

Exhibit A

Tyco-Nellcor statements in blue

Masimo responses in yellow

We appreciate the Subcommittee's interest in examining the operations of Group Purchasing Organizations (GPOs).

This introductory statement by Tyco-Nellcor reflects the disingenuousness of their entire response. Tyco-Nellcor has greatly benefited from dealings with GPOs that eliminate competition. The last thing Tyco-Nellcor wants is for the Subcommittee to examine the operations of GPOs.

Tyco-Nellcor's GPO contracts have been properly awarded on the basis of our superior product quality, superior customer support, and most favorable pricing to the customer.

This statement is pure marketing spin and should not be brought into a serious discussion with the United States Senate without objective, concrete data.

Product Quality:

- There are 49 independent and objective¹ studies so far comparing the quality of Masimo SET to products from Nellcor, including 21 that compare the most current product releases (Masimo SET V3 to Tyco-Nellcor N395/N595). See Attachment 1.
- In all 21 studies comparing the most current product releases, the conclusion is that Masimo SET performs better in detecting true events and rejecting false alarms.
- An overwhelming number (48) conclude that Masimo SET performs better in detecting true events and rejecting false alarms.
- Fifteen of 20 of those hospitals surveyed by Premier, with prior experience with Masimo, rated Masimo SET superior to Tyco-Nellcor's N395.
- Tyco-Nellcor had its sole source contract with Premier renewed despite Premier's own technology assessment group finding that Masimo SET was superior and recommending it be added.
- Tyco-Nellcor had its sole source contract with Novation renewed despite the fact that members of Novation indicated that the two most important issues to them were measurement accuracy and motion artifact technology. Neither of these issues was addressed in the written report issued by Novation in justifying the sole source contract award to Tyco-Nellcor.

Pricing:

- Novation contracted in a sole source arrangement to purchase Tyco-Nellcor products despite the fact that Masimo's prices for stand alone pulse oximeters and adhesive sensors were over 30% less than those from Tyco-Nellcor. See Exhibit 10 of written testimony of Joe Kiani dated April 30, 2002 (the "Kiani Testimony").

1. Independent and objective means that the studies used sound scientific methodology and were not done by employees of any company, nor were the studies paid for by any company.

- Masimo's average pricing across all customers has been lower than Tyco-Nellcor's sole source GPO pricing. See Exhibit 4 of Kiani Testimony.

Customer Service:

- A recent report by Audie Lewis, Consulting, Inc., a health care industry research firm, showed Masimo's customer support and satisfaction to be 9.7 out of 10, the highest ranking ever awarded to a company they have audited.

It is important that you also understand that Masimo Corporation and its CEO, Mr. Joe E. Kiani, have engaged in a strategy to impugn Tyco-Nellcor's reputation in the medical community, the courts, and the news media.

- We don't believe publicly comparing the results of independent third party studies or conducting live side-by-side product demonstrations that show Masimo's technology to be superior to Tyco-Nellcor's technology equates to a strategy of impugning their reputation.

Tyco-Nellcor is proud of its pioneering role in developing pulse oximetry.

- Although Tyco-Nellcor likes to take credit for all pulse oximetry innovation, another company, Nihon Kohden, invented pulse oximetry and Biox (Ohmeda), was actually the first to introduce pulse oximetry in the U.S.

We are unaware of any peer-reviewed publications that both compare the performance of our most recent (post 1999) generations of Tyco-Nellcor technology (O4, O5) with Masimo SET technology and confirm their claim of superiority. There are two comparative studies of Tyco-Nellcor O4 and Masimo SET (and none for O5) that we are aware of and that were published in peer-reviewed journals [see items 7 and 9 in Exhibit 2, Tyco-Nellcor Technology White Paper]. Neither study supports Masimo's claims of product or technology superiority.

- There are no studies comparing Masimo SET to the 05 (N595) because of its recent release date (March 2002). Since that time, we believe that Tyco-Nellcor has been unwilling to make the 05 available to independent testing groups for review. As long as Tyco-Nellcor continues a policy of giving its product a new release number and then suppressing clinical review, it will be impossible to have significant, current studies available comparing technologies.
- However, according to Tyco-Nellcor, the 05 is apparently the same technology as the 04 technology. In the 510(k) premarket notification for the 05 (N595) filed by Tyco-Nellcor, Tyco-Nellcor states "The N-595 uses similar SpO2 and Pulse Rate software algorithm motion-filtering software, and SatSeconds alarm management software as the legally marketed predicate device, N-395..." Therefore, publications comparing Masimo to the 04 are relevant to the 05.
- Our internal comparison shows that the 05 (N595) is actually inferior during motion and low perfusion to the 04 (N395).
- Tyco-Nellcor is aware of the 48 published independent and objective studies that show Masimo SET to be superior to any Tyco-Nellcor pulse oximeter, including the 21 peer-reviewed and independent studies that compare Masimo SET to their most recent clinically available product (the 04/N395).

- Tyco-Nellcor makes its statement by redefining “peer reviewed” from its ordinary usage. This tortured definition (which under Tyco-Nellcor’s definition would eliminate independent peer-reviewed abstracts but allow in company funded peer reviewed manuscripts) would eliminate 21 peer-reviewed and independent studies that show Masimo SET is significantly better than the O4(N395).
- An analysis of the released independent and objective studies shows that there are no independent and objective studies that show that Tyco-Nellcor is superior to Masimo. See Attachments 1 and 2.
- Masimo has always been willing to participate in a test of the latest technology from both companies, using independent clinicians and in an objective setting, and challenges Tyco-Nellcor to support and join in such a comparison.

What Masimo has consistently done is provide "apples-to-oranges" comparisons of our products. They match Tyco-Nellcor products from the 1980's and early 1990's against newer Masimo technology to produce results that appear favorable to Masimo but are meaningless analogies.

- Independent researchers, not Masimo, decide the products they believe are relevant to use in their tests. Often the products tested are those installed in that researcher's hospital.
- But, as stated above, there are 48 independent and objective studies that show Masimo SET technology is superior to that of Tyco-Nellcor, including 21 that compare the most recent technologies.
- The release of Nellcor’s-Nellcor’s O5 technology on the heels of their O4 technology indicates a pattern by Tyco-Nellcor to release new versions quickly; we believe to avoid having to respond to negative clinical research. Prior to Tyco-Nellcor becoming aware of Masimo's breakthrough technology (1982-1992) Tyco-Nellcor had basically one version of signal processing technology. Since then, Tyco-Nellcor has launched four (N3000, N295, N395 and N595) different versions, each following negative research published on the prior. Tyco-Nellcor's own paid-for-publications consistently compare their new named product to older generations of the Masimo SET implementation (Masimo SET V2-the Ivy 2000 also private labeled as Engaurde sold by Ohmeda Medical, OxiReader sold by Allegiance, Oxi-1 sold by Schiller), which contains a three-generation-old version of Masimo software. Tyco-Nellcor's latest abstract (again performed in-house at Tyco-Nellcor) presented at the AACN-NTI meeting in May of this year compares the higher numbered Tyco-Nellcor N-595 to their older N-200 technology.
- We believe that Tyco-Nellcor is well aware that their technology does not compete head-to-head with that of Masimo, and is unwilling to compete with Masimo on a product comparison basis. We are so convinced of Masimo SET superiority that we offer to demonstrate it, side by side with Tyco-Nellcor’s latest device, in an objective setting with independent operators.

Also, several key studies and abstracts cited by Masimo were based on conditions that do not exist in the real world. Therefore, Masimo's claim that those tests prove their products' superiority is meaningless. The tests, especially those of Dr. Steven Barker, used artificial rhythmic conditions that are similar in nature to a heart rate signal, but unlike the patient conditions that exist in a clinical environment. These test conditions bias the study results in favor of the unique underlying design assumptions of Masimo SET technology and against other manufacturers' approaches that are designed to continuously track signals found in actual clinical environments.

- The 48 independent and objective studies referred to earlier include a range of different types of motions in a variety of surroundings, including laboratory and clinical settings. In fact, the vast majority are clinical settings. See Attachment 1.
- With respect to Dr. Barker's study, it is clear that random motion is included as one of the testing categories. Tyco-Nellcor has been told this on numerous occasions, but continues to provide misleading statements regarding these studies.
- This technical argument involving defining various forms of motion, as well as analyzing “underlying design assumptions”, is an attempt to discredit the overwhelming studies showing technological superiority of Masimo SET and to confuse non-technical readers so that they will not believe the clear results of these studies.
- The fact that 48 studies from over 25 different researchers all confirm the results found by Dr. Barker validates that Dr. Barker's testing protocol was a valid simulation of real world conditions that affect pulse oximeters.

Masimo's claim that its oximetry is superior to Tyco-Nellcor's in preventing Retinopathy of Prematurity (ROP) is unfounded.

- When a pulse oximeter falsely reports low oxygen levels, clinicians in the NICU often increase the oxygen delivered to babies. This erroneous increase in oxygen causes eye damage (ROP). While we believe that it is clear that Tyco-Nellcor pulse oximeters give many more false alarms (inaccurately showing low oxygen) than Masimo SET pulse oximeters, Masimo never made the blanket statement Tyco-Nellcor attributes to Masimo.
- Dr. Sola, Professor of Pediatrics at Emory University, has shown a dramatic decrease in ROP and eye surgery by using Masimo SET pulse oximeters along with other good medical practices. Dr. Sola was impassioned enough to write a letter to this Committee. It was his conclusion that Masimo SET pulse oximeters were an important part of the changes he instituted that helped to dramatically reduce ROP in his babies in the NICU. (See Attachment 3)

Masimo's claim that its oximetry saves babies with life-threatening illnesses, and that Tyco-Nellcor's cannot, is unfounded.

- This is a gross mischaracterization of Dr. Goldstein's testimony. Dr. Goldstein was the physician in charge of resuscitation of an infant. The Tyco-Nellcor unit available at the time was not capable of giving a reading and it is his personal opinion that the prototype Masimo SET pulse oximeter was the only indicator of positive improvement in this infant's condition during the early stage of the resuscitation.
- Without that vital information Dr. Goldstein stated he would have stopped the resuscitation. Again, this is not our claim, but a statement from an independent third party clinician.

Masimo's claim that Tyco-Nellcor oximetry jeopardizes infants at risk of sudden infant death syndrome is unfounded.

- Once again, this is Dr. Goldstein's testimony, not Masimo's. In any case, the Tyco-Nellcor statement is a gross mischaracterization of Dr. Goldstein's testimony.
- According to Dr. Goldstein, he decided to conduct his study after the group of Neonatologists he was working with made the decision to implement SatSeconds (from Tyco-Nellcor) as standard for all neonates after being detailed by a Tyco-Nellcor product

representative regarding its utility in the neonatal population. If Tyco-Nellcor's sales staff sells this feature for use with neonates, it would seem only logical and fair that independent clinicians, like Dr. Goldstein, will conduct tests on its effectiveness.

- This same feature, which Tyco-Nellcor in its response to the Senate says "is neither suitable nor intended for use in the population of neonates [Dr. Goldstein] elected to study" is advertised by Tyco-Nellcor by showing it used with a neonate in an incubator!
- To the best of our knowledge, Tyco-Nellcor has not contra-indicated this feature with neonates (never before claimed that this feature is not to be used with neonates).

Mr. Kiani's assertion that Tyco-Nellcor has made "kickbacks" to the GPOs with whom we do business is unfounded.

- Mr. Kiani was referring to payments made by Tyco-Nellcor to GPO's in connection with contracts entered into by GPO's with Tyco-Nellcor on behalf of their member hospitals. They may be legal "kickbacks", but they still fall within what we believe is the ordinary and general definition of the term.

Sole source contracts offer vendors high volume guarantees in exchange for price concessions, not in exchange for larger fees to GPOs. Where Tyco-Nellcor has been awarded a sole source contract, it has done so in exchange for major price concessions for GPO member hospitals.

- The problem is that GPO's, paid by fees from vendors, have no incentive to negotiate for lower prices for its members and have every economic incentive to award sole source contracts for guaranteed minimum purchase requirements, regardless of per unit cost.
- Masimo did not receive the Novation bid notwithstanding pricing that was at least 30% lower than Tyco-Nellcor's. We were informed that Novation planned for a dual source contract until Tyco-Nellcor offered additional incentives to the GPO (not to the member hospitals) for award of a sole source contract.
- Certain of Tyco-Nellcor's sole source contracts have been renewed without taking other bids, and without price concessions for renewal.

On dual and multi-source accounts, Tyco-Nellcor's products have proven to be consistently the favorite among GPO members. As one example, AmeriNet, which has one of the largest memberships of any GPO in the United States, currently has both Tyco-Nellcor and Masimo on contract. Masimo has been on contract with AmeriNet since March 2000. While on a multi-source basis at AmeriNet for over two years, Tyco-Nellcor's sales within AmeriNet continue to increase due to end user preference for Tyco-Nellcor's advanced technology, standardization, and competitive pricing.

- Tyco-Nellcor is giving misleading statements about AmeriNet. While we do not have access to all of AmeriNet's information, we believe that the only reason their sales within AmeriNet have increased is because a large, national hospital network, which already was a long time Tyco-Nellcor customer, joined AmeriNet. The inclusion of this network provided an artificial boost to Tyco-Nellcor's numbers within AmeriNet and does not represent real growth.
- Tyco-Nellcor has not increased their numbers within AmeriNet in situations based on competition with Masimo. We doubt that Tyco-Nellcor is even close to our 139% growth for Q1 2002 over Q1 2001 at AmeriNet only accounts.
- In fact, as we stated in our testimony, in every AmeriNet hospital that we have competed against Tyco-Nellcor, we have won the business of that hospital.

Our aggregate total annual oximetry fees to Novation in our FY01 (or annualized for the current fiscal year) are approximately one tenth of the large amount claimed by Mr. Kiani.

- We clearly stated that we could only estimate the level of fees based on information available. We look forward to the FTC's investigation on the actual payments and practices in this area.

Mr. Kiani's testimony suggesting there is something wrong with providing OEM partners with engineering funds for technical assistance distorts the truth.

- Historically, patient monitoring manufacturers would choose the best pulse oximeter or other technology and pay for their own integration. We believe that Tyco-Nellcor started to offer money for integration after companies recognized that they would otherwise switch to Masimo's superior technology.
- The issue in our testimony, however, was different and related to a GPO providing pressure on a vendor on behalf of Tyco-Nellcor to accept Tyco-Nellcor's offer of \$200,000 to integrate their technology. In one situation, a licensee that resisted this pressure from the GPO, based on the licensee's conclusion that Masimo SET technology was superior to that of Tyco-Nellcor's, subsequently did not have its contract with the GPO renewed.

Mr. Kiani's testimony that Masimo's pricing is 30% better than Tyco-Nellcor's pricing is exaggerated.

- Mr. Kiani's written testimony includes a detailed analysis of how this conclusion was determined. See Exhibit 4 to Kiani Testimony.
- This testimony is backed up with three independent published studies.
- Tyco-Nellcor gives no indication why the 30% number is "exaggerated."

These customers have diverse oximetry needs and financial resources driving GPOs to find vendors that have a breadth of products... By contrast, until recently Masimo offered only one oximeter model.

This is another inaccurate statement, given the facts:

- Masimo's primary strategy is to make its technology widely available through licensing the technology to other patient monitoring companies.
- To date, over 35 companies, representing over 60% of all monitoring product shipments, have licensed Masimo's technology.
- Through these companies, Masimo pulse oximetry is currently available in over 70 different monitoring products that leave no gaps in our product offering.

Attachments:

- 1 – Masimo studies summaries (graphs and list)
- 2 – Tyco-Nellcor studies summary
- 3 – Sola's letter.