

**Clinical Evaluation: Masimo SET<sup>®</sup> vs. Nellcor N-595**  
**Masimo Clinical Research Group**  
**June 2002**

Masimo SET Pulse Oximetry has been shown in numerous independent volunteer motion studies to be superior to not only conventional, but also to other “New Generation” pulse oximeters<sup>1,2,3,4,5</sup>. Nellcor recently introduced a “New Generation” pulse oximeter, the N595, however, with numerous clinical evaluations comparing the Masimo SET Radical<sup>®</sup> to the Nellcor N-595, clinicians are seeing major clinical differences between these two pulse oximeters.

While both perform better than conventional pulse oximeters (e.g., N200), clinically significant differences have been documented in the number of false desaturations that are reported and the amount of false data that is displayed without a warning message. Due to a wide variety of patient conditions, no pulse oximeter is accurate 100% of the time. In difficult situations, it is important for the pulse oximeter to be able to inform the clinician when the data being reported is suspect, so the clinician can take appropriate actions to ensure the patient is properly treated.

The following cases were collected at several hospitals where clinical evaluations were being performed to determine which pulse oximeter system to purchase. These clinical cases show a much lower false alarm rate for the Masimo SET system, as well as a better warning system when the data is erroneous.

Figure 1 shows a 30 minute segment of data on an infant in the NICU with the Nellcor N-595 having difficulty measuring accurate SpO<sub>2</sub> and pulse rate during periods of motion. Masimo SET reads accurately throughout the period. Between minutes 340 to 343 there is a large false desaturation to 63% on the N-595 that is accompanied by erroneous pulse rate. This false desaturation to 63% has an intermittent “Pulse Search” warning displayed. However, false desaturations on the N-595 that happen between minutes 330 to 337 occur with no warning message.

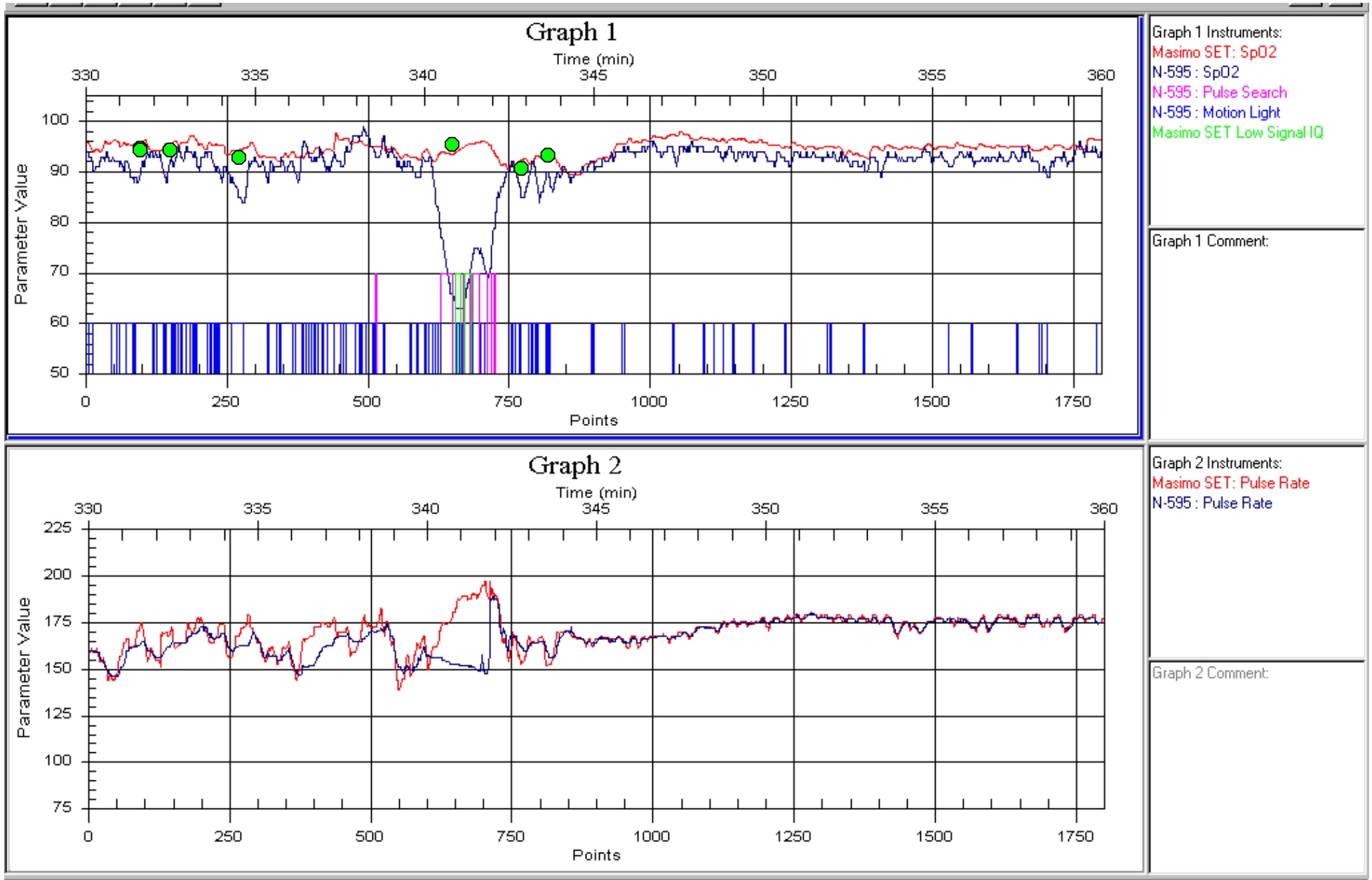


Figure 1 – Thirty minutes of data collection on an infant in the NICU. The actual SpO<sub>2</sub> calculated by SSA is displayed in the figure above by a green dot (●)

Similar data is seen in adult critical care patients. Figure 2 shows a false desaturation on the N-595 with only the “[Motion Indicator Light](#)” activated (Cardiac By-Pass patient).

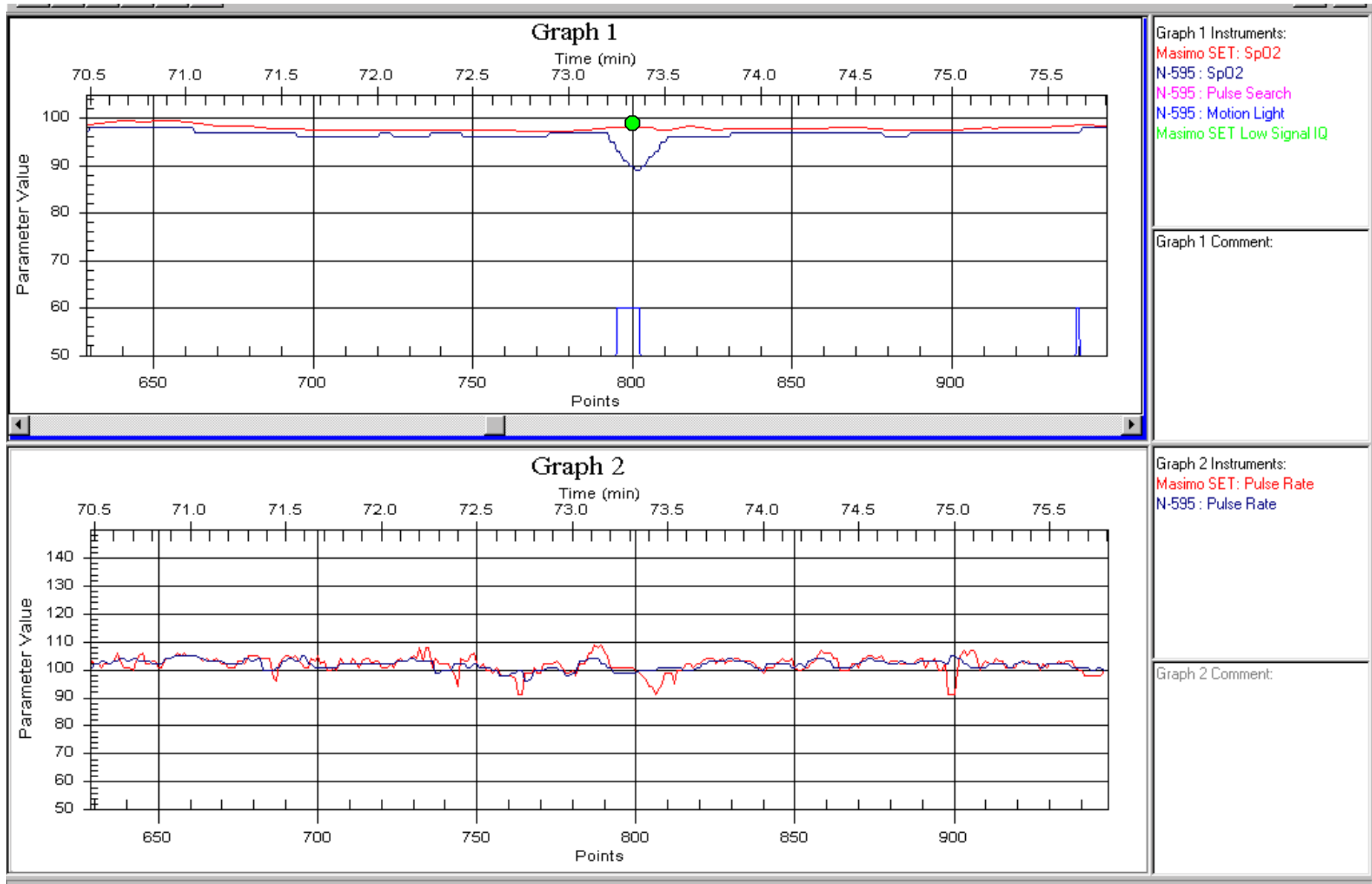


Figure 2 - Five minute segment of data on patient in SICU. The actual SpO<sub>2</sub> calculated by SSA is displayed in the figure above by a green dot (●)

Figure 3 shows data from a 70-year-old Caucasian male in the MICU with tremors. A false desaturation occurs on the Masimo SET pulse oximeter at minute 70.7. The “Low Signal IQ” message activates and warns the clinician that the data may be erroneous during this event. False desaturations occur on the Nellcor N-595 during minutes 70 to 73. The clinician is only alerted briefly (at minute 72.9) by the “Pulse Search” message that these desaturations are erroneous.

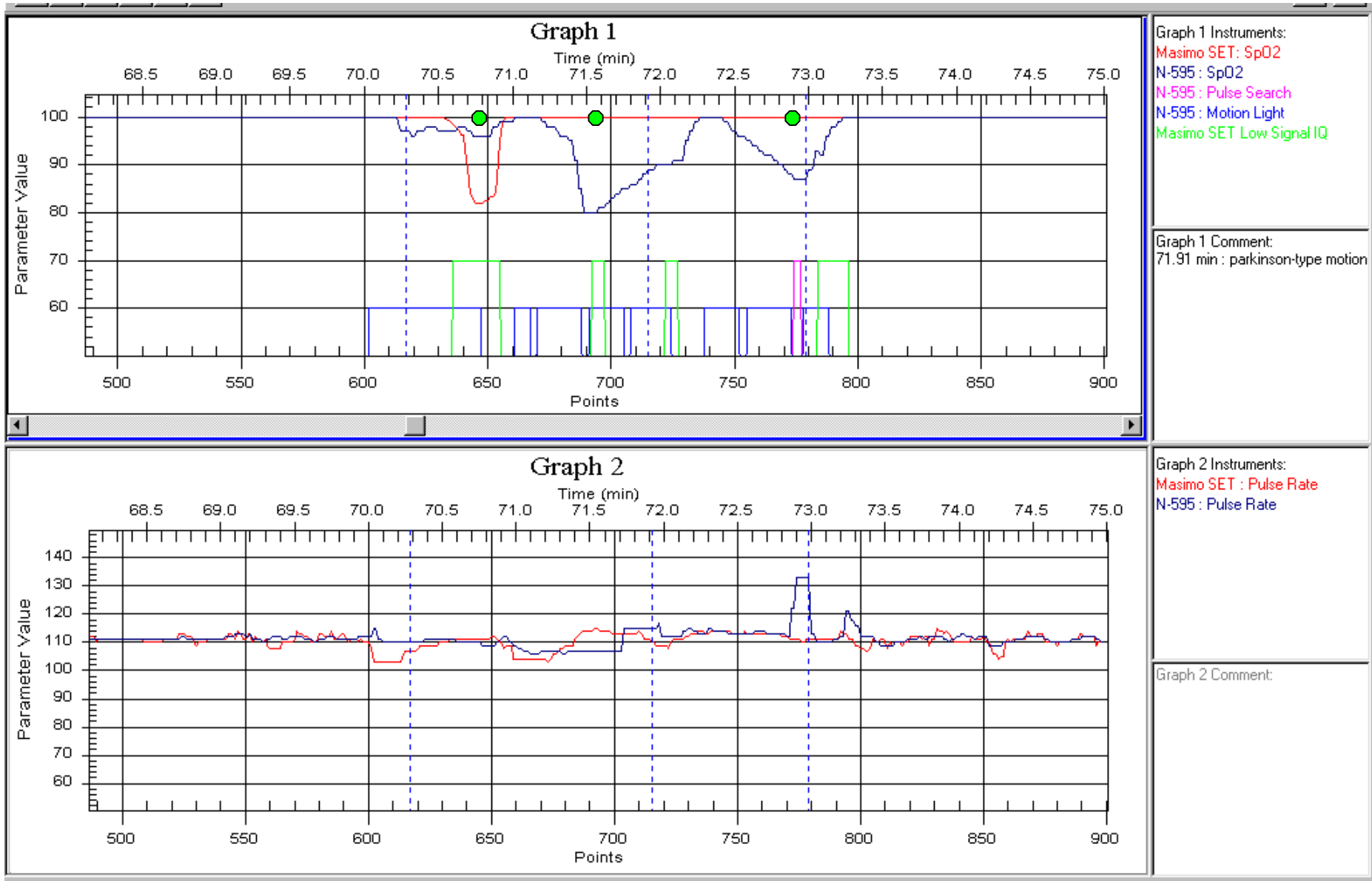


Figure 3 - Seven minutes of data collected on MICU patient with tremors. The actual SpO<sub>2</sub> calculated by SSA is displayed in the figure above by a green dot (●)

In the three cases highlighted above there were 10 events. For the purpose of this paper an event is defined as a period of time (20 seconds or longer in duration) when one but not both of the oximeters report a SpO<sub>2</sub> value below 90% (normal alarm threshold). Each of these 10 events was then analyzed using the Silver Standard Analysis (SSA) technique.<sup>6</sup> The actual SpO<sub>2</sub> calculated by SSA is displayed in the figures above by a green dot (●).

Table 1 shows the results of this analysis. There were 9 events determined to be false alarms for the N595 with mean event duration of 41 seconds (total duration = 365 seconds). One of these events lasted 120 seconds. This compares to 1 event determined to be a false alarm for the Radical, which lasted 20 seconds.

Figure #	Event Time (Mins)	N595 SpO <sub>2</sub>	Radical SpO <sub>2</sub>	SSA SpO <sub>2</sub>	Event Duration (Secs)	False Alarm
1	331.5	88	96	95.2	20	N595
1	332.3	88	95	93.0	20	N595
1	334	84	94	92.5	60	N595
1	340.5	63	94	94.8	120	N595
1	342.7	85	93	90.9	30	N595
1	343.5	84	93	92.1	20	N595
2	73.2	88	100	97.8	20	Radical
3	70.7	96	83	100	20	N595
3	71.5	80	100	98.9	45	N595
3	72.7	87	100	99.6	30	N595

Table 1



The data supplied in this document was representative of the findings at three different hospitals performing clinical evaluations comparing the Masimo SET Radical to the Nellcor N-595. In all cases, the Masimo SET Radical demonstrated far fewer false desaturations and false pulse rate readings. The Masimo SET Radical also demonstrated a superior capability to warn the clinician of suspect data while the N595's reporting of suspect data was absent, or inconsistent. We believe the performance advantage of the Masimo SET Radical over the N-595 is clinically significant, and appears to be as great as that of the Masimo SET Radical to Nellcor's predecessor product, the N-395.

#### References:

1. Barker SJ. The effects of motion and hypoxemia upon the accuracy of 20 pulse oximeters in human volunteers. *Sleep* 2001;24:A406-7.
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4. Shah N, Hoang TD Clack SL, Anderson CT. The impact of motion and low perfusion on the performance of Masimo SET pulse oximeter (PO) and four other POs for measurement of oxygen saturation (SpO<sub>2</sub>) and pulse rate (PR) in human volunteers. *Anesthesiology* 2001;95:A553
5. Barker S. Motion resistant pulse oximetry: Comparison of new and old models. *Anesthesia & Analgesia*. 2002. (In press).
6. Petterson MT, Novak JJ, Kopotic RJ, Goldman JM. A silver standard for corroboration of SpO<sub>2</sub> during motion. *Anesth Analg* 2002;94:S106.