Pan American Health Organization
World Health Organization
Americas

PAHO

Technical and Regulatory Aspects of the Use of Pulse Oximeters in Monitoring COVID-19 Patients

7 August 2020

525 23rd St. NW
Washington, DC 20037

www.paho.org

Summary

- **Pulse oximetry** is a non-invasive method for indirectly measuring the percentage of oxygen saturation (SpO_2) carried by hemoglobin in a patient's blood. The medical device used in pulse oximetry, the *pulse oximeter*, is globally accepted as the standard for detecting and monitoring hypoxemia, a lower than normal level of oxygen in the blood.
- Today, supportive management, including supplemental oxygen administration, is the main treatment for patients with COVID-19.[1] More than 75% of all hospitalized patients require supplemental oxygen treatment. Pulse oximeters are a critical tool for managing patients with COVID-19 due to their role in staging the severity of the illness, as well as indicating and monitoring treatment with supplemental oxygen.
- Non-medical pulse oximeters could be a particularly useful tool in remote monitoring of COVID-19 patients because they would allow early detection of "silent hypoxemia" in patients, potentially preventing clinical deterioration.
- According to available evidence, non-medical pulse oximeters would have comparable efficacy to medical oximeters in ruling out the presence of hypoxemia in patients with COVID-19. The negative predictive value for ruling out patients with hypoxemia, defined as SpO_2 <90%, is 99%, although accuracy decreases significantly for saturations below 90%.
- The PAHO Flowchart for the Management of Suspected COVID-19 Patients at the First Level of Care and in Remote Areas in the Region of the America, in addition to other relevant clinical management guidelines, recommend the use of pulse oximeters in outpatient management and monitoring of patients with confirmed or suspected COVID-19 cases, and provide guidance for their use.
- Pulse oximetry is also used for monitoring oxygen saturation for people in other contexts, such as senior citizen residences, rural areas, and areas with low access to health services.
- It is important to note that while pulse oximetry can be a useful resource in clinical decision-making, it is not a substitute for clinical evaluation and is not in itself sufficient for diagnosis.
- The incorporation of this technology as a tool for managing patients with COVID-19 should be done according to appropriate guidelines and precautions.

Objectives and organization of the document

- This document presents technical and regulatory considerations for the use of pulse oximeters as a tool in clinical monitoring of COVID-19 patients.
- It also summarizes available evidence on the efficacy, effectiveness, and safety of different types of pulse oximeters, their limitations, and recommendations for use.
- The document is presented in two sections:
  - Section 1. Evidence on the effectiveness of pulse oximeters and their implementation in the clinical context
  - Section 2. Technological and regulatory specifications
- It is intended for health professionals, as well as health authorities and other decision makers responsible for health technologies for the care of COVID-19 patients.
- These recommendations are preliminary and are subject to review as new evidence becomes available.

Introduction

- **Pulse oximetry** is a non-invasive method that indirectly measures the percentage of oxygen saturation (SpO_2) carried by hemoglobin in a patient's blood. The medical device used in pulse oximetry is known as a pulse oximeter and is globally accepted as the standard for detecting and monitoring hypoxemia, a lower than normal level of oxygen in the blood. Hypoxemia may occur with conditions that mainly affect the lungs, such as pneumonia, bronchiolitis, asthma, and respiratory failure, among others; however, it can also occur due to systemic diseases such as sepsis and trauma. Along with an appropriate supply, pulse oximetry is necessary for efficient and safe use of oxygen and monitoring the patient's response to oxygen therapy.[2]
- Today, supportive management, including supplemental oxygen administration, is the main treatment for patients with COVID-19.[1] More than 75% of hospitalized patients require supplemental oxygen.[1] Blood oxygen saturation level is essential in classifying the stage of severity of patients and, consequently, the choice of treatment.[3] As a result, pulse oximeters are a critical tool for managing patients with COVID-19.
- A substantial number of patients with COVID-19 reach a significant level of clinical hypoxemia without shortness of breath or other warning signs.[4-8] This phenomenon, called "silent hypoxia", is potentially risky because it could delay management until the patient has entered more advanced stages of lung injury, with increased likelihood of complications and mortality.[4,6,9] This situation could particularly affect patients diagnosed with COVID-19 who do not require hospitalization, such as those in moderate stages, mild stages with risk factors, or those in conditions of vulnerability. Home-use pulse oximeters could be a useful tool in remote monitoring of these patients.
- The ease of use and relatively low cost of home-use pulse oximeters make them an attractive option for monitoring patients. However, there are important considerations about these devices that patients, health professionals, and health authorities must consider when including them as a tool for managing and monitoring COVID-19 patients.

Section 1. Evidence on the effectiveness of pulse oximeters and their implementation in the clinical context.

Silent hypoxia in patients with COVID-19

- A substantial number of patients with COVID-19 reach a significant level of clinical hypoxemia, and even develop respiratory failure, without shortness of breath or other warning signs.[4-8] This phenomenon, called "silent hypoxemia," is more common in older patients[5] and poses a risk, as it may delay management until the patient has advanced stages of lung injury, with increased likelihood of complications and mortality.[4,6,9] Some cases present only mild and nonspecific symptoms (such as mild headache, sore throat, cough, among others)[10,11] and some patients have reported feeling "comfortable" despite showing oxygen saturation levels well below normal values.[11]
- Respiratory rate (RR) may not be an adequate indicator of the degree of clinical deterioration in some patients with COVID-19. There is evidence of significant discrepancy in RR values and oxygen saturation levels (SpO_2) between COVID-19 patients with acute respiratory distress (ARD) and patients with ARD from other causes.[66] A normal breathing rate could mask deep levels of hypoxia, making it difficult to assess severity in COVID-19 patients if their oxygen saturation levels are not measured systematically.[6]
- Silent hypoxia is possible because SARS-CoV2 causes the alveolar sacs to collapse without filling them with fluid or pus, thereby reducing the ability to capture oxygen, but retaining the lung capacity to expel carbon dioxide. Efficient elimination of carbon dioxide would explain why patients with COVID-19 do not feel shortness

of breath in the early stages of COVID-19 pneumonia. Therefore, the ability to detect this silent form of hypoxia in patients with COVID-19 before they begin to experience shortness of breath could allow for early treatment before disease progression. [7-9,12,13]

Accuracy of non-medical pulse oximeters

- There are few studies evaluating the accuracy of pulse oximeters in patient populations, including pathologies such as peripheral vascular disease and others that could affect the accuracy of the device, especially non-medical pulse oximeters.[4] Compared to the number of models available on the market, which also increases over time, little evidence exists. This presents an additional challenge in assessing the accuracy of non-medical oximeters.[4]
- In a narrative review including clinical[14,15] and laboratory studies[16], Luks, Swenson et al.[4] showed that there are no significant differences in results between medical and non-medical pulse oximeters for the oxygen saturation range of 90% to 99%.[14-16] However, non-medical pulse oximeter measurements are less accurate for saturation levels below 93%, and accuracy is inadequate at low oxygen saturation levels.[14-16]
- Lipnick et al.[16], evaluating the accuracy of six low-cost pulse oximeter models (less than US$50), showed that the error level in measurements grew at actual oxygen saturation levels below 90%, and that the error level was higher for lower saturation levels. This pattern, although consistent in more expensive oximeter models, was especially notable for lower-priced models.[16]
- Hudson et al.[14], one of the clinical studies included in the review, compared eight non-medical oximeters to medical and co-oximetry devices, determining that their positive predictive value to rule out patients with hypoxemia (defined as an oxygen saturation <90% in medical devices or measured by co-oximetry) was only 33% while their negative predictive value was 99%.[14]
- Smith et al.[15] concluded that the accuracy of the portable pulse oximeter was comparable to that of a conventional bedside hospital pulse oximeter in perioperative patients with normal blood oxygen saturation ($SpO_2 \geq 93\%$). However, the accuracy of the portable pulse oximeter deteriorated with progressive hypoxemia ($SpO_2 < 93\%$).[15] This clinical study was considered in the review *Pulse Oximetry Monitoring in Patients at Risk of Hypoxia: An Ultra-Rapid Review of Clinical Utility and Guidelines*[17] published by the Canadian Agency for Drugs and Technologies in Health (CADTH). This review highlights that the study was conducted in a highly complex healthcare environment, where device application and measurements were performed by health professionals, and it is impossible to ensure that the results would not vary if the measurements were taken by patients or members of the general population.[17]
- The above review *Pulse Oximetry Monitoring in Patients at Risk of Hypoxia*[17] conducted by CADTH concludes that the available evidence to date, although of moderate quality and at high risk for biases, makes it possible to state that the accuracy of non-medical oximeters is comparable to that of medical oximeters for the detection of patients with hypoxia.[17]
- Pulse oximetry would also detect deterioration of a patient's condition even if their oxygen saturation values remain above the saturation threshold. A retrospective study of patients with chronic obstructive pulmonary disease (COPD) showed correlation between deterioration of a patient's condition and decrease in saturation by more than 4%.[18] A study in the pediatric population (children between 6 and 12 years of age) showed that a saturation of 95% to 96% in this population represents a significant clinical situation that requires early evaluation and intervention to prevent deterioration of other vital signs.[19] Similarly, clinical management guidelines for oxygen use in adults recommend clinical evaluation of the patient if saturation drops by at least 3%.[20,21]

- Pulse oximeters would also be a reliable tool for measuring respiratory rate. A recently published study[22] evaluated the accuracy of plethysmography based respiratory rate measurement using pulse oximeters in a pediatric population, showing evidence that the accuracy is comparable to the gold standard: plethysmography performed by a pediatrician (association = 97%, *p* <0.001; sensitivity and specificity for accelerated respiratory rate detection of 95%, almost 94%, respectively).[22]
- From the evidence cited, it could be stated that **non-medical pulse oximeters could be useful in ruling out the presence of hypoxemia, although they would not be suitable for assessing the degree of hypoxemia.**

Use of pulse oximeters in the context of the COVID-19 pandemic

- Pulse oximetry may be useful for:
  - Triage of potentially hypoxic patients, in health facilities or on an outpatient basis.
  - In conjunction with other criteria, assessing the severity of the illness and determining possible evaluations or treatments to be implemented.
  - Contributing to the monitoring of patients diagnosed with COVID-19 whose condition allows them to stay at home.
- The use of pulse oximeters has been shown to be effective for clinical outpatient monitoring in other clinical situations, such as monitoring patients with chronic obstructive pulmonary disease.[23,24]
- A recently published randomized clinical trial[25] showed that including pulse oximetry in the World Health Organization (WHO) Integrated Management of Childhood Illness (IMCI) algorithm[26] significantly increased (OR: 5.4, 95% CI 2.0 to 14.3, p = 0.001) the number of diagnoses of severe childhood pneumonia in health facilities, and could help substantially reduce infant mortality from hypoxemia.[25]
- Although the Pan American Health Organization (PAHO)[27] and the World Health Organization (WHO)[3] recommend close outpatient monitoring for those with moderate COVID-19 to detect signs or symptoms of disease progression, as indicated in the document *Initial Care of Persons with Acute Respiratory Illness (ARI) in the Context of Coronavirus Disease (COVID-19) in Healthcare Facilities*, at the time of publication there was no evidence to guide the use of pulse oximeters in homes. The most recent COVID-19 management algorithm published by the Pan American Health Organization[28], the *Flowchart for the Management of Suspected COVID-19 Patients at the First Level of Care and in Remote Areas in the Region of the Americas,* includes the use of oximeters in both health centers and outpatient management of confirmed or suspected COVID-19 patients and the measurement of oxygen saturation as key factors in clinical decision-making.
- To date, although clinical studies on pulse oximeter use for monitoring COVID-19 patients are still scarce, there is already evidence of its clinical utility as a tool to identify outpatients at increased risk of deterioration.[29] A recent study that monitored oxygen saturation in the homes of patients with confirmed COVID-19 diagnoses showed a relative risk (RR) of 7 (95% CI 3.4-14.5) in the group of patients with saturation <92% compared to the group with higher saturation.[30]
- Other clinical management guidelines[31-34] also recommend the use of pulse oximeters in outpatient management and monitoring of patients with confirmed or suspected cases of COVID-19, providing recommendations for their use.
  The following is a brief description of some of these guidelines:

<table>
<tr><th>Guidelines</th><th>Recommendations</th></tr>
<tr><td>Guidance from the National Health Service of England. (NHS).

"Pulse oximetry to detect early deterioration of patients with COVID-19 in primary and community care settings"[32]</td><td>
- Principles for the use of oximeters in the initial remote triage and remote monitoring of patients with confirmed or suspected COVID-19 diagnoses.
- Oximeters should be used for mild case monitoring and early detection of silent hypoxemia, although it is noted that remote care and oximeter use is at the discretion of the physician.[32]
- During initial triage, both face-to-face and remote, saturation determines the severity level and actions to follow in each case. In addition to saturation, respiratory rate, heart rate, and NEWS 2 (National Early Warning Score) are considered.

<table>
<tr><th>Stage</th><th>Severe</th><th>Moderate</th><th>Mild</th></tr>
<tr><td>Saturation</td><td>92% or less*</td><td>93%-94%*2</td><td>95% or greater*3</td></tr>
<tr><td>Respiratory rate</td><td>≥25</td><td>21-24</td><td>≤20</td></tr>
<tr><td>Heart rate</td><td>≥131</td><td>91-130</td><td>≤90</td></tr>
<tr><td>NEWS 2 score</td><td>>5</td><td>3-4</td><td>0-2</td></tr>
<tr><td>Actions</td><td>Hospital admission</td><td>Consider hospital admission/face-to-face evaluation</td><td>Consider remote monitoring</td></tr>
</table>
* ≤84% if baseline saturation is 88%
*2 84-85% if baseline saturation is 88%
*3 86% if baseline saturation is 88%
Source: based on guidance from the National Health Service of England.[32]

- "Exertion oximetry" (under the supervision of a professional) is proposed for early identification of patients with silent hypoxemia. It is undertaken in patients with saturations of at least 93%. The most common tests are the 40-step walk and the one-minute "sit-to-stand".[32]
- Patients receive a finger oximeter for a period of 14 days from the onset of symptoms. They are also given a log, where they must record their measurements three times a day.
- The attending health professional contacts the patient or caregiver to obtain measurements as often as he or she deems necessary and makes appropriate clinical decisions.[32]
</td></tr>
<tr><td>COVID-19 Rapid Guideline: Managing Suspected or Confirmed Pneumonia in Adults in the Community

National Institute for Health and Care Excellence (NICE, United Kingdom)[31]</td><td>
- Considers the evaluation of signs and symptoms and the use of assessment tools (including pulse oximeters) to identify patients with more severe illness and make decisions on hospitalization.[31]
- Recommends that, when pulse oximetry is available, oxygen saturation levels below 92% (below 88% in people with COPD) should be considered as a threshold for identifying patients with severe illness.[31]
</td></tr>
<tr><td>Guide to Using pulse oximetry during Covid-19 pandemic Londonwide

London Medical Committees[33]</td><td>
- Includes the use of pulse oximeters in patients with acute respiratory infection, COPD, and severe asthma.
- Notes that pulse oximetry can be a useful aid for clinical decision making, but it is not a substitute for clinical evaluation, and is not in itself sufficient for diagnosis.

Proposed algorithm:

- SpO2 >96%: normal values
- SpO2 93-96%: consider brief exercise and check for desaturation
- SpO2 ≤92%: hypoxia and indication of supplemental oxygen treatment

- The use of oximeters arises in two instances of COVID-19 patient management:
</td></tr>
</table>

	During the initial evaluation: Type of use depends on whether a person is able to leave home or whether they have to remain at home. In the former case, the possibility of organizing "self-service" centers should be considered. These are centers where people can go for their evaluation and to check their oxygen saturation level. For the latter group, a medical team visits their homes to perform the initial evaluation, including measuring saturation. **Continuous monitoring at home:** for patients who do not require hospitalization because of their severity and can be monitored remotely.

Use of oximeters for managing COVID-19 patients in special contexts

- The use of pulse oximeters can be considered in other contexts apart from monitoring patients in health facilities and on an outpatient basis. For example:
  - In **residences for older persons**[35] and other settings where a large number of people live. This possibility is described in the U.S. Centers for Disease Control (CDC) guidelines on COVID-19 response in nursing homes, where pulse oximeter monitoring is recommended for asymptomatic people on a daily basis or every time caregivers change shift, in order to detect potential new infections.[35]
  - In **rural areas or areas with low access to health services**, oximeters have also been used for outpatient management.[36]
  - **Self-monitoring at home for health personnel diagnosed with COVID-19**. The Yale School of Medicine has implemented a self-monitoring program with pulse oximeters for health staff with COVID-19 and is considering expanding use to regular patient care.[37,38]
  - **Self-monitoring of oxygen saturation in the general population.** The Minnesota Department of Health, USA, published a guide for the general population explaining how to self-monitor oxygen saturation with pulse oximeters, as well as steps to take in case of abnormal values.[39]

Implementation and interpretation of results

- If a COVID-19 patient has access to a reliable pulse oximeter at home and can properly measure and report the results to the doctor or health system, oxygen saturation measurement can be used as additional information to assess their clinical status.
- Monitoring should be carried out following appropriate guidelines (see "Guidelines for Use" section).
- **It is important to note that while pulse oximetry can be a useful resource in clinical decision-making, it is not a substitute for clinical evaluation and is not in itself sufficient for diagnosis.**
- Oximetry should only be considered within the context of the patient's general clinical presentation; normal oxygen saturation levels should not allow clinically significant respiratory conditions to be ruled out in patients with other warning signs.[34] Along the same lines, even if the saturation level obtained by oximetry is normal at the time of measurement, it should be borne in mind that the respiratory state may deteriorate as the disease progresses.[34]
- **It is important to note that if a patient's oxygen saturation falls by at least 3% (even if it is still within the target range), an immediate evaluation should be performed, as acute deterioration in the patient's condition may be revealed**.[20,21]

- A clear patient management algorithm should be available for cases where oxygen saturation is below the established threshold or deteriorates.[33]
- Pulse oximetry monitoring should not be performed in patients during end-of-life palliative care, as the information obtained will not impact their management and could cause more stress to the patient and their caregivers.[33]

Interpretation of oxygen saturation results with pulse oximetry in outpatients with confirmed or suspected cases of COVID-19.

SpO_2> 96% (RR<20 and no emergency signs)[28]	- Normal value.[3,27,31.34] - Isolate patients with suspected COVID-19 in their home or assigned facilities to receive care.[28] - Administer acetaminophen (500 mg every 6 to 8 hours, maximum 4 g per day) in case of fever or pain.[28] - Provide appropriate recommendations on hydration and nutrition; and identify emergency signs.[28] - Do not administer antibiotics.[28]
SpO_2 94-96% (RR<20 and no emergency signs)[28]	- Consider whether the patient requires closer evaluation or referral to a health center.[31,33,34] - The patient may be asked to do brief exercise (climb the stairs, walk on site for a minute) to assess whether desaturation occurs with exercise. It is important to note that the clinical importance of desaturation during exercise and its impact on patient management is still under discussion.[31,33,34]
SpO_2 90- 94%*	- Isolate in health care provider facilities and consider moving to the second level of care. - Monitor vital and emergency signs. - Consider oxygen intake and fluid administration. - Analyze available laboratory tests and imaging**
SpO_2 <90%	- Refer to the second level of care and consider supplemental oxygen treatment.[28] - COVID-19 patient management guidelines from the Pan American Health Organization[27] and the World Health Organization[3] recommend administering supplemental oxygen therapy to any patient with or without emergency signs with $SpO_2 < 90\%$.[2,26]
Drop in $SpO_2 \geq 3\%$	- Consider referral to a health center in case of possible progressive clinical deterioration.[20,21]

* If the patient has COPD, a saturation value of 88%[33] should be considered.
** Systematic laboratory tests (depending on availability): Respiratory specimens for viral assessment of COVID-19, liver function, blood count, other laboratory tests based on local epidemiology (such as influenza, other respiratory infections, dengue, malaria), uroanalysis.[28]

Limitations

- Nail polish, dirt, or artificial nails may cause lower values or may not allow reading.[41]
- Poor perfusion (due to hypotension, hypovolemic shock, or cold environment), movements including trembling, arrhythmias, or heart failure can make it difficult to identify the pulse signal properly and may not allow proper reading.[33,41]
- Very bright artificial light or sunlight can cause erroneous low values.[32,41]
- For SpO_2 values <90%, oxygen saturation may be overestimated, particularly in patients with dark skin tones.[16,32]
- In case of carbon monoxide poisoning, erroneous readings may occur.[41]
- Low-output heart failure causes unreliable or invalid readings.[4]
- Patients with anemia may have a normal SpO_2 but inadequate oxygen supply to tissues.[4]

Optimal device use

Given the problems mentioned above, several steps can be taken to reduce the risks of pulse oximetry and facilitate implementation of home monitoring.

Recommendations for technology implementers in health services

- Hospital systems should only use pocket oximeters approved by a regulatory authority that provide information on pulse signal strength. Smartphone apps are not recommended.[4]
- It should be verified that the oximeter produces valid and consistent values before giving it to a person for home monitoring, particularly patients with peripheral vascular disease.[4]
- Clear instructions should be provided to patients before starting home monitoring. Ensure that warning signs (including saturation thresholds) are properly known and how to proceed in each case. These instructions should be translated into the appropriate languages.[4]
- People should be encouraged to seek care if the overall trend in oxygen saturation over a set time period is descending, even if measured values remain above the established threshold.[20,21]
- Thresholds for seeking care may need to be lowered when monitoring in communities located at higher altitudes.[4]

Recommendations for the user or their caregiver

- When monitoring their saturation at home, people should rest, remain silent, and not speak for several minutes before taking a measurement.[4]
- Values should be taken several times a day and recorded to accurately measure trends in oxygen saturation.[32]
- Device readings should be observed for 30 to 60 seconds and the most frequently presented value should be recorded. Only values associated with a strong pulse signal should be considered.[32]
- Any nail polish should be removed from the finger on which measurements will be taken. [41]
- Cold limbs should be heated before measurement.[41]
- In cases where the oximeter is used by more than one person, it must be cleaned between uses.[33]
- The oximeter can be cleaned by gently rubbing with a damp cloth or alcohol swab.[41]

Section 2. Technological and regulatory specifications

Principle of operation

- Pulse oximeters determine SpO_2 based on the principle of differential light absorption. The device sensor is placed on a region of the body (for example, on a finger or toe, or on the earlobe) and transmits different light wavelengths through the skin to the tissue by means of light-emitting diodes (LED); these wavelengths are differentially absorbed by oxyhemoglobin (HbO2) in the blood, which is red, and deoxyhemoglobin, which is blue. A photodetector also located on the sensor (usually located on the opposite side of the LED) converts the transmitted light into electrical signals proportional to absorbance. The pulse oximeter microprocessor processes the signals and displays the SpO_2 reading.[42]

Types of pulse oximeters

- Depending on the application and sophistication of the design, pulse oximeters can be grouped into three categories:

Finger	- Ultra-compact portable device integrated into a clip that is placed directly on the patient's finger or toe[43,44] - Battery powered[43.44] - Displays the SpO_2 value and can show heart rate[43,44] - Normally intended for personal use and suitable for spot checks.[43.44]
Handheld or portable	- Portable device with digital display to which various sensor sizes can be connected depending on use in adult, pediatric, child, or neonatal patients. - Battery powered. - In addition to displaying numerical values and an SpO_2 waveform, the oximeter can calculate and display other parameters, such as heart rate. - These devices can be used for spot checks, patient triage, or continuous monitoring; in the latter case, the alarm function must be activated.[43.44]
Tabletop	- Stationary device (tabletop, wall-, or pole-mounted) with digital display to which various sensor sizes can be connected depending on use in adult, pediatric, child, or neonatal patients. - Powered by alternating current. - In addition to displaying SpO_2 numerical values, the oximeter can calculate and display other parameters, such as heart rate, electrocardiogram (ECG), capnography, blood pressure, and temperature. - These devices are typically placed next to the patient's bed and include alarm settings and trends, as they are used for patient triage or continuous monitoring.[43,44]

Regulation and standards compliance

- Pulse oximeters are regulated medical devices that must meet specific requirements according to the risk classification assigned by the regulatory authority of the country issuing the market license. For example, in Australia, Canada, Japan, and the European Union they are Class IIb devices and are regulated in accordance with the official provisions for this risk classification.

- In the premarket process, medical devices must comply with the essential principles of safety and performance. To show compliance with these principles, among other requirements, some countries recognize international standards in whole or in part. Appropriate application of these standards can be effective in demonstrating individual safety or performance aspects.[45] Among the examples of these standards are those developed by expert groups belonging to international bodies such as the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). Table 1 details the applicable international standards according to the type of pulse oximeter.[44] They are divided into: 1) standards that apply to the manufacturer and the manufacturing process; and (2) standards that apply to the product. Compliance of pulse oximeters with current versions of these standards is recommended or, where appropriate, with equivalent national standards.

Table 1. International standards applicable to pulse oximeters

Standards applicable to the manufacturer and the manufacturing process

Standard		Finger oximeter	Portable handheld oximeter	Tabletop oximeter
ISO 13485	*Medical devices - Quality management systems - Requirements for regulatory purposes*	•	•	•
ISO 14971	*Medical devices - Application of risk management to medical devices*	•	•	•

Standards applicable to the product.

Standard		Finger oximeter	Portable handheld oximeter	Tabletop oximeter
ISO 80601-2-61	*Medical electrical equipment. Part 2-61: Specific requirements for basic safety and essential performance of pulse oximeter equipment*	•	•	•
IEC 60601-1	*Medical electrical equipment. Part 1: General requirements for basic safety and essential performance*	•	•	•
IEC 60601-1-2	*Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic disturbances. - Requirements and tests*	•	•	•
ISO/IEEE 11073-10404	*Health informatics. Personal health device communication. Part 10404: Device specialization. Pulse oximeter*	•	•	•
IEC 60068-2-31	*Environmental testing: Part 2-31: Tests. Test Ec: Rough handling shocks, primarily for equipment-type specimens*	•		
IEC 62366-1	*Medical devices - Part 1: Application of usability engineering to medical devices*	•		
IEC 62133	*Secondary cells and batteries containing alkaline or other non-acid electrolytes. - Safety requirements for portable sealed secondary cells. Part 1: Nickel systems, Part 2: Lithium systems*	•		

There is a wide variety of pulse oximeters on the market that are **not indicated for medical use**. The Food and Drug Administration (FDA) regulates a group of these devices intended for *general well-being* or *exclusive use in sports and aviation activities* (these categories are known as "Wellness" and "Infrared, Sporting, and Aviation", respectively) and assigns them a moderate level of risk (Class II). It is important to note that the

manufacturer determines the intent of use for this group of oximeters, not the FDA. There is also another group of oximeters on the market labeled for non-medical use that are not part of the latter category and are therefore not regulated by the FDA.

- Tables 2, 3, and 4 show the technical specifications for the three types of pulse oximeters, recommended by WHO and the United Nations Children's Fund (UNICEF) for devices used in oxygen therapy.[43,44] These specifications provide minimum requirements according to the type of oximeter, as well as operational, display, alarm, electrical, and portability characteristics. The accessories included with the oximeter and portability characteristics for each type are also listed. Two years of warranty coverage is ideal. However, if not possible, at least one year is acceptable.

Table 2. Finger Pulse Oximeter: Technical Specifications

General requirements	SpO_2 and pulse rate monitor integrated into the finger/toe clip
	For use in adults and children, and all skin pigmentations
	Suitable for spot checks
	Suitable for detection in low perfusion conditions
	Design must enable use in demanding environments (e.g. shock, vibration)
	Enclosure to have ingress protection level IPX2 or better
	Suitable for cleaning and disinfection
Operational characteristics	SpO_2 detection to include the range: 70-99%
	SpO_2 resolution: 1% or less
	SpO_2 Accuracy (in the range at least 70-99%): within ± 3%
	Pulse rate detection range to include: 30-240 bpm
	Pulse rate resolution: 1 bpm or less
	Pulse rate accuracy within ± 3 bpm
	Internal data storage and/or download of external data, for patient trends and optional event log
	Adults. Configuration required for pediatric patients
Display parameters	SpO_2
	Pulse rate
	Signal quality
	Plethysmography waveform (optional)
	Battery and system status
Alarms	Visual and audible (preferably with volume control)
	High/low SpO_2
	High/low pulse rate
	Sensor error or disconnected
	Low battery
Electrical characteristics	Operated by internal battery
	Batteries must allow at least 2,500 spot checks calculated at 30 seconds per spot check, or at least 21 hours of operation.
	Batteries can be single-use or rechargeable. Batteries may be charged via USB connector or by external AC charger. Rechargeable batteries are preferred.
	If rechargeable, operation must be possible while charging.

	The charger, if used, must have protection against over-voltage and over-current line conditions and be certified according to IEC 60601-1
	Automatic power-off
Portability	Portable
Accessories	1 x carrying/storage case
	2 x spare sets of batteries, if single use type (separately packed)
	1 x neck lanyard for carrying
	1 x replacement flexible cover for patient finger contact (if removable)
Warranty	2 years recommended, at least 1 year mandatory

Table 3. Handheld Pulse Oximeter: Technical Specifications

General requirements	SpO_2 and pulse rate monitor, with plethysmography waveform, for adults, children, and newborns, for all skin pigmentations
	Weight range for each patient category must be stated.
	Suitable for detection in low perfusion conditions
	Automatic correction for movement and ambient light artifacts
	Design must enable use in demanding environments (e.g. shock, vibration)
	Capable of working with, and supplied with, adult, child, infant, and neonatal reusable probes.
	Suitable for cleaning and disinfection
Operational characteristics	SpO_2 detection to include the range: 70-99%
	SpO_2 resolution: 1% or less
	SpO_2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use, and within ± 3% for all patients and perfusion/movement conditions.
	If equipment is capable of a wider SpO_2 detection range, the accuracy over that wider range should be stated.
	Pulse rate detection range to include: 30–240 bpm
	Pulse rate resolution: 1 bpm or less
	Pulse rate accuracy within ± 3 bpm
	Data update period for valid data displayed ≤ 10 s
	Internal data storage and/or download of external data, for patient trends and optional event log
	Data interface, suitable for exporting data to external software (optional)
	Automatic power-off function enabling/disabling, to allow continuous monitoring use.
Display parameters	% SpO_2
	Pulse rate
	Plethysmographic waveform (and possibly other indicators of signal quality)
	Alarm messages
	Battery state indication
Alarms	Visual and audible (preferably with volume control)
	High/low SpO_2, threshold set by user
	High/low pulse rate, threshold set by user
	Sensor error or disconnected
	Low battery

	Alarm override and temporary silencing function.
Electrical characteristics	Operated by replaceable battery power supply, either rechargeable or single use. Devices that operate from rechargeable or both battery types will be preferred.
	External or built-in AC battery charger, if rechargeable type. Plug style as per local supply
	Suitable for operation by battery and by mains power supply, if connected and/or recharging
	Automatic switch between battery and mains powered modes, when recharging or in mains power failure.
	The display shall show which power source is in use.
	Running time on battery only ≥ 12 hours.
Portability	Portable, handheld
Accessories	Case
	To be supplied with reusable probes, adult, pediatric, and neonatal sizes (depending on the intended use), recommended 2 or 3 probes of the needed type, probe cable length (including extender if supplied) > 1 m
	The catalog shall include various sizes, fitting all patients, of clip and wrap-up (silicone, woven fabric, adhesive, and other material/design) probes
Warranty	2 years recommended, at least 1 year mandatory

Table 4. Tabletop Pulse Oximeter: Technical Specifications

General requirements	Allow continuous monitoring of SpO_2, pulse, and plethysmographic curve.
	SpO_2 detection range to include: 70–99%.
	SpO_2 resolution: 1% or less
	SpO_2 accuracy (in the range at least 70–100%): within ± 2% under ideal conditions of use. Accuracy within ± 3% for all patients and blood perfusion/movement conditions
	Indicate whether the equipment can detect a wider range of SpO_2
	Pulse rate detection to include the range: 30–240 bpm.
	Pulse rate resolution: 1 bpm or less
	Pulse rate accuracy within ± 3 bpm
	Data update period ≤ 10 s
	Suitable for detection in low blood perfusion conditions (as per ISO 80601-2-61)
	Automatic correction for movement and ambient light artifacts (as per ISO 80601-2-61).
	Design must enable use in demanding environments (e.g. shock, vibration, crises, etc.)
	Internal data storage, and/or external data download. Allow analysis of trends and event log (optional).
	Capable of working with adult, pediatric, and neonatal reusable probes.
	Enclosure to have ingress protection level IPX2 or better
	Suitable for cleaning and disinfection with hospital grade detergents
Display parameters	SpO_2
	Pulse rate
	Signal quality

	Plethysmography waveform (optional)
	Battery and system status
	Display must allow easy viewing in all ambient light levels.
Alarms	Visual and audible (preferably with volume control)
	High/low SpO_2
	High/Low pulse rate
	Sensor error or disconnected
	Low battery
	Alarm override and temporary silencing function.
Portability	Tabletop
Electrical characteristics	Operated with electrical power supply backed by rechargeable batteries.
	Protection against defibrillator discharges and electrosurgical units
	Rechargeable battery integrated into the main unit
	Automatic switch between battery and mains powered modes, when recharging or in mains power failure.
	Display shows which power source is in use.
	Running time on battery only: ≥ 6 hours
	Operation with electric current: 100-240 V ./50-60 Hz.
	Power cables, plugs, and sockets must match the applicable electric standard of the country in which the equipment is being used.
	Power cable length ≥ 2.5 m.
Warranty	2 years recommended, at least 1 year mandatory

References

1. Wiersinga WJ, Rhodes A, Cheng AC, Peacock SJ, Prescott HC. Pathophysiology, Transmission, Diagnosis, and Treatment of Coronavirus Disease 2019 (COVID-19): A Review. JAMA [Internet]. 10 July 2020 [accessed on 22 July 2020]; Available from: http://www.ncbi.nlm.nih.gov/pubmed/32648899
2. World Health Organization. Pulse oximetry: training material [Internet]. Geneva: WHO; 2011 [accessed on 24 July 2020]. Available from: https://www.who.int/patientsafety/safesurgery/pulse_oximetry/tr_material/en/
3. World Health Organization. Clinical Management of COVID-19 [Internet]. Geneva: WHO; 2020 [accessed on 22 July 2020]. Available from: https://www.who.int/publications/i/item/clinical-management-of-covid-19
4. Luks AM, Swenson ER. Pulse Oximetry for Monitoring Patients with COVID-19 at Home: Potential Pitfalls and Practical Guidance. Ann Am Thorac Soc. 10 June 2020;
5. Xie J, Tong Z, Guan X, Du B, Qiu H, Slutsky AS. Critical care crisis and some recommendations during the COVID-19 epidemic in China. Intensive Care Med [Internet]. 1 May 2020 [accessed on 3 July 2020];46(5):837-40. Available from: https://doi.org/10.1007/s00134-020-05979-7

6. Jouffroy R, Jost D, Prunet B. Prehospital pulse oximetry: a red flag for early detection of silent hypoxemia in COVID-19 patients. Crit Care. 8 June 2020;24(1):313.

7. Gattinoni L, Coppola S, Cressoni M, Busana M, Rossi S, Chiumello D. COVID-19 Does Not Lead to a «Typical» Acute Respiratory Distress Syndrome. Am J Respir Crit Care Med. 15 May 2020;201(10):1299-300.

8. Gattinoni L, Chiumello D, Caironi P, Busana M, Romitti F, Brazzi L, et al. COVID-19 pneumonia: different respiratory treatments for different phenotypes? Intensive Care Med. 1 June 2020;46(6):1099-102.

9. Wilkerson RG, Adler JD, Shah NG, Brown R. Silent hypoxia: A harbinger of clinical deterioration in patients with COVID-19. Am J Emerg Med [Internet]. 2020 [accessed on 3 July 2020]; Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7243756/

10. Tobin MJ, Laghi F, Jubran A. Why COVID-19 Silent Hypoxemia is Baffling to Physicians. Am J Respir Crit Care Med [Internet]. 15 June 2020 [accessed on 1 July 2020]; Available from: http://www.ncbi.nlm.nih.gov/pubmed/32539537

11. Couzin-Frankel J. The mystery of the pandemic's 'happy hypoxia'. Science (80-) [Internet]. 1 May 2020 [accessed on 23 July 2020];368(6490):455-6. Available from: https://pubmed.ncbi.nlm.nih.gov/32355007/

12. Ottestad W, Seim M, Mæhlen JO. Covid-19 med stille hypoksemi. Tidsskr den Nor Laegeforening [Internet]. 21 April 2020 [accessed on 8 July 2020];140(7). Available from: https://www.nakos.no/pluginfile.php/23843/mod_forum/attachment/6066/COVID-19 Prehospital.p

13. Teo J. Early Detection of Silent Hypoxia in Covid-19 Pneumonia Using Smartphone Pulse Oximetry. J Med Syst [Internet]. 19 June 2020 [accessed on 3 July 2020];44(8):134. Available from: http://www.ncbi.nlm.nih.gov/pubmed/32562006

14. Hudson AJ, Benjamin J, Jardeleza T, Bergstrom C, Cronin W, Mendoza M, et al. Clinical interpretation of peripheral pulse oximeters labeled "not for medical use". Ann Fam Med [Internet]. 2018 [accessed on 23 July 2020];16(6):552-4. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6231944/

15. Smith RN, Hofmeyr R. Perioperative comparison of the agreement between a portable fingertip pulse oximeter v. A conventional bedside pulse oximeter in adult patients (COMFORT trial). South African Med J [Internet]. 1 March 2019 [accessed on 23 July 2020];109(3):154-8. Available from: https://pubmed.ncbi.nlm.nih.gov/30834870/

16. Lipnick MS, Feiner JR, Au P, Bernstein M, Bickler PE. The Accuracy of 6 Inexpensive Pulse Oximeters Not Cleared by the Food and Drug Administration. Anesth Analg [Internet]. 1 August 2016 [accessed on 23 July 2020];123(2):338-45. Available from: http://journals.lww.com/00000539-201608000-00009

17. Canadian Agency for Drugs and Technologies in Health (CADTH). Pulse Oximetry Monitoring in Patients at Risk of Hypoxia: An Ultra-Rapid Review of Clinical Utility and Guidelines - CADTH Covid-19 Evidence Portal [Internet]. Ottawa: CADTH, 2020 [accessed on 23 July 2020]. Available from: https://covid.cadth.ca/screening/pulse-oximetry-monitoring-in-patients-at-risk-of-hypoxia-an-ultra-rapid-review-of-clinical-utility-and-guidelines/

18. Gokalp H, Clarke M. Analysis of daily oxygen saturation for detecting deterioration in the condition of COPD patients. En: Proceedings of the Annual International Conference of the IEEE Engineering in Medicine and Biology Society, EMBS. Institute of Electrical and Electronics Engineers Inc.; 2015. p. 6840-3.

19. Kobayashi M, Fukuda S, Takano K, Kamizono J, Ichikawa K. Can a pulse oxygen saturation of 95% to 96% help predict further vital sign destabilization in school-aged children? Medicine (Baltimore) [Internet]. 1 June 2018 [accessed on 28 July 2020];97(25):e11135. Available from: http://journals.lww.com/00005792-201806220-00046

20. Kane B, Decalmer S, O'Driscoll BR. Emergency oxygen therapy: From guideline to implementation. Breathe [Internet]. 1 June 2013 [accessed on 28 July 2020];9(4):247-54. Available from: https://breathe.ersjournals.com/content/9/4/246

21. O'driscoll BR. British Thoracic Society Guideline for oxygen use in adults in healthcare and emergency settings. Open Resp Res. 2017;4:170.

22. Alwadhi V, Sarin E, Kumar P, Saboth P, Khera A, Gupta S, et al. Measuring accuracy of plethysmography based respiratory rate measurement using pulse oximeter at a tertiary hospital in India. Pneumonia [Internet]. December 2020 [accessed on 28 July 2020];12(1). Available from: https://pneumonia.biomedcentral.com/articles/10.1186/s41479-020-00067-2

23. Shah SA, Velardo C, Farmer A, Tarassenko L. Exacerbations in chronic obstructive pulmonary disease: Identification and prediction using a digital health system. J Med Internet Res [Internet]. 1 March 2017 [accessed on 13 July 2020];19(3). Available from: https://pubmed.ncbi.nlm.nih.gov/28270380/

24. Bonnevie T, Gravier FE, Elkins M, Dupuis J, Prieur G, Combret Y, et al. People undertaking pulmonary rehabilitation are willing and able to provide accurate data via a remote pulse oximetry system: a multicentre observational study. J Physiother [Internet]. 1 January 2019 [accessed on 13 July 2020];65(1):28-36. Available from: https://pubmed.ncbi.nlm.nih.gov/30573441/

25. Tesfaye SH, Tesfaye SH, Tesfaye SH, Gebeyehu Y, Loha E, Loha E, et al. Pulse oximeter with integrated management of childhood illness for diagnosis of severe childhood pneumonia at rural health institutions in Southern Ethiopia: Results from a cluster-randomised controlled trial. BMJ Open [Internet]. 21 June 2020 [accessed on 27 July 2020];10(6). Available from: https://pubmed.ncbi.nlm.nih.gov/32565474/

26. World Health Organization. Integrated Management of Childhood Illness (IMCI) [Internet]. Geneva: WHO; 2017 [accessed on 28 July 2020]. Available from: http://www.who.int/maternal_child_adolescent/topics/child/imci/en/

27. Pan American Health Organization. Initial care of persons with acute respiratory illness (ARI) in the context of coronavirus disease (COVID-19) in healthcare facilities: assess the risk, isolate, refer. Interim recommendations, version 1 (12 April 2020) [Internet]. Washington, DC. ; 2020 [accessed on 6 August 2020]. Available from: https://iris.paho.org/handle/10665.2/52031

28. Pan American Health Organization. Flowchart for the Management of Suspected COVID-19 Patients at the First Level of Care and in Remote Areas in the Region of the America, July 2020 [Internet]. Washington, DC. PAHO; July 2020 [accessed on 30 July 2020]. Available from: https://iris.paho.org/handle/10665.2/52577

29. Lauren M. Westafer DMM. Pulse Oximetry in Outpatients with COVID-19. NEJM J Watch [Internet]. 26 June 2020 [accessed on 13 July 2020];2020. Available from: https://www.jwatch.org/NA51896/2020/06/26/pulse-oximetry-outpatients-with-covid-19

30. Shah S, Majmudar K, Stein A, Gupta N, Suppes S, Karamanis M, et al. Novel use of home pulse oximetry monitoring in COVID-19 patients discharged from the emergency department identifies need for hospitalization. Acad Emerg Med [Internet]. 17 June 2020 [accessed on 13 July 2020];acem.14053. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/acem.14053

31. COVID-19 rapid guideline: managing suspected or confirmed pneumonia in adults in the community [Internet]. 2020 [accessed on 2 July 2020]. Available from: https://www. https://www.nice.org.uk/guidance/ng165

32. National Health Service (NHS) England. Pulse oximetry to detect early deterioration of patients with COVID-19 in primary and community care settings [Internet]. [accessed on 2 July 2020]. Available from: https://www.england.nhs.uk/coronavirus/publication/pulse-oximetry-to-detect-early-deterioration-of-patients-with-covid-19-in-primary-and-community-care-settings/

33. Londonwide – Local Medical Committees. Guide to using pulse oximetry during Covid-19 pandemic [Internet]. London, UK; [accessed on 24 July 2020]. Available from:

https://www.lmc.org.uk/visageimages/Covid-19/Guide to using pulse oximeters during Covid-19 pandemic.pdf

34. Coronavirus disease 2019 (COVID-19): Outpatient management in adults - UpToDate [Internet]. [accessed on 2 July 2020]. Available from: https://www.uptodate.com/contents/coronavirus-disease-2019-covid-19-outpatient-management-in-adults

35. Responding to Coronavirus (COVID-19) in Nursing Homes | CDC [Internet]. [accessed on 2 July 2020]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-responding.html

36. McCollum ED, King C, Deula R, Zadutsa B, Mankhambo L, Nambiar B, et al. Pulse oximetry for children with pneumonia treated as outpatients in rural Malawi. Bull World Health Organ [Internet]. 1 December 2016 [accessed on 28 July 2020];94(12):893-902. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5153930/

37. Gifted Oximeters Help Those Infected With COVID-19 Monitor Their Recovery at Home. Internal Medicine [Internet]. [accessed on 30 June 2020]. Available from: https://medicine.yale.edu/intmed/news-article/24711/

38. Should You Really Have a Pulse Oximeter at Home? Yale Medicine [Internet]. [accessed on 13 July 2020]. Available from: https://www.yalemedicine.org/stories/covid-pulse-oximeter/

39. Minnesota Department of Health. Pulse Oximetry and COVID-19 INTERIM GUIDANCE [Internet]. [accessed on 30 June 2020]. Available from: https://www.health.state.mn.us/diseases/coronavirus/hcp/pulseoximetry.pdf

40. Pan American Health Organization / World Health Organization. Clinical management of COVID-19: interim guidance, 27 May 2020. 2020.

41. World Health Organization. Using the Pulse Oximeter [Internet]. Geneva: WHO; 2011 [accessed on 28 July 2020]. Available from: https://www.who.int/patientsafety/safesurgery/pulse_oximetry/who_ps_pulse_oxymetry_tutorial2_advanced_en.pdf?ua=1.

42. ECRI Institute. Pulse Oximetry: Factors to Consider When Choosing a Technology [Internet]. [accessed on 24 July 2020]. Available from: https://www.ecri.org/search-results/member-preview/hdjournal/pages/pulse-oximetry-technology-purchasing-considerations

43. World Health Organization and United Nations Children's Fund. WHO-UNICEF technical specifications and guidance for oxygen therapy devices who medical device technical series [Internet]. 2019 [accessed on 28 July 2020]. Available from: https://apps.who.int/iris/bitstream/handle/10665/329874/9789241516914-eng.pdf?ua=1

44. World Health Organization. COVID-19 Technical specifications for procurement of oxygen therapy and monitoring devices. Geneva: WHO, 2020. [accessed on 28 July 2020]. Available from: https://www.who.int/medical_devices/priority/Tech_Specs_O2_Therapy_monitoring_final_draft.pdf?ua=1

45. Food and Drug Administration (FDA). Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices Guidance for Industry and Food and Drug Administration Staff [Internet]. Maryland, United States of America; 2007 [accessed on 28 July 2020]. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

PAHO/HSS/MT/COVID-19/20-0029