

June 30, 2004

## To Whom It May Concern:

This letter is to inform the reader about the modifications performed on the Masimo SET Radical Pulse Oximeter to be used in an NICHD Neonatal Network trial entitled "The Surfactant Positive Airway Pressure and Pulse Oximetry Trial in Extremely Low Birth Weight Infants (SUPPORT) Trial". This study, lead by Dr. Neil Finer (UCSD) will evaluate two oxygenation ranges on infants immediately after birth and during their hospital stay. In order to mask the oxygenation ranges from the clinicians in the study, these researchers have asked Masimo Corporation to slightly alter the reading displayed on the Masimo Radical pulse oximeter between the 84% to 96% range. One group of pulse oximeters will read approximately 3% higher than the actual number while the other group of pulse oximeters will read approximately 3% low in this range. The researchers have required that the actual number be displayed below 85% and above 95%. The alarm will sound at 84% and 96%.

Masimo has performed validation tests on this software and found it works per the researchers' request. In addition, all alarms and error messages are still intact and active.

Masimo was willing to mask the pulse oximeters per the researchers' instructions since the intended ranges used in the study are in common use in Neonatal Intensive Care Units (NICUs) across the country. This study is aimed at refining the guidelines as to the best oxygen management range for neonates.

Respectfully,

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