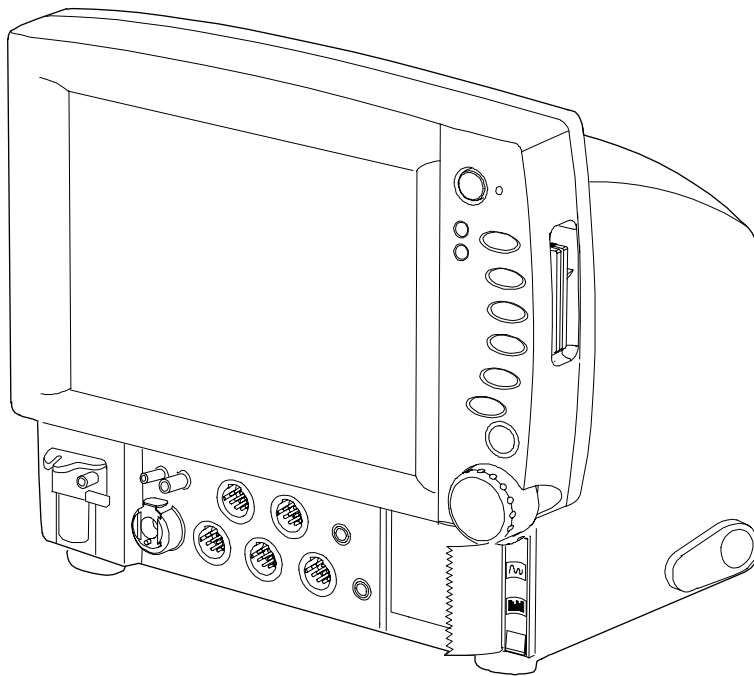


Datex-Ohmeda Cardiocap™/5

Technical Reference Manual



Document Number M1031914

2nd edition

9 May 2007

Datex-Ohmeda, Inc.
P.O. Box 7550, Madison
WI 53707-7550, USA
Tel. +1-608-221-1551
Fax +1-608-222-9147

GE Healthcare Finland Oy
Helsinki, Finland
P.O. Box 900
FI-00031 GE
Tel. +358 10 39411 Fax +358 9 146 3310

www.gehealthcare.com

Copyright © 2007 General Electric company. All rights reserved.

MASIMO 2053
Apple v. Masimo
IPR2024-00296

NOTICE

Intended use

The Datex-Ohmeda Cardiocap/5 and accessories are indicated for indoor monitoring of hemodynamic (ECG, impedance respiration, NIBP, temperature, SpO₂, and invasive pressure), respiratory (CO₂, O₂, N₂O, respiration rate, anesthetic agent, and agent identification), ventilatory (airway pressure, volume, and flow), and relaxation status (NMT) of all hospital patients.

With the N-XOSAT option, monitoring of arterial oxygen saturation includes monitoring hospital patients during conditions of clinical patient motion.

Cardiocap/5 is indicated for patients weighing 5 kg (11 lb.) or more.

Impedance respiration measurement is indicated for patients ages 3 years and older.

The monitor is indicated for use by qualified medical personnel only.

CAUTION: US Federal law restricts this device to sale by or on the order of a licensed medical practitioner. Outside the USA, check local laws for any restriction that may apply.

Classifications

IEC 60601-1:

- Type of protection against electric shock: Class I equipment.
- Degree of protection against electric shock (indicated by a symbol on the panel beside each connector): Type BF applied part or Type CF applied part.
- The equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Mode of operation: Continuous.
- CISPR 11: Group 1, class A

IEC 60529 (degree of protection against harmful ingress of water): IPX1

EU Medical Device Directive: IIb

Responsibility of the manufacturer

GE Healthcare Finland Oy (GE) is responsible for the safety, reliability and performance of the equipment only if:

- Assembly, operation, extensions, readjustments, modifications, service, and repairs are carried out by personnel authorized by GE.
- Electrical installation complies with appropriate requirements.
- The equipment is used in accordance with the Cardiocap/5 User's Guide and serviced and maintained in accordance with the Cardiocap/5 Technical Reference Manual.

GE Healthcare assumes no responsibility for the use or reliability of its software on equipment that is not furnished by GE Healthcare.

Trademarks

Datex®, Ohmeda®, and other trademarks (Cardiocap/5, AS/3, CS/3, S/5, S/5 Light, D-lite, Pedi-lite, D-fend, D-fend+, MemCard, ComWheel, EarSat, FlexSat, OxyTip, Patient O₂, and Patient Spirometry) are trademarks of GE Healthcare Finland Oy.

Nellcor® is a registered trademark of Mallinckrodt Inc.

All other product and company names are the property of their respective owners.

Product availability

Some of the products mentioned in this manual may not be available in all countries. Please, consult your local representative for the availability.

Cardiocap/5 Technical Reference Manual

Part I – General Service Guide

Overview	1
Monitor Structure	
Safety Precautions	
Product Specifications	
Installation and Functional Check	2
Installation	
Interfacing	
Functional Check	
Functional Check Form	
Planned Maintenance	3
Planned Maintenance Instructions	
Planned Maintenance Form	
Troubleshooting	4
Messages	
Troubleshooting Charts	

Part II – Product Service Guide

Frames and Software	5
Hemodynamic Frame (F-MX)	
Hemodynamic with Airway Gases Frame (F-MXG)	
Anesthesia and Critical Care Software	
Measurement Parameters	6
Parameter Unit (NESTPR)	
Invasive Pressures and Second Temperature Option (N-XP)	
Nellcor Pulse Oximetry Option (N-XNSAT)	
Datex-Ohmeda Enhanced Pulse Oximetry Option (N-XOSAT)	
Airway Gas Options (N-XC, N-XCO, N-XCAiO)	
Patient Spirometry Option (N-XV)	
NeuroMuscular Transmission Option (N-XNMT)	
Service Procedures	7
Repair and Replacement	
Checks, Adjustments, and Calibration	
Service Menus	8
Spare Parts	9

Chapter 6. Measurement Parameters

6.1 Introduction	6-1
6.1.1 Hemodynamic parameters and related options	6-1
6.1.2 Airway gases and associated options	6-2
6.2 Measurement principles for hemodynamic parameters	6-3
6.2.1 NIBP	6-3
6.2.2 ECG	6-3
6.2.3 Impedance respiration	6-3
6.2.4 Temperature	6-3
6.2.5 Invasive blood pressure (N-XP option)	6-4
6.2.6 Pulse oximetry, standard	6-4
Plethysmographic pulse wave	6-5
Sensor	6-5
Pulse rate	6-5
6.2.7 Pulse oximetry, Datex-Ohmeda enhanced (N-XOSAT option).....	6-5
Calibration	6-6
6.2.8 Pulse oximetry, Nellcor compatible (N-XNSAT option)	6-7
6.3 Measurement principles for airway gases, spirometry, and NMT	6-8
6.3.1 CO ₂ , N ₂ O, and agent measurement	6-8
6.3.2 O ₂ measurement	6-9
6.3.3 Patient spirometry measurement	6-10
Airway pressure	6-10
Airway flow	6-10
Compliance and airway resistance	6-11
D-lite™ flow sensor	6-11
6.3.4 NeuroMuscular Transmission (NMT) measurement	6-12
Nerve stimulation	6-12
Tetanic/Post-Tetanic Count (PTC)	6-12
Response	6-12
Regional block	6-13
6.4 Components for NESTPR hemodynamic parameters	6-14
6.4.1 Serial communication	6-14
6.4.2 NIBP board.....	6-15
Pressure transducers.....	6-15
Signal processing.....	6-15
Software control.....	6-16
Memory.....	6-16
Watchdog timer	6-16
Valves	6-16
Power supply section.....	6-16
6.4.3 ECG board.....	6-17
Analog ECG section.....	6-18

ECG filtering.....	6-18
Respiration section.....	6-18
Microprocessor section.....	6-19
Isolated section.....	6-19
Power supply section	6-19
6.4.4 STP board.....	6-20
Microprocessor unit.....	6-20
6.4.5 STP board—Pulse oximetry measurement section	6-21
6.4.6 STP board—Temperature measurement section	6-22
6.4.7 STP board—Invasive blood pressure measurement section	6-23
6.5 N-XOSAT or N-XNSAT optional pulse oximetry components	6-24
6.5.1 Datex-Ohmeda enhanced pulse oximetry components (N-XOSAT option).....	6-24
Serial communications connector.....	6-24
Sensor interface connector	6-24
6.5.2 Nellcor pulse oximetry components (N-XNSAT option)	6-25
Communication protocol jumper	6-25
6.5.3 SpO ₂ interface board (for N-XOSAT or N-XNSAT option)	6-26
RS485 drivers.....	6-26
Power supply, non-isolated section.....	6-26
Power supply, isolated section	6-26
Opto isolation	6-27
Microprocessor, UART, nonvolatile memory	6-27
Module bus connector	6-27
Test connector	6-27
6.6 Airway gases and spirometry components.....	6-28
6.6.1 Gas sampling system	6-28
6.6.2 TPX measuring unit.....	6-31
6.6.3 OM measuring unit and board	6-31
OM board	6-31
6.6.4 PVX measuring unit and board (Patient Spirometry, N-XV option)	6-32
PVX board	6-32
6.6.5 Gas unit CPU board	6-32
6.7 NMT components.....	6-34
6.7.1 NMT board.....	6-34
Serial communication.....	6-34
Stimulator.....	6-34
6.7.2 Front panel connector (NMT)	6-35
6.7.3 Module bus connector	6-35

Table of Figures

Figure 6-1. Hemodynamic parameters measurement unit (NESTPR).....	6-1
Figure 6-2. Airway gases measurement unit	6-2
Figure 6-3. Absorption of infrared light in the finger	6-4
Figure 6-4. Comparative light absorption	6-6
Figure 6-5. Extinction versus wavelength graph.....	6-6
Figure 6-6. TPX sensor principle.....	6-8
Figure 6-7. Absorbance of N ₂ O and CO ₂	6-8
Figure 6-8. Infrared absorbance of AAs	6-9
Figure 6-9. O ₂ measurement principle	6-9
Figure 6-10. Principle of response measurement.....	6-12
Figure 6-11. Serial communication and opto isolation	6-14
Figure 6-12. NIBP board functional block diagram.....	6-15
Figure 6-13. ECG board block diagram	6-17
Figure 6-14. STP board block diagram	6-20
Figure 6-15. Pulse oximetry measurement block diagram.....	6-21
Figure 6-16. Temperature measurement principle	6-22
Figure 6-17. Pressure measurement principle	6-23
Figure 6-18. SpO ₂ interface board block diagram.....	6-26
Figure 6-19. Gas sampling system (N-XC option)	6-28
Figure 6-20. Gas sampling system (N-XCO and N-XCAiO options).....	6-29
Figure 6-21. Gas tubing layout	6-30
Figure 6-22. TPX measuring unit.....	6-31
Figure 6-23. OM measuring unit.....	6-31
Figure 6-24. PVX measuring unit	6-32
Figure 6-25. Signal processing.....	6-33
Figure 6-26. Control logic	6-33
Figure 6-27. Calibration data stored in EEPROM	6-33
Figure 6-28. NMT serial communication and opto isolation	6-34
Figure 6-29. NMT stimulator block diagram.....	6-34

6. MEASUREMENT PARAMETERS

6.1 Introduction

This chapter provides information about the Cardiocap/5 standard measurement features and all measurement options.

6.1.1 Hemodynamic parameters and related options

The Cardiocap/5 Parameter unit (NESTPR) provides measurement of general hemodynamic parameters.

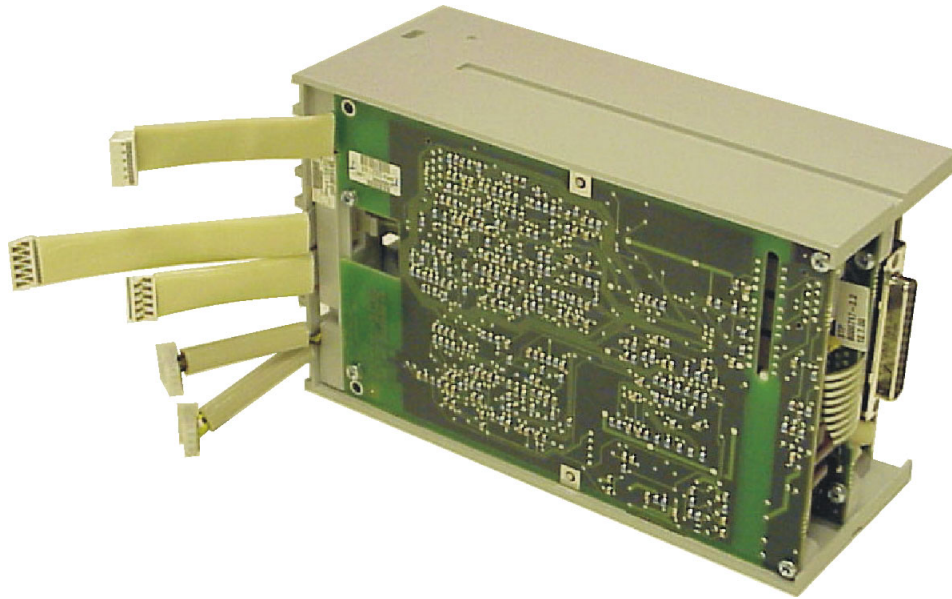


Figure 6-1. Hemodynamic parameters measurement unit (NESTPR)

NESTPR represents the measurement parameters listed below:

N = Non-invasive blood pressure (NIBP)

E = ECG

S = Pulse oximetry (oxygen saturation and pulse rate)

T = Temperature (T1)

P = Invasive blood pressure (N-XP option)—two channels (P1, P2) and a second temperature (T2)

R = Impedance respiration

The pulse oximetry options listed below require hardware and processing that is not part of the NESTPR unit:

- Datex-Ohmeda enhanced pulse oximetry (N-XOSAT option).
- Nellcor® compatible pulse oximetry (N-XNSAT option).

6.1.2 Airway gases and associated options

The Cardiicap/5 Airway Gas options (N-XC, N-XCO, N-XCAiO) provide airway and respiratory measurements through the airway gas measurement unit.

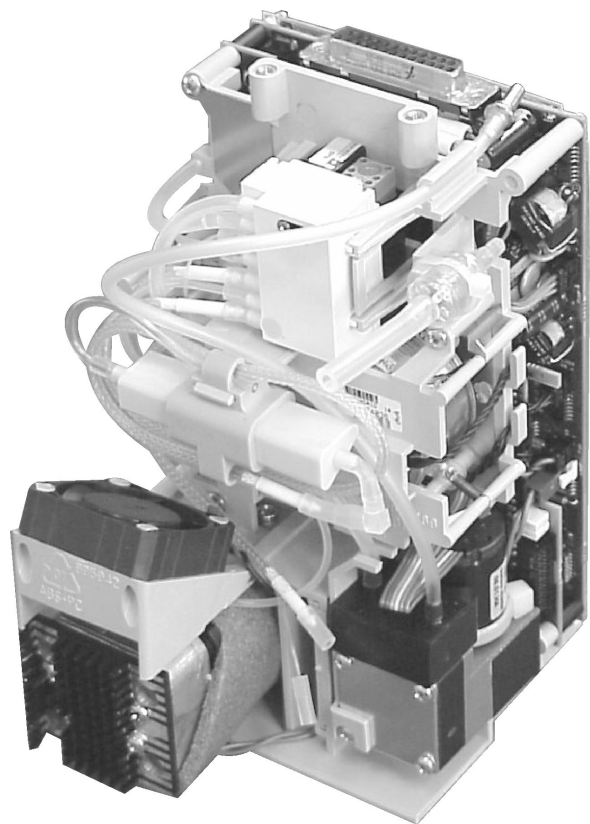


Figure 6-2. Airway gases measurement unit

The features of each option are noted in the chart below.

NOTE: One or more of the airway gas options is required for the Patient Spirometry (N-XV) and NeuroMuscular Transmission (N-XNMT) options.

Option	CO ₂	N ₂ O	O ₂	Anesthetic Agents	Anesthetic Agent id	Patient Spirometry	NeuroMuscular Transmission
N-XC	•						
N-XCO	•	•	•				
N-XCAiO	•	•	•	•	•		
N-XV *						•	
N-XNMT **							•

* Requires N-XCO or N-XCAiO.

** Requires N-XCAiO.

6.2 Measurement principles for hemodynamic parameters

6.2.1 NIBP

NIBP (Non-Invasive Blood Pressure) is an indirect method for measuring blood pressure.

The NIBP measurement is performed according to the oscillometric measuring principle. The cuff is inflated with a pressure slightly higher than the presumed systolic pressure and deflated at a speed based on the patient's pulse. Data are collected from the oscillations caused by the pulsating artery. Based on these oscillations, values for systolic, mean, and diastolic pressures are calculated.

6.2.2 ECG

Electrocardiography analyzes the electrical activity of the heart by measuring the electrical potential produced with electrodes placed on the surface of the body.

ECG reflects

- Electrical activity of the heart.
- Normal/abnormal function of the heart.
- Effects of anesthesia on heart function.
- Effects of surgery on heart function.

See the *User's Reference Manual* for electrode positions and other information.

6.2.3 Impedance respiration

Impedance respiration is measured across the thorax between three ECG electrodes. The respiration signal is made by supplying current between two electrodes and by measuring the differential current from the third electrode. The input current is 200 μ A (31 kHz). The impedance measured is the impedance change caused by breathing. When the patient is breathing or is ventilated, the volume of air in the lungs changes, resulting in impedance between the electrodes. From these impedance changes, the respiration rate is calculated and the respiration waveform is displayed on the screen.

6.2.4 Temperature

Temperature is measured by a probe whose resistance varies when the temperature changes, called NTC (Negative Temperature Coefficient) resistor.

The resistance can be measured by two complementary methods:

- Applying a constant voltage across the resistor and measuring the current that flows through it.
- Applying a constant current through the resistor and measuring the voltage that is generated across it.

The two methods are combined in the form of a voltage divider. The NTC resistor is connected in series with a normal resistor and a constant voltage is applied across them. The temperature dependent voltage can be detected at the junction of the resistors, thus producing the temperature signal from the patient. The signal is amplified by analog amplifiers and further processed by digital electronics.

6.2.5 Invasive blood pressure (N-XP option)

A catheter is inserted into an artery or vein to measure invasive blood pressure. The invasive pressure setup—consisting of tubing, a pressure transducer, and an intravenous bag of normal saline all connected together by stopcocks—is attached to the catheter. The transducer is placed level with the heart and electrically zeroed.

The transducer is a piezo-resistive device that converts the pressure signal to a voltage. The monitor interprets the voltage signal so that pressure data and pressure waveforms can be displayed.

6.2.6 Pulse oximetry, standard

NOTE: Only one pulse oximetry source at a time is allowed by the Cardiicap/5. When the N-XOSAT or N-XNSAT option is installed in the monitor, standard Cardiicap/5 pulse oximetry is not available.

A pulse oximeter measures the light absorption of blood at two wavelengths, one in the near infrared (about 900 nm) region and the other in the red region (about 660 nm) of the light spectrum. These wavelengths are emitted by LEDs in the SpO_2 sensor. The light is transmitted through peripheral tissue and is detected by a PIN diode opposite to the LEDs in the sensor. The pulse oximeter derives the oxygen saturation (SpO_2) using an empirically-determined relationship between the relative absorption at the two wavelengths and the arterial oxygen saturation, SaO_2 .

To measure the arterial saturation accurately, pulse oximeters use the component of light absorption giving variations synchronous with heart beat as primary information on the arterial saturation.

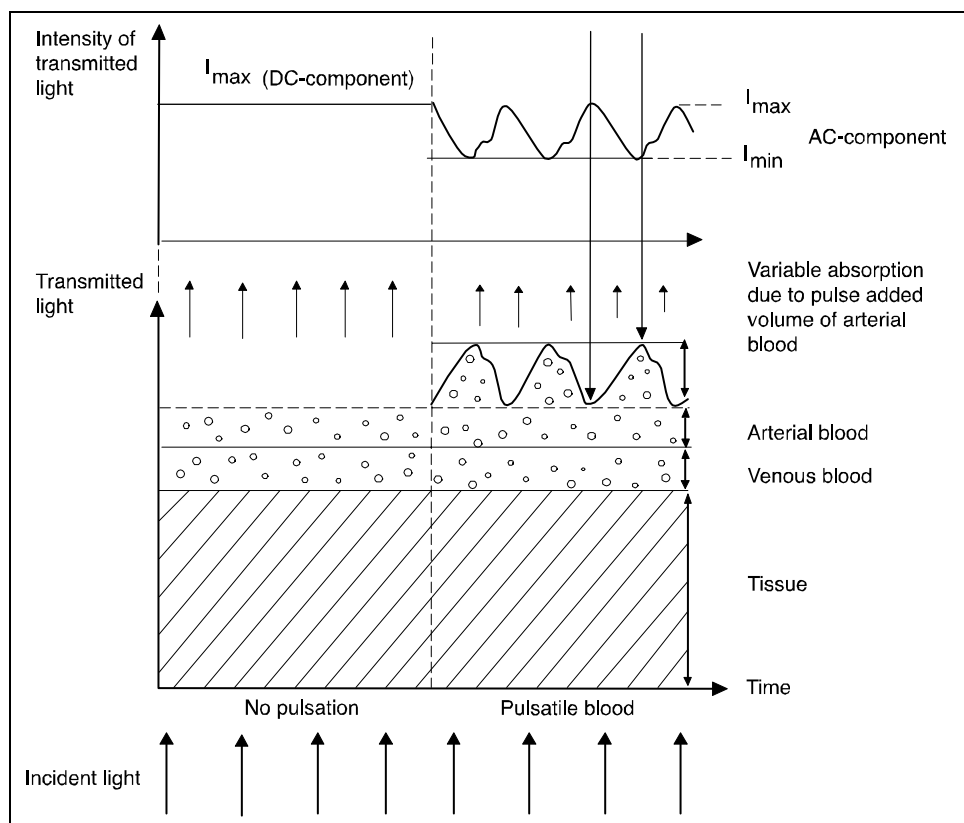


Figure 6-3. Absorption of infrared light in the finger

A general limitation of the above pulse oximetry principle is that due to the use of only two wavelengths, only two hemoglobin species can be discriminated by the measurement.

Modern pulse oximeters are empirically calibrated against fractional saturation (SaO_2frac) or against functional saturation (SaO_2func) as shown below:

$$\text{SaO}_2\text{frac} = \text{HbO}_2 / (\text{HbO}_2 + \text{Hb} + \text{Dyshemoglobin})$$

$$\text{SaO}_2\text{func} = \text{HbO}_2 / (\text{HbO}_2 + \text{Hb}).$$

Functional saturation (SaO_2func) is less sensitive to changes of carboxyhemoglobin and methemoglobin concentrations in blood.

The oxygen saturation percentage SpO_2 is calibrated against the functional saturation (SaO_2func). The advantage of this method is that the accuracy of SpO_2 measurement relative to SaO_2func can be maintained even at rather high concentrations of carboxyhemoglobin in blood. Independent of the calibration method, a pulse oximeter is not able to correctly measure oxygen content of the arterial blood at elevated carboxyhemoglobin or methemoglobin levels.

Plethysmographic pulse wave

The plethysmographic waveform is derived from the IR signal and reflects the blood pulsation at the measuring site. Thus the amplitude of the waveform represents the perfusion.

Sensor

SpO_2 sensors contain the light source LEDs, which are located opposite the photodiode detector. Different kinds of sensors are available from GE Healthcare, including clip-on and wrap styles.

Pulse rate

The pulse rate calculation is done by peak detection of the plethysmographic pulse wave. The signals are filtered to reduce noise and checked to separate artifacts.

6.2.7 Pulse oximetry, Datex-Ohmeda enhanced (N-XOSAT option)

NOTE: Only one pulse oximetry source at a time is allowed by the Cardiocap/5. When the N-XOSAT option is installed in the monitor, standard pulse oximetry and N-XNSAT are not available.

The Datex-Ohmeda enhanced pulse oximetry option uses a two-wavelength pulsatile system—red and infrared light—to distinguish between oxygenated (O_2Hb) and reduced (HHb) hemoglobin, each of which absorbs different amounts of light emitted from the oximeter sensor. The SpO_2 and pulse rate are determined by the oximeter through sensor signal processing and microprocessor calculations.

The SpO_2 sensor contains a light source and a photodetector:

- The light source consists of red and infrared light-emitting diodes (LEDs).
- The photodetector is an electronic device that produces an electrical current proportional to incident light intensity.

The two light wavelengths generated by the sensor light source (the red and infrared LEDs) pass through the tissue at the sensor site. The light is partially absorbed and modulated as it passes through the tissue.

Arterial blood pulsation at the sensor site modulates transmission of the sensor's light. Since other fluids and tissues present generally don't pulsate, they don't modulate the light passing through that location. The pulsatile portion of the incoming signal is used to detect and isolate the attenuation of light energy due to arterial blood flow.

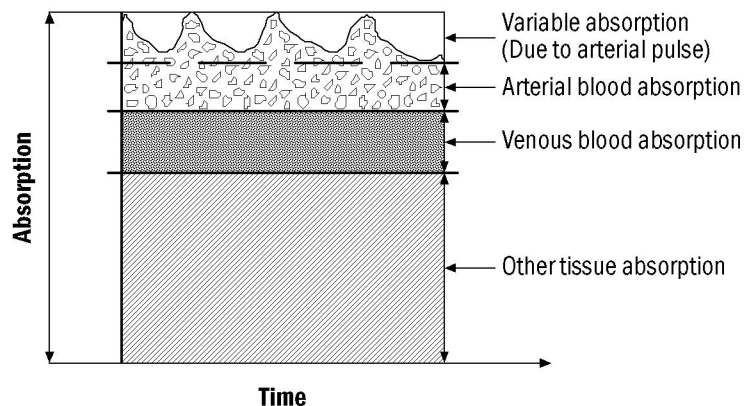


Figure 6-4. Comparative light absorption

The sensor's photodetector collects and converts the light into an electronic signal. Since O_2Hb and HHb allow different amounts of light to reach the photodetector at the selected wavelengths, the electronic signal varies according to which light source is "on" (red or infrared) and the oxygenation of the arterial hemoglobin. The oximeter uses this information to calculate the relative percentage of O_2Hb and HHb .

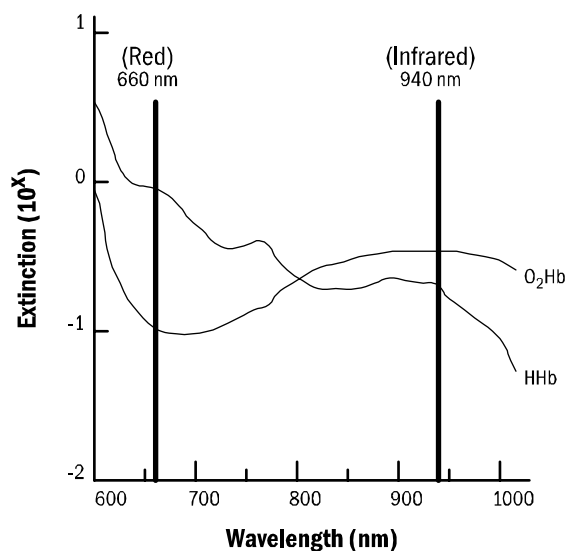


Figure 6-5. Extinction versus wavelength graph

The photodetector sends the electronic signal, which contains the light intensity information, to the oximeter. The oximeter's electronic circuitry processes the electronic signal, calculates the SpO_2 and pulse rate values, and displays them on the screen.

Calibration

Datex-Ohmeda enhanced pulse oximetry uses two wavelength ranges, 650 nm to 665 nm and 930 nm to 950 nm, both with an average power of less than 1 mW. These wavelengths are used to calculate the presence of oxyhemoglobin (O_2Hb) and reduced hemoglobin (HHb).

A CO-oximeter typically uses four or more wavelengths of light and calculates reduced hemoglobin (HHb), oxyhemoglobin (O₂Hb), carboxyhemoglobin (COHb), and methemoglobin (MetHb). Therefore, pulse oximetry readings and CO-oximetry readings will differ in situations where a patient's COHb or MetHb are increased. Increased patient COHb leads to falsely increased SpO₂ in all pulse oximeters.

Datex-Ohmeda enhanced pulse oximetry uses functional calibration, which is represented mathematically as the percentage of hemoglobin capable of carrying oxygen that is carrying oxygen.

$$\text{Functional SpO}_2 = \left(\frac{\text{O}_2\text{Hb}}{\text{Hb}_{\text{TOTAL}} - \text{COHb} - \text{MetHb}} \right) \times 100 = \left(\frac{\text{O}_2\text{Hb}}{\text{O}_2\text{Hb} + \text{HHb}} \right) \times 100$$

The calculation of SpO₂ assumes 1.6% carboxyhemoglobin (COHb), 0.4% methemoglobin (MetHb), and no other pigments. These values are based on the Datex-Ohmeda Pulse Oximeter Empirical Calibration Study. Appreciable variation from these values will influence SpO₂ accuracy.

6.2.8 Pulse oximetry, Nellcor compatible (N-XNSAT option)

NOTE: Only one pulse oximetry source at a time is allowed by the CardiCap/5. When the N-XNSAT option is installed in the monitor, standard pulse oximetry and N-XOSAT are not available.

The N-XNSAT pulse oximetry option uses the Nellcor pulse oximetry algorithm and should be used with Nellcor pulse oximetry sensors only. Refer to the *CardiCap/5 User's Reference Manual* for a list of Nellcor sensors approved for use with this option.