Datex-Ohmeda Pulse Oximetry Analysis

This document is in response to the Datex-Ohmeda white paper found on their website. The white paper is entitled "Datex-Ohmeda TruTrak+ Pulse Oximetry Technology; A 350 Patient, Multi-Site Performance Evaluation During Clinical Motion." In this white paper, Datex-Ohmeda (D-O) discusses a 350-patient study that was used to determine the magnitude, duration and characteristics of patient motion. They include descriptions of the tests (clinical and in-house) they used to validate changes made to their algorithm(s).

This response will be in 4 parts: 1) a discussion of the paper describing data collection on 350 patients during clinical motion; 2) a discussion of the tests run on their new system (TruTrak+); 3) current information concerning TruTrak+ as implemented in the Datex-Ohmeda 3900; and 4) a recent motion study performed by Dr. Steven Barker, Chief of Anesthesiology at the University of Arizona, during volunteer motions.

1. A Discussion of the Datex-Ohmeda White Paper entitled, "A Characterization of Motion Affecting 350 Patients"

- In their paper "A Characterization of Motion Affecting 350 Patients," the authors (all employees of Datex-Ohmeda at the time of the study) attempt to describe patient motion. However, the title of their paper is misleading in that 280 patients they analyzed were not moving during the observation. In addition, of the 70 patients that did move, they only collected data on 35 patients. These 35 patients were monitored with pulse oximetry and an accelerometer for approximately 25 minutes each. The total monitoring time was approximately 14.5 hours for the studied patients (the entire 350 patient study). From this amount of data they attempt to categorize motion to help them develop better algorithms to deal with that problem.[1]

  In their paper, the authors attempt to categorize most motions as being of short duration, with 62% of the motions lasting 10 seconds or less. They do have one case where the motion was continuous for 92 seconds. But what is misleading is the absence of one important piece of information: what type of motion caused conventional pulse oximeters to give inaccurate measurements and false alarms. After all, that's what "Next Generation" pulse oximeters are supposed to solve. All in all, the paper is misleading due to the lack of sufficient quantity of challenging clinical data.

2. The Tests Run On the New Datex-Ohmeda TruTrak+ System

- The bulk of the paper attempts to validate their new algorithm(s) in the clinical environment against conventional pulse oximeters as well as Masimo pulse oximeters. In the clinical data presented there is no control or "gold standard," such as blood gases. Nor did they attempt an analysis like "Silver Standard Analysis" (See Masimo Silver Standard Analysis Technical Bulletin.) They rely only on clinical impressions, which may or may not be accurate. Indeed, D-O shows a figure in which the Masimo pulse oximeter is supposedly "freezing" while the TruTrak+ is catching a desaturation. This may, in fact, be a false desaturation caused by the inability of TruTrak+ to handle the motion. Without the use of a control of some nature (for example, Silver Standard Analysis) you can only guess which oximeter is right. The authors give themselves the benefit of the doubt. It is important to note that the ECRI report showed Masimo as the only next generation oximeter that did not exhibit any freezing. Overall the Datex-Ohmeda authors indicate that the TruTrak+ is better than conventional pulse oximetry and compares "favorably" to the Masimo technology.

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Datex-Ohmeda TruTrak+ Pulse Oximetry Technology

3. Current Information Concerning Tru-Trak+ as Implemented in the Datex-Ohmeda 3900

- It is interesting to note that D-O claims TruTrak+ only "works" in their longest averaging mode. If you move the D-O 3900 out of the default 12 second average into the 3 or 6 second average, the message "TruTrak+ Off" is displayed. In other words, in the longest average (which slows changes and decreases false alarms anyway) TruTrak+ is working, while in the shorter averages it is not active. In clinical practice, Sleep Disordered-Breathing testing should be done in the shortest average available. Many anesthesiologists and neonatologists want the pulse oximeter to be in a short average (fast response) during intubation and resuscitation.

4. A Recent Motion Study by Dr. Steven Barker During Volunteer Motions

- In the October 2004 edition of Anesthesia and Analgesia, Steven J. Barker, MD, PhD, Chairman of the Department of Anesthesia of the University of Arizona and invited ASA speaker on the topic of Oxygen Monitoring, and a team of researchers presented data on the latest generation pulse oximeter models from leading manufacturers, including Masimo. The researchers compared the read-though motion and low perfusion capability of five "Next Generation" pulse oximeters set in their shortest averaging times while rapidly changing the oxygenation of adult subjects. Dr. Barker found that the Masimo Radical, even in its shortest averaging mode, closely corroborated the Masimo SET Radical in its 8-second average (as determined in their previous studies.) The other "motions resistant" pulse oximeters showed decreased sensitivity and specificity compared to the Masimo SET Radical. In particular, the Datex-Ohmeda showed the lowest sensitivity (ability to track true events) when compared to all the other pulse oximeters.[2] With the laboratory room chilled to 16-18°C, the volunteers were subjected to various motions produced by a motion table, which delivered random and periodic motions. Dr. Barker found the Masimo SET Radical, even in its shortest averaging mode, closely corroborated the Masimo SET Radical in its 8-second average (as determined in their previous studies). The other "motion resistant" pulse oximeters showed decreased sensitivity and specificity compared to the Masimo Radical.

Pulse Oximeter	Missed Events	Sensitivity	Specificity	False Alarms	Averaging Time (sec)
Masimo Radical (V 4)	1	99%	97%	4	2
Nellcor N-595 (v 3000)	15	63%	73%	16	2
MARS (v2001)	15	63%	50%	30	2
Datex Ohmeda 3900 (v9 / 11)	16	63%	88%	7	3
Philips Viridia (v9 / 11)	9	78%	82%	11	5

References

1. Editorial Note: 14.5 hours of data may be an insufficient amount to categorize the types of motions and duration of motion in all clinical environments. In contrast, Masimo has thousands of hours of data collected on many patients in numerous clinical areas and in multiple types of clinical conditions during motion, low perfusion and other challenging conditions.
2. Barker SJ, Morgan S. A Laboratory Comparison of the Newest "Motion-Resistant" Pulse Oximeters During Motion and Hypoxemia. *Anesth & Analg* 2004;98(5S):S2.

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