

Clinical and Product Information Package

# Noninvasive, Field-based Measurement of Carbon Monoxide Levels in the Blood







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# 01: Carbon Monoxide (CO)

## A Major Health Risk for the Public and Emergency Responders

### 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,<sup>1</sup> making CO poisoning a major public health concern. In the United States alone, it is estimated that 50,000 emergency department visits each year are a direct result of CO poisoning.<sup>1</sup> The true incidence of CO poisoning is unknown. Because the symptoms are vague, non-specific, and mimic other illnesses, CO poisoning is often misdiagnosed as the flu or food poisoning.<sup>2</sup>

CO is the byproduct of incomplete combustion of any carbon-containing material.<sup>1</sup> Common sources of CO include inadequate ventilation of heating sources, automobile exhaust, faulty furnaces, exposure to methylene chloride (an industrial solvent often used for cleaning and as paint thinner), as well as cigarette smoke and smoke from fires.<sup>3</sup> In fact, CO is a dominant contaminant in fire smoke, creating the possibility of exposure to this deadly poison whenever in the presence of smoke.

When CO is inhaled, it binds with the hemoglobin in the bloodstream with an affinity more than 200 times that of oxygen, creating carboxyhemoglobin (COHb), which is incapable of transporting oxygen throughout the bloodstream.<sup>4</sup> The reduced carrying capacity of COHb starves the vital organs such as the heart and brain of crucial oxygen, often leading to heart attacks, strokes, lifelong disabilities, neurological disorders, and premature death.

**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,<sup>1</sup> 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.<sup>5</sup> 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

### > 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.<sup>7</sup>
- 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.<sup>8</sup>

### > CO poisoning significantly increases long-term health risks

- Just one severe CO poisoning almost doubles the risk of premature death<sup>9</sup>
- Consistent exposure to CO may cause long-term heart and brain damage<sup>10</sup>

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 tends to occur during December.<sup>6</sup>

### 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.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9,10</sup>

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.<sup>11</sup> <sup>12</sup> 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

exceeded recommended exposure limits set by NIOSH and OSHA, reinforcing the need for firefighters to be monitored for CO poisoning.<sup>12</sup> 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.<sup>13</sup>

In addition to CO on the fire ground, fire department responses to CO alarms are increasing each year,<sup>5</sup> and 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 or CO 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.<sup>14</sup> 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 in fact work-related.<sup>15</sup> 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.<sup>16,17</sup>

## O2: Product and Technology Overview

Rad-57 with SpCO®



### Measuring CO in the Blood

Timely identification of CO poisoning is critical but challenging based on signs and symptoms alone and is frequently unrecognized.<sup>2</sup> 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.<sup>4</sup> In the prehospital setting, CO measurement via arterial blood gas analysis is not feasible.<sup>28</sup>

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.<sup>21</sup>

#### SpCO Clinical Benefits

- > SpCO has been shown to help clinicians recognize 64% more cases of CO poisoning in emergency patients<sup>22</sup>
- > Even when patients present with a headache, SpCO has been shown to help clinicians recognize 29% more cases of CO poisoning.<sup>27</sup>
- > SpCO has been shown to help clinicians achieve faster recognition and treatment of CO poisoning<sup>4</sup>
- > SpCO has been shown to protect the public helping first responders identify hidden sources of CO in households, workplaces, schools<sup>22</sup>

#### 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<sup>4</sup>

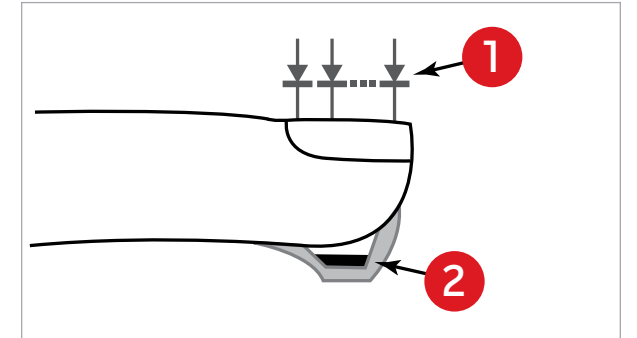
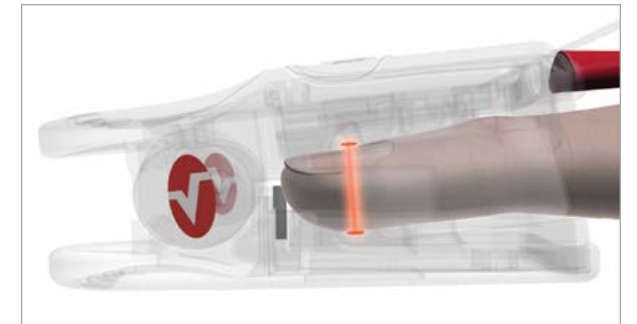
"...there is clear evidence that noninvasive measurement of SpCO has been instrumental in identifying patients with unsuspected CO poisoning and hidden sources of CO. This device is an important tool for public health."

Suner et al<sup>23</sup>

### Measuring SpCO with the Rad-57™

The Masimo Rad-57 is a handheld Pulse CO-Oximeter that noninvasively measures COHb saturation (SpCO) in addition to oxygen saturation (SpO<sub>2</sub>), 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.



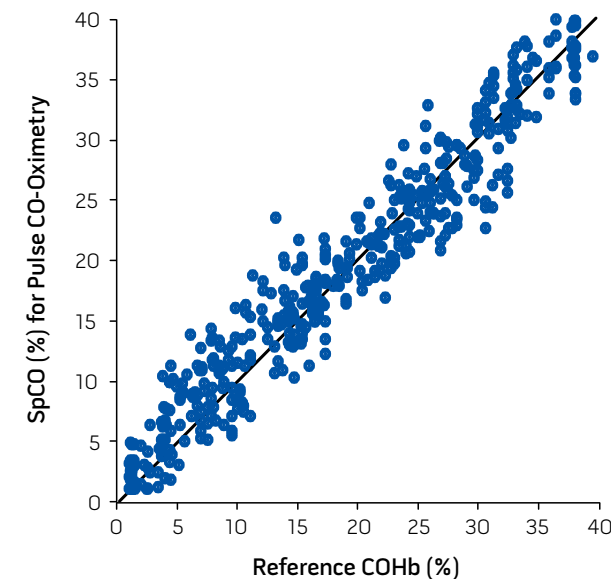
1. Light Emitting Diodes (LEDs) (7+ wavelengths)  
2. Detector

### 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:



\* The Rad-57™ features an upgradeable platform that also allows for the addition of noninvasive methemoglobin (SpMet®) and total hemoglobin (SpHb®)

### Masimo SpCO also Available on the Following Products:

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

#### SpCO 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  $\pm 3\%$  at 1 standard deviation.\* Independent investigations have also validated SpCO accuracy.<sup>29, 30</sup> 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](http://www.masimo.com).

\*Masimo FDA Submission Data



## Rad-57 Pulse CO-Oximeter

### Product Overview:

- > Quick and easy-to-use – requires 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 (SpOC), and Pleth 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 10 hours of continuous battery life
- > Up to 72 hours of trending memory
- > FastSat\* tracks rapid changes in arterial O<sub>2</sub> 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, trouble shooting, sample protocols
- > Training DVD

### Performance

MEASUREMENT RANGE	
SpO <sub>2</sub>	0–100%
SpCO	0–99%
SpHb	0–25 g/dL
SpOC	0–35 mL of O <sub>2</sub> /dL of blood
SpMet	0–99.9%
Pulse Rate	25–240 bpm
Perfusion Index	0.02–20%
ARTERIAL OXYGEN SATURATION ACCURACY	
Saturation	60–80%
No Motion	
Adults, Infants, Pediatrics	±3%
Saturation	70–100%
No Motion	
Adults, Infants, Pediatrics	±2%
Neonate	±3%
Motion	
Adults, Infants, Pediatrics, Neonates	±3%
Low Perfusion	
Adults, Infants, Pediatrics, Neonates	±2%
TOTAL HEMOGLOBIN SATURATION ACCURACY* (%SpHb g/dL)	
SpHb	8–17 g/dL ±1 g/dL

### Specifications

BATTERIES	
Type	4 AA Alkaline
Capacity	up to 8 hours
ENVIRONMENTAL	
Operating Temperature	0–129°F (-18–54°C)
Storage Temperature	-40–158°F (-40–+70°C)
Operating Humidity	15–95%, non-condensing
Operating Altitude	500–1060 mbar pressure, -1,000–18,000 ft (-304–5,486 m)
Effective battery life will be reduced when operating the instrument below 5 degrees Fahrenheit due to alkaline battery technology.	
DIMENSIONS	
Handheld	7" x 3" x 1.5" (15.8 cm x 7.6 cm x 3.6 cm)
WEIGHT	
Handheld	12 oz (with batteries)
TRENDING	
Provides 72 hours of trending at 2-second resolution of SpO <sub>2</sub> , SpCO, SpHb, SpMet, Pulse Rate, Perfusion Index, and PVI. Output to PC running Masimo TrendCom™ Utility.	

CARBOXYHEMOGLOBIN SATURATION ACCURACY (%SpCO)	
SpCO	1–40% ±3%
METHEMOGLOBIN SATURATION ACCURACY (%SpMet)	
SpMet	1–15% ±1%
PULSE RATE ACCURACY	
Pulse Rate	25–240 bpm
No Motion	
Adults, Infants, Pediatrics, Neonate	±3 bpm
Motion	
Adults, Infants, Pediatrics, Neonate	±5 bpm
Low Perfusion	
Adults, Infants, Pediatrics, Neonate	±3 bpm
RESOLUTION	
Oxygen Saturation (%SpO <sub>2</sub> )	1%
Pulse Rate (bpm)	1 bpm
Carboxyhemoglobin Saturation (%SpCO)	
Numeric Display	1%
Total Hemoglobin Saturation (%SpHb)	
Numeric Display	0.1 g/dL
Methemoglobin Saturation (%SpMet)	
Numeric Display	0.1%

SpO <sub>2</sub> MODES	
Averaging mode	2, 4, 8, 10, 12, 14, or 16 seconds
Sensitivity	APOD, Normal, and Max FastSat
FastSat	On / Off
ALARMS	
Audible and visual alarms for high and low saturation and pulse rate (SpO <sub>2</sub> –99%, SpHb 1–24.5 g/dL, SpCO 1–98%, SpMet 1–99.5%, PI 0.03–19%, PVI 1–99%, and pulse rate 30–235 bpm)	
DISPLAY/INDICATORS	
Data Display	%SpO <sub>2</sub> , %SpCO, SpHb g/dL, SpOC mL/dL, %SpCO, %SpMet, SIQ bar, PI bar, Pulse Rate, Perfusion Index, PVI, low Signal IQ, alarm status, alarm silenced status, and battery status.
Type	LED
COMPLIANCE	
EMC Compliance	EN60601-1-2, Class B
Equipment Classification	IEC 60601-1-1, IEC 60601-1-2
Degree of Protection	Type BF-Applied part



Protect your investment and minimize downtime with MasimoCare™ Protection+

### 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

## 03: Standards, Guidelines, and Certifications

Thousands of U.S. fire departments have incorporated SpCO assessment into their firefighter rehab protocols.

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."<sup>24</sup>

### 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<sup>25</sup>

**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)

### Mission Specific Sublist

**Medical:** Advanced Life Support

**Medical:** Hospital

**Medical:** Pre-Hospital

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

- > Presidential Policy Directive, edition PPD-8, is aimed at "strengthening the security and resilience of the United States through systematic preparation for the threats that pose the greatest risk to the security of the nation, including acts of terrorism, cyber attacks, pandemics, and catastrophic natural disasters." The directive is aimed at facilitating a capabilities-based approach to preparedness, identifying the core capabilities necessary for preparedness.<sup>26</sup>

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

**Environmental Response/Health and Safety** – Ensure the availability of guidance and resources to address all hazards including hazardous materials, acts of terrorism, and natural disasters in support of the responder operations and the affected communities.

**Mass Care Services** – Provide life-sustaining services to the affected population with a focus on hydration, feeding, and sheltering those who have the most need, as well as support for reunifying families.

**Mass Search and Rescue Operations** – Deliver traditional and atypical search and rescue capabilities, including personnel, services, animals, and assets to survivors in need, with the goal of saving the greatest number of endangered lives in the shortest time possible.

**Public Health and Medical Services** – Provide lifesaving medical treatment via emergency medical services and related operations to avoid additional disease and injury by providing targeted public health and medical support and products to all people in need within the affected area.

### 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 (USAARL 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 (DMMPPO) 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

**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](http://www.masimo.com/emscasestudies).

## 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 (SpO<sub>2</sub>) level, but firefighters were surprised when the device started alarming. The patient's carboxyhemoglobin (SpCO) blood level measured 15%. Finding that she suffered carbon monoxide (CO) poisoning, the patient was placed on high flow oxygen (O<sub>2</sub>) and her SpCO level dropped to 13% within two minutes.

**The Problem:** A check of the Safeway revealed no signs of a carbon monoxide leak. Although all signs pointed to CO poisoning, the recent warm weather made heating units—a common culprit—seem an unlikely cause. Paramedics arriving from the county ambulance service also expressed surprise at the high SpCO measurement, so they checked the mother and her 17-year-old daughter—both were also in the store with patient—only to find that they too had elevated SpCO levels of 8 to 9%. With the store ruled out as the source of the poisoning, the family vehicle, which was just purchased the prior week, was evaluated.

After starting up the vehicle, a mini-air gas CO detector alarmed within 10 to 15 seconds and quickly rose to 40 PPM with the windows of the van all rolled down. An exhaust leak was found to be the source of the carbon monoxide poisoning. The mother and two daughters were transported by ambulance to the ER while another fire engine was dispatched to the family's home to check out the five other children: an infant, 3-year-old, 9-year-old, 12-year-old, and 18-year-old. The 3-year-old male, who was asleep on the couch, did not wake to verbal commands. Although firefighters were able to awaken him, he was very lethargic. After placing the Rad-57 sensor on his finger, the device immediately alarmed with an SpCO of 13%. He was also placed on high flow O<sub>2</sub> and transported to the same ER as his mother and sisters. The 3-year-old was the only other family member who had recently been in the van. In fact, the mother, along with the 14-year-old and 17-year-old, had spent an hour driving around in the van and running errands the previous night, which explained their elevated SpCO levels. None of the other children had elevated SpCO levels or obvious symptoms and a thorough check of the house revealed no CO leaks.

**The Masimo Difference:** Firefighters and paramedics initially had no reason to suspect CO poisoning as the cause of the 14-year-old's symptoms. Without the elevated SpCO measurements from the Rad-57, we would not have tested the van and confirmed the source of the CO poisoning. The Rad-57's SpCO measurements sent up a red flag that helped a family of eight to escape a potential deadly outcome.

## 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.

The Rad-57 was again used, this time by the fire department to triage all 50+ 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.

## 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 CO 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.

**The Masimo Difference:** With CO poisoning now revealed as the cause of the woman's recurring symptoms, the fire department turned their attention to locating the source of the poisoning. They determined that the 80-year-old home the family lived in had a faulty gas heating system that was emitting very high levels of CO—a common occurrence for older homes in the historic housing district of Birmingham. The two other members of the household regularly used small floor fans in their rooms, which dispersed the CO fumes sufficiently enough for them to avoid CO poisoning, even under identical exposure conditions. The patient was transported to a local-area hospital with a hyperbaric chamber for further treatment.

# Appendix B: Clinical Evidence

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**

Hampson N.B. *Am J Emerg Med.* 2012 Nov;30(9):2021-4.

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

Sebbane M., Claret P.G., Mercier G., Lefebvre S., They R., Dumont R., Maille M., Richard J. P., Eledjam J. J., de La Coussaye, G.E. *Respir Care.* 19 March 2013

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**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.