High/Low alarm limit automatically set by the oximeter when it is turned on.

Parameters	Default Settings	Ranges
High SaO ₂ Limit	OFF indicated by “---“	70 - 100 %
Low SaO ₂ Limit	90 %	50 – 100%
High Pulse Rate	OFF indicated by “---“	70 – 250 BPM*
Low Pulse Rate	50 BPM	40 – 200 BPM*
Alarm Volume	4	1 - 10
Pulse Volume	4	OFF - 10

*BPM = beats per minute

Perform the following tests daily to assure proper operation of the oximeter.

WARNING: Failure of Operation: If the oximeter fails to respond as described, do NOT use it until the situation has been corrected by qualified personnel.

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Pulse Oximeters

Visual Inspection

1. Inspect the oximeter case for damage.
2. Ensure the display windows are clean.

Functional Inspection

1. Connect a probe to the oximeter. Attach the probe to either finger or ear.

CAUTION: Use ONLY the probes supplied for this model of oximeter. Check the identification number/serial number tag (A) that is located on the cable near the connector. The model number must read: MOD 8122-00X or MOD 8121-00X (X represents a digit from 1 through 7).

2. Turn the oximeter on. Verify that the oximeter displays OHMEDA-BIOX 3700/3710 REVISION: X SYSTEM CHECK on the Graphic Display during the diagnostic self-test. Verify that the status message SYSTEM OPERATIONAL appears after the diagnostic self-test. Adjust the displays with the Viewing Angle Thumbwheel Adjustment located under the right side of the front panel if necessary.
3. Verify that high and low SaO₂ and pulse rate alarm limits and readings appear on the digital display.
4. Verify that the patient alarms are functional. Set the high and low SaO₂ and pulse rate alarm limits beyond the patient readings. Ensure the alarm tone sounds, and the violated alarm limit and reading flashes on the digital display and the red alarm light flashes.
5. Verify the Probe Alarms are functional:
 - A. Remove the probe from the finger or ear. Ensure the Alarm Message PROBE OFF PATIENT appears on the Graphic Display and the alarm tone sounds and the red alarm light flashes.

NOTE: The PROBE OFF PATIENT Alarm Message occurs with the finger probe and the ear probe and may occur with the flex probes.

- B. Unplug the probe from the oximeter. Ensure the Alarm Message NO PROBE CONNECTED TO UNIT appears on the Graphic Display and the alarm tone sounds and the red alarm light flashes.

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2. Diagrams and Schematics of Pulse Oximeters

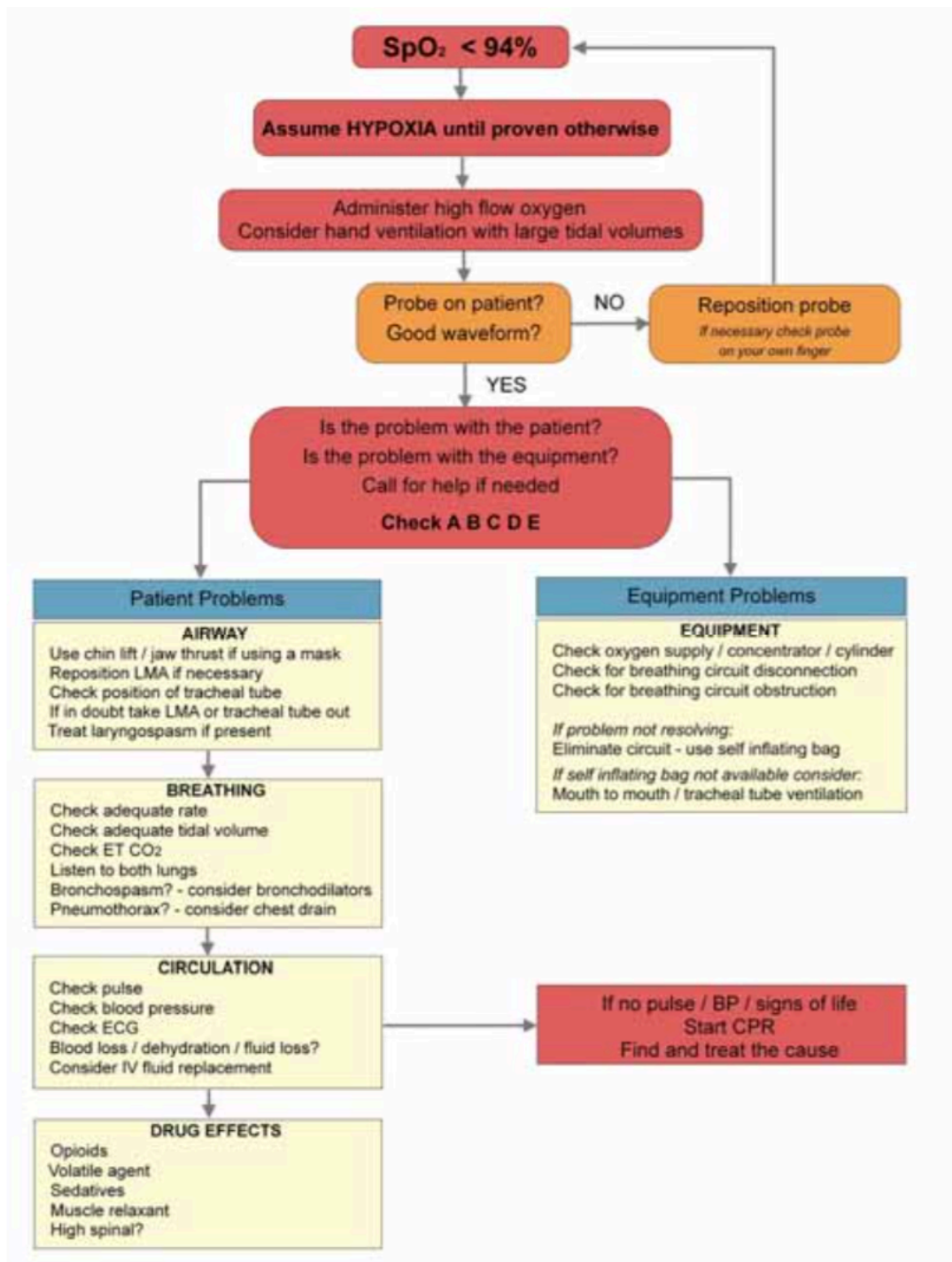
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http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Figure 1: Flowchart for Addressing Hypoxia



MEDICAL DEVICE SPECIFICATION		
i	Version No.	1
ii	Date of initial version	6/13/12
iii	Date of last modification	6/18/14
iv	Date of publication	
v	Completed / submitted by	WHO working group
NAME, CATEGORY AND CODING		
1	WHO Category / Code	(under development)
2	Generic name	Pulse oximeter
3	Specific type or variation (optional)	line-powered
4	GMDN name	Pulse oximeter, line-powered
5	GMDN code	17148
6	GMDN category	02 Anaesthetic and respiratory devices , 04 Electro mechanical medical devices , 06 In vitro diagnostic devices
7	UMDNS name	Oximeters, Pulse
8	UMDNS code	17148
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Pulse oxymeter; Oximeter, pulse
11	Alternative code/s (optional)	MS 34378; MS 42246
12	Keywords (optional)	SpO2, oxygen, monitor
13	GMDN/UMDNS definition (optional)	A mains electricity (AC-powered) photoelectric device intended for the continuous transcutaneous measurement and display of haemoglobin oxygen saturation (SpO2). The signals, typically produced by light-emitting diodes (LEDs) and a receiving detector in a probe, or directly built-in, are used to make the measurements using the principle of spectrophotometry. The oximeter displays the SpO2 values and may calculate / display other parameters, e.g., pulse rate, electrocardiogram (ECG). The device is typically used at the bedside.
PURPOSE OF USE		
14	Clinical or other purpose	monitor the haemoglobin oxygen saturation of patient, diagnosis for respiratory disorder
15	Level of use (if relevant)	Health center, district hospital, provincial hospital, specialized hospital
16	Clinical department/ward(if relevant)	Intensive-care unit, inpatient ward, Operating room
17	Overview of functional requirements	Continuously displays patient oxygen saturation in real time using an external probe on the skin Contains adjustable alarms to alert when either saturation or heart rate is low Reusable, sterilisable probes are robust and easily connected and disconnected Operates from mains voltage or from internal rechargeable battery
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	SpO2 measurement range at least 70 to 99 %, minimum gradation 1% Accuracy of SpO2 better than $\pm 3\%$ Pulse rate range at least 30 to 240 bpm, minimum gradation 1 bpm Accuracy of pulse rate better than ± 5 bpm Signal strength or quality to be visually displayed
19	Displayed parameters	
20	User adjustable settings	Audiovisual alarms required: high and low SpO2 and pulse rate (operator variable settings), sensor disconnected, sensor failure, low battery Alarm override and temporary silence facility to be included
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	Case is to be hard and splashproof Display must allow easy viewing in all ambient light levels Supplied in protective case for clean storage and safe transport
22	Mobility, portability(if relevant)	
23	Raw Materials(if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Power input to be ***** fitted with ***** compatible mains plug Internal, replaceable, rechargeable battery allows operation for at least four hours in the event of power failure Battery charger to be integral to mains power supply, and to charge battery during mains power operation of unit Voltage corrector / stabilizer / UPS to allow operation at $\pm 30\%$ of local rated voltage Electrical protection by resettable circuit breakers in both live and neutral supply lines Mains supply cable to be at least 3m in length
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Two reusable probes each for adult, paediatric and infant use
26	Sterilization process for accessories (if relevant)	
27	Consumables / reagents (if relevant)	
28	Spare parts (if relevant)	Two sets of spare fuses (if non-resettable fuses used)
29	Other components (if relevant)	
PACKAGING		
30	Sterility status on delivery (if relevant)	
31	Shelf life (if relevant)	
32	Transportation and storage (if relevant)	
33	Labelling (if relevant)	
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	
36	Requirements for commissioning (if relevant)	Supplier to perform installation, safety and operation checks before handover Local clinical staff to affirm completion of installation
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided Advanced maintenance tasks required shall be documented
38	User care(if relevant)	The case is to be cleanable with alcohol or chlorine wipes
WARRANTY AND MAINTENANCE		
39	Warranty	
40	Maintenance tasks	
41	Type of service contract	
42	Spare parts availability post-warranty	
43	Software / Hardware upgrade availability	
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals to be supplied in ***** language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost. Contact details of manufacturer, supplier and local service agent to be provided
DECOMMISSIONING		
45	Estimated Life Span	7 years
SAFETY AND STANDARDS		
46	Risk Classification	Class B (GHTF Rule 10); Class II (USA); Class II (EU, Japan, Canada and Australia)
47	Regulatory Approval / Certification	Must be FDA, CE or UL approved product.
48	International standards	ISO 14971:2007 Medical devices – Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests ISO 80601-2-61:2011 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment ISO/IEEE 11073-10404:2010 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter
49	Reginal / Local Standards	
50	Regulations	US regulations 21 CFR part 820 21CFR part 870.2700 oximeter JP regulations MHLW Ordinance No.169 17148010 Pulse oximeter

Figure 2: WHO Line Powered Pulse Oximeter Specification

Figure 3: WHO Battery Powered Pulse Oximeter Specification

NAME, CATEGORY AND CODING		
1	WHO Category / Code	(under development)
2	Generic name	Pulse oximeter
3	Specific type or variation (optional)	battery-powered
4	GMDN name	Pulse oximeter, battery-powered (handheld)
5	GMDN code	45607
6	GMDN category	02 Anaesthetic and respiratory devices , 04 Electro mechanical medical devices , 06 In vitro diagnostic devices
7	UMDNS name	Oximeters, Pulse
8	UMDNS code	17148
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Oximeter; Pulse oxymeter; Oximeter, pulse
11	Alternative code/s (optional)	MS 46612; MS 34378; MS 42246
12	Keywords (optional)	SpO2, oxygen, monitor, portable
13	GMDN/UMDNS definition (optional)	A portable, battery-powered, photoelectric device intended for the transcutaneous measurement and display of haemoglobin oxygen saturation (SpO2). The signals, typically produced by light-emitting diodes (LEDs) and a receiving detector in a probe, or directly built-in, are used to make the measurements using the principle of spectrophotometry. The oximeter displays the SpO2 values and may calculate/display other parameters, e.g., pulse rate, electrocardiogram (ECG). The device is typically applied to the fingertip or around the wrist; it may be used by healthcare facilities, emergency services, or in the home.
PURPOSE OF USE		
14	Clinical or other purpose	monitor the haemoglobin oxygen saturation of patient, diagnosis for respiratory disorder
15	Level of use (if relevant)	Health post, health center, district hospital, specialized hospital
16	Clinical department/ward(if relevant)	Intensive-care unit, Inpatient ward, Operating room
17	Overview of functional requirements	Displays patient oxygen saturation and pulse rate in real time using an external probe on the skin Display and probe built into one case Intended for time-limited spot checks, so alarm features not required Operates from internal battery (locally available type, rechargeable or non-rechargeable)
TECHNICAL CHARACTERISTICS		
18	Detailed requirements	SpO2 measurement range at least 70 to 99 %, minimum resolution 1% Accuracy of SpO2 better than $\pm 2\%$ Pulse rate range at least 30 to 240 bpm, minimum gradation 1 bpm Accuracy of pulse rate better than ± 4 bpm Signal strength or quality to be visually displayed Automatic power-off facility required after minimum of 1 minute Low battery display required Facility for data download preferred Digital equipment with autocorrelation algorithm.
19	Displayed parameters	Integrated display for data visualization with size not less than 5 inches. Video display of at least the following parameters: a) SpO2 sensor connected; b) alarms disabled; c) low battery; d) battery in charge. 12) Plethysmographic curves and tendency lines visualization capabilities for monitored parameters. 13) At least the following audio alarms: a) high frequency; b) low frequency; c) low saturation.
20	User adjustable settings	
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	Case is to be hard and splashproof Display must allow easy viewing in all ambient light levels Supplied in protective case for clean storage and safe transport Handle bar or facilities for easy transportation.
22	Mobility, portability(if relevant)	Portable
23	Raw Materials(if relevant)	N/A
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Charger electrical source requirements: Amperage: _____; Voltage: _____; Frequency: _____; Phases: _____ Protections against over-voltage and over-current line conditions. Compliance with _____ electrical standards and regulations. Battery charger (if required) to be "*****" fitted with "*****" compatible mains plug Battery to allow at least eight hours' continuous operation
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		
25	Accessories (if relevant)	Battery charger, Batteries Oximeterable with a length of at least 1.2 m; 1 adult patient reusable oximeter sensor; 1 pediatric patient reusable oximeter sensor; 1 neonatal patient reusable oximeter sensor.
26	Sterilization process for accessories (if relevant)	
27	Consumables / reagents (if relevant)	
28	Spare parts (if relevant)	
29	Other components (if relevant)	
PACKAGING		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	N/A
33	Labelling (if relevant)	N/A
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	
36	Requirements for commissioning (if relevant)	Supplier to perform installation, safety and operation checks before handover Local clinical staff to affirm completion of installation
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided Advanced maintenance tasks required shall be documented
38	User care(if relevant)	The case is to be cleanable with alcohol or chlorine wipes
WARRANTY AND MAINTENANCE		
39	Warranty	
40	Maintenance tasks	
41	Type of service contract	
42	Spare parts availability post-warranty	
43	Software / Hardware upgrade availability	
DOCUMENTATION		
44	Documentation requirements	User and maintenance manuals to be supplied in "*****" language. Certificate of calibration and inspection to be provided. List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost. Contact details of manufacturer, supplier and local service agent to be provided
DECOMMISSIONING		
45	Estimated Life Span	7 years
SAFETY AND STANDARDS		
46	Risk Classification	Class B (GHIF Rule 10); Class II (USA); Class II (EU, Japan, Canada and Australia)
47	Regulatory Approval / Certification	Must be FDA, CE or UL approved product.
48	International standards	ISO 13485:2003 Medical devices – Quality management systems – Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices – Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests ISO 80601-2-61:2011 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment ISO/IEEE 11073-10404:2010 Health informatics – Personal health device communication – Part 10404: Device specialization – Pulse oximeter
49	Reginal / Local Standards	
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3. Preventative Maintenance and Safety of Pulse Oximeters

Featured in this Section:

Cooper, Justin and Alex Dahinten for EWH. "Pulse Oximeter Preventative Maintenance." From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Developing World Healthcare Technology Laboratory. "Pulse Oximeters." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." *Engineering World Health*, March 1, 2011, p. 1-161.

Pulse Oximeter Preventative Maintenance

Preventive Maintenance

- Inspect exterior of equipment for damaged or missing hardware.
- Inspect the power cord, strain relief and plug/s for any signs of damage.
- Turn unit off, unplug***, open user accessible covers and inspect unit for damage.
- Clean unit interior components and exterior with compressed air.
- Inspect interior for signs of corrosion or missing hardware. Repair as required.
- Inspect electrical components for signs of excessive heat or deterioration.
- Clean exterior with warm water and liquid soap or mild detergent.
- Replace probe if disposable.
- Ensure nothing is blocking LEDs or photodetector on probe. If blocked, clean with isopropyl alcohol solution or mild detergent, mild chlorine bleach solution, hydrogen peroxide solution, or isopropyl alcohol. Do not use acetone, butyl alcohol, denatured ethanol, Freon, trichloroethylene or any petroleum-based solutions. Verify red light is being emitted in probe.
- Place probe on finger and make sure SpO₂ and heart rates (if applicable) appear.
- Remove probe from finger and verify that alarm is working.
- Unplug probe and verify that alarm is working.
- Examine switches and controls for proper function.
- Confirm lights, indicators, and displays are working.
- Verify machine can run on line power without battery.
- Check suggested replacement date for battery to see if date is passed or approaching and replace battery if necessary.

Pulse Oximeter Safety

Pulse Oximeters

► **IMPORTANT:** All patient and probe alarms are audibly suppressed for one minute, after the SYSTEM OPERATIONAL message.

6. Depress POWER/STANDBY to turn the oximeter off. No displays should be visible.

Probes

1. Check probes for foreign material such as tape or cotton. Remove any substances present that may interfere with transmission of light between the emitter and detector.
2. Verify that the probes open and close smoothly. If there is any unevenness or variations in the closing motion, replace the probe.
3. Check that the probe is the correct model before connecting it to the oximeter.

CAUTION: Use ONLY the probes supplied for this model of oximeter. Check the identification number/serial number Tag (A) that is located on the cable near the connector. The model number must read: MOD 8122-OOX or MOD 8121-OOX (X represents a digit from 1 through 7).

4. Check that the probe connector makes a firm connection with the oximeter.
5. Check that the probe cable is not twisted.
6. Turn the oximeter on.
7. Check that the red probe LED is lit upon turning the oximeter on.

WARNING: EXPLOSION HAZARD: Do NOT use in the presence of flammable anesthetics.

SAFETY

A WARNING indicates a potentially harmful situation.

Handle the oximeter equipment with care. Oximeter damage or inaccurate operation may result from improper handling.

Electrical Shock Hazard: Do NOT remove top cover. Refer to qualified personnel.

Failure of Operation: If the oximeter fails to respond as described, do NOT use it until the situation has been corrected by qualified personnel.

Developing World Healthcare Technology Laboratory. "Pulse Oximeters." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 1-161.

Pulse Oximeters

Explosion Hazard: Do NOT use in the presence of flammable anesthetics.

Data Validity: Do NOT expose the probe detector to strong ambient light while it is being used to monitor a patient. A poor signal may result.

Data Validity: Do NOT attach a probe to the same limb with an inflated blood pressure cuff. Valid data will NOT be received when the cuff is inflated. Attach probe to the limb opposite the site used for the blood pressure cuff.

Patient Safety: Patient condition may require changing the probe test site periodically. This should diminish the possibility of pressure necrosis of the test site.

Patient Safety: LEDs (Light Emitting Diodes) generate a small amount of heat as a by-product of light emission. Although the rise in temperature is minimal, the probe should be checked periodically in the event of long term monitoring.

Patient Safety: The ear probe should be moved to the opposite ear periodically if it is used for long term monitoring.

Patient Safety: Exercise extreme care to assure continued circulation distal to probe site after application.

Electrical Shock Hazard: Always unplug the oximeter before cleaning.

Data Validity: Do NOT operate the oximeter unless it is properly calibrated. Inaccurate patient SaO₂ readings will result.

A CAUTION indicates a condition that may lead to equipment damage or malfunction.

Do NOT apply tension to the probe cable. Probe damage may result.

Check rear panel voltage setting before connecting the oximeter to AC main power.

Avoid storing the oximeter and probes at temperatures exceeding 20°C (-4°F) to 60° C (140°F).

Connect only a high impedance device (1K Ohm or higher) to the analog output jacks. Improper loading will upset the correspondence between the measured voltage and the intended output voltage.

Never immerse the oximeter in liquid.

Do NOT autoclave the oximeter.

Do NOT gas sterilize the oximeter.

Developing World Healthcare Technology Laboratory. "Pulse Oximeters." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." Engineering World Health, March 1, 2011, p. 1-161.

Pulse Oximeters

Do NOT soak or immerse the probes in any liquid solution.

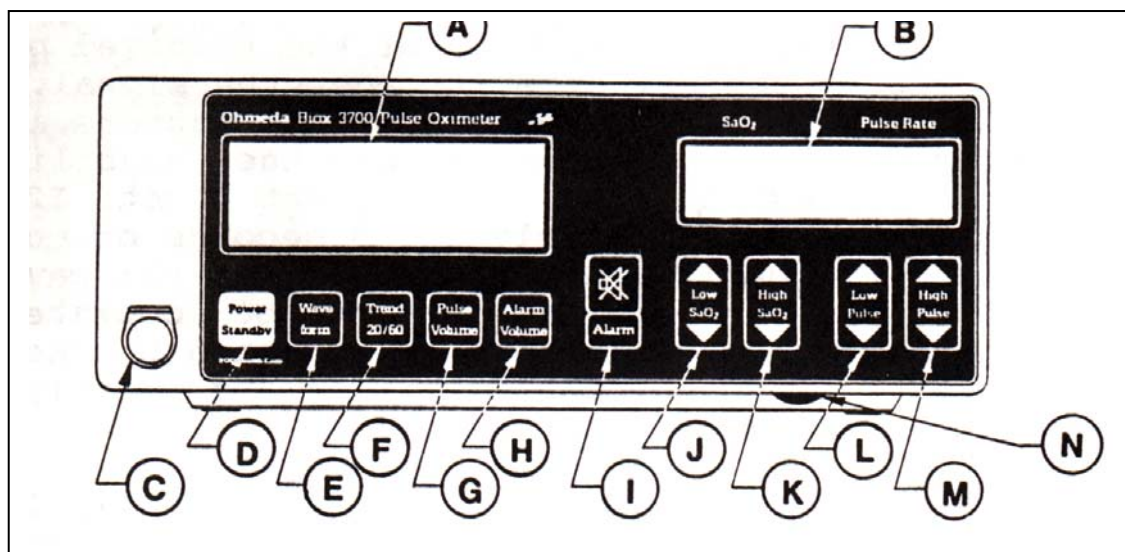
Do NOT autoclave probes.

Following sterilization with ethylene oxide, probes should be quarantined in a well-ventilated area to allow dissipation of residual ethylene oxide gas absorbed by the probe. Follow sterilizer manufacturer's recommendations for specific aeration periods required.

Do NOT turn on the oximeter after the RECHARGE BATTERY alarm condition is displayed without plugging it into AC main power. Operating the oximeter on battery power during a RECHARGE BATTERY alarm condition may permanently damage the lead-acid battery.

No repair should be undertaken or attempted by unqualified personnel.

Use hospital-grade grounded receptacle only.



FRONT PANEL

A. GRAPHIC DISPLAY: This displays the Signal Strength Indicator, Response Mode Information, Battery Status Information, Plethysmographic Waveform, Trend Data, Status Messages, and Alarm Messages.

1. SGNL" SIGNAL STRENGTH INDICATOR – The signal strength Bar Graph provides a visual indication of the received pulsatile signal. The higher the bar, the stronger the signal. The height of the bar is determined by several factors including tissue perfusion at the probe site, and the capability of the tissue under test to pass the incident light. If the bar is 5 pixels or less continuously for 5

4. Troubleshooting and Repair of Pulse Oximeters

Featured in this Section:

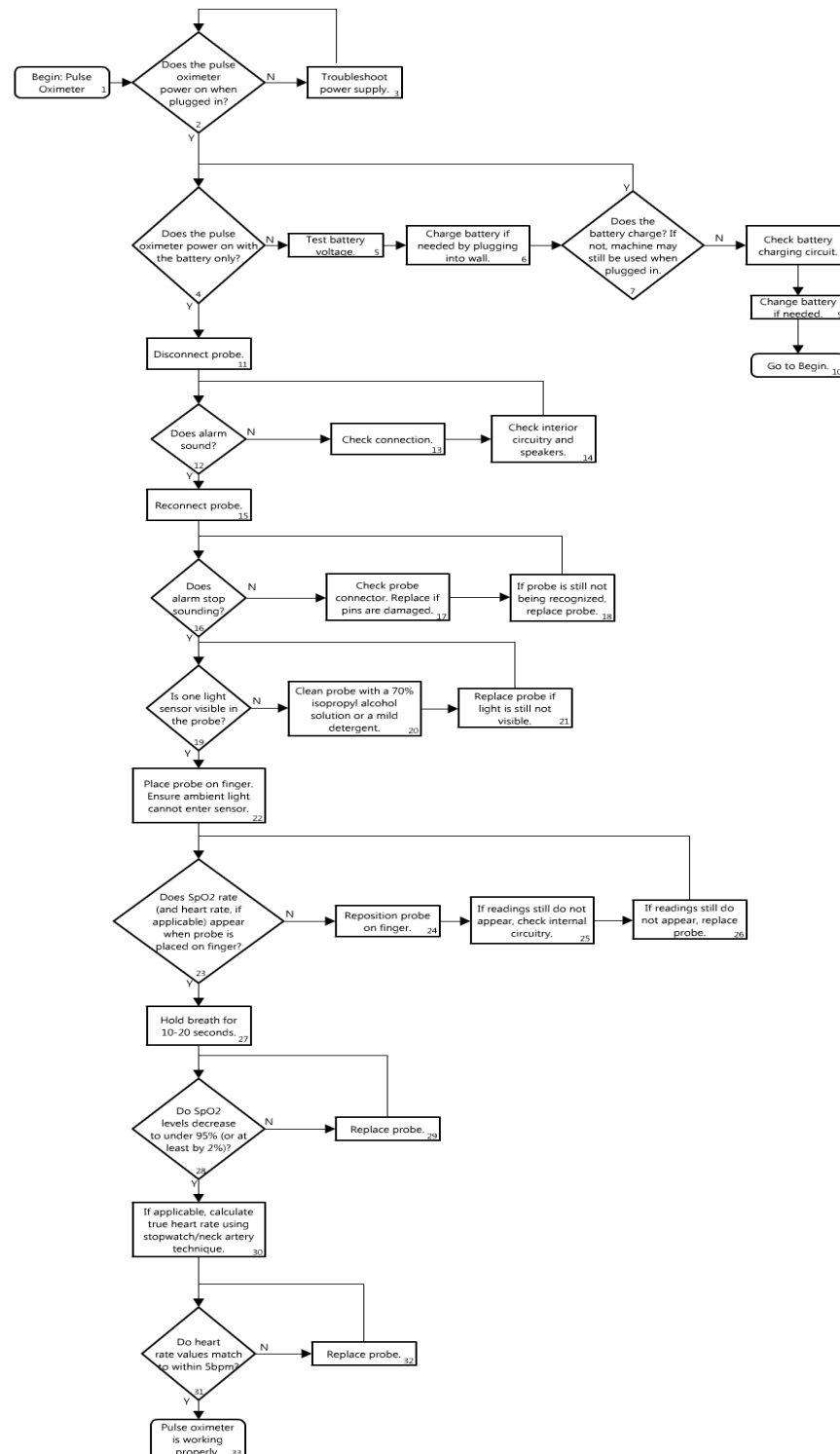
Cooper, Justin and Alex Dahinten for EWH. "Pulse Oximeter Troubleshooting Flowchart." From the publication: *Medical Equipment Troubleshooting Flowchart Handbook*. Durham, NC: Engineering World Health, 2013.

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Pulse Oximeter Troubleshooting and Repair Flowchart

Pulse Oximeter Repair and Troubleshooting

Flowchart



Description

#	Text Box	Explanation or Comment
1	Begin: Pulse Oximeter	Begin diagnostic process on a work order for pulse oximeter. Maintenance is generally requested on a pulse oximeter when it cannot read SpO ₂ or heart rate levels.
2	Does the pulse oximeter power on?	The displays should appear on working pulse oximeter when powered on.
3	Troubleshoot power supply (separate chart).	If no power reaches the machine, there may be problems with the switch, fuse, or wiring. See flowchart for Power Supply and BTA skills on Power Supply.
4	Does the pulse oximeter power on with the battery only?	Though the machine can still be used even if the battery charging circuit is faulty, the battery should be checked for functionality.
5	Test battery voltage.	Use a multimeter to determine if proper voltage is reaching the pulse oximeter. See flowchart for Batteries and BTA skills on Power Supply.
6	Charge battery if needed by plugging into wall.	The battery needs fourteen hours to recharge completely.
7	Does the battery charge?	If the battery does not hold charge, the machine may still be used when plugged in.
8	Check battery charging circuit.	Ensure that the circuitry that charges the battery is intact.
9	Change battery if needed.	Check the battery's replacement date and change it if it is faulty or if the date has passed.
10	Go to begin.	Restart the diagnostic process to see if the corrective measures have repaired the machine.
11	Disconnect probe.	Remove probe from pulse oximeter.
12	Does the alarm sound?	The alarm should not only sound when heart rate or SpO ₂ levels reach outside the acceptable ranges but when the probe connection with the machine is lost.
13	Check connection.	Ensure that there is nothing blocking the probe

		receptacle. Clear any debris or dirt that may interfere with probe connection.
14	Check internal circuitry and speakers.	Ensure internal circuitry and speaker connections are intact. See BTA skills for Electrical Simple.
15	Reconnect probe.	Reinsert probe into pulse oximeter.
16	Does the alarm stop sounding?	Ensure that the probe connection alarm stops when the probe is reconnected.
17	Check probe connector. Replace if pins are damaged.	If the pins on the probe connector are damaged, bent, or broken, the probe should be replaced.
18	If probe is still not being recognized, replace probe.	If the alarm continues, the problem may be with the probe itself. Replace the probe.
19	Is one light sensor visible in the probe?	There should be one red light being visibly emitted from inside the probe.
20	Clean probe with a 70% isopropyl alcohol solution or a mild detergent.	Probe can also be cleaned with warm water, liquid soap, mild chlorine bleach solution, or a hydrogen peroxide solution. Do not use acetone, butyl alcohol, denatured ethanol, Freon, trichloroethylene or any petroleum-based solutions. See BTA skills on Mechanical Cleaning.
21	Replace probe if light is still not visible.	If light is not being emitted, the photodetector cannot read the signals. The pulse oximeter cannot calculate the SpO ₂ value or heart rate.
22	Place probe on finger. Ensure ambient light cannot enter sensor.	When not in use, the probe should be shielded from direct light. If any outside light enters the sensor, it can drastically affect readings, as they are calculated through photodetection sensors.
23	Does SpO ₂ rate (and heart rate, if applicable) appear when probe is placed on finger?	The rate(s) should appear on the display once the probe is placed on the finger.
24	Reposition probe on finger.	The probe may be placed incorrectly on the finger. Ensure it is not too tight or loose and no outside light is entering the sensor.

25	If readings still do not appear, check internal circuitry.	Ensure internal circuitry is intact and connections are strong. See BTA skills on Electrical Simple.
26	If readings still do not appear, replace probe.	Ensure correct probe is being used. Other probes may not connect correctly.
27	Hold breath for 10-20 seconds.	This is to manually check if the SpO ₂ readings decrease with less oxygen supply.
28	Do SpO ₂ levels decrease to under 95% (or at least by 2%)?	As you hold your breath longer, the rate should decrease a few percent at least.
29	Replace probe.	Attempt again with a new probe.
30	If applicable, calculate true heart rate using stopwatch/neck artery technique.	If applicable, calculate heart rate manually using a stopwatch and counting pulse rate of neck artery (or wrist).
31	Do heart rate values match to within 1bpm?	Compare manually calculated values to pulse oximeter display.
32	Replace probe.	If values are not within 1bpm, replace probe.
33	Pulse oximeter is working properly.	Return the machine to the appropriate clinical personnel.

Pulse Oximeter Troubleshooting Table

User Care of Medical Equipment – First line maintenance for end users

Troubleshooting – Pulse Oximeters

Fault	Possible Cause	Solution
1. Equipment is not running	No power from mains socket	Check power switch is on. Replace fuse with correct voltage and current if blown. Check mains power is present at socket using equipment known to be working. Contact electrician for rewiring if power not present.
	Battery (if present) is discharged	Recharge or replace battery
	Electrical cable fault	Try cable on another piece of equipment. Contact electrician for repair if required.
2. SpO ₂ or pulse rate not displayed or unstable	Probe is not mounted correctly	Connect probe and cable properly
	Probe not able to read through dirt, nail polish, etc.	Remove grease, dirt, nail polish and clean probe
	Patient movement	Request patient to remain still
	Patient's SpO ₂ value is too low to be measured	Further clinical examination of patient. Resite probe if necessary
	Internal malfunction	Call biomedical technician.
3. "Probe off" displayed on screen	Probe is not connected properly	Connect the sensor
	The connection between the probe and oximeter is loose	Refer to biomedical technician for repair
4. "Error" displayed on screen	Faulty probe or control circuit	Refer to biomedical technician
5. Continuous alarm sounds	Alarm limits set too low or high	Set appropriate alarm limits
	Power disconnected	Connect power cable
	Internal malfunction	Refer to biomedical technician
6. Electrical shocks	Wiring fault	Refer to biomedical technician immediately

User Care Checklist – Pulse Oximeters

Daily	
Cleaning	<ul style="list-style-type: none"> ✓ Remove any dust / dirt ✓ Remove any tape, paper or foreign body from equipment ✓ Clean probe with alcohol wipe after each use
Visual checks	<ul style="list-style-type: none"> ✓ Check all parts are present and connected ✓ Check cables are not twisted and remove from service if any damage is visible
Function checks	<ul style="list-style-type: none"> ✓ Check operation on healthy subject before use ✓ Store probe and cable carefully, replace equipment cover

Weekly	
Cleaning	<ul style="list-style-type: none"> ✓ Unplug, clean outside with damp cloth and dry off
Visual checks	<ul style="list-style-type: none"> ✓ Check all screws and parts are fitted tightly ✓ If plug, cable or socket are damaged, replace
Function checks	<ul style="list-style-type: none"> ✓ Check operation of all lights, indicators and visual displays ✓ Check probe disconnection alarm.

Every six months
Biomedical Technician check required

5. Resources for More Information about Pulse Oximeters

Featured in this Section:

Malkin, Robert. "Pulse Oximeter: Use and Operation." *Medical Instrumentation in the Developing World*. Engineering World Health, 2006.

Resources for More Information:

Internal Resources at library.ewh.org: For More Information about pulse oximeters, please see this resource in the BMET Library!

1. Malkin, Robert. "Pulse Oximeter: Use and Operation." *Medical Instrumentation in the Developing World*. Engineering World Health, 2006.

Pulse Oximeter Bibliography:

Developing World Healthcare Technology Laboratory. "Pulse Oximeters." From the Publication: "Biomedical Technicians Training Program, Session 3 v2, Special Topics: Cardiac Equipment." *Engineering World Health*, March 1, 2011, p. 1-161.

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WHO. "Using the Pulse Oximeter, Tutorial 2 – Advanced." *World Health Organization*, 2011.