Datex-Ohmeda TruTrak®+ Oximetry Technology; A 663 Patient, Multi-Site Performance Evaluation During Clinical Motion

TruTrak®+ is a new proprietary technology developed by Datex-Ohmeda to measure oxygen saturation during conditions of clinical patient motion. Studies were conducted over a one-year period in the laboratories at Datex-Ohmeda Louisville facility and at five hospitals in the United States. TruTrak+ technology was compared to traditional non-motion oximetry, Nellcor® and Masimo® motion technologies and arterial saturations measured by hemeoximetry. To provide a clinically representative sample, studies were conducted in a wide variety of hospital environments including neonatal, pediatric and adult intensive care units, operating rooms, post anesthesia care units and general wards. The following evaluation focuses on analyzing and scoring the performance of various oximetry technologies throughout the one-year study period. Particular emphasis was placed on observing oximetry monitoring anomalies such as volatility, accuracy, freezing, dashing and dropouts that are particularly disconcerting to the clinician. The results of this evaluation confirm that Datex-Ohmeda TruTrak+ technology demonstrates fewer instances of freezing, dashing and dropouts versus traditional oximetry and other oximetry technologies with motion capabilities. Finally, TruTrak+ compared favorably to the Masimo Signal Extraction Technology (SET®) motion oximetry.

INTRODUCTION

Pulse oximetry has been in use for over twenty years and is an important monitoring tool in modern medicine. This frequently over-simplified parameter is now one of the essentials of clinical practice. Timely recognition and correction of low saturation conditions can prevent potentially devastating patient complications. Oximeter manufacturers are continually improving their products to reduce the margin of error and provide safer monitoring tools, thus providing clinicians with the most technologically advanced systems. In this case, the issue is the ability to provide an accurate saturation reading during clinical motion episodes.

Clinical motion, which is defined as motion seen in the patient population, often results in dashing of the display, volatility, inaccuracy, freezing and dropouts of the saturation readings. Over the years, many laboratory motion studies have been conducted using methodologies designed to simulate clinical motion conditions. However, the types of motions used by researchers in previous laboratory studies have been, at best, based on anecdotal descriptions of motions seen in the clinical setting. Therefore, prior to conducting the laboratory portion of these tests, Datex-Ohmeda carried out a large multi-institution study of 350 patients designed to identify and characterize the most commonly seen clinical motions.[1] We found that the most common motions are clenching, extending, rubbing, pressing and flexing in the adult population; and kicking, clenching and flexing in the infant population. Moreover, we observed that clinical motions tended to be irregular and short in duration. Based on this information, the laboratory portion of this study utilized clinical motion types that corresponded to authentic hospital patient motion.

The purpose of the one-year study was to compare the performance of a new technology, the Datex-Ohmeda TruTrak+, to commercially available oximetry technologies (with and without motion capability), and to arterial saturations measured by hemeoximetry, the "gold standard". To that end, TruTrak+ technology was compared to traditional oximetry, Nellcor and Masimo motion oximetry, non-moving reference oximeters and Radiometer OSM-3 CO-oximeters.

METHODS

Technology Description. Many traditional oximeters calculate the saturation by measuring the peak and trough of each plethysmographic waveform. This type of calculation is beat-to-beat dependant. During motion the pleth waveform becomes unstable without physiologic peaks and troughs; at these times, the traditional pulse rate dependant oximeter is unable to calculate an accurate SpO_2 measurement.

Instead of beat-to-beat, TruTrak+ is time dependant. TruTrak+ technology is a proprietary technique that identifies the presence of motion, quantifies the intensity of motion and then corrects the internal data so that an accurate SpO_2 measurement is calculated. During motion correction, TruTrak+ subdivides the signal into measurement components (bone, tissue, venous, pulsatile arterial, non-pulsatile arterial, etc.). At this stage, TruTrak + simultaneously tracks the various saturation components. The algorithm disregards those components affected by motion and is able to directly track the unperturbed SpO_2 components to calculate the SpO_2. Then these calculations are weighted and averaged before displaying the saturation reading.

Patient Demographics and Conditions. Six hundred sixty three human studies were conducted on patients and healthy volunteers over a one-year period. All studies in the hospital and laboratory settings received Human Subjects Committee approval prior to the start of testing. These tests took place in the laboratories at Datex-Ohmeda, Louisville Colorado, and at five hospitals in a wide variety of environments including NICU, Pediatrics, ICU, OR, PACU and general wards. The ages of the patients ranged from 27 weeks gestation to 85 years. The population also included a wide variety of skin pigmentation from deep to very light. Weights ranged from 2 to 285 pounds (0.9 to 129kg). Thirty-five percent of the patients were classified into the very low perfusion category (hypovolemic/ cardiogenic shock & cold extremities). Other conditions included high motion in both infants and adults, rapid changes in the oxygen saturation and very thick sensor sites. The patient tests involved medical procedures ranging from CABG in the OR to mechanical ventilation in the ICU. Other conditions and procedures were Ortho, Neuro, EENT, Gastric and anesthesia recovery.

Table 1.

DEMOGRAPHICS

	LABORATORY	**CLINICAL (HOSPITAL)**
AGE RANGE	3 days – 44 years	27 weeks gestation – 85 years
WEIGHT RANGE	5 lbs – 210 lbs/2.3 kg – 95 kg	2 lbs – 285 lbs//0.9 kg – 129 kg
SKIN PIGMENT		
DARK	10%	11%
MEDIUM	20%	20%
LIGHT	70%	69%
MALE	35%	40%
FEMALE	65%	60%
TOTAL NUMBER TESTS	534	127
TOTAL NUMBER HUMAN BLOOD TESTS	58 correlation studies (desaturation) to FDA	NA
AREAS TESTS CONDUCTED	Laboratory	OR, PICU, NICU, ICU, CCU, PACU, PEDS

Hospital Methods. Data collection times ranged from 30 minutes to 5 hours. Two to three oximeters were placed on each subject with simultaneous graphing of the data. Pulse oximeter readings were compared to arterial blood gases when blood was drawn. In the hospital setting, no blood was drawn specifically for the purpose of the study (refer to Table 2).

Laboratory Methods. During the lab tests, extremely low perfusion, motion (clinical & mechanically imposed), and a combination of motion with low perfusion conditions were created in the healthy volunteer subjects. Throughout the low perfusion and motion tests, it was necessary to determine whether the oximeter was freezing or whether it was able to track a saturation change during the perturbing condition. For that reason, two different types of desaturation episodes were induced in the volunteer adult subjects. One caused rapid saturation changes of 10% or more in the space of a few seconds. The other, called a Human Desaturation Study, caused a gradual desaturation from 100% to about 67% over the period of 30 minutes. Both methods involved having the subjects breath a hypoxic mixture of nitrogen and oxygen.

Table 2.

Test Protocol

- All tests compared two or more oximeters on the same subject at the same time.
  - In infants, an oximeter was used on each foot or each hand.
  - In adults, the first three digits, excluding the thumb and/or great toe, were used. This allowed for three oximeters to be tested simultaneously.
- Each oximeter was rotated to each site to eliminate site-to-site differences.
- A reference oximeter that was not subject to the motion or low perfusion condition was used in all adult laboratory tests.
- In the desaturation studies, the reference was the "gold standard" multiwavelength hemeoximeter (CO-oximeter).

Infants were tested during periods of kicking, crying, feeding, reaching, coughing, laughing and other motions typical to normal infant behaviors. Parents were present during all laboratory testing of minors.

Data Analysis. Two types of data analysis tools were employed to assess performance of the oximeters in this study. One involved routine statistics such as the average difference and standard deviation of the paired data. This method was used in the arterial blood comparisons to assess the desaturation/motion performance of the oximeters (see Figures 3 and 4).

The other data analysis tool, the Datex-Ohmeda Clinical Use Scoring System, was used to evaluate the saturation volatility, accuracy and freezing. The Clinical Use Scoring System is a data analysis tool that allows evaluation of the saturation output of an oximeter from a clinical use point of view. Specific criteria were used to score the saturation trend of each oximeter during challenging performance conditions. The oxygen saturation trend from each test was graphed and then divided into segments (low perfusion, motion, intubation, etc.). During each performance episode, each oximeter was evaluated versus a reference oximeter. Each time an oximeter displayed deficient behavior from the test oximeter, a negative numeric value was assigned.

For example, the Clinical Use Scoring System did not assign a value (score = 0) when the test oximeter saturation reading was close to or the same as the reference. As the reading of the test oximeter deviated further from truth, a more negative score was assigned for that episode. Finally, all of the episodes for each oximeter were summed to provide an overall total score for each oximeter. The total score reflected deficient behavior; the more the negative, the more deficient the performance.

An example of scoring is shown in the saturation graph in Figure 1, which depicts a dropout of a traditional oximeter during intubation. In this example TruTrak+ and Masimo motion were able to measure the

saturation throughout the intubation, while the traditional oximeter dropped out at a critical point. In this instance TruTrak+ and Masimo both received a favorable score of "0" and the traditional oximeter was given a poor score of "–6".

Figure 2 shows an oximeter with a frozen display. In this example, TruTrak+ was tracking a desaturation event while the Masimo motion oximeter did not reflect the desaturation event. In this instance TruTrak+ scored a favorable "0" and the Masimo scored a poor "–6" due to freezing.

Figures 5 through 7 combine the scores of accuracy, freezing, dashing and dropouts. In these histograms the lower the bar, the more deficient the behavior. In other words, the closer the bar is to zero (0), the better the overall performance. The bar charts in this report show the totals of over two thousand performance challenges similar to Figures 1 and 2. Each time an oximeter displayed an inaccurate reading it was reflected in a numerical score, and as the deficient behaviors were summed the scores decreased. Again, in this study, the closer the score is to zero (0), the better the performance.

RESULTS

Human Arterial Blood Comparisons.[2] Two arterial samples were taken from the radial artery of the non-moving hand during each motion period. The saturation of each sample was then measured by a CO-oximeter.

Figures 3 & 4 were taken from two of the subjects in the test population. Figure 3 is a test in which TruTrak+ and a traditional oximeter were compared to blood samples. Figure 4 is a test in which TruTrak+ and a motion oximeter were compared to blood samples.

The test depicted in Figure 3 shows that the saturation of the subject started at about 95% and went down to about 73%. The arterial samples demonstrated that TruTrak+ was in close agreement with the CO-oximeter during periods of motion. At the same time, the traditional oximeter was about 5% low during motion.

Arterial samples (Figure 4) again show TruTrak+ to be in close agreement with the CO-oximeter. The Masimo motion oximeter displayed similar readings to TruTrak+.

Examples of Deficient Behavior

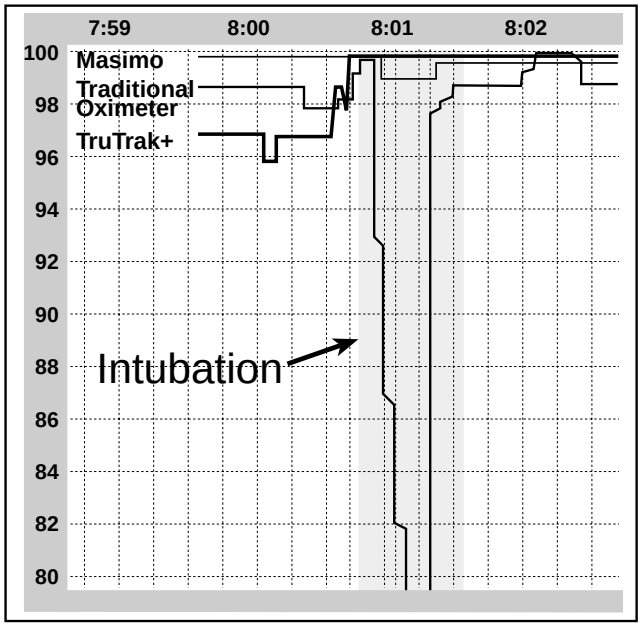

FIGURE 1: Drop Out

This real-time graph, collected in the OR, demonstrates a SpO_2 dropout with a traditional oximeter during intubation. This behavior is not acceptable during a critical phase of anesthesia delivery. Consequently, this behavior was given a score of –6. Notice TruTrak+ and Masimo continue to track the SpO_2 during this critical phase, thus each oximeter was given a score of 0.

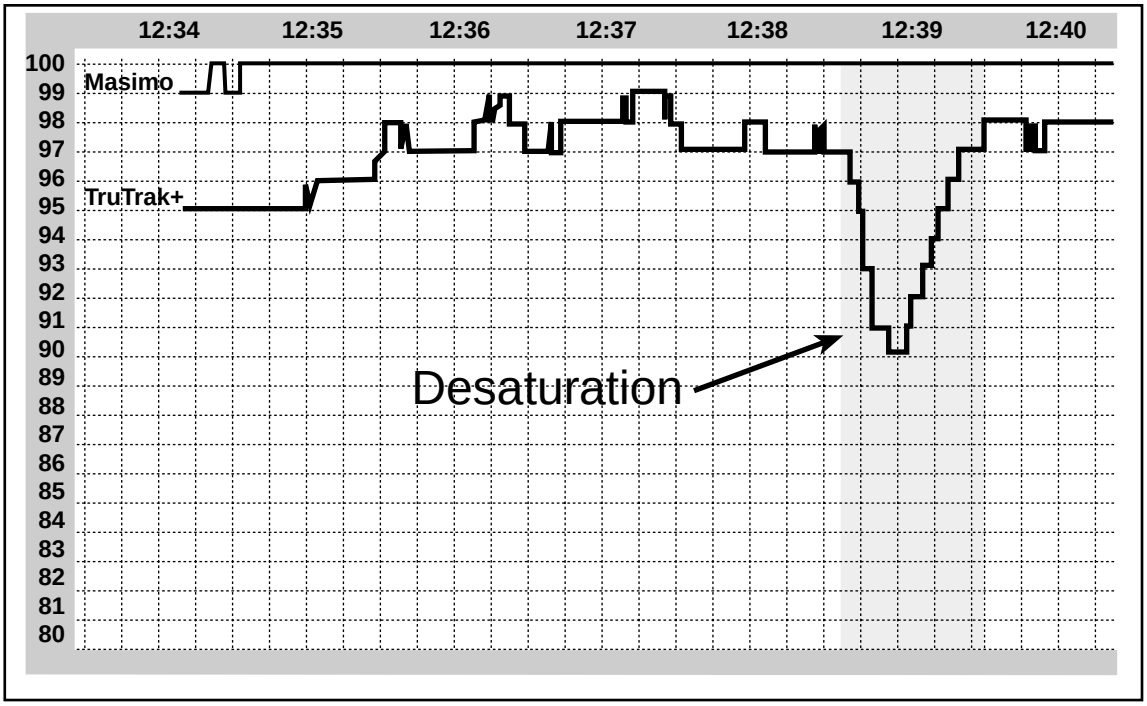

FIGURE 2: Sat Freeze

This real-time graph depicts the Masimo freezing its saturation reading during a valid desaturation event. The patient is moving and working with the nurse. Due to this patient's medical condition, the activity causes him to have a desaturation event. Note TruTrak + tracks this valid desaturation event in agreement with the clinical signs. Therefore, Masimo would be given a score of –6 and TruTrak + a score of 0.

A note about oximetry calibration: Pulse oximeter manufacturers use different hemeoximeters as their "Gold Standard" during arterial calibration of the devices. Therefore, baseline pulse oximeter readings vary.[3]

Blood Comparison [TruTrak+ & Traditional Oximeter]

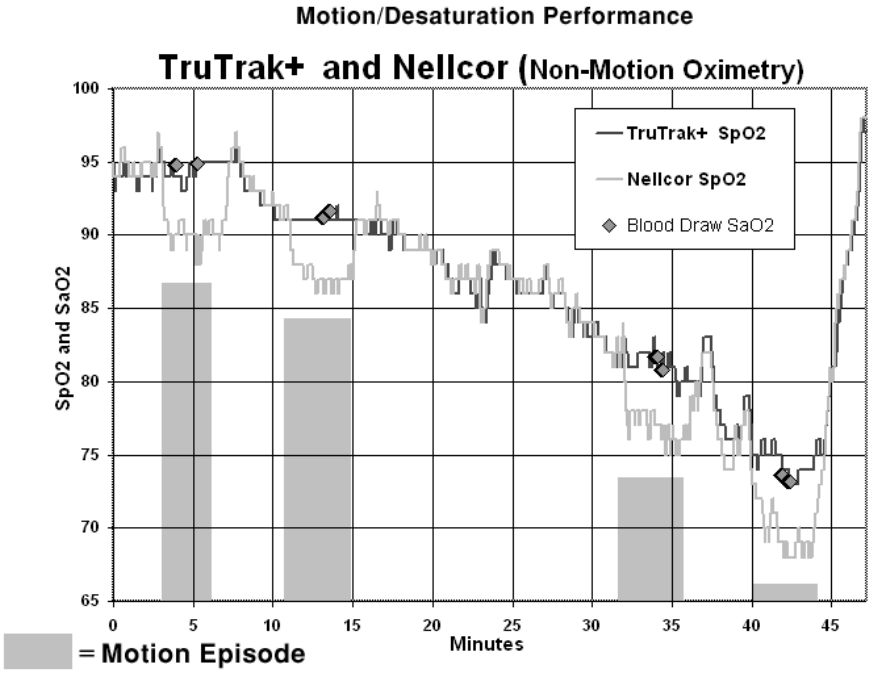

FIGURE 3: Motion Desaturation

This graph demonstrates a motion arterial blood study comparing TruTrak+, to the Nellcor traditional oximeter in a mechanical motion rub/ tap test at 3 Hz. The diamonds represent the arterial blood draws and value demonstrated by the CO-oximeter. The gray areas signify motion periods.

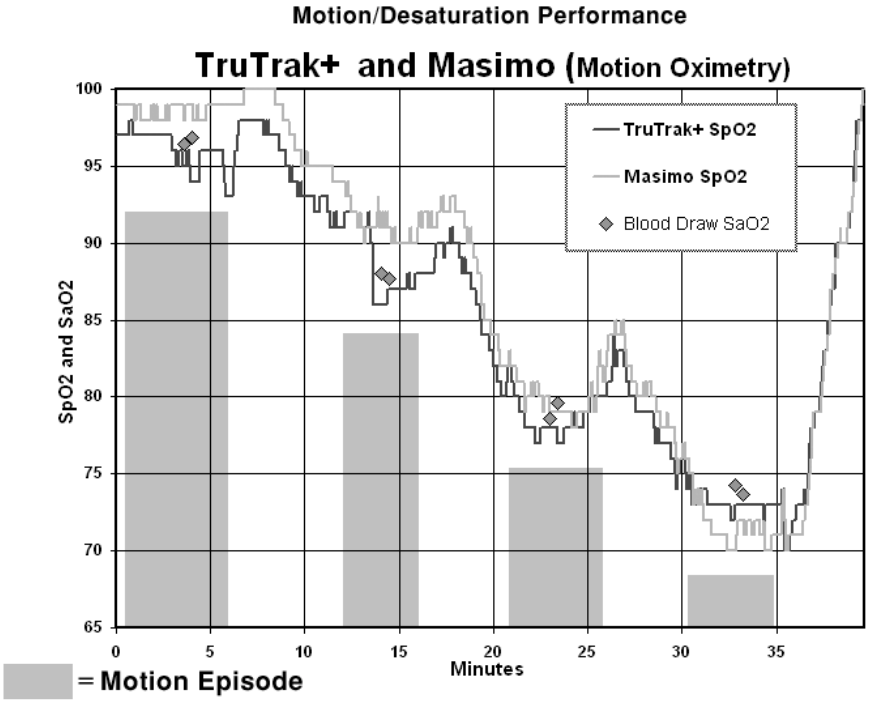

FIGURE 4: Motion Desaturation

This graph demonstrates mechanical motion during an arterial blood study. This graph compares the performance of TruTrak+ to the Masimo, during a tap test at 3 Hz. The diamonds denote arterial blood draws and their values. Notice that TruTrak+ SpO_2 value is closer to the arterial blood value than Masimo in this test set. The gray areas signify motion periods.

Total Measures of Deficient Behavior.
The scores reported here reflect a total of deficient behavior; the oximeter with the highest total score had the best performance in this test (refer to Figure 7). Figures 5-7 show total scores from multiple performance tests.

Figure 5
When TruTrak*+* was compared to traditional oximetry in the hospital, the traditional oximeter demonstrated less accuracy with more freezing, dashing and dropouts.

Figure 6
In hospital comparisons to the Nellcor motion oximeter during low perfusion conditions, TruTrak*+* demonstrated greater accuracy with less dashing, freezing and fewer dropouts.

Figure 7
TruTrak*+* was compared to traditional oximetry and Masimo motion oximetry in laboratory clinical motion tests. In this set of tests, it was necessary to determine whether each oximeter was freezing or whether it was able to track a saturation change during the motion condition. Thus, rapid desaturation changes of 10% or more in the space of a few seconds were induced in the volunteer adult subjects. In this test set, TruTrak+ demonstrated greater accuracy in the ability to track a saturation change.

TruTrak+ Compared to Traditional Oximetry in the Hospital

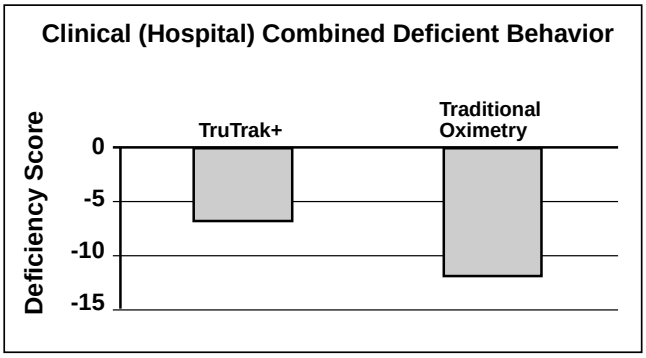

FIGURE 5: Overall Performance

This chart sums the scores of several-hundred performance episodes that were recorded at five hospitals over the adult population in ICU, OR, PACU and General Wards. Points were subtracted for less accuracy, more freezing, dashing and dropouts. [The lower the negative score, the poorer the performance]

TruTrak+ Compared to Nellcor Motion in Low Perfusion

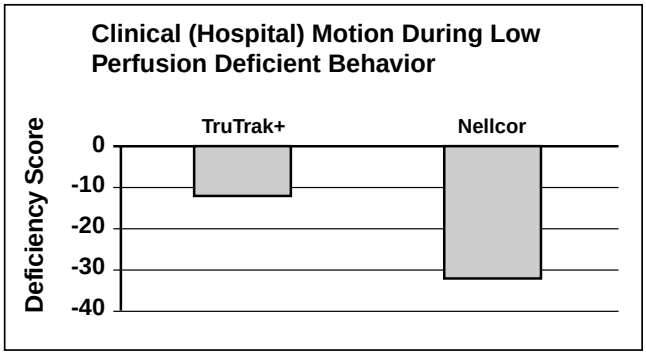

FIGURE 6: Low Perfusion

This chart sums the performance scores from low perfusion episodes. In this group of tests TruTrak+ was compared to the Nellcor motion oximeter. The patient conditions included poor perfusion due to hypovolemia, decreased cardiac output and cold extremities. Perfusion levels were determined by Datex-Ohmeda PI_r ™ (Relative Perfusion Index). [4,5] *In this test set, inaccurate saturations combined with dashing, freezing and dropouts were evaluated during low perfusion. The oximeter with the most deficient behavior had the lowest total in this chart.*

TruTrak+ Compared to Masimo Motion and Traditional Oximetry -Rapid Saturation Changes During Motion-

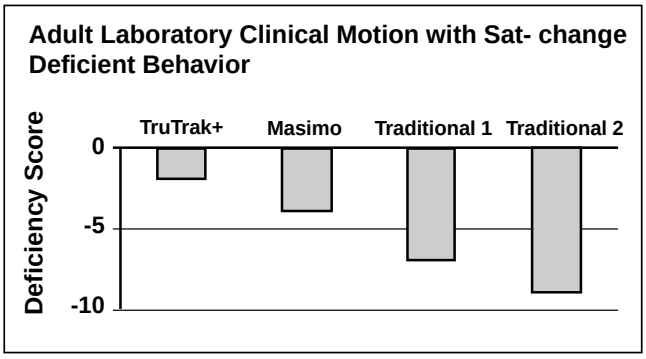

FIGURE 7: Rapid Sat Change During Motion

This chart sums the performance scores from a large group of performance tests that were conducted in the Datex-Ohmeda Labs. In these tests adults simulated clinical motion.[1] *Rapid desaturation episodes were induced to evaluate the oximeter's ability to track a saturation change during clinical motion. In this chart as the saturation reading of the oximeter got further from the reference, the deficient behavior score got lower. Thus, the higher the score (closest to 0) the better the performance.*

DISCUSSION

This study was designed to assess oximetry performance in both the laboratory and the hospital setting. By utilizing these two different approaches, an exceptionally large set of test conditions were made available.

The hospital portion of the study included an extensive patient age range with a wide scope of physiologic and clinical conditions.

The laboratory portion of the study focused on both motion and low perfusion conditions during desaturation episodes. Laboratory tests utilized clinical motion that was derived from an in-depth analysis of hospitalized patients. In the laboratory, comparisons were made to human arterial blood saturations as measured by CO-oximetry over the range from 100% to 70%.

The results of this study confirm that TruTrak+ technology demonstrates fewer instances of freezing, dashing and dropouts over traditional oximetry and other oximetry technologies with motion capabilities. Finally, TruTrak+ compared favorably to the Masimo Signal Extraction Technology (SET) motion oximetry.

In conclusion, TruTrak+ technology promises to provide the clinician with an improvement in accuracy and stability of the saturation data, specifically during conditions of patient clinical motion.

1. Tobin, Pologe, Batchelder, ***A Characterization of Motion Affecting Pulse Oximetry in 350 Patients,*** Analgesia & Anesthesia, S54, Volume 94, Number 1S, January 2002

2. FDA Clearance letter; 510K # 011670, Datex-Ohmeda S/5 Oxygen Saturation Module with TruTrak+ Motion Correction Performance. Indications: "Monitoring arterial oxygen saturation of hospitalized patients including monitoring during conditions of clinical patient motion."

3. Aoyagi, ***Is the Co-oximeter a Gold Standard?,*** Analgesia & Anesthesia, A1, Volume 94, Number 1S, January 2002

4. Banks T, ***The Preoperative Evaluation for Radial Artery Harvesting Using the Datex-Ohmeda 3900 Perfusion Index,*** surgical Physicians Assistant, 6 (5), May 2000.

5. Ozaki M, et al, ***Pulse Oximeter Based Flow Index Correlates well with Fingertip Volume Plethysmography,*** Anesthesiology, 79 (3A), 1993

The Nellcor 200 series technology, N-395 and Masimo Radical were used in this study.

For purposes of this paper, all deficiency scores assigned by the Clinical Use Scoring System, (as shown in figures 5, 6 ,7) are reported as less than zero (0). This allows the data to be presented as the closest the deficiency score is to zero (0), the better the performance. Originally, however, each deficient behavior was assigned a positive score so that the larger the score, the more deficient the behavior. This change does not alter the accuracy of the data.

OS3959-B 05/02