Accuracy of Noninvasive Carbon Monoxide Detection by SpCO: The Rainbow SET Technology Platform

INTRODUCTION

Carbon monoxide (CO) is a colourless, odorless, and poisonous gas that kills or permanently harms thousands of people each year. It is the leading cause of accidental poisoning in the U.S. Over 500 people die annually from unintentional CO exposure, and there are more than 50,000 reported emergency department visits resulting from CO poisoning each year. Carbon monoxide is a byproduct of combustion, with the most common sources including fire, exhaust from automobiles, gas furnaces and ovens, propane and kerosene heaters, and charcoal grills. Carbon monoxide is harmful when inhaled because it binds to the haemoglobin in red blood cells 200 times more strongly than oxygen, producing carboxyhaemoglobin (COHb). Carboxyhaemoglobin decreases the oxygen carrying capacity of the blood, thereby reducing the amount of oxygen delivered to the tissues and vital organs.

Carbon monoxide poisoning can be very difficult to diagnose unless the poisoning is the result of exposure to an obvious incident such as fire or intentional exposure to exhaust fumes. The initial symptoms of CO poisoning are similar to other less critical conditions such as the flu or fatigue and include shortness of breath, chest pain, headache, fatigue, dizziness, drowsiness, and/or nausea. During prolonged or high exposures, symptoms can worsen and include vomiting, confusion, muscle weakness, and loss of consciousness. The symptoms of CO poisoning may occur sooner in those most susceptible: the elderly, very young, people at high altitude, people with existing heart or lung conditions, or those who already have elevated CO blood levels (COHb)—for example, smokers. CO poisoning can be reversed if caught in time. However, even if the patient recovers, acute poisoning may result in permanent damage to vital organs and pronounced neurological deficits.

METHODS

The accurate measurement of CO poisoning has been limited to invasive blood tests analysed by blood gas machines with CO-Oximetry measurement capability. Many smaller hospitals do not have CO-Oximeters, which makes confirmed diagnosis of CO poisoning in these situations impossible. Masimo has introduced a new technology called Rainbow SET, providing accurate measurement of COHb in the blood. Rainbow SET SpCO was examined during a large clinical trial. The following sections will describe the study and its results.

One hundred and sixty (160) volunteers were tested for normal and elevated COHb levels. Levels of greater than 15% COHb were caused by very excessive smoking in volunteers with a substantial smoking history that has resulted in elevated COHb baseline levels. Each subject had Rainbow DC-I digit sensors attached to as many as 4 digits. The sensors were connected via patient cables to Rainbow SET Pulse CO-Oximeters. The data from the Pulse CO-Oximeters was downloaded onto a laptop computer to continuously log oxygen saturation (SpO_2), Pulse Rate (PR), and carbon monoxide saturation (SpCO). [NOTE: SpCO is defined as COHb that is noninvasively measured via Masimo's Signal Extraction multi-wavelength pulse CO-Oximeter.] Once a stable baseline for SpO_2, Pulse Rate and SpCO were achieved, a venous sample of blood was drawn. The blood was immediately analysed on an ABL 700 series blood analyser with CO-Oximetry, which measures Hb, O_2Hb, COHb, and MetHb. The demographics for the test population are shown in Table I. All were healthy volunteers, although many were enrolled in the study because of their significant smoking history and corresponding elevated COHb levels.

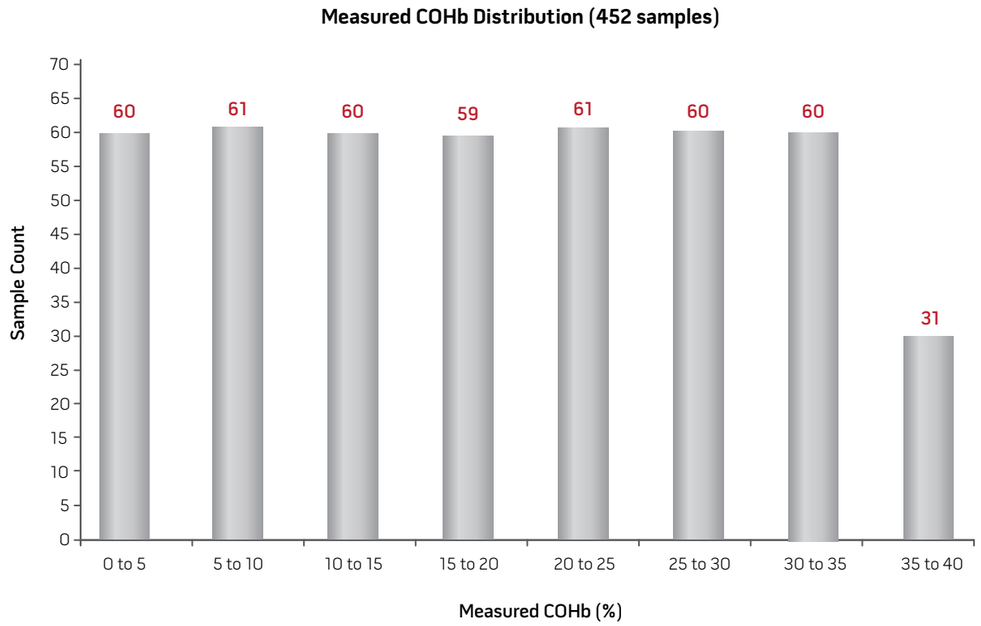
TABLE I: VOLUNTEER DEMOGRAPHICS

SpCO Volunteer Demographics												
	Gender		Age (Year)			Weight (Kg)			Skin Pigmentation			Total
	male	female	19 - 25	26 - 35	36 - 55	50-70	71 - 90	91-110	light	medium	dark	
Subjects	102	58	50	78	32	86	65	9	66	51	43	160
Percentage	64%	36%	31%	49%	20%	53%	41%	6%	41%	32%	27%	100%

RESULTS

To help ensure that any subsequent statistics were unbiased, there was a need for an equal distribution of COHb data in the instrument's calibration range. To accomplish this, samples were entered into 5% bins for COHb. Each bin was filled to approximately the same number of samples. The frequency distribution of COHb level is shown in Chart I. In this study, 452 blood samples were analysed for COHb and contrasted against the SpCO measurements obtained by the Rainbow SET Pulse CO-Oximeters. The range of values was 0.9 to 39.9%. The bias and precision for the difference between SpCO and COHb were -0.2 % and 2.8 % respectively (Table II).

CHART I: MEASURED COHB DISTRIBUTION



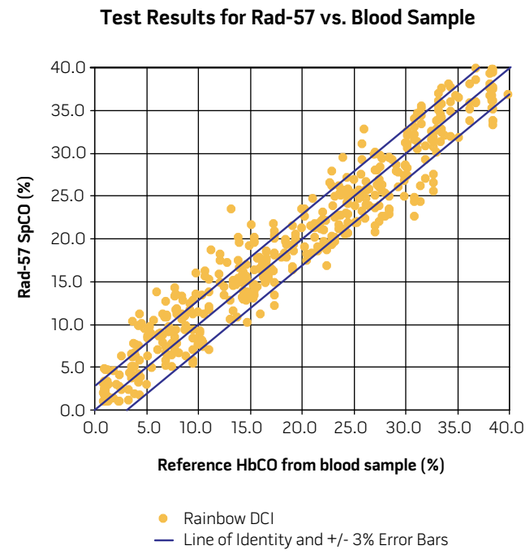
Overall COHb results are shown on the next page.

TABLE II: RAINBOW DCI SENSOR ON DIGIT

Analysis of Volunteer Data				
COHb Range	r value	Bias	Precision	Accuracy (A_{RMS})
0.9 - 39.9%	0.9%	-0.2%	2.8%	2.8%

The graph below displays the invasively measured COHb compared to the noninvasive measured COHb (SpCO) for all 452 data points obtained on the entire population of 160 volunteer subjects.

CHART II: SCATTER CHART OF VOLUNTEER DATA (2.8% A_{RMS}, R=0.97)



Masimo Rainbow SET is clinically proven to measure COHb saturation in the range of 0 to 40% with accuracy of +/-3% (1 S.D.). This encompasses 67% of the data.

CONCLUSION

The results show the Masimo Rainbow SET (Pulse CO-Oximetry) accurately measures COHb in the range of 0 to 40%. This accuracy, combined with the ability to place the technology in a small handheld device (the Rad-57), has the potential to change the way victims of CO exposure are diagnosed and treated. Because the Rad-57 is easy to use and provides accurate measurements of Carbon Monoxide saturation, Oxygen saturation, Pulse Rate, and Perfusion Index, it is the ideal patient assessment tool for first responders, fire department personnel, and Emergency Department personnel, as well as safety personnel in areas of high industrial pollution and automobile exhaust.

SELECTED REFERENCES AND WEB SITE INFORMATION

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