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Pulse Oximetry; Approved Guideline—Second Edition

Pulse oximetry is a widely used device for the clinical assessment of arterial oxygenation and pulse rate. The clinical applications, quality assessment, and limitations are discussed in this guideline.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

Clinical and Laboratory Standards Institute

Advancing Quality in Health Care Testing

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Pulse Oximetry; Approved Guideline—Second Edition

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Abstract

Clinical and Laboratory Standards Institute document POCT11-A2—*Pulse Oximetry; Approved Guideline—Second Edition* provides recommendations for the use of pulse oximeters according to the path of workflow: decisions that need to be made before initiating monitoring; concerns during monitoring; interpretation of the data; and information management. Considerations that should accompany use of these instruments, including a thorough summary of the limitations of existing technology, have also been outlined.

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Foreword

This guideline replaces the original document, HS03-A—*Pulse Oximetry; Approved Guideline,* to focus on the medical use of pulse oximetry devices. The guideline has been expanded to address standard precautions, pulse CO-oximetry, data trending, device interfaces, and patent ductus arteriosus and intercardiac shunt detection. In addition, this edition of the guideline includes illustrations of a revised depiction of the schematic representation of light transmission through tissue, transmittance and reflectance sensors, and a pulse oximetry plethysmograph tracing.

The ease of use, noninvasive nature, and low cost associated with pulse oximeters have resulted in their widespread use in diverse clinical settings by a wide variety of medical personnel, including physicians, nurses, respiratory care practitioners/therapists, paramedics, and other allied health personnel. There are certain principles that should guide the use of these instruments regardless of the setting. Concern has been expressed regarding the general lack of basic understanding by caregivers of the related physiology, technical operation, and limitations of pulse oximetry.[1,2] Some conclude that inadequate knowledge of pulse oximetry could compromise patient safety and contribute to morbidity.[3,4] This document presents guidance for the use of pulse oximeters and is organized on the basis of the path of workflow: decisions that need to be made before initiating monitoring; concerns during monitoring; interpretation of the data; and information management. Considerations that should accompany use of these instruments, including a summary of the limitations of existing technology, are highlighted.

Key Words

Hemoglobin, oximetry, oxygen, oxygen saturation, oxyhemoglobin, oxyhemoglobin saturation

Pulse Oximetry; Approved Guideline—Second Edition

1 Scope

This guideline describes important premonitoring, monitoring, and postmonitoring activities in the path of workflow for pulse oximetry, including clinical applications, quality assessment, and limitations.

This guideline is intended for use by all individuals involved in the path of workflow for pulse oximetry, including physicians, nurses, respiratory care practitioners/therapists, paramedics, clinical equipment services managers and technicians, and other allied health personnel.

The focus of this guideline is to provide guidance on the medical use of pulse oximetry devices. This guideline is not intended to be an examination of pulse oximetry literature or a detailed description of the technology. For this information, refer to the device documentation and review articles.[5-8]

2 Introduction

Multiwavelength laboratory oximeters use spectrophotometric absorption of a blood specimen to determine the percentage of hemoglobin saturated with oxygen and the percentage of dyshemoglobins (DysHbs). The variety of hemoglobins that can be detected by the multiwavelength laboratory oximeters varies by model. Pulse oximetry is a noninvasive method of estimating the arterial oxygen saturation and pulse rate (PR) from pulsatile absorption signals derived from a sensor placed on the skin. The principle is based on the fact that oxyhemoglobin (O_2Hb) and deoxyhemoglobin (HHb) have different absorption spectra (see Figure 1), at the commonly used wavelengths of 660 nm (red light) and 905 to 940 nm (infrared [IR] light).

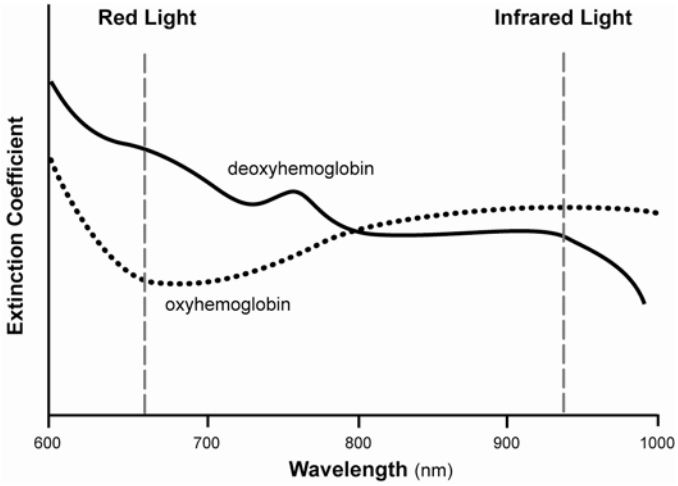

Figure 1. Absorption Spectra of O_2Hb and HHb

The sensor consists of light sources (light-emitting diodes [LEDs]) at the red and IR wavelengths and a photodetector (photodiode). When light from the sensor passes into the tissue, a portion is absorbed and the photodetector measures the residual. A fixed amount of light is absorbed by tissue, including nonpulsatile blood, and a modulating amount is absorbed by the pulsating arterial inflow (see Figure 2).

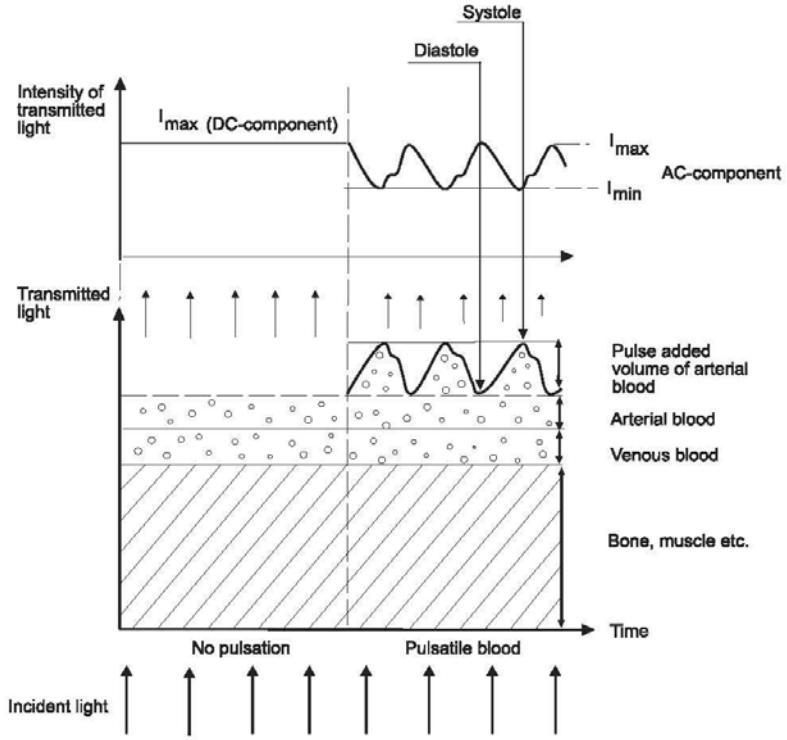

Figure 2. Schematic Representation of Light Transmission Through Tissue. The amount of transmitted light is determined by light absorbed by the static tissue components, which are venous and static arterial blood and bone, muscles, etc., and the pulse added volume of the arterial blood. In the transmitted light, the pulsatile arterial signal (AC) is typically only about 0.5% to 5% from the total transmitted light (DC). Reprinted with permission from GE Healthcare.

The ratio (*R*) is quantitatively related to the oxygen saturation of arterial blood measured in a laboratory oximeter.

$$R = \frac{\mathrm{AC}_{\mathrm{red}}/\mathrm{DC}_{\mathrm{red}}}{\mathrm{AC}_{\mathrm{infrared}}/\mathrm{DC}_{\mathrm{infrared}}}$$

Because the mathematical relationship between oxygen saturation and *R* is not fixed, pulse oximeter manufacturers calibrate their devices empirically using a laboratory oximeter and arterial blood from healthy human volunteers. Two wavelength pulse oximeters are unable to distinguish DysHb due to the inherent limitations of using only two wavelengths of light. But pulse CO-oximeters based on multiple wavelengths of light will report the presence of DysHb and provide measurements of these species. However, unlike multiwavelength laboratory oximeters, they cannot accurately measure these DysHbs at saturation lower than 100% or other DysHbs such as sulfhemoglobin (SulfHb).

Regardless of whether they have the ability to distinguish abnormal hemoglobin species, all currently manufactured noninvasive oximeters (pulse oximeters and pulse CO-oximeters) estimate only functional oxygen saturation.

$$\textit{Functional oxygen saturation} = \frac{O_2\,Hb}{\left(O_2\,Hb + HHb\right)} \bullet 100$$

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI document HS01—*A Quality Management System Model for Health Care.* The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are:

Documents and Records	Equipment	Information Management	Process Improvement
Organization	Purchasing and Inventory	Occurrence Management	Customer Service
Personnel	Process Control	Assessments—External and Internal	Facilities and Safety

POCT11-A2 addresses the QSEs indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Documents and Records	Organization	Personnel	Equipment	Purchasing and Inventory	Process Control	Information Management	Occurrence Management	Assessments—External and Internal	Process Improvement	Customer Service	Facilities and Safety
H11		H11	H11		X C46 H11				H11		H11 M29

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow, which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

POCT11-A2 addresses the clinical laboratory path of workflow steps indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				**Examination**			**Postexamination**	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
C46 H11	C46 H11	C46 H11	C46 H11	C46	C46	X C46	C46	

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

Related CLSI Reference Materials*

C46-A2 **Blood Gas and pH Analysis and Related Measurements; Approved Guideline—Second Edition (2009).** This document provides clear definitions of the quantities in current use, and provides a single source of information on appropriate specimen collection, preanalytical variables, calibration, and quality control for blood pH and gas analysis and related measurements.

H11-A4 **Procedures for the Collection of Arterial Blood Specimens; Approved Standard—Fourth Edition (2004).** This document provides principles for collecting, handling, and transporting arterial blood specimens to assist with reducing collection hazards and ensuring the integrity of the arterial specimen.

M29-A3 **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

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