Clinical and Product Information Package

Noninvasive, Field-based Measurement of Carbon Monoxide Levels in the Blood
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Overview of CO Poisoning

Carbon monoxide (CO) is a colorless, odorless, and poisonous gas that unnecessarily kills and permanently harms thousands of people each year. It is the leading cause of poisoning deaths in industrialized countries, accounting for more than half of all fatal poisonings in virtually every country throughout the world.1 Making CO poisoning a major public health concern. In the United States alone, it is estimated that 50,000 emergency poisoning cases are treated each year. In the United States, CO poisoning is the leading cause of poisoning deaths in industrialized countries, accounting for more than half of all fatal poisonings in virtually every country throughout the world.1, making CO poisoning a major public health concern.

Carbon monoxide (CO) is a colorless, odorless, and poisonous gas that unnecessarily kills and permanently harms thousands of people each year. It is the leading cause of poisoning deaths in industrialized countries, accounting for more than half of all fatal poisonings in virtually every country throughout the world.1, making CO poisoning a major public health concern.

Because of the insidious nature of CO, many states are now putting into effect legislation that mandates the installation and maintenance of CO alarms in residential structures. This increase in legislation has led to a subsequent increase in fire department responses to activated CO alarms.2 Cases of CO poisoning often increase following disasters. Unintentional, non-fire-related CO poisoning is the leading cause of morbidity and mortality following disasters such as hurricanes, severe winter storms, and floods. Power outages as a result of these events that occur both during the disaster and post-disaster clean-up are primarily responsible for a large number of fatal and non-fatal CO poisoning cases, because of improper use of portable gas-powered generators. Incidence of unintentional, non-fire-related CO poisoning are also highly seasonal. Significant variation has been found in colder months, with increased incidence in October, November, December, January, and March. The peak of CO poisoning incidents tend to occur during December.4

CO — Implications for Emergency Responders

Firefighters, paramedics, and other emergency responders are at an increased risk of exposure to CO because of the nature of their duties. Carbon monoxide poisoning puts firefighters at significant risk at the scene of a fire. Even mild CO poisoning causes mental confusion which can lead to poor decision making, putting both the exposed firefighter and others on the fire scene at risk.5 Mild CO poisoning can also rob the heart and brain of oxygen – nearly 50% of line of duty firefighter deaths are attributed to heart disease or stroke.6 In addition to the immediate dangers, CO poisoning significantly increases long-term health risks. Just one severe CO poisoning almost doubles the risk of premature death, and consistent exposure to CO may cause long-term heart and brain damage.7,8

Any time these personnel respond to an incident where smoke is present, they are at risk of exposure to CO — especially at the scene of a structure fire. Research from Underwriters Laboratories has indicated that CO is a dominant gas in fire smoke and another study has shown CO to be the most common air contaminant when a fire is being extinguished. In addition, smoke production from fires has increased with the increased use of synthetic materials in modern construction.9,10 In small-scale tests, all materials that were burned released CO. In large-scale and field testing, during various stages of fire from growth to overhaul, CO concentrations often exceed recommended exposure limits set by NIOSH and OSHA, reinforcing the need for firefighters to be monitored for CO poisoning.11 Ambient levels of CO during structure fires often exceed 500 parts per million (ppm), which is more than twice the short-term exposure limit of 200 ppm. Ambient CO levels have been measured as high as 27,000 ppm.12

In addition to CO on the fire ground, fire department responses to CO alarms are increasing each year,2 while ambient air monitoring may be performed upon arrival of fire department or EMS personnel. It is critical for responders to be equipped with tools to monitor occupants at the scene for CO exposure. Even if firefighters test the air and no CO is detected, the potential still exists for CO to sources to be present because of improper use of gas meters, malfunctioning meters, or the elimination of CO through a recently opened door or window. During responses to CO alarms, monitoring both the air and the occupants is important for determining whether an actual exposure has occurred.

Heart attacks and strokes among firefighters continue to be the leading cause of line of duty deaths (LODDs). In 2012, cardiovascular events accounted for more than half (51.8%) of all LODDs.13 A report published by the National Institute for Occupational Safety and Health (NIOSH) recommended methods to reduce these preventable deaths, including following established medical screening guidelines and controlling exposure to CO. This report also highlights findings demonstrating that fatal heart attacks suffered by firefighters while on-duty are far more likely to be work-related.14 Other studies have determined a direct link between moderate to severe CO poisoning and damage to the heart, and their findings demonstrated that victims of CO poisoning have substantially increased long-term mortality.15,16
Measuring CO in the Blood

Timely identification of CO poisoning is critical but challenging based on signs and symptoms alone and is frequently unrecognized. CO levels in the blood have historically been measured using a laboratory CO-Oximeter. Up to 50% of hospitals do not have on-site laboratory COHb testing capability. In the prehospital setting, CO measurement via arterial blood gas analysis is not feasible.

In 2005, Masimo introduced rainbow® Pulse CO-Oximetry,™ a continuous and noninvasive method of measuring the levels of carbon monoxide in the blood (SpCO), making it feasible to perform measurement on-scene. Thousands of fire departments, EMS agencies, and emergency departments around the world routinely utilize this technology to assess firefighters and the public for CO exposure in the field. A survey of fire departments and EMS agencies in major metropolitan areas across the United States showed that 89% currently have SpCO measurement capabilities or planned to implement the technology within twelve months.

Rad-57 with SpCO™

The Masimo Rad-57 is a handheld Pulse CO-Oximeter that noninvasively measures COHb saturation (SpCO) in addition to oxygen saturation (SpO2), pulse rate (PR), and perfusion index.* The Rad-57 enables providers to quickly and noninvasively measure COHb levels of firefighters, EMS personnel, or civilians at the scene of a fire, during CO alarm responses, or at any incident where an individual may have been exposed to CO.

The Rad-57 uses more than 7 wavelengths of light and a noninvasive finger sensor to acquire data based on the absorption of light. Advanced signal processing algorithms and unique adaptive filters work together to isolate and identify the various types of hemoglobin, and the blood measurement results are then displayed numerically.

Rad-57 Product Features and Specifications

SpCO – Noninvasive Carboxyhemoglobin

SpCO is a breakthrough measurement that allows providers to noninvasively and immediately measure CO in the blood. SpCO measurement should not be used as a substitute for laboratory CO measurement, but SpCO can help clinicians by supplementing laboratory CO measurement.

Accuracy:

In comparisons of SpCO readings with invasive COHb measurements taken at the same time and analyzed by a laboratory CO-Oximeter, SpCO was validated by Masimo in the range of 1-40% with an accuracy of +3% at 1 standard deviation.* Independent investigations have also validated SpCO accuracy. Investigations that do not follow the SpCO directions for use or do not compare SpCO to simultaneous laboratory CO measurements may have varying results. All known SpCO studies are available at www.masimo.com.

Masimo SpCO also Available on the Following Products:

- Physio-Control LIFEPAK 15
  http://www.physio-control.com/LIFEPAK15/
- ZOLL E Series
  http://www.zoll.com/medical-products/defibrillators/e-series/
- ZOLL X Series
  http://www.zoll.com/medical-products/defibrillators/x-series/

SpCO Clinical Benefits

> SpCO has been shown to help clinicians recognize 64% more cases of CO poisoning in emergency patients.
> Even when patients present with a headache, SpCO has been shown to help clinicians recognize 29% more cases of CO poisoning.
> SpCO has been shown to help clinicians achieve faster recognition and treatment of CO poisoning.
> SpCO has been shown to protect the public helping first responders identify hidden sources of CO in households, workplaces, schools.

Populations That May Benefit from SpCO Assessment

> Individuals on the fire scene with potential CO exposure
> Workers at increased risk of occupational CO exposure
> Individuals presenting with nonspecific symptoms or illness

*...there is clear evidence that noninvasive measurement of SpCO has been instrumental in identifying patients with unsuspected CO poisoning and hidden sources of CO. This device is an important tool for public health.* Suner et al.

SpCO Accuracy *

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*Masimo FDA Submission Data
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1. Light Emitting Diodes (LEDs) (7+ wavelengths)
2. Detector

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2. Detector
Rad-57 Pulse CO-Oximeter

Product Overview:

- Quick and easy-to-use — no user calibration and does not require patient cooperation or consciousness
- Complete replacement for existing handheld pulse oximeters, with factory-ordered options or simple field-installed software upgrades to continuous monitoring and spot-check measurements of SpCO, noninvasive methemoglobin (SpMet), noninvasive total hemoglobin (SpHb), oxygen content (SpO2), and Plieth Variability Index (PVI)
- Rugged and lightweight — ideal for both field and hospital settings
- Awarded Airworthiness Release Certification by the United States Army

Features:

- User may program default power-up settings
- Delivers more than 110 hours of continuous battery life
- Up to 72 hours of trending memory
- FastSat tracks rapid changes in arterial O2 with unmatched fidelity
- SmartTone™ beeps in sync with pulse, even under patient motion conditions (user can disable)
- Sensitivity options of APOD™, Normal, and MAX provide flexibility to support a range of clinical applications

Accessories:

- Both Adult and Pediatric reusable sensors available
- Disposable/adhesive sensors available for all patient populations
- Ambient light shield to help prevent external light interference
- Rugged, water-resistant carry case
- Quick Reference Guide — includes basic operations, troubleshooting, sample protocols
- Training DVD

Performance

**MEASUREMENT RANGE**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO2 (%)</td>
<td>0–100%</td>
</tr>
<tr>
<td>SpCO (%)</td>
<td>0–49%</td>
</tr>
<tr>
<td>SpHb (g/dL)</td>
<td>8–17</td>
</tr>
<tr>
<td>PVI (%)</td>
<td>1–99%</td>
</tr>
<tr>
<td>Pulse Rate (bpm)</td>
<td>25–240</td>
</tr>
</tbody>
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**ARTERIAL OXYGEN SATURATION ACCURACY**

- Adults, Infants, Pediatrics: ±3%
- Adults, Infants, Pediatrics, Neonates: ±5%
- Adults, Infants, Neonates: ±7%
- Adults, Infants: ±10%
- Adults: ±20%

**CARBON MONOXIDE SATURATION ACURACY (%SpCO)**

- Adults, Infants, Pediatrics, Neonates: ±3%
- Adults, Infants, Pediatrics, Neonate: ±5%
- Adults, Neonates: ±7%

**METHEMOGLOBIN SATURATION ACCURACY (%SpMet)**

- Adults, Infants, Pediatrics: ±1–15%
- Adults, Infants, Pediatrics, Neonates: ±15%
- Adults, Infants: ±20%
- Adults: ±30%

**MOTION**

- Adults: ±3%
- Infants, Children: ±5%
- Neonates: ±7%

**SPECIFICATIONS**

- **Batteries**
  - Type: 4 AA Alkaline
  - Capacity: up to 8 hours
- **Environmental**
  - Operating Temperature: 0–120°F (16–50°C)
  - Storage Temperature: 0–158°F (−20–70°C)
  - Operating Humidity: 15–95%, non-condensing
  - Operating Altitude: 500–1060 mbar pressure, ≤5 degrees Fahrenheit due to alkaline battery technology
- **Dimensions**
  - Handheld: 7 x 3 x 1 1/2 (15 cm x 7.6 cm x 3 1/2 cm)
  - Weight: Handheld: 12 oz (340 g), Handheld (with battery): 12 oz (340 g)
- **Accuracy**
  - Provides 72 hours of trending at 2-second resolution of SpO2, SpCO, SpMet, SpHb, Pulse Rate, Perfusion Index, and PVI. Output to PC running Masimo TrendCom™ utility.

Extended Warranty – MasimoCare™ Protection+

All Masimo equipment comes standard with a one-year limited warranty (6 months on sensors), but in an environment as rugged and demanding as Fire and EMS, having additional protection for your devices helps ensure you’re never without the ability to test for CO exposure. Although Masimo has a reputation for building reliable equipment designed for the medical environment, accidental damage to equipment is unpredictable. Additionally, major repairs may take a device out of service because of high or unpredictable repair costs. MasimoCare Protection+ helps protect your equipment and your budget, and helps keep your devices in service – where you need them.

Features:

- Covers damage outside of standard warranty: e.g., damage from unplanned events, including an unintentional drop or liquid intrusion
- Provides Rad-57 owners full replacement coverage for SpCO sensors with a paid deductible
- Covers any damage to the sensor, excluding loss or theft
- Provides expedited service when getting equipment back in service is critical
- Includes a fully refurbished replacement or a loaner unit shipped next business day for a nominal per-event charge
When justifying an investment in any new piece of equipment it’s important to understand how it will help satisfy national standards, and improve interoperability between departments by standardizing regions or agencies. The capabilities of the Rad-57 have been recognized in multiple standards and included on widely-used standardized equipment lists. The U.S. Military has also made the Rad-57 its pulse oximeter of choice and validated the ruggedness and reliability of the device through certifications from numerous branches.

**NFPA 1584 — Firefighter Rehabilitation**

In 2008, the National Fire Protection Association upgraded the guidelines for firefighter rehabilitation to a national Standard with the release of NFPA 1584: Standard on the Rehabilitation Process for Members during Emergency Operations and Training Exercises. This Standard made medical monitoring a requirement of firefighter rehab in order to observe personnel for potential adverse health effects. One form of medical monitoring supported by NFPA 1584 is the use of on-scene CO monitoring. While it may soon be a requirement, the current version of the Standard recommends that “any firefighter exposed to CO or presenting with headache, nausea, shortness of breath, or gastrointestinal symptoms at an incident where CO is present should be assessed for CO poisoning.”

**FEMA Preparedness Grants Authorized Equipment List (AEL) and Standardized Equipment List (SEL)**

The Rad-57 is included on both the AEL and SEL and satisfies multiple capabilities listed on the Core Capabilities List. The Federal Emergency Management Agency (FEMA) Grant Programs Directorate publishes the Authorized Equipment List (AEL), which provides information on allowable equipment expenditures. All Homeland Security Grant Programs utilize the AEL. The Standardized Equipment List (SEL) is produced by the InterAgency Board for Equipment Standardization and Interoperability (IAB). The SEL contains minimum equipment recommendations for response to WMD incidents. It includes recommended features and operating considerations.

**AEL/SEL Number: 09ME-03-BCNI**

**Title:** Monitor, Blood Chemistry, Non-Invasive

**Description:** Non-invasive medical device used to monitor blood levels of substances such as methemoglobin and carboxyhemoglobin.

**Important Features:** May be combined with other functions such as pulse oximetry into a single unit.

**Operating Consideration:** Consider devices constructed as features built into other devices (EKG monitors, pulse oximeters, etc.). Consider durability of probes, disposable probe accessories and/or infection control, and related maintenance issues. Device cases should be impervious to infectious fluids.

**Certain toxic exposures, as well as environmental conditions, can lead to inaccurate readings.** Consider devices with commercial off-the-shelf batteries; disposable items may require replacement during a protracted incident.

**Training Requirements (Recommendations from IAB)**

- **Core Training:** ASTM F1651-95, NFPA 450, NFPA 473 (within medical scope of practice)
- **Initial Training:** Minimal (-1 day)
- **Sustainment Training:** Minimal (-1 day)

**Missen Specific Sublist**

- **Medical:** Advanced Life Support
- **Medical:** Hospital
- **Medical:** Pre-Hospital

**Related PPD-8 Core Capabilities Associated with the Monitor, Blood Chemistry, Non-Invasive**

- **Environmental Response/Health and Safety**
- **Mass Search and Rescue Operations**
- **Public Health and Medical Services**

**The Rad-57 satisfies the following PPD-8 Core Capabilities:**

- **Environmental Response/Health and Safety**
- **Mass Search and Rescue Operations**
- **Public Health and Medical Services**

**Airworthiness Release Certification — United States Army**

The Rad-57 has received Airworthiness Release Certification (AWR 1330) from the United States Army. This designation allows the Rad-57 to be used during flight operations aboard rotary aircraft. After extensive testing and evaluation by the U.S. Army Aeromedical Research Laboratory (USAMRL Report No. 2011-13), including electromagnetic interference and compatibility, environmental, vibration/motion, and human factors testing, the device was certified as meeting the stringent requirements to operate onboard U.S. military aircraft in flight. This certification affirms the durability, reliability and performance of the Rad-57 across a wide range of demanding environments, including those faced by fire, EMS, and aeromedical providers.

**Joint Product of Choice — U.S. Department of Defense Military Health System**

The U.S. Defense Medical Materiel Program Office (DMMPO) and Medical Materiel Enterprise Standardization Office (MMESO) of the U.S. Department of Defense Military Health System has selected the Rad-57 as the military’s standardized handheld pulse oximeter for use worldwide. This designation makes the Rad-57 available to all branches of Military Medical Treatment Facilities and Field Units. The goal of the MMESO is to support the Military Health System and combine efforts to standardize on quality medical materials that support service members, veterans, and family members for the purpose of improving clinical outcomes, enhancing readiness and training, controlling costs, and improving interoperability. These objectives closely mirror those of U.S. fire departments and EMS agencies.
Appendix A: Case Studies

**Exhaust Gas Sickens Mother and Three Children**

**Masimo® Rad-57™ Pulse CO-Oximeter™ Alerts Paramedics to an Unsuspected Source of Poisoning**

**Location:** Farmington Fire Department, Farmington, NM  
**Clinician Reporting:** Jay Balfour, Battalion Chief  
**Patient Event:** Faulty car exhaust sickens family

The Situation: Farmington firefighters responded to a call of a sick patient at a Safeway Supermarket. They arrived to find the 14-year-old female, who had passed out at the checkout counter, alert with no obvious symptoms. The Masimo Rad-57 sensor was initially placed on the patient’s finger to check her oxygen saturation (SpO2) level, but firefighters were surprised when the device started alarming. The patient's carboxyhemoglobin (SpCO) level was measured 15%. Finding that she suffered carbon monoxide (CO) poisoning, the patient was placed on high flow oxygen (O2) and her SpCO level dropped to 13% within two minutes.

The Rad-57 was again used, this time by the fire department to triage all 55+ motel residents and staff. Eight residents with elevated SpCO measurements were transported to the hospital and treated promptly for CO poisoning.

**Missed Signs and Symptoms of CO Poisoning leads to Emergency Intervention**

**Masimo Rad-57™ Helps Clinicians Diagnose CO Poisoning on Scene**

**Location:** Birmingham, Alabama  
**Clinician Reporting:** Deputy Chief Jeff Parker - Minor Heights Fire District  
**Patient Event:** 9-1-1 Call Uncovers Undiagnosed Carbon Monoxide Poisoning

The Situation: Two emergency 9-1-1 calls were placed by family members reporting that an elderly woman had fallen and was exhibiting signs of a stroke. When Minor Heights Fire District paramedics arrived at the home, the family informed them that the patient had been to the doctor a few days prior complaining of persistent dizziness and nausea. But despite a thorough exam, the doctor could not provide a clear diagnosis.

Following routine procedure, the attending medic used the Masimo Rad-57 Pulse CO-Oximeter to assess the patient’s oxygen saturation and pulse rate, only to discover that her carboxyhemoglobin (SpCO) level was 15%. Combined with the patient’s symptoms and the results from the Rad-57 the medic was able to diagnose carbon monoxide (CO) poisoning and immediately administered oxygen.

**CO Intervention Before Dawn Saves Lives**

**Masimo Rad-57 Helps First Responders Avoid Mass Casualty**

**Location:** State Raleigh, NC  
**Clinician Reporting:** Chief, EMS Division, Wake County Dept. of Emergency Services – Skip Kirkwood, M.S., J.D., EMT-P  
**Patient Event:** CO exposure at motel endangers 50+

The Situation: Wake County EMS responded in the middle of the night to a vehicle parked on the side of the road with five occupants complaining of headaches, nausea, vomiting, confusion, and tingling skin. The family had been driving in search of a hospital, but were so confused and ill they had to pull over to flag down help. Paramedics used the Masimo Rad-57 Pulse CO-Oximeter to assess the possibility of carbon monoxide (CO) poisoning and found all five family members had elevated SpCO measurements. Further inquiry revealed that they had been staying in a hotel that had many other guests. Paramedics called in a CO emergency and the Raleigh Fire Department was dispatched to the motel where the family was staying. Upon arrival, firefighters found dangerously high CO levels in the air and immediately evacuated 50+ guests and staff. The source of the CO exposure was found to be a malfunctioning central HVAC unit, which was circulating CO throughout the entire building and poisoning the motel guests.

**CO/O2 Oximetry Prevents a Hospital Disaster**

**Masimo Rad-57 Helps First Responders Avoid Mass Casualty**

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**Clinician Reporting:** Chief, EMS Division, Wake County Dept. of Emergency Services – Skip Kirkwood, M.S., J.D., EMT-P  
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The Situation: Wake County EMS responded in the middle of the night to a vehicle parked on the side of the road with five occupants complaining of headaches, nausea, vomiting, confusion, and tingling skin. The family had been driving in search of a hospital, but were so confused and ill they had to pull over to flag down help. Paramedics used the Masimo Rad-57 Pulse CO-Oximeter to assess the possibility of carbon monoxide (CO) poisoning and found all five family members had elevated SpCO measurements. Further inquiry revealed that they had been staying in a hotel that had many other guests. Paramedics called in a CO emergency and the Raleigh Fire Department was dispatched to the motel where the family was staying. Upon arrival, firefighters found dangerously high CO levels in the air and immediately evacuated 50+ guests and staff. The source of the CO exposure was found to be a malfunctioning central HVAC unit, which was circulating CO throughout the entire building and poisoning the motel guests.

The Rad-57 was again used, this time by the fire department to triage all 55+ motel residents and staff. Eight residents with elevated SpCO measurements were transported to the hospital and treated promptly for CO poisoning.

The Rad-57’s quick, noninvasive results enabled both EMS and fire department first responders to immediately diagnose the family and triage motel guests and staff. This allowed for rapid intervention when precious minutes could have made the difference between life and death.

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**Solutions in Action:** Each year, Masimo receives compelling reports and firsthand accounts of how the Rad-57 is making a definitive, lifesaving difference for patients and emergency responders in situations that they may not have walked away from. The following case studies, along with our full collection of Rad-57 success stories can be found at www.masimo.com/emscasestudies.
Noninvasive carboxyhemoglobin (SpCO) has been shown to help clinicians assess carbon monoxide levels in the blood. More than 50 independent and objective studies by researchers around the world have demonstrated the accuracy and clinical advantages of SpCO.

Noninvasive Pulse CO-Oximetry Expedites Evaluation and Management of Patients with Carbon Monoxide Poisoning

Emergency Department Management of Suspected Carbon Monoxide Poisoning: Role of Pulse CO-Oximetry

Accuracy of Noninvasive Multiwave Pulse Oximetry Compared With Carboxyhemoglobin From Blood Gas Analysis in Unselected Emergency Department Patients

Accuracy of Carboxyhemoglobin Detection by Pulse CO-Oximetry during Hypoxemia

Practice Recommendations in the Diagnosis, Management, and Prevention of Carbon Monoxide Poisoning

Screening for Carbon Monoxide Exposure in Selected Patient Groups Attending Rural and Urban Emergency Departments in England: A Prospective Observational Study

The Measurement of Carboxyhemoglobin and Methemoglobin using a Non-Invasive Pulse CO-Oximeter

Use of Pulse CO-Oximetry as a Screening and Monitoring Tool in Mass Carbon Monoxide Poisoning

Victim of Carbon Monoxide Poisoning Identified by Carboxyhemoglobin Oximetry

Non-invasive Carboxyhemoglobin Monitoring: Screening Emergency Medical Services Patients for Carbon Monoxide Exposure

The Noninvasive Carboxyhemoglobin Monitoring of Firefighters Engaged in Fire Suppression and Overhaul Operations

Masimo Rad-57 Pulse CO-Oximeter for Noninvasive Carboxyhemoglobin Measurement


Noninvasive Pulse CO-Oximetry Screening in the Emergency Department Identifies Occult Carbon Monoxide Toxicity

Measurement of Carboxyhemoglobin and Methemoglobin by Pulse CO-Oximetry: A Human Volunteer Study

Diagnosis and Management of Carbon Monoxide Poisoning in the Emergency Department

Carbon Monoxide Treatment Guidelines Must Acknowledge the Limitations of the Existing Evidence

Elevated Carboxyhemoglobin in Active Asthma and Allergic Rhinitis as Measured by Pulse CO-Oximetry

Association of Transcutaneous Carbon Monoxide and Bilirubin Levels in Healthy Term Newborns
Gonulal D., Bilgin B., Altun Koroglu O., Yalaz M., Kultursay N. Arch Dis Child 2012;97:A379

Evaluation of Inflammation in Bronchopulmonary Disease with Transcutaneous Carboxyhemoglobin Measurement: Preliminary Results
Noninvasive Measurement of Carboxyhemoglobin in Cystic Fibrosis Patients by Pulse CO-Oximeter


Noninvasive Carbon Monoxide Detection: Insufficient Evidence for Broad Clinical Use

Susan R Wilcox and Jeremy B Richards

False Positive Rate of Carbon Monoxide Saturation by Pulse Oximetry of Emergency Department Patients

Weaver L.K., Churchill S.K., Deru K., Cooney D.

Comparison of Pulse Carbon Monoxide Oximetry with Laboratory Carbon Monoxide Oximetry Regarding the Time to Diagnosis and Treatment of Patients with Carbon Monoxide Poisoning: Is it a Reasonable and Necessary Comparison?


Screening by Pulse CO-Oximetry for Environmental Tobacco Smoke Exposure in Preanesthetic Children

Cardwell K., Pan Z., Boucher R., Zik J., Friesen R.H.
Paediatr Anaesth. 2012 Sep;22(9):859-64.

The Current Status of Continuous Noninvasive Measurement of Total, Carboxy, and Methemoglobin Concentration


Non-Invasive Measurements of Carboxyhemoglobin and Methemoglobin in Children with Sickle Cell Disease


Mass Sociogenic Illness Initially Reported as Carbon Monoxide Poisoning


Determination of Blood Volume by Pulse CO-Oximetry

Lalonde S., Kelsey J.W., Joyner M.Y., Johnson B.D.

Carbon Monoxide Poisoning: Case Studies and Review


Noninvasive Carbon Monoxide Screening for Environmental Tobacco Smoke Exposure in Children


Multi-Wavelength Pulse Oximeter Is Not Suitable for Adjusting DLCO Measurements


Noninvasive Measurement of Carbon Monoxide Burden in Guatemalan Children and Adults following Wood-fired Temazcal (Sauna-bath) Use


The Detection of Changes in Carboxyhemoglobin Levels in Asthmatics


Pulse Carboxyhemoglobin-Oximetry and Cigarette Smoking


Performance of the RAD-57 Pulse CO-Oximeter Compared with Standard Laboratory Carboxyhemoglobin Measurement


Performance of the Rad-57 Pulse CO-Oximeter Compared With Standard Laboratory Carboxyhemoglobin Measurement


Second-Hand Smoking and Carboxyhemoglobin Levels in Children: A Prospective Observational Study


A New Tool for the Early Diagnosis of Carbon Monoxide Intoxication


Association of Carboxyhemoglobin Levels with Clinical Measures of Acute Asthma Severity


Non-Invasive Measurements of Carboxyhemoglobin and Methemoglobin in Pediatric Patients with Sickle Cell Disease


Fire and Ice: Diagnosis of Carbon Monoxide Poisoning in a Remote Environment


Carbon Monoxide Pulse Oximetry vs Direct Spectrophotometry for Early Detection of CO Poisoning


Appendix B: Clinical Evidence (Continued)
Reliability of New Pulse CO-Oximeter in Victims of Carbon Monoxide Poisoning

The Incidence of Carbon Monoxide Poisoning During CO Alarm Investigations

Noninvasive Measurement of Carboxyhemoglobin Levels for Adjustment of Diffusion Capacity Measured During Pulmonary Function Testing

The Usefulness of Noninvasive CoHb Monitoring at HBOT Department (Pulse CO-Oximetry Rad-57)

Carboxyhemoglobin Levels in Smokers vs. Non-Smokers in a Smoking Environment

Clinical Analyses of 429 Cases of Acute CO Poisoning

Carboxyhemoglobin monitored by bedside continuous CO-Oximetry

Detection of CO-Poisoning Through Pulse CO-Oximetric Measurement
Man F. Respir Care. 2007; 52(11): 225.

Noninvasive Pulse CO-Oximetry as a Tool to Detect Smoking Status in an Outpatient Setting

Carboxyhemoglobin Elevation Due to Hemolytic Anemia

Evaluation of a New Pulse CO-Oximeter: Noninvasive Measurement of Carboxyhemoglobin in the Outpatient Pulmonary Lab and Emergency Departments

Noninvasive Carboxyhemoglobin Monitoring: Screening Emergency Department Patients for Carbon Monoxide Exposure

Unsuspected Carbon Monoxide Toxicity Detected by Noninvasive Monitoring: A Case Report

Use of a Noninvasive Pulse CO-Oximeter to Measure Blood Carboxyhemoglobin Levels in Bingo Players

Comparison of the Masimo Rad-57 Pulse Oximeter with SpCO Technology against a Laboratory CO-Oximeter Using Arterial Blood
References


Caution: Federal law restricts this device to sale by or on the order of a physician. SpCO measurement should not be used as a substitute for laboratory CO measurement, but SpCO can help clinicians by supplementing laboratory CO measurement.

Prior to use, please refer to the instructions for use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events. An electronic copy of the instructions for use may be found at: http://www.masimo.com/rad-57/index.htm. A hard copy is available by contacting Masimo at 1-800-326-4890.