STATE OF CALIFORNIA
EMERGENCY MEDICAL SERVICES AUTHORITY

CURRENT TRIAL STUDIES
as of 06/21/2011

Local EMS Agency	Study Title	EMS Agency Medical Director and Primary Investigator	Date of Initiation of Trial Study	Commission Notified	18 Mo. Report Due	Commission Action	36 Mo. Report Due	Disposition of Study
Los Angeles County	Field Administration of Stroke Therapy – Magnesium (FAST-MAG) Project	William Koenig, MD, Medical Director	1/1/04	12/9/03	9/31/05	The Commissioners reviewed the 18-month report at their 9/21/05 meeting. The Commissioners reviewed the 36-month report at their 3/28/07 meeting.	3/31/07 9/30/08 9/30/11	Active
Ventura County EMS Agency	Use of King Airway & ResQPOD Impedance Threshold Device by BLS & ALS personnel	Angelo Salvucci, MD	9/1/09	12/3/08	3/1/11	Commission notified on 12/3/08 of EMSA approval of the study on 10/20/08.		Active
S-SV EMS Agency	Use of CO-Oximeter devices by paramedic personnel.	Troy Falck, MD	6/1/10	12/1/10	12/1/11			Active

Interim Report on the Field Administration of Stroke Therapy – Magnesium (FAST-MAG) Phase 3 Trial

May 2011

Progress of the Study

Since the prior interim report of January 2010, the study has been progressing steadily. As of May 13, 2011, 1271 of the planned 1700 patients have been enrolled.

In Los Angeles County, 228 ambulances are carrying study drug and actively enrolling patients being transported to 50 active study hospitals. Over 2200 LAC paramedics have been trained in study procedures. All 31 EMS Provider Agencies in the County are participating.

In Orange County, study expansion is proceeding apace. Initial FAST-MAG training has been performed for 552 of the 788 paramedics in the County, including paramedic members of 7 of the 13 EMS Provider Agencies in the County. St. Jude Medical Center became the first Orange County Stroke Center to become active in the trial in February 2011 and St. Joseph Medical Center became the second active center in late April 2011. We anticipate having all 9 designated Stroke Centers in the County active by September 2011

At receiving hospitals across both Los Angeles and Orange County, official study investigators include over 405 Emergency Physicians, 101 Neurologists and Neurosurgeons, and 10 Internal Medicine Hospitalists.

Tthe key study goal of enrolling patients in a hyperacute time window continues to be achieved. The median time from last known well to start of study drug in the study cohort is 46 minutes. 74% of patients received study agent within one hour after onset and 25% between one to two hours after onset.

Detailed Enrollment Report

Enrollment rates have increased as a result of study implementation refinements. In the 9 months up to April 2011, patients were enrolled at an average of 21.2 per month. This rate is stable compared with the prior 8 months (22 per month) and increased by 20% over the 9 months prior to that (17.7 per month). The sustained increase in trial accrual reflects several developments in Los Angeles County, including:

1) Launch of a Stroke Center routing system by Los Angeles County EMS in November 2009. All 18 of the Approved Stroke Centers within LA County that preferentially receive under 2 hour acute stroke patients are active FAST-MAG sites. Consequently, patients who in the past might have been routed to a non-FAST-MAG hospital and not offered trial enrollment are now usually routed to a trial hospital and offered study participation.
2) Addition of enrollment by exception from explicit consent in emergency circumstances. Since the last EMS Authority report, we have continuted public disclosure and community consultation meetings, and have increased the number of sites that have

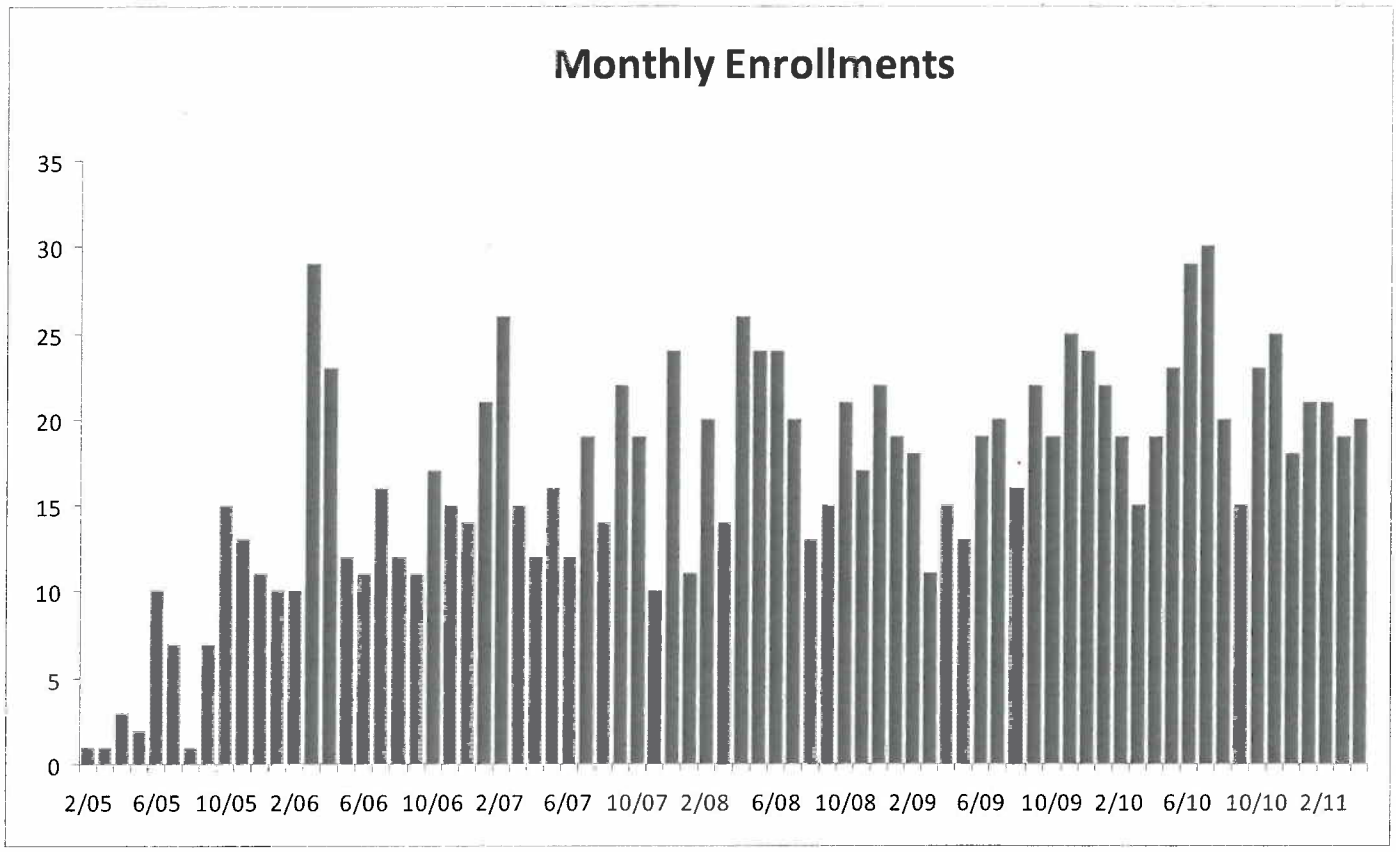
approved the exception enrolling mechanism from 25 to 27, including 14 of the 18 Approved Stroke Centers in the County.

3) Increase in the number of participating hospitals.

Of these activities, the launch of the Stroke Center routing system has had the greatest impact.

In 2009, study enrollments continued at an average rate of 17.7 per month. At the close of December 2009, 911 patients had been enrolled in the trial. Amongst these, 908 were enrolled under explicit informed consent from the patient or an on-scene legally authorized representative and 3 patients under waiver of explicit consent in emergency circumstances regulations.

The following figures and tables show enrollment trends over time, patient characteristics, and enrollment contributions of each EMS Provider Agency and Hospital:


Monthly Enrollments
35
30
25
20
15
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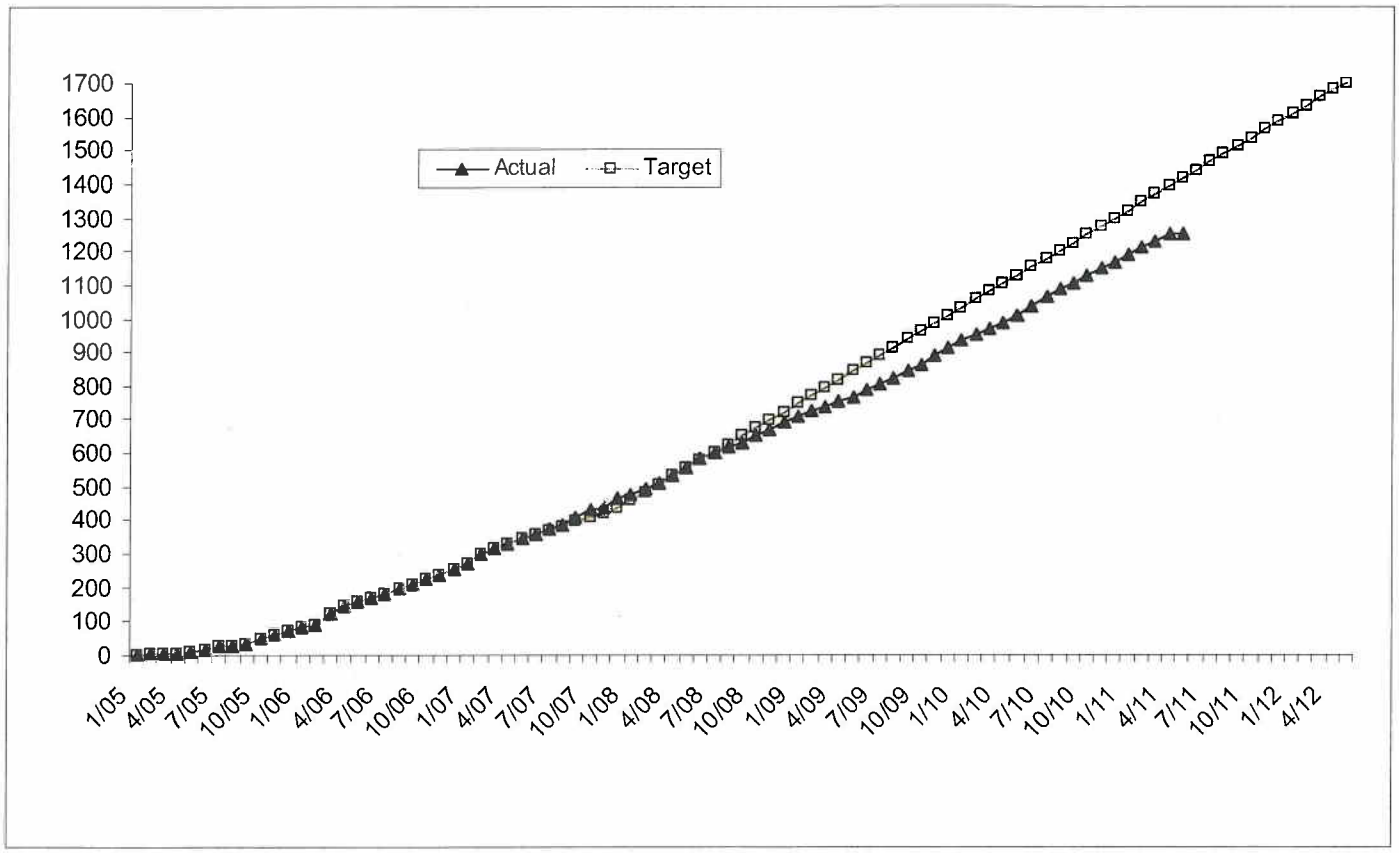
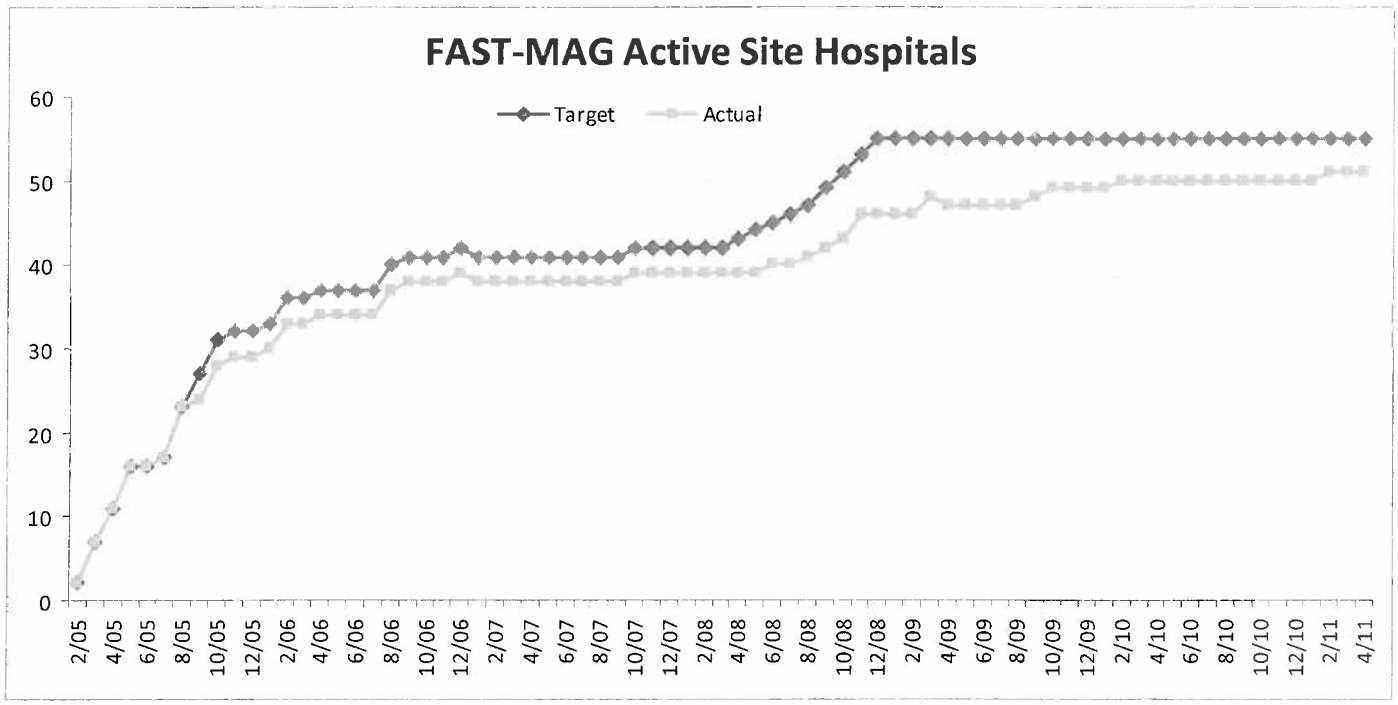

Actual
Target
1700
1600
1500
1400
1300
1200
1100
1000
900
800
700
600
500
400
300
200
100
0
1/05 4/05 7/05 10/05 1/06 4/06 7/06 10/06 1/07 4/07 7/07 10/07 1/08 4/08 7/08 10/08 1/09 4/09 7/09 10/09 1/10 4/10 7/10 10/10 1/11 4/11 7/11 10/11 1/12 4/12


FAST-MAG Active Site Hospitals
Target
Actual
60
50
40
30
20
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2/05
4/05
6/05
8/05
10/05
12/05
2/06
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12/10
2/11
4/11

FAST-MAG Enrollment Summary	5/1/2011
Number of patients	1253
Mean Age	69
Median Interval Onset to Drug (mins)	48
Mean Interval On scene to Drug (mins)	27
Mean Interval On scene to ED (mins)	32
Female	41%
Median Field LAMS Score	4
Median Arrival NIHSS	9
Enrolled 15-60 min after onset	68%
Enrolled 61-120 min after onset	26%
Enrolled >120 min after onset	3%

Stroke Type	
Cerebral Infarct	733
TIA	203
Intracerebral Hemorrhage	281
Other	14

Enrolling Hospital		Enrolling EMS Provide Agency	
Long Beach Memorial	84	Los Angeles City Fire Department	452
Huntington	78	Los Angeles County Fire Dept	435
Presbyterian Intercommunity Hospital	72	Long Beach Fire Department	57
Little Company of Mary - Torrance	62	Torrance Fire Department	45
Torrance Memorial Medical Center	61	Santa Monica Fire Department	35
UCLA (Westwood) Medical Center	58	Pasadena Fire Department	34
Henry Mayo Newhall	54	Glendale Fire Department	23
Antelope Valley Hospital	51	Burbank Fire Department	21
Providence Saint Joseph Medical Center	50	La Verne Fire Department	19
Methodist Hospital of Southern California	43	Redondo Beach Fire Department	15
St. Francis Medical Center	42	Arcadia Fire Department	13
Cedars - Sinai	39	West Covina Fire Department	12
Northridge Hospital	39	San Marino Fire Department	12
White Memorial Medical Center	37	Downey Fire Department	11
Pomona Valley Hospital	35	Manhattan Beach Fire Department	11
Lakewood Regional Medical Center	31	South Pasadena Fire Department	8
Santa Monica - UCLA Medical Center	30	Compton Fire Department	8
California Hospital Medical Center	29	Culver City Fire Department	7
Sherman Oaks	26	El Segundo Fire Department	6
Glendale Adventist	26	Monrovia Fire Department	5
Providence Holy Cross	25	Beverly Hills Fire Department	4
St. John's Hospital and Health Center	24	Hermosa Beach Fire Department	3
West Hills Hospital and Medical Center	22	Montebello Fire Department	3
Citrus Valley MC - Queen of the Valley Campus	19	Fullerton Fire Department	3
CFRMC - Marina Campus	17	Alhambra Fire Department	2
LAC - USC	16	Santa Fe Springs Fire Department	2
Little Company of Mary - San Pedro	15	Sierra Madre Fire Department	2
Verdugo Hills Hospital	14	Monterey Park Fire Department	2
Glendale Memorial	14	unknown	2
LAC - Olive View	13	San Gabriel Fire Department	1
San Dimas	12	Brea Fire Department	1
Providence Tarzana Medical Center	11	Orange County Fire Authority	1

Brotman	10
Kaiser - Woodland Hills	10
Lancaster Community Hospital	9
LAC - Harbor	9
St. Mary Medical Center	9
Citrus Valley MC - Intercommunity Campus	9
Whittier Hospital Medical Center - AHMC	9
Olympia Medical Center	9
Mission Community Hospital	6
St. Jude	6
Good Samaritan	5
Kaiser - West LA	4
Kaiser - Sunset	4
CFRMC - Memorial Campus	2
EMS Provider Agency	1
Garfield - AHMC	1
Encino Hospital Medical Center	1
Hollywood Presbyterian	1
City of Vernon Fire Department	1

Beneficial Effects

The study remains under blind. The independent, NIH-appointed trial Data Safety and Monitoring Board meets every 6-12 months to review unblinded trial data, with formal interim analyses by the NIH-appointed Data and Safety Monitoring Board at 25%, 50%, and 75% milestones in recruitment. The Board most recently met on May 2, 2011 and reported to the investigators that the DSMB found that it was both safe and ethical to continue the trial.

Adverse Reactions or Complications

There have been 52 serious adverse events adjudicated by the Medical Safety Monitor as possibly related to study drug, 3 as probably related, and none as definitely related (Tables H10, H12). Among the possibly related, manifestations included hypotension in 41 patients and bradycardia in 10 patients. The 3 probably related events were bradycardia episodes. All had concomitant medications and/or conditions that could have contributed to the event. The blind was not broken in any of the cases.

Cumulative safety data in the FAST-MAG Trial is supervised by the independent, NIH-appointed Data and Safety Monitoring Board (DSMB), which consists of the following individuals:

- Clarke Haley, MD (Chair) – Professor of Neurology, University of Virginia, Charlottesville, VA, Stroke Neurologist
- Ed Jauch, MD –Professor of Emergency Medicine, Medical University of South Carolina, Emergency Physician
- Rafael Llinas, MD – Associate Professor of Neurology, Johns Hopkins, Stroke Neurologist
- Oscar Benavente, MD –Professor of Neurology, University of British Columbia, Canada, Stroke Neurologist
- Jeffrey Dawson, PhD – Professor of Biomathematics, University of Iowa, Statistician

This Board meets every 6-12 months to review cumulative data on all adverse events in the FAST-MAG Trial. The Board most recently met on May 2, 2011 and reported to the investigators that the DSMB found that it was both safe and ethical to continue the trial.

Appropriate Statistical Evaluation

The DSMB performed the second formal statistical interim analysis of study results after the first 649 patients were enrolled in the trial. No stopping boundaries for safety, efficacy, or futility were crossed. The third formal interim analysis will take place after the 1275th patient reaches the 3 month final outcome visit, and is currently anticipated to occur in November 2011.

General Conclusions

The trial is achieving its goal of demonstrating that prehospital initiation of study agent permits drug start within the first 1-2 hours after onset, a time frame never before accomplished in a stroke trial, when salvageable brain tissue is maximal in volume. Enrollment of additional

patients will permit definitive evaluation of magnesium sulfate as a potential neuroprotective therapy for acute stroke.

Plans

Over the next 18 months, leading study goals are:

- Enroll an additional 400-425 patients, potentially completing the 1700 patient target by December 2012
- Perform the 75% enrollment formal interim analysis, likely in November 2011

Ventura County Emergency Medical Services

Early use of the King Airway and impedance threshold device by basic and advanced life support personnel in the treatment of adult patients with out-of-hospital cardiac arrest.

Trial Study - 18 Month Report
May 15, 2011

Introduction:
The Ventura County EMS system has BLS and ALS first responders and ALS ambulance services. Cardiac arrest treatment protocols begin with 2-rescuer CPR with bag-mask ventilation (BMV) at a 30:2 compression:ventilation ratio and use of an AED. Paramedics continue 30:2 CPR with BMV, and include rhythm assessment, defibrillation, IV/IO medications, and advanced airway as needed.

In the 2005 American Heart Association (AHA) Guidelines for CPR and Emergency Cardiovascular Care (ECC), the impedance threshold device (ITD) was designated as Class IIa (Benefit >> Risk. It is reasonable to perform procedure/administer treatment).

- "Although increased long-term survival rates have not been documented, when the ITD is used by trained personnel as an adjunct to CPR in intubated adult cardiac arrest patients, it can improve hemodynamic parameters and ROSC (Class IIa)."

The King Airway (KA) is not specifically mentioned in the 2005 Guidelines, but two other perilaryngeal airways, the Combitube and Laryngeal Mask Airway (LMA) were also Class IIa.

- "Thus, it is acceptable for healthcare professionals to use the Combitube as an alternative to the endotracheal tube for airway management in cardiac arrest (Class IIa)."
- "It is acceptable for healthcare professionals to use the LMA as an alternative to the endotracheal tube for airway management in cardiac arrest (Class IIa)."

The objective of this trial study was to determine if a revision of EMS treatment protocols, to include early insertion of a KA and application of an ITD in adult (age >= 18) patients with out-of-hospital cardiac arrest, would increase the likelihood of survival with favorable neurologic function (CPC 1 or 2).

Methods:

Study Design
The trial is a prospective, non-randomized, historically controlled intervention study to evaluate the effect of the introduction of the KA and ITD into EMS cardiac arrest treatment protocols. All adult cardiac patients who met clinical criteria were included. Historical controls were all cardiac arrest patients over the 18 months prior to the intervention meeting the same criteria.

The trial study was approved by the Ventura County Medical Center (VCMC) Institutional Review Board. The VCMC IRB also approved the continuation of the trial on request for renewal at one year.

Setting
Ventura County, California. Population 800,000. EMS response with BLS and ALS fire department first responders and paramedic-staffed ambulances.

Duration
Control period: March 1, 2008 through August 31, 2009
Intervention period: September 1, 2009 through February 28, 2011
Proposed extension period: March 1, 2011 through August 31, 2012

Inclusion criteria
All patients who are presumed to be 18 years of age or older and sustain a non-traumatic cardiac arrest.

Exclusion criteria
Patients less than 18 years of age, traumatic cardiac arrest and patients that had return of spontaneous circulation (ROSC) prior to KA insertion attempt.

Training
All EMTs and paramedics in Ventura County that treat EMS patients attended an in-service training that included the use of the KA and ITD. Training materials and personnel were provided by Ventura County Fire Protection District (VCFPD) and the ITD device manufacturer (Advanced Circulatory Systems, Minneapolis, MN). Train-the-trainer sessions were conducted for individual service providers. The two hour training session taught field providers the indications, contraindications, use and trouble shooting of the ITD. For BLS personnel, training included the indications, contraindications, placement, trouble shooting and use of the KA. ALS personnel had received training on use of the KA prior to the study. Also included in the training was a review of the 2005 AHA Guidelines as well as reinforcement of a team approach and how to work together when using the device.

Protocol
Treatment protocols were revised.
Prior to the trial the cardiac arrest protocol included:

BLS:

- CPR with BMV at 2 ventilations/30 compressions
- AED analysis, shock as indicated

ALS:

- Advanced airway after IV, medications, earlier if unable to ventilate

Trial protocol for the first 9 months included:

BLS/ALS:

- Chest compressions at 100/min
- Insert KA and attach ITD
- Asynchronous ventilations at 10/min
- AED analysis, shock as indicated
- If ROSC, remove ITD

Trial protocol for the second 9 months included:

BLS/ALS:

- Chest compressions at 100/min
- BMV and attach ITD
- 30:2 compression:ventilation ratio

Hospital care

The KA and ITD remained in place until the patient's care was transferred to hospital personnel. All hospital respiratory therapy and emergency department personnel were advised of the study.

Primary Outcome Measure

Survival to Hospital Discharge with CPC 1 or 2

Data Collection

The following data was collected on all patients:

- name (for hospital follow-up)
- sex
- age
- incident number
- date
- time of arrest
- etiology of arrest
- time of first CPR
- time of defibrillation (if applicable)
- bystander witnessed/EMS witnessed/not witnessed
- initial rhythm
- airway management (BVM only, KA, ETT)
- waveform capnography / initial ETCO2 in mmHg values
- return of spontaneous circulation (ROSC) (Y,N)
- time of spontaneous circulation (ROSC)
- timing light use
- admission to hospital
- outcome
  - died in hospital
  - survived to discharge
    - cerebral performance category
    - overall performance category

Patient care reports and equipment use forms were submitted by all prehospital care providers to the EMS Division of VCFPD, in a paperwork-equipment exchange system. VCFPD secured all data received from hospitals regarding survival outcomes of study patients. All records regarding this trial have been maintained in a locked file and or secured electronic data base which can be accessed by the EMS quality managers involved in the study.

Results:

Table 1

EMTs trained	484
Paramedics trained	230
EMT King Airway insertion attempts EMT King Airway insertion success	168 total patients, 1 attempt only 111 (66%)
PM King Airway insertion attempts PM King Airway insertion success	227 total patients 159 1st attempt, 13 2nd attempt = 172 (76%)
Complications	20: Unable to insert: Emesis in oropharynx 48: Unable to insert: No emesis 29: Unable to ventilate after insertion 21: Emesis in airway section of device

EMT King Airway insertion success rate was 66% and paramedic was 76%.
Complications are listed in Table 1.

Table 2

Dates	3/08-11/08		12/08-8/09		9/09-5/10					6/10-2/11				
N	101	%	281	%	247	%	BVM	ETT	KA	240	%	BVM	ETT	KA
VT/VF	35	35%	77	27%	62	25%				43	18%			
AS	53	52%	126	45%	127	51%				138	58%			
PEA	14	14%	78	28%	56	23%				58	24%			
ROSC	28	27.7%	101	35.9%	88	35.6%				82	34.2%			
D/C Alive	10	9.9%	34	12.1%	29	11.7%	7	1	21	22	9.2%	18	3	1
CPC 1/2	9	8.9%	29	10.3%	18	7.3%	7	0	11	20	8.3%	17	2	1
CPC 3/4	1	1.0%	5	1.8%	11	4.5%	0	1	10	2	0.8%	1	1	0

N = All cardiac arrests, cardiac etiology

487 patients were enrolled in the intervention period (247 in the first 9 months, 240 in the second 9 months) and results were compared to the 382 patients in the prior 18 month control period.

During the first 9-month intervention period, results for ROSC (33.8% vs. 35.6%) and overall survival (11.5% vs. 11.7%) remained essentially unchanged from the control period.

There was a trend toward a reduction in the proportion of patients with CPC 1 and 2 scores (9.9% to 7.3%) and an increase in CPC 3 and 4 (1.6% to 4.5%). These differences were not statistically significant.

The KA was discontinued after the first 9 month intervention period and the protocol changed to include 2-hand mask grip for BMV ventilation with an ITD.

In the second 9-month period the overall survival was 9.2% with a CPC 1 and 2 proportion of 8.3%.

Discussion:
In the first 9 months there was no improvement in the overall survival or proportion of patients with CPC 1 or 2 with use of the KA and ITD. The KA was removed from the BLS protocol and used by paramedics only if unable to ventilate and unable to insert an endotracheal tube.

The King Airway is a Class IIa device in the 2010 AHA Guidelines (2):

- During CPR performed by providers trained in its use, the supraglottic airway is a reasonable alternative to bag-mask ventilation (Class IIa, LOE B) and endotracheal intubation (Class IIa, LOE A).

However, this recommendation is based upon studies that reported ability to insert the device and to adequately ventilate patients (3-5). We were unable to identify a study that evaluated the effect of the device on cardiac arrest survival with favorable neurologic outcome.

A possible explanation for the observed increase in patients with hospital discharge CPC scores of 3 and 4 is the potential for reduced brain circulation from carotid artery compression by the KA oropharyngeal balloon. Carotid bulb compression with the LMA has been shown to decrease carotid blood flow in anesthetized normotensive adults (6), and this effect would be expected to be more prominent in the low-flow setting. Further investigation is needed.

The ITD is a Class IIb (Benefit >= Risk, Procedure/treatment may be considered) device in the 2010 AHA Guidelines (2):

- "The use of the ITD may be considered by trained personnel as a CPR adjunct in adult cardiac arrest (Class IIb, LOE B)."

Preliminary results (7) from the ROC PRIMED study (8) indicate that the ITD did not improve survival. However, the trial was conducted in a number of sites with varying protocols, many of them different than in Ventura County, and the individual site results are yet not published. Two recent studies conclude that the ITD, as part of a bundle of care with standard CPR (9) and active compression-decompression CPR (10) is associated with improved cardiac arrest survival.

Limitations:
The sample size for the first 9 months of the trial was insufficient to have statistically significant results for the KA/ITD portion. The IRB approval was to evaluate whether the change in protocol resulted in an improvement in care, and, when it was clear that there was no patient benefit, it was necessary to revise the protocol.

Similarly, there are no statistically significant results for the ITD portion of the study at this time, and data collection is continuing.

Hospital care has changed during the trial that will affect the analysis. All patients with ROSC are now triaged to a STEMI Receiving Center to be evaluated for therapeutic hypothermia.

Conclusion/Recommendations:
We did not find a benefit from use of the King Airway as a routine device and will continue to use bag-mask ventilation and endotracheal intubation as indicated.

The potential benefit of the impedance threshold device is not yet known and should be further evaluated.

We recommend that the impedance threshold device portion of the trial be continued for an additional 18 months.

References:

1. The ECC Committee, Subcommittees and Task Forces of the American Heart Association. 2005 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation.* 2005;112:IV1-203.
2. Neumar RW, Otto CW, Link MS, et al: Part 8: adult advanced cardiovascular life support: 2010 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation.* 2010 Nov 2;122(18 Suppl 3):S729-67.
3. Schalk R, Byhahn C, Fausel F, Egner A, Oberndorfer D, Walcher F, Latasch L. Out-of-hospital airway management by paramedics and emergency physicians using laryngeal tubes. *Resuscitation.* 2010;81:323–326.
4. Heuer JF, Barwing J, Eich C, Quintel M, Crozier TA, Roessler M. Initial ventilation through laryngeal tube instead of face mask in out-of-hospital cardiopulmonary arrest is effective and safe. *Eur J Emerg Med.* 2010;17:10–15.
5. Wiese CH, Semmel T, Muller JU, Bahr J, Ocker H, Graf BM. The use of the laryngeal tube disposable (LT-D) by paramedics during out-of-hospital resuscitation—an observational study concerning ERC guidelines 2005. *Resuscitation.* 2009;80:194–198.
6. Colbert SA, OHanlon DM, Flanagan F, et al: The laryngeal mask airway reduces blood flow in the common carotid artery bulb. *Canadian J Anaesth.* 1998 45(1): 23-7.
7. Aufderheide TP, Nichol G, Rea TD, et al: The resuscitation outcomes consortium (ROC) PRIMED impedance threshold device (ITD) cardiac arrest trial: a prospective, randomized, double-blind, controlled clinical trial. *Prehospital Emergency Care.* 2011;15:104–137.
8. Aufderheide TP, Kudenchuk PJ, Hedges JR, et al: Resuscitation Outcomes Consortium (ROC) PRIMED cardiac arrest trial methods part 1: rationale and methodology for the impedance threshold device (ITD) protocol. *Resuscitation.* 2008 Aug;78(2):179-85.
9. Hinchey PR, Myers JB, Lewis R, et al: Improved out-of-hospital cardiac arrest survival after the sequential implementation of 2005 AHA guidelines for compressions, ventilations, and induced hypothermia: the Wake County experience. *Ann Emerg Med.* 2010 Oct;56(4):348-57.
10. Aufderheide TP, Frascone RJ, Wayne MA, et al: Standard cardiopulmonary resuscitation versus active compression-decompression cardiopulmonary resuscitation with augmentation of negative intrathoracic pressure for out-of-hospital cardiac arrest: a randomised trial. *Lancet.* 2011 Jan 22;377(9762):301-11.

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TEHAMA CO.

July 29, 2010

R. Steven Tharratt, MD, MPVM - Director
California Emergency Medical Services Authority
1930 9th Street
Sacramento, CA 95811-7043

Dear Dr. Tharratt,

As defined by California Code of Regulations, Title 22, Division 9, Chapter 4, Section 100146 "Paramedic Trial Studies", please find enclosed the required trial study plan for the paramedic use of non-invasive CO-Oximeter devices.

1. 100146 (a)(1) Description of the procedure(s) or medication(s) proposed, the medical conditions for which they can be utilized, and the patient population that will benefit.

   A. Description of the procedure(s) or medication(s) proposed:

      - Use of a non-invasive CO-Oximeter device by properly trained and approved paramedic personnel.

   B. Medical conditions for which they can be utilized:

      - Known or suspected CO exposure.

   C. Patient population that will benefit:

      - S-SV EMS is a 10 county Regional EMS Agency with a population of 1.3 million people. Multiple areas in our region have seasonal characteristics that result in increased risk of CO exposure/poisoning. There have been several fatalities and high profile cases involving CO exposure patients in these areas in the past several years. See included EMS provider documentation.

      - The use of CO-Oximeter devices will benefit patients in these areas as well as others who have an increased risk of CO exposure, especially in the winter months. In addition, the use of CO-Oximeter devices will benefit firefighter personnel who have an increased risk of CO exposure while operating on the fire ground.

2. 100146 (a)(2) A compendium of relevant studies and material from the medical literature.

   A. California EMSA Scope of practice position statement 'CO-Oximeter Devices (July 2010), Use and Level' states "Authorized for Paramedics when approved by the Medical Director of the Local EMS Agency and approved by the Director of the Emergency Medical Services Authority".

   B. NFPA, section 1584 published on January 31, 2008, establishes that "any firefighter exposed to CO or presenting with headache, nausea, shortness of breath, or gastrointestinal symptoms" must be measured for CO poisoning by Pulse CO-Oximetry or other available methods.

   C. NAEMT, NAEMSE and the IAFF have recently issued similar recommendations that EMS professionals "noninvasively screen patients for carbon monoxide poisoning that have had a suspected exposure, or present with any of the signs or symptoms of carbon monoxide poisoning."

   D. Attached are several medical literature documents as well as case studies regarding the use of CO-Oximeters by EMS personnel.

3. 100146 (a)(3) A description of the proposed study design including the scope of the study and the method of evaluating effectiveness of the procedure(s) or medication(s), and the expected outcome.

   A. Scope of the study:

      - The use of CO-Oximeter devices by S-SV EMS ALS providers is optional. It is anticipated that CO-Oximeter devices will be primarily utilized by ALS Fire Department EMS providers who have obtained these devices through the use of grant funds.

      - Any S-SV EMS ALS provider wanting to utilize a CO-Oximeter device for patient assessment must obtain previous approval from the S-SV EMS Agency.

      - Prior to the implementation of a CO-Oximeter device by approved prehospital providers, all paramedic personnel must complete S-SV EMS required training and demonstrate appropriate competency.

      - All patient uses of a CO-Oximeter device by prehospital personnel in the S-SV EMS Region will be tracked on the 'S-SV EMS Agency CO-Oximeter Trial Study Data Tracking Tool', a sample of which is included in this section immediately following this letter.

   B. Method of evaluating effectiveness:

      - Each use of a CO-Oximeter must be thoroughly documented according to S-SV EMS policy and in compliance with Title 22 regulatory requirements for prehospital documentation. In addition, a copy of this documentation is required to be forwarded to the S-SV EMS Agency within 30 days of use. This documentation will be reviewed by the S-SV EMS Agency and the S-SV EMS Regional Continuous Quality Improvement Committee (RCQI) on a routine basis. Each use will be entered into the trial study data tracking tool as described above.

      - Effectiveness will be evaluated by reviewing the prehospital documentation on the patients these devices are utilized on as well as reviewing additional hospital and outcome data as appropriate.

C. Expected outcome:

- It is expected that the use of non-invasive CO-Oximeter monitoring devices will assist in the assessment of patients with known or suspected CO exposure/poisoning. This will be an effective tool to determine the severity of patients who have experienced CO exposure as well as assist in ruling out CO exposure in patients with unexplained symptoms consistent with this type of condition.

4. 100146 (a)(4) Recommended policies and procedures to be instituted by the local EMS agency regarding the use and medical control of the procedure(s) or medication(s) used in the study.

   See included S-SV EMS CO-Oximeter Device policy, Reference No. 1105.

5. 100146 (a)(5) A description of the training and competency testing required to implement the study.

   See included training material and competency testing.

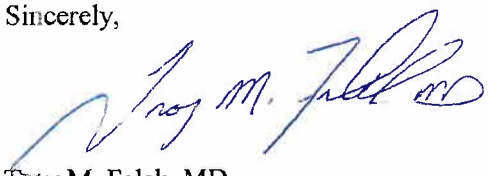
6. 100146 (b) The medical director of the local EMS agency shall appoint a local medical advisory committee to assist with the evaluation and approval of trial studies.

   1. The S-SV EMS Regional Medical Control Committee (MCC) has assisted in the development and approval of the S-SV EMS CO-Oximeter Device policy, Reference No. 1105.

   2. The S-SV EMS Regional Continuous Quality Improvement Committee (RCQI) will be tasked with monitoring the ongoing utilization of these devices by EMS personnel.

Thank you for your consideration of this proposed trial study. Please feel free to contact me with any additional questions or concerns you may have.

Sincerely,



Troy M. Falck, MD
Medical Director

S-SV EMS AGENCY CO-OXIMETER TRAIL STUDY DATA TRACKIN(

Date	EMS PROVIDER AGENCY	PATIENT NAME &/OR ID	TIME OF 9-1-1 CALL	TIME OF FIRST EMS CONTACT	SUSPECTED CO EXPOSURE (YES/NO)	SYMPTOMS OF CO EXPOSURE	TIME OF CO-OXIMETER APPLICATION	PREHOSPITAL CO LEVEL (OXIMETER READINGS)	TRANSPORT (YES/NO)	NAME OF RECEIVING FACILITY	1(>1
6/12/2010	NTFPD	11854	11:30	11:32	Yes	Dizziness	11:38	0.0	No	N/A	

RAD-57 SpCO MONITOR
CARBON MONOXIDE EMERGENCIES

The North Tahoe region is particularly prone to Carbon Monoxide (CO) incidents for it is one of the nation's largest alpine resort communities, with greater snowfall, and frequented by visitors not accustomed to the alpine environment and its unique hazards. Our community has a greater propensity for CO poisoning due to: our reliance on a large variety of combustion type heating appliances, heavy snow & ice build-up, air-tight construction, absentee (second) home ownership, uninformed guests, forest canopy debris, nest building rodents, and stranded snow bound motorists.

Every winter Tahoe-Truckee's fire services respond to numerous incidents involving CO. North Tahoe Fire District alone has responded to over 100 CO related incidents since 2002.

A few local examples involving deaths, serious injury, or a significant 'near-miss':

-Aspen Ave, S. Lake Tahoe Incident February, 2000 (Critical)
-Emerald Bay Road Incident, West Shore Tahoe February, 2001
-Horizon Casino, South Tahoe Incident September, 2001 (MCI)
-Tahoe Donner Incident Sept, 2004 (Fatality)
-Alpine Meadows Incident January 2005 (MCI with Fatality)
-Dollar Hill Incident, North Tahoe January, 2006 (Near-Miss MCI)
-Brook Ave Incident, Kings Beach September, 2006
-Coachland Mobile Homes Incident, Truckee October, 2006 (Fatality)
-Chinquapin Condo Incident, Tahoe City February, 2008 (MCI)
-Incline Village Incident February, 2008 (Near-Miss MCI)
-Squaw Valley Incident December, 2008 (Multiple Fatalities)
-State Line, So. Lake Tahoe January, 2009 (Fatality)
-Mt Rose Highway Incident, Incline Village February 2009 (Critical)
-Carnelian Bay Incident, North Tahoe October, 2009 (MCI)

The North Tahoe Fire District believes this data supports the development of an EMS policy that would allow for and guide the use of field Pulse CO-Oximetry (SpCO). This is an emerging and promising technology that has recently been cleared by the FDA, proven by over 100 case studies, and has been recently adopted by FEMA, NFPA, FDNY, National Association of Emergency Medical Technicians (NAEMT), National Association of EMS Educators (NAEMSE), International Association of Fire Fighters (IAFF).

The Masimo Rad-57 is an FDA cleared handheld pulse CO-Oximeter that quickly measures carboxyhemoglobin (COHb) through a simple to apply finger sensor. The device measures COHb which is displayed as a percentage that can help guide field providers in the general assessment and proper triage of persons suffering CO exposure. Because signs and symptoms of CO poisoning are so vague and subtle the device would greatly aid field personnel in the determination of CO exposure, allowing for prompt and possibly life saving intervention.

According to the Center for Disease Control's National Center for Environment Health, accidental CO poisoning kills 38,000 Americans every year with 43,000 emergency room visits a year and 15,200 of these requiring hospital admission. CO causes more accidental deaths than any other household poison and is the most common poisoning seen in the ER.

CO is only just slightly lighter than air and usually rises to the ceiling with the warm currents of air blown into a house. Because its specific gravity is so close to that of air it blends quickly with a home's atmosphere and is quite pervasive. A typical alpine home can be charged within minutes with lethal levels of CO by a malfunctioning forced air furnace.

The General public should realize the initial symptoms of CO are insidious, similar to the flu and thus seemingly benign. They include dizziness, headache, nausea, and fatigue--without fever. This silent killer is particularly adept at killing those in their sleep, as they tend to succumb without any waking symptoms. CO has an affinity with hemoglobin, the oxygen carriers of the blood, which is over 200 times greater than that of oxygen. The hemoglobin becomes saturated with CO, like a magnet, bumping off the oxygen molecules greatly reducing available oxygen to the cells of the body-particularly the brain.

Many times a year District personnel are asked to respond to residences and commercial occupancies for activated CO alarms. Based on our findings, and our ability to reproduce the hazardous condition, we then determine whether the occupancy is safe for re-habitation. This is a risky endeavor, for many times the structure has been aired-out prior to our arrival and we are unable to measure or recreate the hazardous condition. We can only determine in real-time the current atmospheric condition with our conventional multi-gas (CGI) monitoring devices. This sets us up for prematurely declaring an occupancy as safe when the hazardous condition may possibly reoccur. The half life of carboxyhemoglobin (COHb) is 4-6 hours. Now, with the advent of **Blood CO Saturation (SpCO)** monitoring, the occupants can be sampled and their hemoglobin can provide us with a living 4-6 hour record of past possible CO exposure.

First Aid	EMR	EMT	AEMT	Paramedic

CO-Oximeter Devices (July 2010)

Item:
Use of CO-Oximeter devices for measuring concentrations of Carbon Monoxide (CO) in the blood.

Classification:
- Advanced Life Support procedure
- Although non-invasive, the use of CO-Oximeters to measure CO exposure is considered a laboratory test rather than measurement of vital signs.
- Laboratory testing is not specifically listed in the scope of practice regulations for EMT or paramedics.

Use and Level:
- Not authorized for EMT's
- Authorized for Paramedics when approved by the Medical Director of the Local EMS Agency and approved by the Director of the Emergency Medical Services Authority.

Authority:
California Code of Regulations 100145 (c) (2) Chapter 4, allows the Medical Director of a Local Emergency Medical Service Agency to add additional items to the Paramedic local optional scope of practice with approval of OSHA.

Training:
Local EMS Agency's Medical Directors who wish to add the use of the CO-Oximeter devices to local optional scope of practice must submit proposed protocols, training and testing as part of a request to Emergency Service Medical Authority (EMSA) in accordance with EMSA publication # 125.

Equipment:
- Use of CO-Oximeter devices should be approved by the Medical Director of the Local Emergency Medical Services Agency following application to EMSA as an optional scope of practice procedure.

Medical Direction:
Used in accordance with a protocol written and approved by the local EMS agency medical director (HS 1797.220).

Considerations and Recommendations:

Measurement of Carboxyhemoglobin and Methemoglobin by Pulse Oximetry; A Human Volunteer Study

Barker SJ, Curry J, Redford D, Morgan S. *Anesthesiology* 2006; 105(5): 892-897

Introduction

Until recently, all pulse oximeters on the market used two wavelengths of light to estimate arterial hemoglobin saturation. These two-wave length technologies do not have the capability to distinguish dyshemoglobins from oxygenated hemoglobin resulting in erroneous SpO_2 readings when dyshemoglobins are present in the blood. Masimo Corporation has developed a new, 8-wavelength Pulse CO-Oximetry platform, Masimo Rainbow SET, which is designed to measure carboxyhemoglobin (SpCO) and methemoglobin (SpMet) as well as traditional SpO_2 values. This study tests the accuracy and reliability of Masimo Rainbow SET Pulse CO-Oximetry in measuring these dyshemoglobins in human volunteers.

Methods

Twenty healthy volunteers (two groups of 10) were fitted with peripheral venous and radial arterial cannuli and monitored by a three-lead electrocardiograph and automated sphygmomanometer. Each subject also wore six Masimo Rainbow sensors (on digits 2, 3 and 4 of both hands), each connected to a different Rainbow SET Pulse CO-Oximeter.

Carboxyhemoglobin Group

The ten subjects of the carboxyhemoglobin group wore a tight fitting breathing mask connected to an anesthesia machine for the delivery of a controlled mixture of air and CO. After obtaining baseline values, subjects breathed approximately 500 ppm of CO until they reached a maximum COHb level of 15%, at which point the F_iO_2 was changed to 100% until subjects reached a COHb level of 10%, then the mask was removed and they breathed room air. During baseline, CO administration and recovery, blood samples were taken every 10 minutes, via the radial artery cannula, for analysis by laboratory CO-Oximetry. Data was pooled for the 10 subjects to determine bias, precision, linear regression and the correlation coefficient for the data collected from the Rainbow SET Pulse CO-Oximeter compared to the average of the readings from three laboratory CO-Oximeters.

Methemoglobin Group

The ten subjects of the methemoglobin group were given an intravenous infusion of sodium nitrite at a rate of 6 mg/min to a total dose of 300 mg to induce methemoglobinemia. Prior to nitrite administration, during treatment and during recovery, blood samples were taken every 10 minutes, via the radial artery cannula, for analysis by laboratory CO-Oximetry. Recovery phase lasted until the methemoglobin level of each subject had decreased by at least 5% from its peak value. Data was pooled for the 10 subjects to determine bias, precision, linear regression and the correlation coefficient for the data collected from the Rainbow SET Pulse CO-Oximeter compared to the average of the readings from three laboratory CO-Oximeters.

Results

Figure 1.

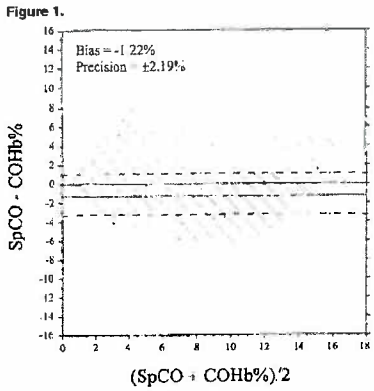


Figure 2.

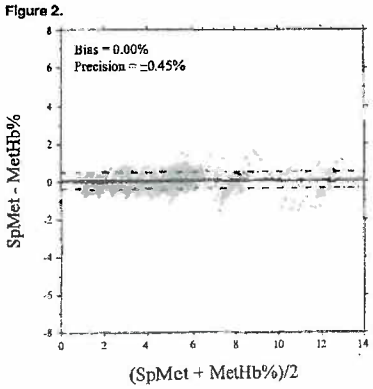


Fig 1. Bias plot of (SpCO - COHb%) verses (SpCO + COHb%) / 2
Pooled data for 10 subjects. SpCO is the Rainbow Pulse CO-Oximetry measurement of carboxyhemoglobin; COHb% is the average of three laboratory CO-Oximeters' measurements of carboxyhemoglobin. Lines show values of bias (solid) +/- precision (long/short dash).

Fig 2. Bias plot of (SpMet - MetHb%) versus (SpMet + MetHb%)/2
Pooled data for 10 subjects. SpMet is the Rainbow Pulse CO-Oximetry measurement of methemoglobin; MetHb% is the average of three laboratory CO-Oximeters' measurements of methemoglobin. Lines show values of bias (solid) +/- precision (long/short dash).

The pooled data for the ten subjects of the carboxyhemoglobin group show that Rainbow Pulse CO-Oximetry has a bias of -1.22 and a precision of 2.19 for SpCO, when compared to the average COHb reading from a laboratory CO-Oximeters. The Rainbow Pulse CO-Oximetry had a bias of 0 and a precision of 0.45 when calculated from the pooled SpMet readings, compared to the average MetHb reading collected from a laboratory CO-Oximeter. The precision of Rainbow Pulse CO-Oximetry SpCO measurement is about the same as that specified for conventional pulse oximeters. The precision of Rainbow Pulse CO-Oximetry SpMet measurement is approximately the same as a laboratory CO-Oximeter, when used within the ranges covered by this study.

Discussion

Carbon monoxide poisoning is the most common type of fatal poisoning in the United States with at least 5,000 fatalities and accounting for 49,000 ER visits annually in the U.S. alone. Methemoglobinemia, another potentially fatal dyshemoglobin disorder, can be caused by the use of commonly prescribed drugs like dapsone, benzocaine and other "caine" sprays as well as dehydration, sepsis, or accidental ingestion or inhalation of industrial chemicals. A retrospective study conducted at Johns Hopkins Bayview Medical Center found 138 cases of acquired methemoglobinemia over a 28 month period, including one fatality and three near fatalities[1]. Despite the high incidence of these two dyshemoglobin disorders, methods for measuring COHb and MetHb have been limited to time and labor consuming invasive blood tests done in hospitals and laboratories with laboratory CO-Oximeters. However, less than half the hospitals in the US have the capability to measure COHb and MetHb via laboratory analysis.[2] Masimo Rainbow SET Pulse CO-Oximetry provides an inexpensive and easily integrated method for solving this serious public health deficiency.

Authors' Conclusions

"Masimo Rainbow SET [Pulse CO-Oximetry] seems to be a major advance ...We have found it to be capable of detecting and measuring both methemoglobin and carboxyhemoglobin. It represents a significant improvement in our oxygenation monitoring capability."

1 Ash-Bernal R, Wise R, Wright S. Acquired Methemoglobinemia. A Retrospective Series of 138 Cases at 2 Teaching Hospitals. Medicine. 2004; 83:265-273.

2 Hampson, N. Carboxyhemoglobin Measurement by Hospitals: Implications for the Diagnosis of Carbon Monoxide Poisoning. Journal of Emergency Medicine. 2006 Jul; 31(1): 13-6.

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

Partridge R, Chee KJ, Suner S, Sucov A, Jay GD. *Respiratory Care*. 2006; 51(11); 1332.

Introduction

Symptoms of carbon monoxide toxicity (COT) are variable and non-specific and so are often confused with the symptoms of other common illnesses like flu. It is likely, therefore, that many cases of COT go undiagnosed by healthcare professionals, even though it is the most common type of accidental poisoning in the United States. The researchers utilized a new monitor, the Masimo SET Rainbow Rad-57 Pulse CO-Oximeter, to noninvasively measure carboxyhemoglobin in the blood of all ER admissions at their hospital, to determine the prevalence of unexpected cases of COT.

Methods

Pulse oximeters in the Emergency Department (ED) of an urban, academic hospital (with 95,000 annual visits) were replaced with Masimo SET Rainbow Rad-57 Pulse CO-Oximeters, prior to a retrospective chart review. Nurses were instructed to use the Rad-57 Pulse CO-Oximeter to noninvasively measure the carboxyhemoglobin levels (SpCO) of all adult patients presenting to the ER over a 3-month period, in order to determine if unsuspected cases of COT could be detected.

Results

Over the three-month period, over 10,000 emergency room patients were monitored for carboxyhemoglobin as part of the intake procedure. Nine of these patients, who presented with non-specific symptoms or unrelated complaints, were found to have toxic COHb levels with the Masimo Rad-57 Pulse CO-Oximeter. The toxic levels ranged from 16-33% and were confirmed with blood gas analysis. The sources of the CO exposures in the patients with COT were later identified and were usually in the home. Additionally, all patients with presumed toxic COHb levels due to smoke inhalation were identified with the Masimo Rad-57. Thirteen patients had false positive SpCO values with the Masimo Rad-57 (based on laboratory CO-Oximetry), but no false negatives were observed.

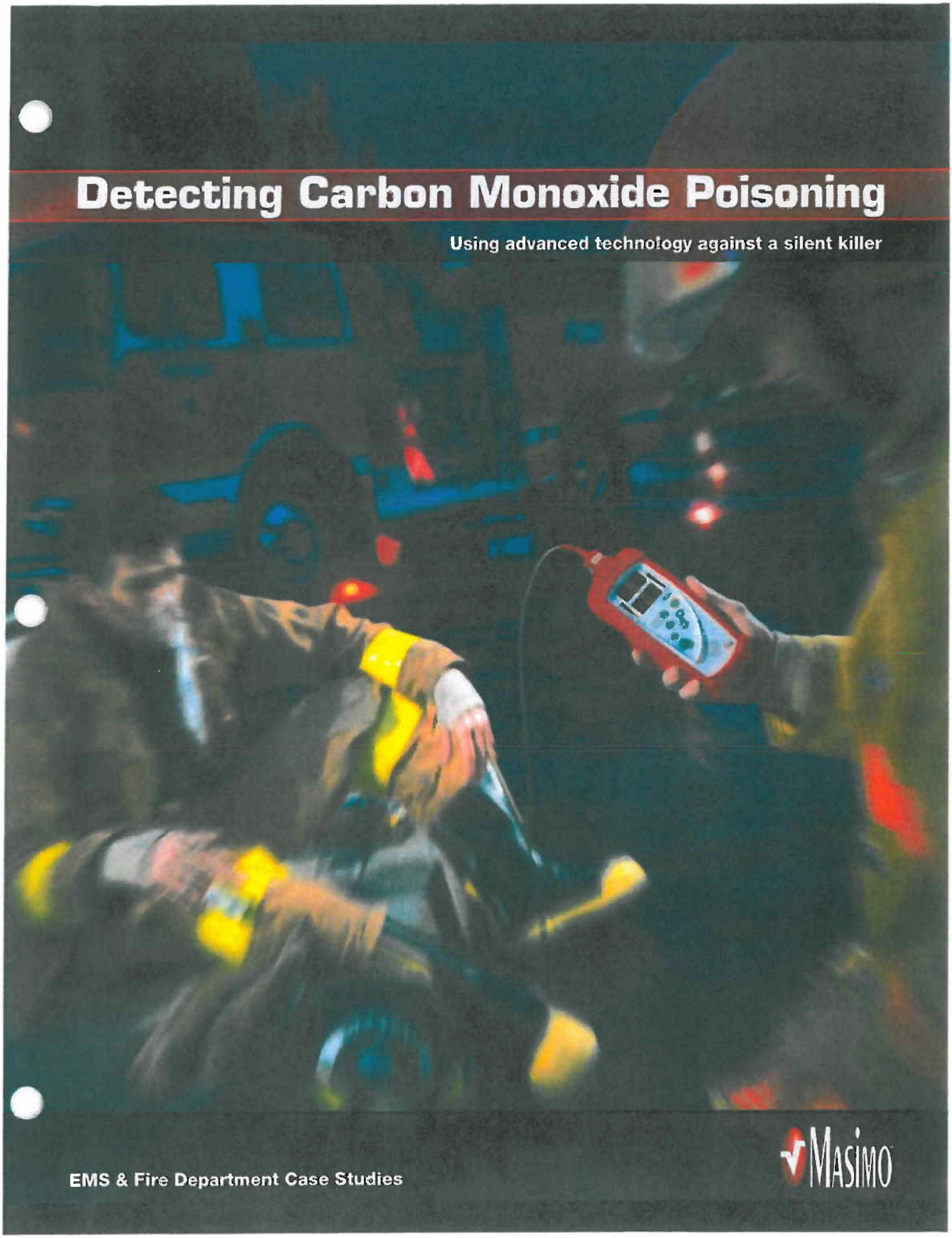
SEE 406

Conclusions

If the rate of unexpected CO poisonings found in this study was indicative of all US hospitals, it would equate to as many as 50,000 cases of unsuspected CO toxicity annually, nationwide. In this study, the Masimo SET Rainbow Rad-57 Pulse CO-Oximeter provided an easy and effective means of identifying both suspected and unexpected cases of COT as part of the ED patient admissions process. According to the authors of this study, "noninvasive testing for COT can be performed at ED triage...Unsuspected COT may be identified using noninvasive COHb screening and the prevalence of COT may be higher than previously recognized."

Detecting Carbon Monoxide Poisoning

Using advanced technology against a silent killer



EMS & Fire Department Case Studies

MASIMO

Using advanced technology against a silent killer

Bryan E. Bledsoe, DO, FACEP, EMT-P
Adjunct Professor of Emergency Medicine
The George Washington University Medical Center

Carbon monoxide (CO) is the number one cause of poisoning in industrialized countries. Each year, approximately 6,000 Americans die from CO poisoning and another 40,000 to 50,000 people seek ER care for CO-related problems.

CO is an odorless, colorless, tasteless gas that results from the incomplete combustion of carbon-containing fuels. Often called the "silent killer," CO's initial symptoms are often vague, subtle and easily misdiagnosed. The gas is so lethal because it readily displaces oxygen from hemoglobin and forms a compound called carboxyhemoglobin, which does not carry oxygen. As carboxyhemoglobin levels rise, the amount of oxygen transported in the blood progressively declines, depriving the victim of oxygen and eventually resulting in death.

As exposure levels increase, more significant signs and symptoms include mental clouding, severe headache, confusion, dizziness, and fainting. If exposure is severe or prolonged, coma and death may ensue.

Groups with an increased risk of CO poisoning include firefighters, children, the elderly, pregnant women, and people with heart and/or with respiratory disease. Individuals with pre-existing medical conditions can develop moderate to severe symptoms, even with low levels of CO exposure.

"The signs and symptoms of CO poisoning include malaise, flu-like symptoms, headache, shortness of breath on exertion, and fatigue."

Firefighters are at greater risk of developing CO poisoning. Poor-fitting SCBA gear or entering fire zones without an SCBA can significantly raise CO exposures. Recent research has shown that firefighters without SCBAs can develop elevated carboxyhemoglobin levels during the overhaul phase of fire operations. Research has also shown that both acute and chronic CO exposure can increase the risk

of developing long-term permanent complications (primarily neurological and cardiac).

Fortunately, the innovative new Masimo Rad–57 Pulse CO-Oximeter can monitor carboxyhemoglobin levels in the field. The non-invasive Rad-57 works like a conventional pulse oximeter (and has pulse oximetry capabilities), but this sophisticated monitor uses 7+ wavelengths of light to detect carboxyhemoglobin and other compounds. Detected carboxyhemoglobin is displayed as a percentage and can guide subsequent care. Because the signs and symptoms of CO poisoning are vague and subtle, EMS personnel and firefighters should routinely screen all persons for possible CO exposure.

Thanks to Masimo Rad-57 technology, EMS and firefighters can now quickly and accurately screen patients for possible CO poisoning. If elevated carboxyhemoglobin levels are detected, informed care decisions can rapidly be made. When dealing with patients suffering from CO poisoning, speed of treatment is the key to a successful outcome and reduced risk of long-term neurological and cardiac damage.

Since CO poisoning is easy to miss, even for emergency department personnel, the Masimo Rad-57 can serve as a risk management tool. By screening all possible victims for CO exposure, emergency personnel can now quickly identify CO poisoning and prevent victims from returning to toxic environments.

Detecting carbon monoxide poisoning in seconds with Masimo Rad-57

The Masimo Rad-57 is the only FDA-cleared noninvasive way to detect elevated levels of carbon monoxide in the bloodstream in seconds, letting EMS and fire professionals quickly and easily diagnose carbon monoxide poisoning on the scene.

Just slip the sensor on a firefighter or patient's finger and press a button. The Masimo Rad-57 will detect the percentage of carbon monoxide in the bloodstream in just seconds, allowing for prompt and possibly life-saving treatment.

To find out more about how the Masimo Rad-57 can help you quickly and accurately detect carbon monoxide poisoning, call 1-800-257-3810 or go to: www.masimo.com/rad-57

The Averted Tragedy

Tim Bradley, Captain
Aurora Fire Department
Aurora, IL

The call: Heat exhaustion

At 1242 hours on a very hot, humid summer afternoon in June 2006, the Aurora Fire Department responded to a report of a male with heat exhaustion. The call originated from a large factory where this person had been working for the past four hours. Engine 9 and Medic 4 arrived on scene and were taken by security to the patient who was on a second floor landing at one end of the factory. He appeared confused and agitated. We placed the patient on O_2 with a non-rebreather mask. ALS care was initiated and the patient was removed to the ambulance. At this point, everyone thought it was a normal case of heat exhaustion.

Masimo Rad-57 identifies CO poisoning

Once in the ambulance, the paramedic used the Masimo Rad-57 to check the patient's SpO_2 when he noticed a carbon monoxide reading of 9%. Once the medic advised me of the patient's CO level, I sent my crew into the building with a handheld gas meter. Immediately we found CO levels between 40 and 55 ppm. The levels continued to increase as we walked farther into the structure, eventually getting as high as 556 ppm.

Immediate evacuation of 100+ employees

A truck company and battalion chief were requested to the scene as we immediately began evacuating over 100 employees from the structure. Some of the people being evacuated began complaining of headaches and fatigue, including some pregnant females. These people were taken to an ambulance where their vitals and CO levels were evaluated.

CO source identified

The CO originated from propane- and gasoline-operated power lifts used to install rack storage. The lifts were removed from the building and the CO levels slowly dropped to 0 ppm. About three hours later, the employees were allowed to re-enter the building.

Masimo Rad-57 prevents a serious situation

The original patient was transported to a local hospital where he was treated and released. The Masimo Rad-57 made a huge difference, preventing a serious situation from spiraling out of control. It also saved the local hospitals from an avalanche of patients. Fortunately we were able to handle it all on scene, without overwhelming our system's resources. This incident was mitigated with only one minor injury, but I am left to wonder what would have happened if we did not have the Masimo Rad-57 that day.

City of Aurora Fire Department, Aurora, IL

The City of Aurora Fire Department is responsible for a 39 square-mile area about 40 miles west of Chicago. They serve a population of 157,267 with three battalion chiefs, 203 career firefighters, nine pumpers, three aerial/platform units, and six medic units.

Glenn Joseph
Boca Raton Fire Rescue
Boca Raton, Florida

Mary Russell
ER nurse
Boca Raton Community Hospital
Boca Raton, Florida

Hospital Alerted to Lethal Threat

The call: Security guard complains of dizziness, headache

On September 7, 2006 at 1350 hours, a security guard from a construction site at a nearby condominium complex presented to the ED at Boca Raton Community Hospital complaining of dizziness and a headache.

Aware and prepared...with a Masimo Rad-57

"Carbon monoxide was already very much on our radar screen," said Mary Russell, an ED nurse at Boca Raton. After hurricanes Frances and Jeanne, the hospital had admitted entire families with CO poisoning caused by generators.

"We had just gotten a Masimo Rad-57, and I thought that this would be a great opportunity to put it to the test and verify my suspicion that CO poisoning was responsible for the symptoms." said Russell. "Before getting the Rad-57, testing CO levels in patients had been a long and painful process, involving drawing blood from an artery and waiting for lab results."

The results of the Rad-57 test confirmed Russell's suspicion of elevated CO levels, and she had the presence of mind to ask the patient whether there were any generators being used on the constuction site. After the patient confirmed there were multiple generators in use, the hospital called Boca Raton Fire Rescue, which rushed its HazMed unit to the site at 2800 S. Ocean Blvd.

CO levels 100 times higher than normal prompt evacuation of 100

"When they arrived at the site, our HazMed unit got a CO reading of 900 ppm in the lobby," said Glenn Joseph of Boca Raton Fire Rescue. "That's 100 times higher than normal. Other areas showed readings of 500 ppm."

The 20-story condo had been undergoing hurricane damage repairs, and the construction crews had generators going in the garage area. "We had them stop all operations," said Joseph. "Rescue crews went floor by floor, telling the 100 or so persons in the building they needed to leave." After field triaging each of the building's occupants with the Rad-57, only one other person was taken to the hospital. That person and the security guard were given oxygen and recovered quickly.

The ability to quickly assess the CO levels of all of the building's occupants meant that the HazMed team was able to speed treatment to those who needed it. And, just as importantly, the team could avoid unnescessarily transporting the 99 unaffected patients to the hospital, freeing up valuable clinician time and bed space at the ED, and avoiding the cost and time associated with a large scale transport operation.

Boca Raton Fire Rescue

The Boca Raton Fire-Rescue Services Department provides fire suppression, fire safety inspections, fire investigations, fire and emergency medical service education, hazardous materials response, and emergency medical services to the community of Boca Raton in southeast Florida. The department is comprised of 207 certified professionals. Over 90 percent of the personnel are licensed paramedics. 10 percent are certified emergency medical technicians. The department serves approximately 83,760 year-round residents.

Boca Raton Community Hospital

Located an hour away from Miami on Florida's southeast coast, Boca Raton Community Hospital is a 394-bed not-for-profit health care organization with more than 750 primary and specialty physicians on staff who provide preventative and acute hospital care. Nearly 2,100 employees and over 1,200 volunteers enable the hospital to provide quality healthcare to its patients.

The Converted Paramedic

JD Postage
Firefighter/Paramedic
Violet Township Fire Department
Pickerington, OH

The call: An ill person at restaurant

In November 2006, Medic 593 was called out for an ill person at a local restaurant. We found the patient sitting in the back of a police car. He had been driving erratically and ended up striking a parked car and trash can in the restaurant parking lot. The patient was alert but very confused, complaining of a headache, nausea, vomiting, weakness and dizziness. The patient's physical exam was normal, with no signs of trauma.

Hypoglycemia? Possible medication overdose?

At this point, I was sure I knew what was wrong with the patient--it was hypoglycemia. A check of the patient's blood sugar quickly proved me wrong. His sugar was 232 mg/dL. I thought about a medication overdose, but couldn't find anything to support that after searching the patient and his car. We had tried everything we could think of to determine why this patient was so altered, each time coming up blank.

Then someone suggested we try "that new piece of equipment." I was not one of the Rad-57's biggest fans; I thought it was just one more thing we had to carry around, taking up space on the truck. However, as we had gone through everything else with this patient, I didn't think it could hurt. Within 20 seconds, the Masimo Rad-57 had changed the entire direction of the call.

Masimo Rad-57 reveals the problem

The patient had a CO level of 40% with a SpO_2 of 94%. Now that we knew exactly what was wrong with the patient, we immediately began treatment with high flow O_2. With the patient's condition under control, we needed to find the source of the CO, in case there were others who were being poisoned along with the patient.

CO source: not in the home

As the patient was transported to the hospital, we had another engine respond to check the man's house and disabled wife. Fortunately, there was no CO found in the patient's residence and the wife was okay. Eventually, the source of the CO was attributed back to a bad exhaust system on the vehicle the patient had been driving.

Man might have been released back to a CO-poisoned environment

There was nothing about this patient, as he initially presented, which would have led us to suspect CO poisoning. If not for the Masimo Rad-57, he would have been just another altered mental status with unknown cause. We would have taken him into the ED where it is likely they would not have discovered the true cause of the patient's condition because he didn't have a history that would make carbon monoxide poisoning an obvious diagnosis. He would have been released from the ED back to his poisoned environment.

The Masimo Rad-57 took the guesswork out of diagnosis

The treatment for CO poisoning in the field is oxygen. That's the easy part. It is a matter of detection. Can you tell if it is food poisoning, the flu, a headache or is it actually CO poisoning? What about when your patient is too confused to appropriately answer your questions? The Masimo Rad-57 took the guess work out of it for us. I thought it was just one more piece of equipment until I saw what a difference it made on this call. Now I wouldn't be without it.

Violet Township Fire Department

The Violet Township Fire Department in Pickerington, Ohio is about 20 miles outside of Columbus in Fairfield County. They cover 42 square miles and serve 30,000 residents in Pickerington, parts of Canal Winchester and Reynoldsburg. The department has 39 career firefighters, 22 part-time and 12 volunteers who respond to about 4,000 medical and fire calls per year.

The Rescued Mother

Shaughn Maxwell
Captain/Paramedic
Medical Services Officer
Fire District 1
Everett, WA

The call: Unconscious female

On a fall morning, Snohomish County Fire District 1 received an emergency call from two young children who said their mother had passed out. Fire District 1 responded with an ALS Ladder, Medic Unit and an MSO (EMS supervisor). On arrival the children sent us to the upstairs bathroom where we found the mother unconscious but breathing, with signs of seizure activity.

The source of the problem

While moving her into the bedroom, one of the firefighters/paramedics noted a faint odor of exhaust. After 5 minutes in the house, other firefighters started to complain of headaches. Some of the crew searched the house and discovered a running car inside the closed garage, directly below the upstairs bedroom.

Masimo Rad 57 reveals high CO level

The Masimo Rad-57 was placed on the patient. Her initial CO reading was 80% (manufacturer's note: the Masimo Rad-57 accuracy is specified to a range of 0-40%). The four gas meter read 400ppm inside the bedroom. We evacuated the patient and her children from the residence. The kids were evaluated with the Masimo Rad-57 and found to have very low levels of CO.

Patient transported to ER, CO level drops to 37%

Inside the medic unit the patient was RSI'ed and transported to an emergency room 20 minutes away. A later Rad-57 reading showed that the patient's CO level had dropped to 37% while the hospital's blood gas CO-Oximeter read 36%.

Snohomish County Fire District 1

Located 20 miles north of Seattle, along the I-5 corridor, Snohomish County Fire District 1 serves a community of 160,000 residents, including the cities of Mountlake Terrace and Brier. The district has eight stations, 150 firefighters, a HAZMAT and rescue team. They respond to over 13,000 calls annually and provide BLS and ALS transport. The district originally bought two Masimo Rad-57s to monitor their own firefighters during fire rehab, but they're now used mainly for EMS responses.

Masimo Rad-57 showed mild CO exposure in response team

While still at the hospital, the firefighter/paramedics that had been in the house checked their own CO levels with the Rad-57. The battalion chief, who carries our second Rad-57, responded to the station where the ladder is housed to evaluate the crew for CO exposure. Our responders did have a mild CO exposure; however we did not have to place any units out of service. The battalion chief returned to the station a few hours later to assure that the crew's CO levels had dropped to normal.

Masimo Rad-57 provided fast, accurate CO diagnosis

The Rad-57 helped to quickly, and with certainty, diagnose a very sick patient. By knowing the identity and severity of what we were dealing with, it allowed us to provide treatment for the carbon monoxide poisoning much more effectively than if we weren't able to measure for CO.

Just in Time for Holiday Inn

Allan R. Goodwin, B.Comm., EMT-P
A/Superintendent
Incident Response Planning & Preparedness
The City of Calgary
Emergency Medical Services (165)
Calgary, Alberta

The call: Hotel guests dizzy, nauseated

On August 13, 2006 at approximately 1000 hours, Calgary EMS responded to a sick person call at the Holiday Inn at Macleod Trail and 42nd Avenue S.E. Paramedics arrived to find guests in the hotel's banquet room who were dizzy, weak and nauseated. Paramedics quickly called the fire department when they suspected potentially deadly CO poisoning. "These were symptoms consistent with CO poisoning," said Calgary EMS spokesman Doug Odney. Upon arrival, firefighters confirmed high levels of gas throughout the building, especially in the kitchen where CO levels were over 1,000 ppm. Evacuations are triggered when CO concentrations reach 50 ppm.

200 guests evacuated, 16 hospitalized

Hotel guests eating breakfast, swimming in the pool, and some still sleeping were rushed outside while firefighters ventilated the building. Firefighters searched the hotel room by room to ensure all guests were outside. Once evacuated, paramedics assessed 45 patients and transported 16 people with CO poisoning to three city hospitals.

Masimo Rad-57 quickly triaged patients

Using a Rad-57 Signal Extraction Pulse CO-Oximeter--which Calgary EMS had acquired just two weeks before--paramedics quickly triaged all 45 patients for CO poisoning. "Hopefully, we'll see these devices soon on every ambulance," said Odney, crediting the equipment for the speedy triage.

In addition to the ability to speed treatment to the affected patients, using the Masimo RAD-57 allowed Calgary EMS to avoid tying up valuable pre-hospital and ED resources by unnecessarily transporting 29 unaffected persons

Venting problem in mechanical room

Fire department spokeswoman Deb Bergeson said the source of the carbon monoxide appeared to be a venting problem in the hotel's mechanical room.

City of Calgary Emergency Medical Services

Calgary EMS, an entirely ALS system, is responsible for over 96,000 emergency responses a year, and operates 41 advanced life support (ALS) response vehicles during peak times of the day when call volumes are highest. They operate 20 full-transport units 24 hours per day, 19 units 12 hours per day and a 24-hour air medical crew, stationed at the Calgary International Airport. Additionally, the department operates 3 Paramedic Response Units 24 hours per day. On certain time-dependent life threatening calls, the department receives backup by Calgary Fire Department First Responders.

Saving Lives in Anchorage

Mike Melchert, Captain
F. X. Nolan, Chief Medical Officer
Anchorage Fire Department
Anchorage, AK

The call: Family perished

In 2005, an entire family died in Anchorage, Alaska when deadly amounts of carbon monoxide leaked into their house in the middle of the night. Their tragic deaths caused a heightened awareness of carbon monoxide poisoning and brought about the passage of a new law making carbon monoxide detectors mandatory.

193 calls found CO in Anchorage homes

So far this year, the Anchorage Fire Department has responded to 580 carbon monoxide calls, 193 of which actually revealed elevated carbon monoxide in the home. Fire officials recommend people have a working carbon monoxide detector in their home. They insist it's not only the law but it can save lives. The tragedy in 2005 also prompted the city's fire department to take another critically important step.

Anchorage first city in U.S. to include Pulse CO-Oximeters in ambulances

The Anchorage Fire Department has added Masimo's Pulse CO-Oximeters to its ambulance units. AFD is hoping the new devices will help save lives throughout the city.

The department says the devices will come in handy for calls where symptoms are vague, letting response teams accurately measure CO levels in the blood in less than 30 seconds. "It will allow us to assess people suspected of CO exposure in the presence of only vague symptoms," said F. X. Nolan, AFD's chief medical officer. "Airborne CO meters allow us to measure how much CO is in the air, but when we are called to a scene, our first concern is how much CO is in the patient's blood."

"The Rad-57s give us an idea of how much CO is in the body. This helps paramedics and emergency workers determine how badly you've been exposed and guides them in administering the right treatment," said AFD's Captain Mike Melchert. The meters are also being used in Girdwood and in Chugiak. Funding for the new gear came from a federal grant.

Anchorage Fire Department

The Anchorage Fire Department encompasses 12 fire stations and 391 personnel. There are seven Basic Life Support and five Advanced Life Support engine companies, four truck companies, three aerials, a heavy rescue company and four tankers that serve as front line suppression and EMS response units. Seven Mobile Intensive Care Units, Fire and EMS battalion chiefs complete the 24-hour unit staffing. An additional rescue company and a variety of specialized units, including dive, foam, hazmat, mountain and water rescue are also available through cross-manning. Each engine company serves as a non-transport Basic Life Support unit equipped with a semi-automatic defibrillator to enhance response to cardiac emergencies. The engine companies assist the Department's 66 firefighter/paramedics who provide Advanced Life Support care and transport in conjunction with firefighter/emergency medical technicians.

The Transport Decision

Karen Gibbins
Firefighter
Greenfield Center Volunteer Fire Company
Greenfield, NY

The call: Carbon monoxide alarm/man down

On January 16, 2007, in the midst of a brutal winter storm where over 1600 homes lost power, I was at the firehouse coordinating field teams to go door to door checking on our large population of elderly residents and answering phone calls from those who weren't home when the field teams stopped by. Among those in the field teams were my husband, Gary Gibbins (Assistant Chief and EMT), and my sons Jason (Captain and EMT) and Joshua (Lieutenant). At ~1730, a 911 call came in for a carbon monoxide alarm with illness/ man down. Gary & Jason responded immediately in the chief's vehicle with our rescue truck and pumper following.

Propane stove left on

Once on scene, they found a 76 year old male conscious but very confused. He was not complaining of anything, but was answering all questions inappropriately. The patient's wife stated she had just returned home and found her husband acting strange, so she opened all the doors and windows and called 911.

Gary noticed that the propane stove was on and shut it off. Jason went immediately to the patient and put him on 12 liters per minute of oxygen via NRB and then took the patient's vitals.

Greenfield Center Volunteer Fire Company No. 1

Greenfield Center Volunteer Fire Co. #1 is one of four departments that make up Greenfield Fire District, located an hour north of Albany, NY. Greenfield Center Fire Company has 40 members and operates two engines, one heavy rescue, one medical vehicle and one brush truck. They cover a mostly rural area and are usually first on scene with EMS calls, since the nearest ambulance is 5-20 minutes away.

42% carboxyhemoglobin level, man flown to hospital for hyperbaric treatment

The Masimo Rad-57 showed that the patient's SpCO was 42%, so Jason increased the oxygen to 15 liters. Gary informed the crew on the incoming ambulance about the patient's CO level and while still en route, the ambulance called for a helicopter to fly the patient out. EMS continued giving the patient oxygen and prepared him for the short trip to the waiting helicopter. The patient was flown to Westchester Medical Center where he went to the hyperbaric chamber and fully recovered.

Masimo Rad-57 allowed fast decision on best method of transport

While we suspected that the patient was suffering from carbon monoxide poisoning, the Rad-57, allowed us to quickly identify just how severe the poisoning was and use that knowledge to select the most appropriate form of transport and destination for the patient. This decision was instrumental in saving his life.

The Missed Diagnosis

John Andrews, EMT-P
Field Training Officer
Tuolumne County Ambulance
Sonora, CA

The call: Dizziness

On November 11, 2006 at 2307 hours, Tuolumne Medic 41 and a California Department of Forestry engine were dispatched out to a 58 year-old female complaining of dizziness. Upon arrival, we found the patient sitting in a recliner in her mobile home, complaining of severe dizziness that had caused her to fall four days ago. The prior fall resulted in an ambulance transport and an emergency room visit with repair of soft-tissue injuries to her face. She returned home after the ER visit and continued to have problems with dizziness which remained undiagnosed.

Masimo Rad-57 reveals SpCO level of 13%

The patient had a very extensive respiratory and cardiac history. She answered questions appropriately (GCS 15) and did not appear to be in severe distress. When the Masimo Rad-57 sensor was applied to obtain the SpO_2 reading, the alarm began to sound due to a SpCO level of 13%. Given that the patient's SpO_2 was 83%, her fractional saturation was at best 70%, so it was no surprise she was dizzy. The room was filled with cigarette smoke and after further questioning, we discovered that her husband had turned on their furnace for the first time that season about five days before.

The problem finally diagnosed

The patient was removed from the house, placed on a non-rebreather oxygen mask at 15 liters and taken to the local hospital. She continued to improve throughout transport. Her O_2 saturation came up to 96% and her SpCO fell from 13% to 7% over the 45 minute transport. Upon our arrival at the hospital, the patient had no complaint of dizziness and continued to improve during her emergency department stay. The hospital did not have a CO-Oximeter in the facility and relied on the Masimo Rad-57 readings to make their assessment and treatment decisions.

Masimo Rad-57 saves wife and husband

The Masimo Rad-57 helped us identify the CO poisoning that had most likely been missed four days prior by fire, EMS and ER crews. While a SpCO of 13% by itself is not terribly high, combined with her complex medical history the patient's condition became dangerous. The positive CO reading from the Masimo Rad-57 led to the woman's prompt diagnosis and treatment, prevented her condition from continuing or worsening, and kept her husband from becoming the next patient.

Tuolumne County Ambulance

Tuolumne County Ambulance service is the exclusive ambulance provider for Tuolumne County and is based in Sonora, California. They are located in the Sierra Nevada mountain range of Central California which includes a large portion of Yosemite National Park. Ambulance services are provided from four locations throughout the county including a new joint operations center for both ambulance and fire service in Sonora. The ambulance service covers over 2,000 square miles with an annual call volume of just over 6,000 calls.

The Triage Tool

Russell Chisholm
Firefighter /Paramedic
Miami Beach Fire Rescue
Miami Beach, FL

The call: Food poisoning

On October 23, 2006 Rescue 1 'C' shift was dispatched to a suspected food poisoning call at a hotel on Ocean Drive. Upon arrival, we knocked on the door and had to wait several minutes before the guest, who could barely walk, was able to answer the door. He was very altered, complaining of nausea and a really bad headache. We found the patient's wife, who was on the commode, in the same state of mind as her husband. Both patients were severely incontinent and their skin was a blotchy red color.

Miami Beach Fire Rescue
Miami Beach Fire Rescue serves a 7.1 square mile barrier island in Dade County, Florida, which hosts over 7.5 million tourists annually. Beach populations usually run from 90,000-92,000, swelling to 200,000 on a normal weekend, and rising to 500,000 on holidays and special event weekends. The department is comprised of 200 firefighters divided into 3 shifts, with each shift running 6 ALS ambulances with three medics onboard. They have two 100 ft. ALS ladder trucks and four ALS engines--all staffed with firefighters/paramedics. The department responds to 20,000 calls per year, 85% of which are medical.

Patients' SpO2 saturations in the low 90's, crew suffer headaches

Both patients' SpO2 levels were in the low 90's. Our crew had only been in the room for about five minutes before we started getting headaches. There was a distinct stale odor in the room so the windows were opened for some ventilation. Both patients were moved into the hallway, placed on high flow O2 and within 5-10 minutes started to feel better.

Masimo Rad-57s called to the scene

We called for the four gas meter and one of two Masimo Rad-57s in field that night to be brought to the scene. (The other nine Rad-57s were going into service the next day.) The equipment arrived as the two rescue units were transporting the patients to Mt Sinai Medical Center in Miami Beach. Upon arrival at the ER, we alerted the nursing supervisor to the suspected CO poisoning. She took the initiative to run ABGs.

Rad 57 helps triage 60 guests

We transported another patient to the same hospital 45 minutes later. The RN showed us the blood gas report on the two patients- the male was 38%, the female 37%. The hotel was immediately closed down and the guests evacuated. The Rad-57 was used to triage the 60 guests, who ranged from a low of 3% to a high of 21%. There were two families of four who were transported to the hospital, with the parents' CO levels in the low teens and the children anywhere from 6% to 10%. In total, 14 people were transported for CO poisoning. All patients taken to the hospital had blood gas CO levels almost identical to the Masimo Rad-57 readings.

The cause: hot water heater venting stack

The suspected cause of the incident was a hot water heater on the north side of the building whose venting stack ran under the crawl space and up the south side of the building. The facility was closed for three weeks while repairs were made.

Masimo Rad-57 proved invaluable to patients, rescue personnel and hospital

The City of Miami Beach is now actively trying to get an ordinance passed that would require CO detectors in all buildings and would be part of the annual fire inspection. This call could have had a disastrous outcome if everyone from the hospital staff to the rescue crews, engine and ladder crew, and the command staff didn't work together. The Masimo Rad-57 was immensely helpful with the triage of a large number of patients. If we only had the four gas meter to base treatment decisions off of, we could have tied up rescue units transporting patients who did not need transport or worse yet, left people on scene who really needed to go to the hospital.

Rapid Triage

Anthony Butkus and Micheal Daly
Battalion Chiefs
Bridgeview Fire Department
Bridgeview, IL

The call: An ill person at printing company

On January 18, 2007, the Bridgeview Fire Department responded to the report of an ill person at a commercial printing operation. Upon arrival, fire and EMS personnel were met outside by company employees with vague flu-like symptoms that, given the environment, were thought to be the result of carbon monoxide poisoning or exposure.

Masimo Rad-57 reveals elevated CO–29% in one patient

Using a Masimo Rad-57 monitor, the patients were quickly examined and triaged. EMS personnel determined that all patients had an elevated level of CO—the highest being 29%. While patients felt their symptoms were improving, their CO levels had not diminished to normal ranges; subsequently, three of the four patients were transported to area hospitals.

Bridgeview Fire Department

Located in a suburb of Chicago, the Bridgeview Fire Department is a full time department providing fire, rescue, and ambulance services to the more than 5,000 households in the area. The department currently employs 1 fire chief, 3 battalion chiefs, and 35 firefighters/EMTs, and operates two strategically-located fire stations.

400 ppm CO level traced to faulty propane forklift

A check of the building with the four-gas monitor revealed a CO level exceeding 400 ppm. The source of the carbon monoxide was traced to a malfunctioning propane forklift operating in the building's storage area. The high CO level was mitigated through simple ventilation of the work area.

Masimo's non-invasive diagnostic tool speeds patient assessment

The Rad-57 proved to be a valuable component of patient treatment. Its diagnostic capabilities aided EMS personnel in rapidly and accurately assessing patients exposed to elevated CO levels. The non-invasive nature of this technology is an asset to our department and the EMS field in general.

A Day for Making a Difference

Mark Brewer
Masimo Corporation
Account Executive

The incident: Demo reveals danger

Masimo's Mark Brewer was recently performing a pulse-ox demo at the Phoenix Indian Medical Center for their Director of Respiratory, Karen Chief Onesalt and her supervisor Wanda. "When I placed our Rad-57 on Wanda's finger, her CO reading was 6," said Mark. Then I placed the probe on Karen's finger and got the same CO reading—a 6. Finally, I put the probe on my finger and got a 1. Linda Lopez, supervisor for OR/PACU, joined us and I placed the probe on her and got a reading of 1. Something didn't add up."

Complaining of flu-like symptoms

Karen and Wanda had recently noticed feeling ill whenever they spent time in the break room. Both complained of flu-like symptoms. "As I continued my presentation—Linda and I had now been in the break room for over 30 minutes—I stopped and retested our CO levels. Both of us were now reading a 3 and Linda began complaining that she was now feeling ill," said Mark.

Mystery solved

"I asked Karen if the department was located next to a boiler or furnace room, and it turns out their office is next to the delivery dock," said Mark. "Karen called Facilities and they are now having the area tested for elevated CO levels. Karen was very thankful for what I had done for her today, but I responded that it's not what I did; it's what Masimo can do for your hospital. And yes, Karen and Linda are convinced that the hospital needs and will be converted to Masimo Pulse CO-Oximetry."

Race Against Time Prevents CO-Related Tragedy

Brandon Johnson
Firefighter/Paramedic
Hebron, Kentucky Fire Protection District
Hebron, Kentucky

The call: Allergic reaction

In February 2006, firefighter/paramedics with the Hebron, Kentucky Fire Protection District were called to a local hotel in response to a young girl experiencing a potential allergic reaction to chlorine. The girl had been in the hotel's indoor pool for about an hour when she started feeling sick. Upon arrival, firefighter/paramedic Brandon Johnson tried to assess the situation, "I think the kids were a little nervous to talk to our crew, so we didn't get too good of a read from them." The crew quickly requested an engine company to perform CO screening on victims. While waiting for the engine to arrive, the crew's air monitors began detecting high levels of CO-at least 900 ppm in the indoor pool area and more than 1,200 ppm in the adjacent boiler room.

Masimo Rad-57 arrives, patients gone

When the engine company arrived with the Masimo Rad-57, the families had already left the hotel--despite the crew's warnings. "Luckily they gave us some cell phone numbers and contact information," said Johnson. The crew began testing hotel staff and detected 16% SpCO in a maintenance worker who'd been working in the boiler room for about 20 minutes. Johnson and his crew became extremely concerned at that point, knowing the children had been in the pool for about an hour. The crew quickly called dispatch and requested that an ambulance respond to the hotel where the families had returned.

Kids sick with 22% CO, mothers 18% CO

En route to the hotel, Johnson's crew contacted one of the mothers via cell phone and explained the danger they were in. By the time the families returned to their hotel, all four children had vomited. When Johnson and his crew arrived, they immediately tested the families with the Rad-57 and detected COHb levels of 20% to 22% in all four kids and 17% to 18% percent in the mothers. All were immediately taken to hospitals and recovered without incident.

Rad-57 quickly quantified seriousness of the problem

Johnson gives much of the credit for the patients' fortunate outcome to the Rad-57, adding that other than taking the patients to an ED or actually witnessing symptoms, there wouldn't have been any way to quantify the seriousness of the problem. "It couldn't have been done without that instrument," Johnson said of the Rad-57. "It's been really beneficial for us, especially in responding to incidents when air monitors can't find the source." Johnson's experience underscores the complexity of CO-related incidents and the need for vigilance by first responders in dealing with them.

Hebron, Kentucky Fire Protection District

Hebron Fire Protection District is located in the northern part of Boone County, KY, and covers approximately 42 square miles. The fire district has 2 stations, 32 full-time personnel with 13 of those being paramedics. There are also about 20 volunteers that serve the district. The district maintains 3 engines, 1 tower ladder, 1 rescue, 2 ambulances, 2 utility trucks, 3 staff vehicles, and 1 regional hazmat unit that responds throughout Northern Kentucky stations.

SIERRA-SACRAMENTO VALLEY EMS AGENCY
PROGRAM POLICY

REFERENCE NO. 1105

SUBJECT: CO-OXIMETER DEVICES

PURPOSE:

To define the indications and use of CO-Oximeter devices in the prehospital setting by paramedic personnel.

AUTHORITY:

Health and Safety Code 1797.220 and 1798

California Code of Regulations, Title 22, Division 9, Section 100146 & 100169

OVERVIEW:

As carbon monoxide (CO) is considered the "silent killer", its presence should be considered on the fire ground, in confined spaces, when multiple unexplained illnesses occur within the same occupancy, or when a CO detector has alarmed.

CO is only slightly lighter than air and usually rises to the ceiling with the warm currents of air blown into a house. Because its specific gravity is so close to that of air, it blends quickly with a home's atmosphere and is quite pervasive. A typical home can be charged within minutes with lethal levels of CO by a malfunctioning forced air furnace. This silent killer is particularly adept at killing those in their sleep, as they tend to succumb without any waking symptoms.

CO has an affinity with hemoglobin, the oxygen carriers of the blood, which is 250 times greater than that of oxygen. The hemoglobin becomes saturated with CO, like a magnet, replacing oxygen molecules and greatly reducing available oxygen to the cells of the body – particularly the brain.

INDICATIONS:

The use of CO-Oximeters to measure CO exposure is an advanced life support skill because it is considered a laboratory test rather than a measurement of vital signs.

S-SV EMS paramedic personnel may utilize an approved CO-Oximeter as a laboratory testing device on any patient (adult and pediatric) with suspected carbon monoxide (CO) exposure.

Signs & Symptoms of Possible CO exposure

The initial symptoms of CO exposure are insidious, similar to the flu and thus seemingly benign. These symptoms increase in severity as the SpCO level rises and may include:

1. Dizziness / vertigo
2. Headache
3. Shortness of breath
4. Nausea / vomiting
5. Fatigue
6. Confusion / altered judgment
7. Syncope
8. Tachycardia
9. Cardiac arrhythmias
10. Seizures
11. Shock
12. Coma
13. Apnea

PROCEDURE:

A. All persons entering areas of suspected elevated CO levels should don appropriate PPE, including, but not limited to SCBA.

B. Remove all ambulatory persons / patients to fresh air as soon as safely permitted. Remaining patients should be triaged and extricated according to START-TRIAGE procedures.

C. Secondary triage including application of the CO-Oximeter away from the CO source in accordance with the accompanying algorithm will allow for determination of further treatment and transport considerations.

D. Approved triage tags should be used when necessary with CO level, time measured, and time O2 applied recorded on the triage tag along with standard information.

E. Use of the CO-Oximeter should not interfere with treatment or transport of any other suspected or identified injury or illness nor does it negate the need for further management and investigation of the symptomatic patient as other medical conditions may still be present.

F. The following guidelines should be utilized regarding placement of the CO-Oximeter finger sensor:

   1. Sensor should be placed on the middle or ring finger. Index finger may be used, but as a last choice.

2. Thumb placement may be utilized for patients 10 – 50 kg.

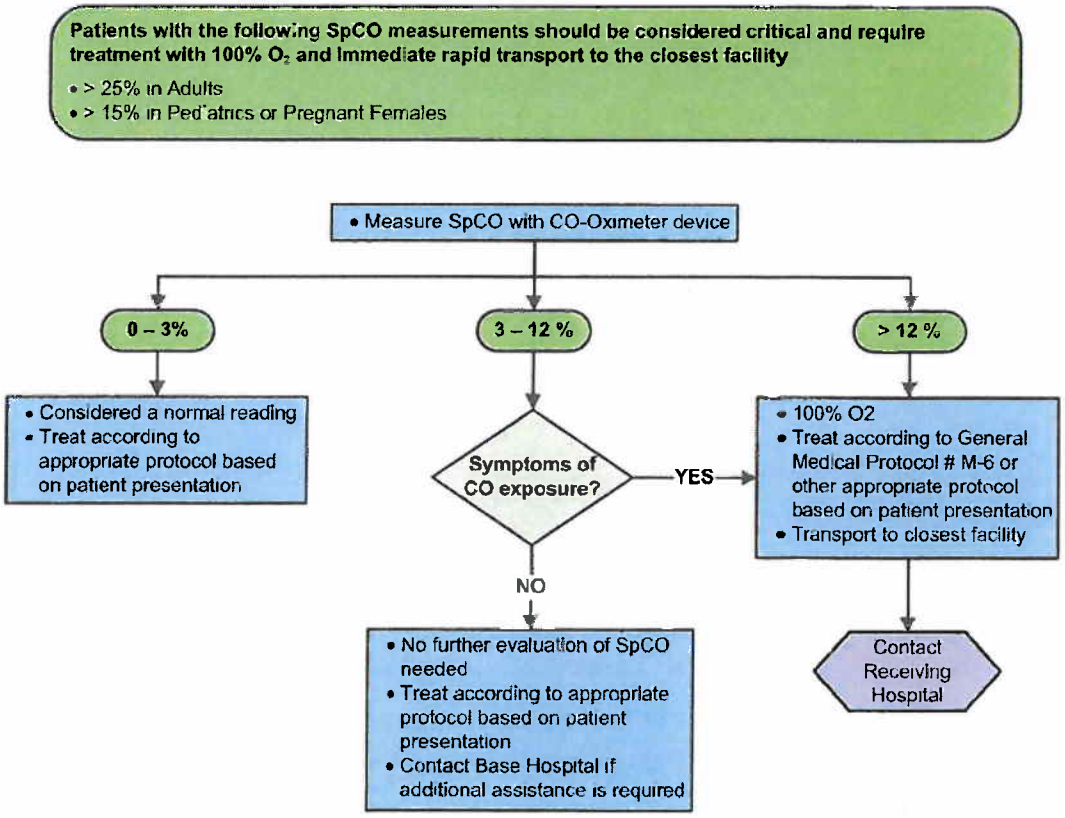
3. Sensor should not be below heart level.

4. Insert finger until the tip of finger hits the "Stop Block", LED's (red light) should pass through mid-nail, not cuticle.

CONTINUOUS QUALITY IMPROVEMENT

A copy of the completed PCR for any patient on whom a CO-Oximeter monitoring device is utilized must be forwarded to the S-SV EMS Agency within 30 days for Continuous Quality Improvement purposes.

CARBON MONOXIDE (CO) EXPOSURE ASSESSMENT AND TRIAGE ALGORITHM:



Masimo

Understanding and Using the RAD-57 Pulse Co-Oximeter

RAD-57 Pulse CO-Oximeter

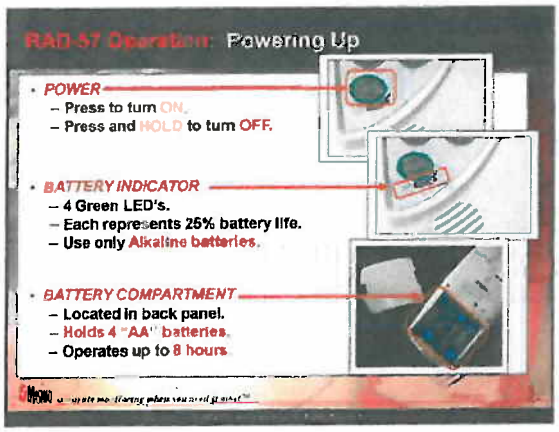
The RAD-57 is the world's first and only Pulse CO-Oximeter:

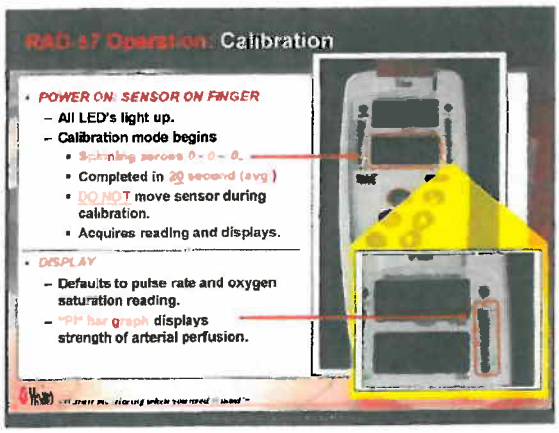
- That can accurately measure carboxyhemoglobin (SpCO) levels noninvasively, in *SECONDS!*
- Masimo SET SpO2.
- Masimo SET pulse rate.
- Masimo SET PI and low Signal IQ Indicator.
- Continuous CO bar graph.
- Adjustable alarms.
- 8-10 hour battery life on four AA's.
- Easy to read in bright sunlight.
- Durable EMS soft carry-case.

Introduction of the RAD-57

- Product Description
  - The Rad-57 Rainbow SET Pulse Co-oximeter is a noninvasive, arterial saturation and pulse rate monitor. The Rad-57 features a multicolored LED display that continuously displays numeric values for Sp02 and pulse rate, a Low Signal IQ indicator (Low SIQ) indicator, LED indicator bars for Perfusion Index (PI), Carboxyhemoglobin saturation (%SpCO), alarm status, alarm silence, battery life and SpCO sensor connected.
- Indications For Use:
  - The Rad-57 Pulse Co-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate and carboxyhemoglobin saturation (measured by an SpCO sensor). The Rad-57 and accessories are indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile and home environments.

RAD-57 EMS Carry Case
• Lightweight: 13 oz
• Small: 6.2" x 3.0" x 1.4".
• Portable: operates on 4 "AA" batteries.
• Supplied with high-visibility, water-resistant protective case.
– Protective cover.
– Extra sensor pocket.
– Reference card holder.
– Department ID holder.
– Pen holder.
– Spare battery pocket.


RAD-57 Operation: Powering Up
• POWER
– Press to turn ON.
– Press and HOLD to turn OFF.
• BATTERY INDICATOR
– 4 Green LED's.
– Each represents 25% battery life.
– Use only Alkaline batteries.
• BATTERY COMPARTMENT
– Located in back panel.
– Holds 4 "AA" batteries.
– Operates up to 8 hours.


RAD-57 Operation: Calibration
• POWER ON: SENSOR ON FINGER
– All LED's light up.
– Calibration mode begins
• Scrolling across 0 - 0 - 0.
• Completed in 20 second (avg.)
• DO NOT move sensor during calibration.
• Acquires reading and displays.
• DISPLAY
– Defaults to pulse rate and oxygen saturation reading.
– "PI" bar graph displays strength of arterial perfusion.

RAD-57 Operation: Sensor Placement

- *SENSOR PLACEMENT IS VERY IMPORTANT*
  - When possible, use ring finger, non-dominant hand.
  - Insert finger until the tip of finger hits the STOP Block.
  - Sensor should not rotate or shift freely on finger.
  - LED's (red light) should pass through mid-nail, *not* cuticle.
  - There is a top and bottom, cable should be on top (nail side).

RAD-57 Operation: Pulse Rate and Saturation

- *DISPLAY AFTER INITIAL CALIBRATION*
  - Oxygen Saturation on top in Red
  - Pulse Rate on bottom in Green.
  - Green PI scale, indicates strength of arterial pulse
  - Low SIQ LED indicates poor signal quality
  - Press SpCO to display % carboxyhemoglobin
  - Press "Bell" to silence alarms

RAD-57 Operation: Pulse Rate and Saturation

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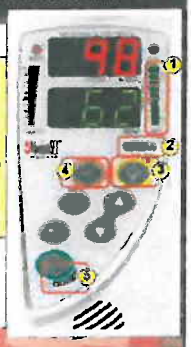
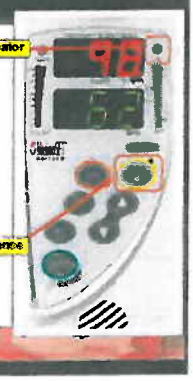


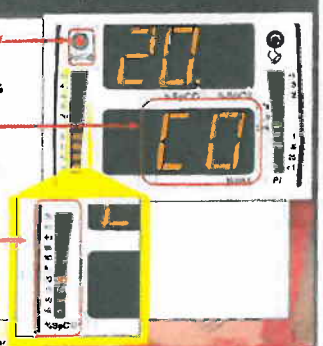
RAD-57 Operation: Alarms

- When violated, audible alarm will sound, parameter will flash
- Preset at factory:
  - Sa02 (oxygen saturation)
    - Low: 90%
    - High: none
  - Pulse Rate
    - Low: 50
    - High: 140
  - SpCO (carboxyhemoglobin)
    - Low: none
    - High: 10%
- Alarms adjust:
  - Press "Mode/Enter" twice
  - Press "Next" key to scroll through parameters
  - Use up and down keys to adjust
  - Reverts to Factory settings after turned off.



RAD-57 Operation: Measuring CO

- PRESS ORANGE SPCO BUTTON
- Display will toggle to CO mode for 10 seconds
- Carboxyhemoglobin reading in % on top
- "CO" displayed on bottom confirming mode
- ALWAYS confirm high readings by taking several measurements on DIFFERENT fingers and average
- Real-time SpCO indicator continuously reads SpCO
  - Green: 1-9%
  - Orange: 10-19%
  - Red: 20% and above



RAD-57 Operation: Troubleshooting

1. WILL NOT TURN ON:
   - Check battery compartment
   - Replace batteries
2. CALIBRATION MODE WILL NOT STOP:
   - Shield from flashing lights, strobes or high ambient light
   - Try other digits
3. "NO CBL" MESSAGE:
   - Cable not seated into top of Rad-57
   - Defective cable
4. "SEN OFF" MESSAGE:
   - Sensor off finger
   - Sensor misaligned
5. "Err" MESSAGE
   - Return for service
6. CONTINUOUS SPEAKER TONE
   - Internal failure, return for service

Carbon Monoxide: Introduction

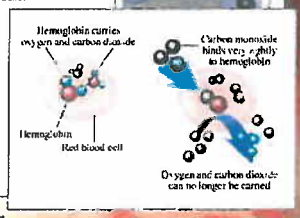
EXPOSURE RISKS:

- **Some degree of exposure to carbon monoxide at or near the scene of a fire is almost impossible to avoid. Firefighters may not be afforded continuous protection from carbon monoxide due to a variety of factors that include:**
  - Limited or restricted use of SCBA such as in wildland fires.
  - Premature removal of SCBA prior to or during overhaul.
  - Availability of SCBA during search and rescue operations.
  - Faulty or defective face mask on SCBA equipment.
  - Exposure near fire ground while not actively involved in fire (engineer at or near apparatus).
  - Exposure at command, staging, rest and rehab areas

Carbon Monoxide: Physiology Review

REVIEW:

- **Carbon monoxide is inhaled and passed from the lungs to the blood binding to hemoglobin.**
  - Produces carboxyhemoglobin.
  - Affinity to hemoglobin 250 X greater than oxygen.
  - Reduces oxygen carrying capacity of blood.
  - Alters release of remaining oxygen to cells.
- **Acts as an intracellular toxin.**
  - Poisons cells and tissue.
- **Binds with myoglobin in muscle.**
  - Interferes with heart and skeletal muscle.
- **Immediate threat to life.**
  - Oxygen starvation.
  - Cardiac arrhythmias.
  - Alters judgment, reasoning.
- **Long-term health effects**
  - Central nervous system damage
  - Cardiovascular damage.



Carbon Monoxide: Signs and Symptoms

$HbCO$ Level	Clinical Manifestations
>5%	Mild headache
10%	Mild headache, shortness of breath with exertion
10-20%	Moderate headache, shortness of breath
20-30%	Worsening headache, nausea, dizziness, fatigue
30-40%	Severe headache, vomiting, vertigo, altered judgment
40-50%	Confusion, syncope, tachycardia
50-60%	Seizures, shock, apnea, coma

Carbon Monoxide: Treatment Review

ALWAYS FOLLOW LOCAL EMS PROTOCOLS

- Scene safety, protect yourself:
  - Consider SCBA's
- Remove patient safe distance from the poison!
- ABC's (airway, breathing and circulation).
- 100% High-flow oxygen with non-rebreather mask:
  - Wash poison out of system
  - Decrease half-life of CO in blood.
  - Increase delivered oxygen in blood.
  - Support ventilations as needed.
- Transport to [illegible] facility.
- Consider hyperbaric treatment center:
  - Adults >25%, Ped! & Pregnant female >15%.
- Consider air transport for extended distance.
- Monitor all ABC's, vital signs and SpCO.

Carbon Monoxide: Firefighter Risk Review

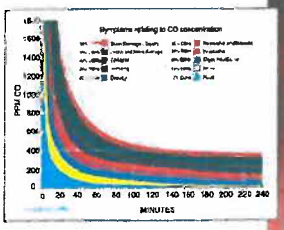
FIRE SERVICE SUMMARY

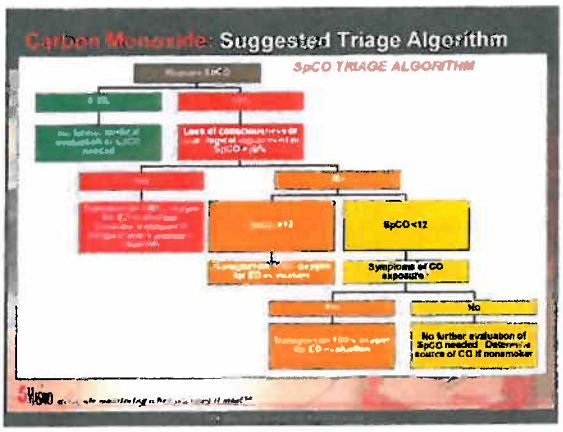
- Firefighters are routinely exposed to carbon monoxide as part of their firefighting duties.
- Firefighters are at risk for CO poisoning during periods the SCBA's (self-contained breathing apparatus) are not worn.
- CO levels are highest during the poor fire or "overhaul", search & rescue operations and wildland firefighting.
- Firefighters typically have little or no protection from CO at wildland fires.
- Studies have shown low levels of intravascular CO lead to central nervous system and cardiovascular disease
- Moderate to high levels are immediate threats to health and safety and cause cardiovascular injury
- Firefighters should receive CO screening at every fire to spot carbon monoxide and receive prompt treatment in order to reduce the immediate and long-term health effects.

Carbon Monoxide: Translating PPM to SpCO

PPM TO SpCO TRANSLATION

- PPM or "Parts Per Million" is the atmospheric concentration of the gas.
- PPM is common fireground safety measurement, often misleading as CO forms in pockets.
- SpCO as measured by RAD-57 is a function of PPM CO and total time of exposure of the poison.
- Age and health may be a factor.
- Even low PPM levels can lead to high SpCO if exposure is long enough, common in overhaul.
- Even at 50 PPM for 60 minutes requires assessment and possible medical treatment with oxygen




Carbon Monoxide: Suggested Triage Algorithm
SpCO TRIAGE ALGORITHM
SpCO<12
Symptoms of CO exposure?
No
No further evaluation of SpCO needed. Determine source of CO if nonsmoker

Keys to Successful SpCO and SpMet Monitoring with the Masimo Rad-57

The Masimo Rad-57 is a Pulse CO-Oximeter, not a conventional pulse oximeter. Depending on the product configuration you have, the device is capable of continuously and noninvasively measuring just carbon monoxide (SpCO) or SpCO and methemoglobin (SpMet) levels in the blood, in addition to oxygen saturation and pulse rate.

The Masimo Rad-57 uses multiple (7+) wavelengths of light housed in a single, simple-to-apply sensor to accurately determine the dyshemoglobins SpCO and SpMet, as well as SpO_2, and pulse rate. Conventional pulse oximetry technologies use only two wavelengths of light and lacks the sensitivity to determine dyshemoglobin levels.

What to Expect: Because of the increased sensitivity of the Masimo Rad-57 as compared to conventional pulse oximeters, extra care is needed to assure that the sensor is placed on the patient's finger correctly and that excessive external light is not present in order to achieve an accurate reading.

Proper Sensor Placement is the Key:

To achieve the most accurate results from the Masimo Rad-57, follow these simple steps:

1. Place the sensor on the middle or ring finger (Figure 1). Index finger may be used, but as the last choice
2. The finger should be pushed up to the "stop" on the lower pad (Figure 2). The emitter (lights) should go through the middle of the nail bed. If the finger nail bed is short, position so emitter lights go through middle of the nail bed
3. Beware of slender digits. The light can go around small digits and display false high readings
4. Keep the site as still as possible
5. Shield site from bright and especially flashing and strobing lights
6. Check for nail polish—certain nail polishes with metallic components can alter the readings

Troubleshooting

In the case of apparently errant SpCO readings:

1. Check sensor placement and reposition the sensor following steps 1-6 at left
2. Shield site from bright light, especially in the presence of flashing or strobing lights
3. Ensure site is as still as possible
4. Take measurements on two other fingers and average results
5. Verify absence of elevated methemoglobin levels (>1%). Elevated MetHb levels may cause falsely high SpCO readings
6. Make sure the device is not being used outside the published environmental temperature specifications (7°F - 104°F)

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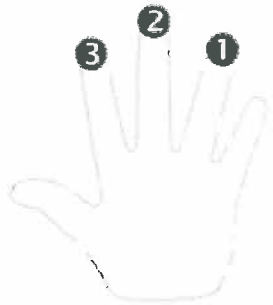
Figure 1



Use the ❶ ring, ❷ middle, and ❸ index fingers for measuring

Figure 2

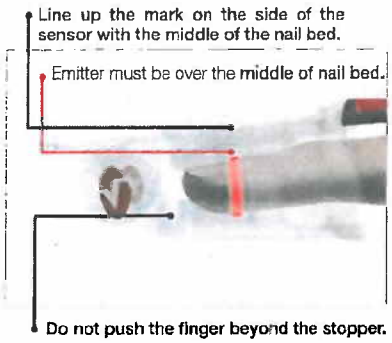


Figure 3

When comparing SpCO readings to invasive CO-Oximetry readings, always repeat SpCO measurements within one minute of blood draw. COHb will decrease by approximately 50% after 45 minutes on oxygen.

MASIMO

For questions, please call Masimo at 1-877-4-MASIMO

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S-SV EMS
CO-Oximeter
Self-Learning Module

PURPOSE:

This Training Module has been developed to serve as a template for EMS provider training on the use of CO-Oximeter devices. The intent is to provide consistent and concise information to paramedic personnel practicing in the S-SV EMS Region whose agency implements the use of this optional device.

OBJECTIVES:

Upon completion of this learning module the participant will be able to:

1. Identify the causes and physiology of CO exposure
2. Identify the Signs and Symptoms of CO exposure
3. Identify the triage, assessment and treatment of patients with possible CO exposure
4. Identify the indications and proper use of a CO-Oximeter

INSTRUCTIONS:

1. Read the accompanying information, S-SV EMS CO-Oximeter policy and any additional reference material as necessary.
2. Complete the attached post test and return to your provider representative.
3. A score of greater than 80% on the post test is required for successful completion of this training module.
4. Please contact your provider representative with any questions, suggestions or concerns.

TRAINING MODULE FOR CO-OXIMETER DEVICES

Background Information

The use of field Pulse CO-Oximetry (SpCO) is an emerging and promising technology that has recently been cleared by the FDA, proven by over 100 case studies, and has been recently adopted by FEMA, NFPA, National Association of Emergency Medical Technicians (NAEMT), National Association of EMS Educators (NAEMSE), and the International Association of Fire Fighters (IAFF).

FDA approved pulse CO-Oximeters quickly measure carboxyhemoglobin (COHb) through a simple to apply finger sensor. These devices measure COHb which is displayed as a percentage that can help guide field providers in the general assessment and proper triage of persons suffering from CO exposure. Because signs and symptoms of CO poisoning are so vague and subtle, these devices aid field personnel in the determination of CO exposure, allowing for prompt and possibly life saving intervention.

According to the Center for Disease Control's National Center for Environmental Health, accidental CO poisoning kills 38,000 Americans every year. In addition, Co poisoning also results in 43,000 emergency department visits each year, 15,200 of which require hospital admission. CO causes more accidental deaths than any other household poison and is the most common poisoning seen in the emergency department.

CO is just slightly lighter than air and usually rises to the ceiling with the warm currents of air blown into a house. Because its specific gravity is so close to that of air, it blends quickly with a home's atmosphere and is quite pervasive. A typical home can be charged within minutes with lethal levels of CO by a malfunctioning forced air furnace.

Additionally, some degree of exposure to carbon monoxide at or near the scene of a fire is almost impossible to avoid. Firefighters may not be afforded continuous protection from carbon monoxide due to a variety of factors that include:

- Limited or restricted use of SCBA such as in wildland fires.
- Premature removal of SCBA prior to or during overhaul.
- Availability of SCBA during search and rescue operations.
- Faulty or defective face mask on SCBA equipment.
- Exposure near fire ground while not actively involved in fire (engineer at or near apparatus).
- Exposure at command, staging, rest and rehab areas.

As carbon monoxide (CO) is considered the "silent killer", its presence should be considered on the fire ground, in confined spaces, when multiple unexplained illnesses occur within the same occupancy, or when a CO detector has alarmed.

Carbon Monoxide Physiology:

Carbon monoxide is inhaled and passed from the lungs to the blood binding to hemoglobin:

- CO produces carboxyhemoglobin.
- CO has an affinity to hemoglobin that is 250 times greater than oxygen.
- CO reduces the oxygen carrying capacity of blood.
- CO alters the release of remaining oxygen to cells.
- Hemoglobin that becomes saturated with CO, displaces oxygen molecules greatly reducing available oxygen to the cells of the body – particularly the brain.

Carbon monoxide acts as an intracellular toxin:

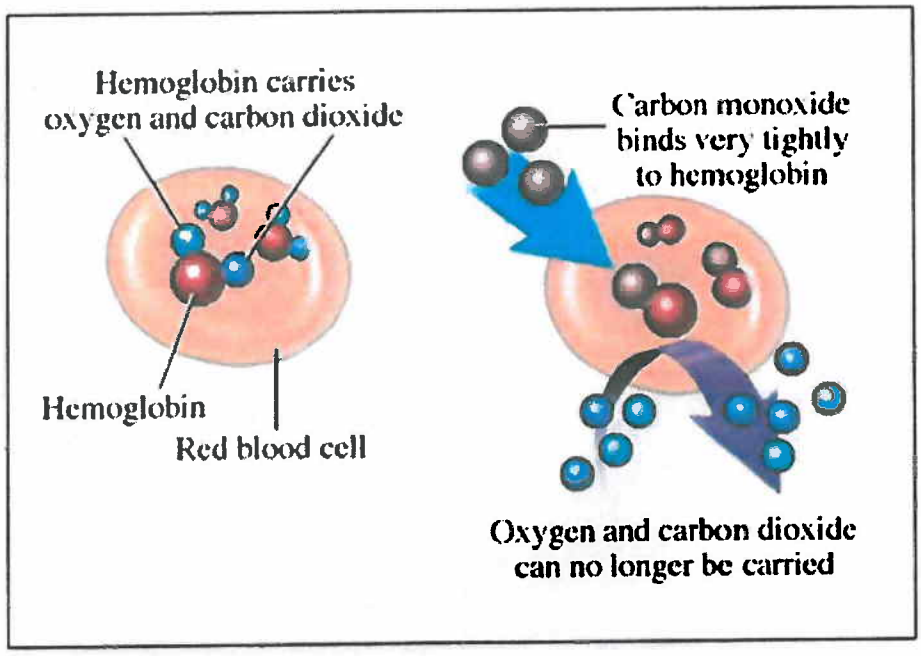
- CO poisons cells and tissue.

Carbon monoxide binds with myoglobin in muscle.

- CO interferes with heart and skeletal muscle.

The half life of carboxyhemoglobin (COHb) in the blood stream is 4-6 hours.

Carbon monoxide exposure can result in both immediate threat to life as well as long-term health effects such as central nervous system damage and cardiovascular damage.



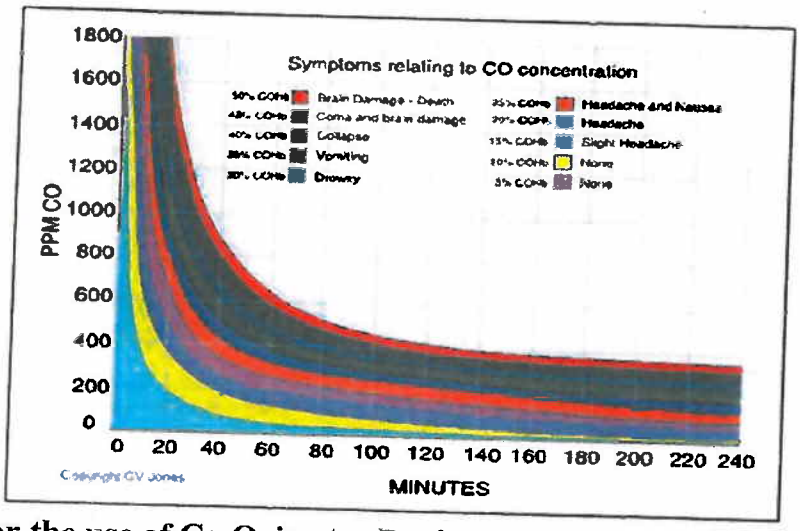
Carbon Monoxide Exposure Signs and Symptoms:

The initial symptoms of CO exposure are insidious, similar to the flu and thus seemingly benign. They include dizziness, headache, nausea, and fatigue – without fever. This silent killer is particularly adept at killing those in their sleep, as they tend to succumb without any waking symptoms.

SpCO Level	Clinical Manifestations
>5%	Mild headache
10%	Mild headache, shortness of breath with exertion
10-20%	Moderate headache, shortness of breath
20-30%	Worsening headache, nausea, dizziness, fatigue
30-40%	Severe headache, vomiting, vertigo, altered judgment
40-50%	Confusion, syncope, tachycardia
50-60%	Seizures, shock, apnea, coma

Translating PPM to SpCO:

PPM or "Parts Per Million" is the atmospheric concentration of the gas. PPM is a common fireground safety measurement, often misleading as CO forms in pockets. SpCO as measured by a CO-Oximeter is a function of PPM CO and total time of exposure of the poison. Age and health may be a factor and even low PPM levels can lead to high SpCO if exposure is long enough which is common in overhaul situations. Even at 50 PPM for 60 minutes requires assessment and possible medical treatment with oxygen.



Indications for the use of Co-Oximeter Devices:

The use of CO-Oximeters to measure CO exposure is an advanced life support skill because it is considered a laboratory test rather than a measurement of vital signs.

S-SV EMS paramedic personnel may utilize an approved CO-Oximeter as a laboratory testing device on any patient (adult and pediatric) with suspected carbon monoxide (CO) exposure.

Carbon Monoxide (CO) Exposure Assessment and Triage Procedures:

- All persons entering areas of suspected elevated CO levels should don appropriate PPE, including, but not limited to SCBA.

- Remove all ambulatory persons / patients to fresh air as soon as safely permitted. Remaining patients should be triaged and extricated according to START-TRIAGE procedures.

- Secondary triage including application of the CO-Oximeter away from the CO source in accordance with the accompanying algorithm will allow for determination of further treatment and transport considerations.

- Approved triage tags should be used when necessary with CO level, time measured, and time O2 applied recorded on the triage tag along with standard information.

- Use of the CO-Oximeter should not interfere with treatment or transport of any other suspected or identified injury or illness nor does it negate the need for further management and investigation of the symptomatic patient as other medical conditions may still be present.

- The following guidelines should be utilized regarding placement of the CO-Oximeter finger sensor:

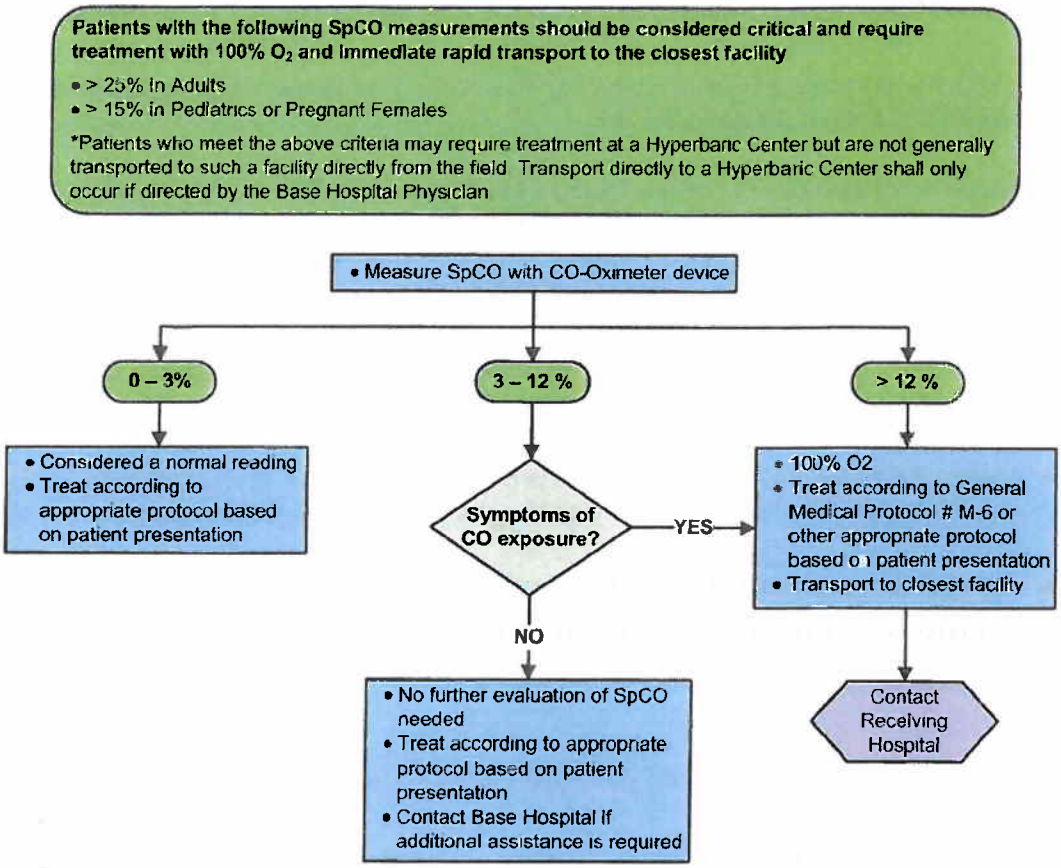
    1. Sensor should be placed on the middle or ring finger. Index finger may be used, but as a last choice.

    2. Thumb placement may be utilized for patients 10 – 50 kg.

    3. Sensor should be not below heart level.

    4. Insert finger until the tip of finger hits the "Stop Block", LED's (red light) should pass through mid-nail, not cuticle.

Additional Measurement Considerations for Smokers:

Consideration should be given to the fact that smokers routinely have elevated baseline blood CO levels. This factor can vary widely from one individual to another; a margin of 4% should be allowed for smokers as reflected in the following assessment and triage guidelines.

Carbon Monoxide (CO) Exposure Assessment and Triage Algorithm: