UNVALIDATED IMITATION SENSORS DEMONSTRATE POOR PERFORMANCE

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EXECUTIVE SUMMARY

Pulse oximetry permits noninvasive monitoring of arterial blood oxygen saturation (SpO_2). A pulse oximeter consists of the SpO_2 sensor attached via cable to a monitor. The performance of a pulse oximeter depends on the quality of the signal from the SpO_2 sensor. A number of unvalidated imitation SpO_2 sensors have entered the market, purporting to be compatible with Nellcor™ pulse oximetry monitors, including compatibility with Nellcor™ pulse oximetry with OxiMax™ technology, without supporting clinical validation. An examination of 14 imitation sensors from eight manufacturers found deficiencies in each for performance and/or design that could prevent accurate SpO_2 monitoring. Features that affect sensor performance, including sensor calibration, optical signal strength, and shielding against ambient light and against electronic noise and crosstalk were examined. The imitation sensors demonstrated unacceptable inaccuracy, with average error in SpO_2 readings greater than 7%, and bias towards overestimating SpO_2 values by as much as 18%, which is well beyond the clinically acceptable 4 point error. Poor performance of imitation sensors has the potential to be dangerous, particularly in patients with low oxygenation levels or with poor perfusion.

INTRODUCTION

Pulse oximetry is a noninvasive technique to provide an estimate of arterial blood oxygen saturation (SaO2).[1] The pulse oximeter consists of a sensor, placed on the patient, connected to a monitor via a cable (Figure 1). A combination of circuit board and algorithm interprets light absorption data from the sensor and reports the resulting SpO_2 value on the monitor.

The SpO_2 sensor contains LED light sources that emit red and infrared light and a detector that measures the absorbance of the light as it passes through tissue.[2] By measuring absorption of both wavelengths of light and comparing the value to a calibration curve appropriate for the sensor, the SpO_2 value can be calculated.[3]

The accuracy and precision of pulse oximetry measurements decrease when oxygen saturation is low (SaO_2 below 90%) and when the light signal strength is low. A low light signal can result from reduced light transmittance (which is affected by skin pigment, thick tissue beds, and nail polish).[1,3] Patient motion can also introduce artifacts and these artifacts are compounded when perfusion is low.[3,4] Good sensor design is essential to achieving accurate performance under challenging conditions, such as low SpO_2 or low perfusion.

Figure 1: Pulse Oximeter

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KEY DESIGN FEATURES THAT AFFECT SENSOR PERFORMANCE

SpO_2 sensor components important for performance are highlighted in Figure 2.

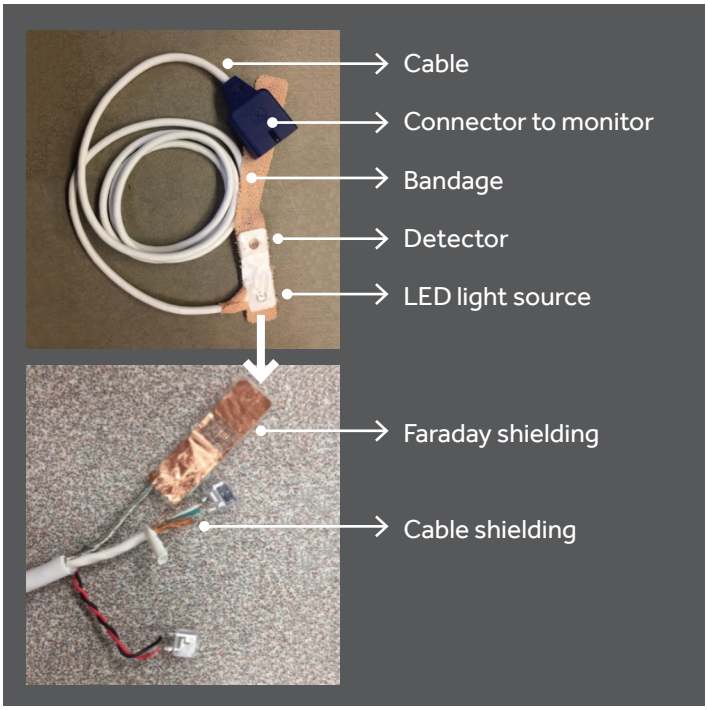

Figure 2: Expected Pulse Oximeter Sensor Components

BANDAGE DESIGN

The bandage must securely position the sensor on the patient in the correct orientation and without causing discomfort or skin damage. A variety of sensor types and sizes are available for use based on patient size and on clinical context. For adults and pediatric patients, a butterfly-shaped bandage that positions the sensor over a finger is commonly used. For infants and neonatal patients, a sensor is usually wrapped around the foot.

Sensors may be single-use or reusable. Single-use sensors may be adhesive or may be held against the skin without adhesive (with hook and loop straps for example) when adhesive may be damaging to delicate skin. Single-use sensors may reduce the risk of cross-contamination as reusable sensors have been demonstrated to host bacteria in clinical settings.[5,6]

In addition to securely positioning the sensor on the patient, the bandage should prevent ambient light from reaching the detector resulting in artifactually high SpO_2 readings. Nellcor™ pulse oximetry sensors are designed to block ambient light.

LIGHT SOURCE AND DETECTOR

Sensors contain LEDs that emit red and infrared light. Commonly, wavelengths of 660 nm and 900 nm are used, but LED sources vary.[7] Signal strength is important to accurate and reliable SpO_2 measurement. Signal strength is a function of the LED brightness, detector sensitivity, and any sensor components that attenuate transmission of the signal. LED control is housed in the pulse oximeter monitor, so the sensor signal must be optimized with the monitor for accurate and reliable results. Low signal level due to a poor quality LED and/or detector can cause significant errors or dropouts in reported SpO_2 data, particularly in challenging patients. The LED and detectors of Nellcor™ pulse oximetry sensors are designed to achieve optimal performance when used with Nellcor™ pulse oximetry with OxiMax™ technology monitoring systems.

SENSOR CALIBRATION

Accurate SpO_2 readings depend upon using the correct calibration curve to translate light absorption data to SpO_2 values. Optics (LED wavelengths), bandage color and material, and other construction features affect a sensor's calibration. Therefore, calibration must be verified for every unique sensor design and the calibration curve determined for one sensor cannot be used with a different sensor, even when two sensors have a similar overall design or appearance. Mismatch between the LED spectrum and the calibration curve can result in significant errors in reported SpO_2. The calibration of all Nellcor sensors is validated, and for Nellcor™ pulse oximetry sensors with OxiMax™ technology, the calibration information is stored within the sensor itself.

ELECTRIC SHIELDING

Visible and infrared ambient light as well as radiofrequency electromagnetic interference in clinical care settings can disturb sensitive monitoring equipment, including SpO_2 measurements.[8-10] International standards assert that sensors and cables should be designed with appropriate shielding to prevent interference.[11] A Faraday shield blocks electromagnetic fields and can reduce the conductance of noise within the sensor. Shielding between detector wires and emitter wires can prevent crosstalk. In the absence of such shielding, the detector may report an artificially high signal leading to inaccurate SpO_2 values higher than the patient's actual SpO_2 level. Nellcor™ pulse oximetry sensors include both Faraday shielding and cable shielding to minimize electronic interference and crosstalk.

These design features were assessed across a selection of imitation sensors.

METHODS

Fourteen imitation sensors from eight manufacturers observed in clinical use were studied, as shown in Table 1.

PHYSICAL EXAMINATION

Sensors were dissected and photographed, and examined with respect to their bandage design, cable construction, emitter and detector optics, and calibration means. Note was taken of the presence or absence of shielding from ambient light, shielding within the cable of the detector wires, and of a Faraday shield. One sensor, the Envitec Y-2217-9 sensor, was examined and photographed but not dissected.

EVALUATION OF LED EMISSION SPECTRA AND SENSOR CALIBRATION MISMATCH

All sensors except the Y-2217-9 were dissected to expose the emitter and placed in an optical spectral measurement system to assess the emitted red and infrared wavelengths. These data were compared to each sensor's calibration to identify potential mismatch.

As a follow-up to this test, five sensors from each of two models that demonstrated significant wavelength/calibration mismatch were assessed to confirm the mismatch between the LED values and sensor calibration. Then, SpO_2 values were calculated based on the mismatched calibration to estimate the error in reported SpO_2 that would result from the use of these sensors.

MEASUREMENT OF DC LIGHT LEVELS

To measure optical signal strength, each sensor was placed on an adult fingertip (index finger or pinky, depending on optical spacing), plugged into a Nellcor™ N-600x bedside monitor, and DC light levels were recorded using Wincollect™* software (Medtronic). Nellcor™ pulse oximetry sensors, MAX-A and MAX-P, were also tested as references.

MEASUREMENT OF CROSSTALK DUE TO UNSHIELDED DETECTOR WIRES

To evaluate the effect of crosstalk, sensors were tested using a patient simulator ProSim™* 8 SpO_2 test module (Fluke Biomedical). The ProSim™* 8 simulator was set up to mimic a neonatal foot with pulse amplitude 1%, respiration 1%, heart rate 90 BPM, and no ambient light. The sensors were tested under simulated SpO_2 levels of 70%, 80%, and 90%. Because LED drive signals can differ for different monitors, the sensors were tested with four different monitors enabled with Nellcor™ pulse oximetry technology.

MEASUREMENT OF CONDUCTED NOISE DUE TO LACK OF FARADAY SHIELD

Four imitation sensors that lacked a Faraday shield were placed between plates connected to a noise generator. Noise was introduced over a specified range of frequencies and noise that was conducted to the detector was measured by a spectrum analyzer. The sensors tested were: the MedLinket S0026K-S, the Envitec DA-2211-1, the MPC Int'l (Asmuth) AS52ONE, and the MPC Int'l (Asmuth) AS502E. The MAX-A Nellcor™ pulse oximetry sensor was also tested as a reference.

Manufacturer	Model number/product name	Sensor Type
MedLinket	S0026K-S	Pediatric
MedLinket	S0026L-L	Infant
MedLinket	S0026M-L	Neonate/Adult
Chun Ji In	CJ340NA	Neonate/Adult
Chun Ji In	CJ30A	Adult
Envitec	DA-2211-1	Adult
Envitec	Y-2217-9	Multisite Y
MPC Int'l (Asmuth)	AS52ONE	Neonate/Adult
MPC Int'l (Asmuth)	AS502E/ Oxi-Pro™* DN sensor	Neonate
Bio Protech	Oxi-Pro™* DP sensor	Pediatric
Insung Medical	Oxitransducer™* sensor	Not listed
Metko	FMT-DIF/NLO	Infant
Metko	FMT-DPF/NLO	Pediatric
BioMedical Technologies	BM-200/Oxiprobe™* sensor	Neonate/Adult

Table 1: Imitation sensors studied

RESULTS

The results of the tests carried out on Imitation sensors are summarized in Table 2.

MANY IMITATION SENSORS LACK NECESSARY SHIELDING

The majority of the unvalidated imitation sensors lacked shielding, either against ambient light, or against conducted electronic noise and/or crosstalk between the emitter and detector wires (Table 2). Ambient light sources emit the wavelengths measured by pulse oximeters; therefore, excessive ambient light, from room or procedure lighting, that reaches the detector can cause false SpO_2 readings.[3]

LACK OF DETECTOR WIRE SHIELDING IN IMITATION SENSORS RESULTS IN EXCESSIVE CROSSTALK

A patient simulator allowed the study of crosstalk under low SpO_2 conditions. An imitation sensor demonstrated a high bias when tested at low (70%) SpO_2 levels, reporting SpO_2 values 2 to 5 points higher than the actual value with 3 monitors, and 18 points higher with a fourth monitor. Such a large degree of bias could impede recognition of hypoxic events and lead to clinical errors. For example, treatment would be delayed if a protocol calls for intervention when SpO_2 falls below 90% and the sensor incorrectly reports an SpO_2 value that is significantly higher than the patient's actual value. When sensor output was examined, it was apparent that the corrupted waveform produced by the imitation sensor crosstalk resulted in significant SpO_2 measurement errors. The effects of crosstalk would be most pronounced under conditions of low DC light signal, which include thick tissue bed such as a neonate foot or hand and dark pigment.

LACK OF FARADAY SHIELDING IN IMITATION SENSORS RESULTS IN INCREASED CONDUCTED NOISE

Across a range of frequencies representative of the noise band in typical clinical settings (1 Hz to 100 kHz), four imitation sensors conducted substantially more noise than the Nellcor™ pulse oximetry MAX-A sensor. Conducted noise for the imitation sensors peaked at over 47 dBmV compared to only 30 dBmV for the Nellcor™ pulse oximetry MAX-A sensor. Such increased conducted noise would be expected to result in increased detector noise in a clinical setting, leading to inaccurate SpO_2 readings or dropouts in the reporting of SpO_2.

IMITATION SENSORS DEMONSTRATE MISMATCH BETWEEN LED EMISSION AND CALIBRATION

Three sensors, the CJ340NA, CJ30A, and the Oxitransducer™* sensor, were found to have a significant mismatch between the LED wavelengths and the sensor's calibration curve. Such a mismatch would be expected to result in reduced accuracy of SpO_2 measurements. Follow-up testing of additional representatives of these sensors confirmed the LED wavelength-calibration curve mismatch. Theoretical calculations of SpO_2 values that would be reported based on the sensors' mismatched calibration curves indicated that the mismatch would result in an average error of SpO_2 readings of ±7.45, which exceeds the ISO standard requiring SpO_2 error be less than 4 points.[11]

Historically, calibration has been done using pre-programmed calibration curves stored in the monitor via a method called resistor calibration (RCal). More recently, digital calibration (digical) technology, such as Nellcor™ pulse oximetry with OxiMax™ technology, has been introduced, in which the calibration curve is stored in the sensor itself rather than the monitor. To take advantage of this technology, the sensor must be used with a monitor enabled with Nellcor™ pulse oximetry with OxiMax™ technology. Several imitation sensors claimed compatibility with Nellcor™ pulse oximetry with OxiMax™ technology, indicating that the sensors should activate monitor readings. Claims of compatibility are not equivalent to clinical validation. One of these sensors, the AS52ONE, did not function with the Nellcor™ pulse oximetry monitor when tested.

LOW LIGHT SIGNALS OBSERVED WITH IMITATION SENSORS

Two sensors from the manufacturer Chun Ji In demonstrated extremely low DC light levels, 10-fold lower than those measured for Nellcor™ pulse oximetry MAX-A and MAX-P sensors (Table 2). Such low light signals may lead to poor clinical performance, including inaccurate SpO_2 measurements or inability to post SpO_2 readings at all. The effects of low DC light levels are expected to be exacerbated under challenging conditions such as low SpO_2 levels or in the presence of factors such as dark pigment or nail polish that themselves can decrease light transmission.

ADDITIONAL EVIDENCE OF POOR DESIGN IDENTIFIED THROUGH PHYSICAL EXAMINATION

A variety of other design flaws with the potential to impact sensor safety and performance were identified (Table 2). The bandage of the CJ30A did not adhere well to itself and easily came loose. The Posey wrap of the Y-2217-9 and the overall length of the AS52ONE were short, which could risk skin damage if the hook and loop intended to hold the bandage in place were to come into contact with neonatal skin. Gaps in the bottom bandage of the FMT-DIF/NLO were likely to expose wires. And, the Faraday shield of the Oxiprobe™* BM-200 sensor was one-sided and only covered the face of the detector. All of these flaws could reduce the safety and accuracy of the sensors.

Manufacturer	Model Number	TEST PERFORMED								
		Dissection/Examination								
		No Ambient Light Shield	No Faraday Shield	Detector Wires Unshielded	Other	LED Wavelength vs Calibration	SpO2 Error	DC Light Levels	Crosstalk	Conducted Noise
MedLinket	S0026K-S	■	■							■
MedLinket	S0026L-L		■	■					■	■
MedLinket	S0026M-L		■	■					■	■
Chun Ji In	CJ340NA					■	■	194/ 438		■
Chun Ji In	CJ30A	■			A	■	■	215/ 520		■
Envitec	DA-2211-1	■	■							■
Envitec	Y-2217-9		■		B C	■				■
MPC Int'l (Asmuth)	AS52ONE		■		C D E					■
MPC Int'l (Asmuth)	AS502E/ Oxi-Pro™* DN sensor		■	■					■	■
Bio Protech	Oxi-Pro™* DP sensor		■	■					■	■
Insung Medical	Oxitransducer™* sensor					■	■			
Metko	FMT-DIF/NLO	■			F					
Metko	FMT-DPF/NLO	■								
BioMedical Technologies	BM-200				G					
MAX-A Nellcor™ pulse oximetry sensor (reference)		■	■	■	■	■	■	1880/ 5040	■	■
MAX-P Nellcor™ pulse oximetry sensor (reference)		■	■	■	■	■	■	1470/ 4560	■	■
MAX-N Nellcor™ pulse oximetry sensor (reference)		■	■	■	■	■	■	■	■	■

Table 2: Overview of Test Results

A-D based on bench testing and qualitative data.

■ Negative finding/poor performance
■ Positive finding/satisfactory performance
■ Not tested because satisfactory performance expected based on design
■ Not tested

A. Poor bandage adherence
B. Posey wrap too short
C. Hook and loop surface could risk skin damage
D. Overall bandage length too short
E. Digical clone did not function on the Nellcor™ N-600x bedside monitor
F. Open gaps in bottom bandage
G. Faraday shield only covers face of detector
H. Additional models not available for follow-up testing

CONCLUSIONS

No imitation sensors proved to be suitable substitutes for Medtronic Nellcor™ pulse oximetry sensors. Across the sensors tested, significant flaws in sensor design were identified, outlined in Table 3. The identified issues are predicted to result in unreliable and inaccurate data and, in several cases, would result in artificially inflated SpO_2 readings. Artifactually high SpO_2 data could impede detection of hypoxemia and alter clinical decision making.

This study has limitations. With the exception of the SpO_2 error experiment, only one representative of each sensor type was examined or tested. Testing conditions were identical for every sensor, but it is possible that a sensor could perform differently under a different set of test conditions. Some of the issues identified may not cause noticeable problems except under the most difficult conditions of low patient SpO_2 values or low signal strength. However, such conditions occur in situations when accurate SpO_2 data is most important, such as in NICU patients or patients with poor perfusion. Based on these results, imitation sensors cannot be recommended and are not considered validated as an alternative to Nellcor™ pulse oximetry sensors from Medtronic.

Flaw	Consequence
Lack of shielding from ambient light	Extraneous light reaches detector, less reliable data, potential for artificially high SpO_2 readings
Lack of or poorly designed electronic shielding	Increased noise, increased crosstalk, less reliable data, potential for artificially high SpO_2 readings
Emitted light from LEDs inconsistent with sensor calibration	Incorrect SpO_2 readings
Low light signal strength	Inaccurate SpO_2 readings, particularly in challenging patient conditions

Table 3: Impact of Observed Flaws in Imitation Sensor Design

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