

JOURNAL OF CLINICAL MONITORING AND COMPUTING

Volume 14 Number 6 August 1998

379-380 *Brief Reviews*

J. S. Gravenstein

Original Articles

381-384 **INFLUENCE OF THE REFERENCE GAS OF PARAMAGNETIC OXYGEN ANALYZERS ON NITROGEN CONCENTRATIONS DURING CLOSED-CIRCUIT ANESTHESIA**

Jan F. A. Hendrickx, MD, Andre A. J. van Zundert, MD, PhD, and Andre M. de Wolf, MD

385-391 **AVAILABILITY OF RECORDS IN AN OUTPATIENT PREANESTHETIC EVALUATION CLINIC**

Gordon L. Gibby, MD, and Wilhem K. Schwab, PhD

393-402 **IN VIVO EVALUATION OF A CLOSED LOOP MONITORING STRATEGY FOR INDUCED PARALYSIS**

Deepak Ramakrishna, MS, Khosrow Behbehani, PhD, PE, Kevin Klein, MD, Jeffrey Mokhtar, MS, Wolf W. von Maltzahn, PhD, PE, Robert C. Eberhart, PhD, and Michael Dollar, MS

403-412 **REFLECTANCE PULSE OXIMETRY - PRINCIPLES AND OBSTETRIC APPLICATION IN THE ZURICH SYSTEM**

Volker König, Renate Huch, and Albert Huch

413-420 **ACCURACY OF VOLUME MEASUREMENTS IN MECHANICALLY VENTILATED NEWBORNS:**

A COMPARATIVE STUDY OF COMMERCIAL DEVICES

Kai Roske, Bertram Foitzik, Roland R. Wauer, and Gerd Schmalisch

421-424 **AN EVOLUTIONARY SOLUTION TO ANESTHESIA AUTOMATED RECORD KEEPING**

Alvin A. Bicker, PhD, John S. Gage, MD, and Paul J. Poppers, MD

425-431 **EVALUATION OF A PITOT TYPE SPIROMETER IN HELIUM/OXYGEN MIXTURES**

Soren Sondergaard, MD, Sigurbergur Kárasón, MD, Stefan Lundin, MD, and Ola Stenqvist, MD

433-439 **DETECTION OF LUNG INJURY WITH CONVENTIONAL AND NEURAL NETWORK-BASED ANALYSIS OF CONTINUOUS DATA**

Jukka Räsänen, MD, and Mauricio A. León, MD

Algorithm

441-446 **A REAL-TIME ALGORITHM TO IMPROVE THE RESPONSE TIME OF A CLINICAL MULTIGAS ANALYSER**

Lawdy Wong, MSc, Ruth Hamilton, MB, ChB, Eileen Palayiwa, PhD, and Clive Hahn, D. Phil

Book Review

447 **L. C. HENSON AND A. C. LEE (EDS): SIMULATORS IN ANESTHESIOLOGY EDUCATION**

Richard Morris

449-450 **INFORMATION FOR CONTRIBUTORS**

KLUWER ACADEMIC PUBLISHERS

OFFICIAL JOURNAL OF THE EUROPEAN SOCIETY

**DOCKET
ALARM**

Find authenticated court documents without watermarks at docketalarm.com.

WESTON LIBRARY

JUL 30 1999

J5/120 CLINICAL MEDICINE
600 HIGHWAY 99, SUITE 100, WISCONSIN, WI 53792

Apple Inc.

APL 1014

JOURNAL OF CLINICAL MONITORING AND COMPUTING

Volume 14 Number 6 August 1998

OFFICIAL JOURNAL OF THE EUROPEAN SOCIETY FOR COMPUTING AND TECHNOLOGY IN ANAESTHESIA AND INTENSIVE CARE (ESCTAIC)
AND OF THE SOCIETY FOR TECHNOLOGY IN ANESTHESIA (STA)

THE PARENT JOURNALS

International Journal of Clinical Monitoring and Computing, founded by Omar Prakash in 1984; Reed Gardner, senior editor; and the

Journal of Clinical Monitoring, founded in 1985 by N. Ty Smith, Allen K. Ream, and J. S. Gravenstein.

EDITORS

Jeffrey M. Feldman, MD
Allegheny University Hospitals, MCP
Dept. of Anesthesiology
3300 Henry Avenue
Philadelphia, PA 19129, U.S.A.
E-mail: FeldmanJ@auhs.edu

J. S. Gravenstein, MD, Coordinating Editor
UF/College of Medicine
Dept. of Anesthesiology
P.O. Box 100254
Gainesville, FL 32610, U.S.A.
E-mail: jgravens@anest2.anest.ufl.edu

Ilkka Kalli, MD, PhD
City Maternity Hospital
Dept. of Anaesthesiology
P.O. Box 61
FIN-00971 Helsinki, Finland
E-mail: ilkka.kalli@iki.fi

Publisher

Kluwer Academic Publishers
P.O. Box 990
3300 AZ Dordrecht, The Netherlands
E-mail: Loes.Wils@wkap.nl

EDITORIAL BOARD

Paul G. Barash, MD
Gerard Bashein, MD, PhD
Charlotte Bell, MD
Jan E. W. Beneken, PhD
J. A. Blom, PhD
J. G. Bovill, MD, PhD
Peter Carstensen
William P. Coleman, PhD
Jeffrey B. Cooper, PhD
John Doyle, MD
Ronald Dueck, MD
Peter C. Duke, MD

Harvey L. Edmonds, MD
John H. Eichhorn, MD
Tammy Y. Euliano, MD
M. Fisher, MD
A. Dean Forbes
Wolfgang Friesdorf, MD
Yasuhiro Fukui, PhD
Leslie Geddes, PhD
Nikolaus Gravenstein, MD
A. Gerson Greenburg, MD, PhD
G. Hedenstierna, MD
Wolfgang Heinrichs, MD
R. C. G. Gallandat Huet, MD
Kazuyuki Ikeda, MD
Ville Jantti, MD
Gavin N. C. Kenny, MD
Samsun Lampotang, PhD
J. W. R. McIntyre, MD
James H. Philip, MD
Michael L. Quinn, PhD
Pradeep Ramaaya, MD
Ira J. Rampil, MD
Gunter Rau, MD
Michael F. Roizen, MD
J.-A. Romand, MD
William B. Runciman, MD
Keith Ruskin, MD
David A. Sainsbury, MD
H. Schillings, MD
John W. Severinghaus, MD
M. Michael Shabot, MD
Dean Forrest Sittig, PhD
Bradley E. Smith, MD
Richard Teplick, MD
Kevin K. Tremper, MD
Jorge Urzua, MD, PhD
Karel H. Wesseling, PhD
Dwayne Westenskow, PhD
J. C. Wyatt, PhD

WESTON LIBRARY

JUL 30 1999

J5/120 CLINICAL SCIENCES CENTER
600 HIGHLAND AV-MADISON, WI 53792

VOLUME 14, 8 ISSUES, 1998

Issues include:

Brief Reviews, Editorials, Clinical Articles, Research Articles, Educational Articles, Book Reviews, Correspondence, Selections from the Anesthesia Patient Safety Foundation Newsletter.

Kluwer Academic Publishers, Dordrecht, Boston, London

Kluwer Academic Publishers Online

Visit our website at <http://www.wkap.nl>

The *Journal of Clinical Monitoring and Computing* is indexed in *Index Medicus*, *Current Contents/Clinical Medicine*, *Excerpta Medica*, *Current Awareness in Biological Sciences*, and the *Biomedical Engineering Citation Index*, and is indexed/abstracted in *Engineering Index*, *Science Citation Index*, *Index Medicus*, *Current Contents/Clinical Medicine*, *Excerpta Medica*, *Current Awareness in Biological Sciences*, and the *Biomedical Engineering Citation Index*.

All rights reserved

ISSN 1387-1307

© 1998 Kluwer Academic Publishers

No part of the material protected by this copyright notice may be reproduced or utilised in any form or by any means, electronic or mechanical, including photocopying, recording or by any information storage and retrieval system, without written permission from the copyright owner.

DOCKET
ALARM

Find authenticated court documents without watermarks at docketalarm.com.

REFLECTANCE PULSE OXIMETRY – PRINCIPLES AND OBSTETRIC APPLICATION IN THE ZURICH SYSTEM

Volker König, Renate Huch, and Albert Huch

König V, Huch R, Huch A. Reflectance pulse oximetry – principles and obstetric application in the zurich system.

J Clin Monit 1998; 14: 403–412

ABSTRACT. Transmission and reflectance are the two main modes of pulse oximetry. In obstetrics, due to the absence of a transilluminable fetal part for transmission oximetry, the only feasible option is the reflectance mode, in which sensor and detector are located on the same surface of the body part. However, none of the reflectance pulse oximeters developed for intrapartum use are fully satisfactory, as indicated by the fact that none have entered routine use. We have designed, developed, constructed and tested a reflectance pulse oximeter with the possibility to adjust the electronic circuits and signal processing in order to determine the effects of various parameters on signal amplitude and wave-form and to optimize the sensitivity and spatial arrangement of the optical elements.

Following an explanation of the principles of reflectance pulse oximetry, we report our experience with the design, development, construction and field-testing of an in-house reflectance pulse oximetry system for obstetric application.

KEY WORDS. Oxygen saturation, reflectance pulse oximetry, intrapartum fetal monitoring.

INTRODUCTION

Pulse oximetry is the combination of spectrophotometry and plethysmography. It permits rapid noninvasive measurement of arterial oxygen saturation with the added advantages of simple sensor application and direct measurement, requiring neither calibration nor pre-adjustment. Pulse oximeters are thus in widespread and fast-increasing use, e.g. in intensive care, anesthetics and neonatology [1]. All these applications employ “transmission” pulse oximetry, so called because the light used to determine blood oxygen saturation is “transmitted” from a light emitter on one side of the body part to a light receiver on the other side; suitable sites are the fingers in adults or hands and feet in neonates or children, which are said to be “transilluminated.”

In obstetrics, fetal oxygen status during labor is a crucial parameter. However, no transilluminable fetal part is available. The only option in this case is reflectance oximetry [2], using a sensor with its light emission and detection elements on the same surface of the body part. Various types of such a reflectance pulse oximeter have been developed for intrapartum use at various locations. However, for a wide variety of reasons, all are still experimental and not in full routine use [3–7].

Basically a reflectance measurement can be achieved using planar sensors – which can be produced, for example, by modifying conventional transmission sen-

From the Perinatal Physiology Research Department, Department of Obstetrics, Zurich University Hospital, CH-8091 Zurich, Switzerland.

Received Nov 13, 1997, and in revised form Jun 23, 1998. Accepted for publication Aug 4, 1998.

Address correspondence to Volker König, Perinatal Physiology Research Department, Department of Obstetrics, Zurich University Hospital, CH-8091 Zurich, Switzerland.

such instruments come with a "black-box" microprocessor-controlled mode of operation making constructional adjustments to the electronic circuits and signal processing virtually impossible. As a result, it becomes difficult to determine the effect of various parameters on signal amplitude and wave-form, optimize sensor sensitivity to light intensity and the arrangement of the optical elements, and hence assess the dependence of arterial oxygen saturation measurement on key physical, technical and above all physiological variables. This was the aim driving our decision to design, develop and construct in-house a system dedicated to obstetric applications.

Following a brief review of the principles of pulse oximetry, we report our experience with the development of the new device, together with some field-testing results.

PRINCIPLES OF PULSE OXIMETRY

Signal recording

Light is absorbed on passing through matter. The degree of absorption depends on the nature of the trans-illuminated material and the wavelength of the light employed. All optical techniques for determining arterial oxygen saturation use the marked difference in the absorption of red light between oxygenated and reduced hemoglobin.

The absorption of light passing through bone or nonpulsatile tissue is constant over time. Oxygenated and reduced hemoglobin in the arterial vascular bed, on the other hand, cause changes in absorption timed by the heart rate due to the pulsatile variation in artery thickness. The total intensity of the light after passing through tissue can be measured, for example, as the photocurrent $I(t)$ of a photodiode, and is obtained from the Lambert-Beer absorption law as:

$$I(t) = I_0 \cdot \exp(-\varepsilon_{\text{tissue}} \cdot s) \cdot \exp(-(SO_2 \cdot \varepsilon_{\text{HbO}} + (1 - SO_2) \cdot \varepsilon_{\text{Hb}}) \cdot d(t)) \quad (1)$$

where

- I_0 intensity of incident light
- $\varepsilon_{\text{tissue}}$ mean absorption coefficient of tissue (function of wavelength)
- s mean thickness of transilluminated tissue
- SO_2 oxygen saturation to be determined (= $\text{HbO}/(\text{HbO} + \text{Hb})$, i.e. ratio of oxygenated hemoglobin concentration to sum of oxygenated and reduced hemoglobin concentrations)
- ε_{HbO} absorption coefficient of oxygenated hemoglobin

- ε_{Hb} absorption coefficient of reduced hemoglobin (function of wavelength)
- $d(t)$ time function of mean pulsatile change in artery thickness, with amplitude $d = d(\text{diastole}) - d(\text{systole})$

Measurement may be impaired by light transmitted directly from the light source to the receiver or light which does not pass through arterially perfused tissue. If this "direct light" I_{dir} is taken into account, Equation (1) changes to:

$$I(t) = I_{\text{tissue}} \cdot \exp(-(SO_2 \cdot \varepsilon_{\text{HbO}} + (1 - SO_2) \cdot \varepsilon_{\text{Hb}}) \cdot d(t)) + I_{\text{dir}} \quad (1a)$$

where

$$I_{\text{tissue}} = I_0 \cdot \exp(-\varepsilon_{\text{tissue}} \cdot s)$$

Since the pulsatile component of the absorption is at most a few percent, i.e. the exponent of the second e function in Equation (1) is very small, we can use the approximation:

$$\exp(x) = 1 + x \quad \text{for } |x| \ll 1$$

to obtain the very close approximation:

$$I(t) = I_{\text{tissue}} \cdot (1 - (SO_2 \cdot \varepsilon_{\text{HbO}} + (1 - SO_2) \cdot \varepsilon_{\text{Hb}}) \cdot d(t)) + I_{\text{dir}} \quad (1b)$$

This light intensity is measured in the photodiodes and can be broken down electronically into two components, a time-independent signal

$$DC = I_{\text{tissue}} + I_{\text{dir}} \quad (2)$$

with amplitude equal to the value of this signal

$$dc = DC = I_{\text{tissue}} + I_{\text{dir}} \quad (3)$$

and a signal which varies in time with the pulsatile change in artery thickness

$$AC = I_{\text{tissue}} \cdot (SO_2 \cdot \varepsilon_{\text{HbO}} + (1 - SO_2) \cdot \varepsilon_{\text{Hb}}) \cdot d(t) \quad (4)$$

with amplitude

$$ac = I(\text{diastole}) - I(\text{systole}) = I_{\text{tissue}} \cdot (SO_2 \cdot \varepsilon_{\text{HbO}} + (1 - SO_2) \cdot \varepsilon_{\text{Hb}}) \cdot d. \quad (5)$$

The ratio between the ac and dc amplitudes is then

$$r = ac/dc = (I_{\text{tissue}} / (I_{\text{tissue}} + I_{\text{dir}})) \cdot (\text{SO}_2 \cdot \varepsilon_{\text{HbO}} + (1 - \text{SO}_2) \cdot \varepsilon_{\text{Hb}}) \cdot d. \quad (6)$$

In the case that "direct light" $I_{\text{dir}} = 0$, this ratio r is independent of the incident light intensity I_0 and of the absorption in the nonpulsating tissue value I_{tissue} :

$$r = ac/dc = (\text{SO}_2 \cdot \varepsilon_{\text{HbO}} + (1 - \text{SO}_2) \cdot \varepsilon_{\text{Hb}}) \cdot d \quad \text{for } I_{\text{dir}} = 0. \quad (6a)$$

This ratio r is then dependent only on the oxygen saturation SO_2 to be determined, the known absorption coefficients ε_{HbO} and ε_{Hb} , and the mean pulsatile change d in the thickness of the arterial vessels in the transilluminated region.

To eliminate this dependence on d , the measurement is performed at two wavelengths with maximally differing absorption coefficients. On the assumption that the d values are the same for both wavelengths, we obtain a variable

$$R = r_{\text{red}}/r_{\text{ir}} = (ac/dc)_{\text{red}}/(ac/dc)_{\text{ir}} \quad (7)$$

$$= (\text{SO}_2 \cdot \varepsilon_{\text{HbO}} + (1 - \text{SO}_2) \cdot \varepsilon_{\text{Hb}})_{\text{red}} / (\text{SO}_2 \cdot \varepsilon_{\text{HbO}} + (1 - \text{SO}_2) \cdot \varepsilon_{\text{Hb}})_{\text{ir}} \quad (7a)$$

from which the unknown SO_2 is readily calculated without knowing the incident light intensity or tissue thicknesses.

Calculation assumes the following physical prerequisites:

- No light must be measured that has not passed through the pulsatile vascular bed e.g. light passing directly from light source to receiver (I_{dir}).
- The pulsatile changes in artery thickness must be the same for both wavelengths, i.e. both wavelengths must transilluminate the same tissue region.
- Valid measurement assumes that the pulsatile signal originates only from varying absorption by arterial oxygenated and reduced hemoglobin. The results are falsified by other causes of pulsatile changes in optical thickness, e.g. hemoglobin derivatives, circulating pigments, pulsatile changes in thickness produced mechanically in nonarterially perfused tissue by cardiac action, and, above all, venous pulsation.
- To simplify description of the principle behind measurement and its limitations, the Lambert-Beer law was assumed valid for the passage of light through tissue. However, as light is not only absorbed in tissue but also scattered, the law is of limited applicability.

However, despite various theoretical models [9, 10], the scatter coefficients of the various tissue types are not known with sufficient accuracy to permit exact calculation. Experimental calibration thus has to be performed by directly comparing the pulse oximeter readings with arterial blood sample values.

Transmission pulse oximetry

The optical elements are located on opposite sides of a body part. The sensors are applied mainly to the fingers and toes. Ears and nose are used only rarely due to poor perfusion. In neonates the sensor is applied around the hand or foot. This arrangement largely ensures that the optical paths are the same for both wavelengths. Nevertheless, incorrect sensor attachment can give spurious results, e.g. if some of the transmitted light reaches the receiving diodes around the outside of a finger as "direct light."

Signal magnitudes are an important determinant of measurement accuracy: in normal fingertips, the ratio of the signal due to absorption in pulsating blood (ac) to the signal due to absorption in total tissue (dc), $r = ac/dc$, is 0.02–0.05.

Reflectance pulse oximetry

In this method the light backscattered in the body is used to determine oxygen saturation. The optical elements are thus located on the same plane on the same body surface. Reflection originates from nonhomogeneity in the optical path, i.e. at the interfaces between materials with different refractive indices. This means that on physiological grounds, strong reflections can be expected on the entry of light into bone. The transilluminated tissue must also be well perfused to obtain as strong a signal as possible. Not all body parts are as well perfused as the fingers or hands, but an ac/dc ratio of 0.001–0.005 can be achieved on the forehead. Perfusion is also good over the sternum. One method of signal enhancement is to heat the measurement site to induce hyperperfusion, which can safely be performed up to 42 °C. A rubefacient, e.g. nicotinic acid (Rubiment), can also be applied to the measurement site.

The principal physical limitations are the following:

- The sensor design must eliminate "direct light," i.e. light passing directly from the light sources to the photodiodes or that is only scattered in the outer part of the skin.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.