

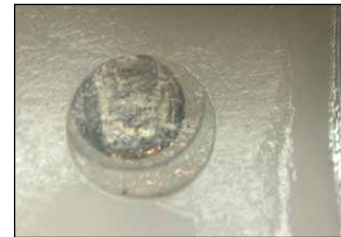
Up to 91% of Third-Party Reprocessed Pulse Oximetry Sensors Fail to Meet Masimo Sensor Performance or Quality Standards

SUMMARY

- > Masimo has designed its adhesive sensors for single-patient-use, but the FDA has allowed third-party manufacturers to reprocess single-use sensors
- > Reprocessing alters single-use sensors from their original form and function, which may have an adverse effect on patient care
- > Masimo regularly receives complaints about third-party reprocessed sensors, but complaints alone do not allow Masimo to quantify the true frequency of quality and performance issues with third-party reprocessed sensors
- > Masimo performed a study of third-party reprocessed sensors (Stryker Sustainability Solutions, formerly Ascent) to evaluate their performance and quality compared to Masimo sensors
- > 91% of third-party reprocessed sensors tested would fail one or more Masimo performance standards
- > 79% of third-party reprocessed sensors tested would fail Masimo quality inspection due to visible defects, including 6% that had some form of biological debris



Yellow stain covering detector of third-party reprocessed sensor



Third-party reprocessed sensor emitter obscured by window placement and glue

- > Masimo offers its customers choices for reducing pollution and waste in our world while also reducing costs
 - > Masimo Reprocessed Sensors are the only reprocessing solution that maintains new sensor performance
 - > Masimo ReSposable™ Sensors offer unprecedented sustainability with a lower carbon footprint and greater waste reduction than reprocessing. Masimo ReSposable Sensors offer equivalent performance and comfort as single-patient-use sensors and a similar sensor price-per-patient as using mixed third-party reprocessed and single-use sensors

HOW CAN REPROCESSING ADVERSELY AFFECT THE SAFETY AND EFFECTIVENESS OF PULSE OXIMETRY SENSORS?

Masimo has designed its adhesive sensors for single-patient-use. Reprocessing alters single-use sensors from their original form and function, which may have an adverse effect on patient care. The Masimo SET and rainbow® systems must detect very small signals in the presence of electromagnetic noise such as competing physiological and environmental signals. In order to distinguish the signals of interest, SET® and rainbow® technologies rely on the assumption that the sensor shields electromagnetic noise. If this assumption is violated, as it is when imitation or altered sensors and cables are used, erroneous measurements can be displayed. Erroneous measurements lead to false alarms and missed true alarms (especially during motion and low perfusion), which can impact timely and accurate diagnosis and treatment.

Third-party pulse oximetry sensor reprocessors typically decontaminate the returned sensor, remove the old outer adhesive, and then apply an adhesive on top of the inner adhesive wrap, which encases the electronic components. Reprocessing techniques that use a tape overwrap also create sensors that are thicker and stiffer, which could lead to less comfort and potentially more pressure on the tissue.



The FDA has stated: "It is essential that users understand that the performance of reprocessed sensors might be different from that of the original sensor."¹ Masimo has found that customers do not always understand how sensors are reprocessed. Customers often assume third-party reprocessed sensors function to the same specification as Masimo sensors. This is not the case. Masimo testing of third-party reprocessed sensors identified a variety of performance issues including biological debris, functional defects, risk of component failure, and adhesive properties that are likely to cause discomfort with infants and neonates.

HOW DOES A THIRD-PARTY REPROCESSOR VALIDATE THE QUALITY AND PERFORMANCE OF REPROCESSED SENSORS?

The FDA 510k clearance process requires only that the reprocessing entity state that the reprocessed medical device is "substantially equivalent" to the original device. The FDA does not require reprocessors to provide clinical data to validate the safety and effectiveness of reprocessing. The FDA also does not require reprocessed sensors to be tested and inspected in the same way Masimo performs testing and inspection on its single-patient-use sensors. To Masimo's knowledge, third-party reprocessors do not guarantee that their reprocessed sensor will provide the same clinical performance as a Masimo sensor through a range of conditions, patients, and settings. For example, Stryker Sustainability (Ascent) reprocesses Masimo LNCS[®]/M-LNCS[™] sensors; however, unlike Masimo, their sensors do not have an indication for use during motion or low perfusion, nor have they demonstrated compatibility with the non-Masimo pulse oximeters of Nellcor and Philips FAST. Another example is the Stryker Sustainability (Ascent) "L style" sensor. Its labeling states the sensor is indicated for use on adults, pediatrics, and infants – not neonates. Hospitals should assess the risk of using sensors that are not indicated for neonates.

Compounding these issues is the fact that third-party reprocessed sensors are not easily distinguishable from Masimo sensors, whether or not the sensor is still inside the packaging. Often a hospital's decision to use reprocessing is not communicated to the clinicians who are applying the sensors to patients, which cause many clinicians to believe that the source of their non-performing sensor was Masimo, when in fact they were from a third-party reprocessor.

MASIMO TESTED THIRD-PARTY REPROCESSED SENSORS TO EVALUATE QUALITY AND PERFORMANCE COMPARED TO MASIMO SENSORS

Masimo regularly receives complaints about third-party reprocessed sensors, but complaints alone do not allow Masimo to quantify the true frequency of quality and performance issues with third-party reprocessed sensors. Masimo ran multiple tests on sensors produced by a third-party reprocessor (Stryker Sustainability Solutions, formerly Ascent) to evaluate the performance on three important sensor characteristics: light transmission, electrical noise immunity, and sensor adhesion.

91% OF THIRD-PARTY REPROCESSED SENSORS TESTED WOULD FAIL ONE OR MORE MASIMO SENSOR PERFORMANCE STANDARDS

A random sample of 162 third-party reprocessed sensors was subjected to Masimo's standard sensor performance tests for 1) light transmission; 2) electrical noise immunity; and 3) sensor adhesion.

Light transmission performance: 91% of the tested sensors did not meet Masimo sensor specifications. Failing this specification means that these sensors could allow light to be read by the detector without passing through the tissue, affecting measured light absorption in a way that could compromise the accuracy of the oxygen saturation measurement.

Electrical noise immunity: 9% of the tested sensors failed electrical noise immunity testing. Electrical noise, such as electrocautery equipment and exposure to electro-static discharge (ESD), can cause erroneous readings, intermittent interruptions or sensor failure.

Sensor adhesion: Testing of Infant and Neonatal versions of third-party reprocessed sensors showed that almost three times the pull force was required to remove the sensor compared to Masimo Infant and Neonatal sensors. Single-patient-use sensors need to be removed and reapplied during a patient's hospital stay. Masimo sensors are designed with an adhesive that allows for multiple reapplications and with electrical components that withstand the mechanical forces due to reapplication. At almost three times the pull force to remove the adhesive sensor, third-party reprocessed sensors are likely to cause significant irritation and discomfort to infants and neonates.

79% OF THIRD-PARTY REPROCESSED SENSORS TESTED WOULD FAIL MASIMO QUALITY INSPECTION STANDARDS

A random sample of 974 third-party reprocessed sensors was subjected to Masimo's visual quality inspection. Visual quality inspection revealed that 79% of third-party sensors had visible defects, which would not meet Masimo's acceptance criteria. Six percent of third-party sensors had some form of biological debris including hair, skin, and red and yellow stains from bodily fluids. It is unclear what clinical risk is associated with the presence of biological residue in third-party reprocessed sensors, regardless of sterility.



Figure 1. Hair embedded in third-party reprocessed sensor adhesive

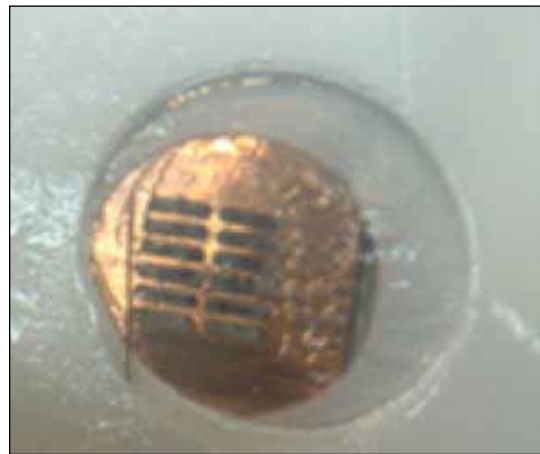


Figure 2. Hair embedded in third-party reprocessed detector



Figure 3. Yellow stain covering detector of third-party reprocessed sensor



Figure 4. *Third-party reprocessed sensor emitter obscured by glue and adhesive placement*



Figure 5. *Third-party reprocessed sensor emitter with excess glue*

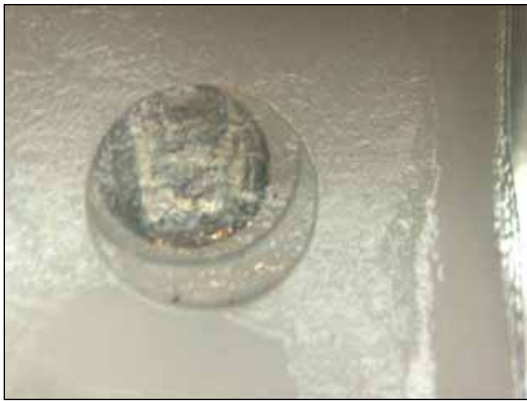


Figure 6. *Third-party reprocessed sensor emitter obscured by window placement and glue*

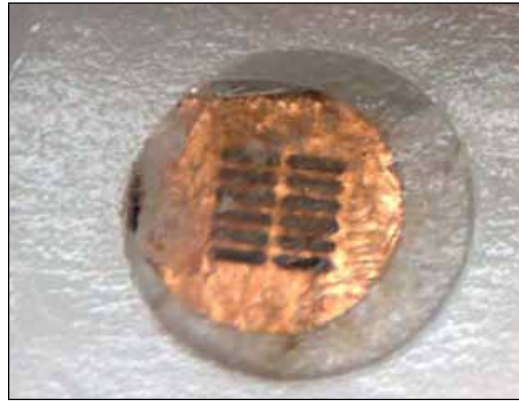


Figure 7. *Third-party sensor detector obscured by excess glue*

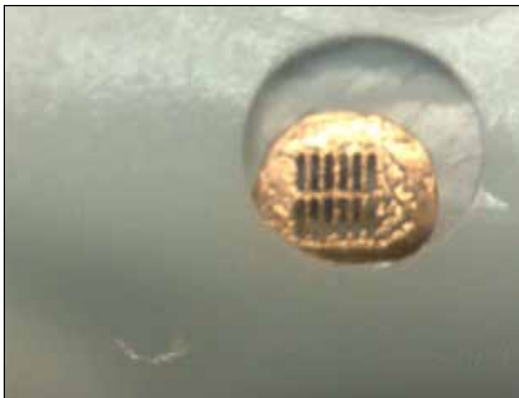


Figure 8. *Transparent film over detector missing on third-party reprocessed sensor*



Figure 9. *Transparent film over emitter on third-party reprocessed sensor missing*



Figure 10. *Embedded particle embedded in detector of third-party reprocessed sensor*



Figure 11. *Embedded particle in adhesive of third party reprocessed sensor*



Figure 12. *Folded adhesive on third-party reprocessed sensor*



Figure 13. *Chipped sensor cable on third-party reprocessed sensor*

WHAT OTHER HIDDEN COSTS ARE ASSOCIATED WITH THE USE OF THIRD-PARTY REPROCESSED SENSORS?

In addition to the price, hospitals might wish to critically assess the personnel costs associated with the reprocessing program administration, including managing multiple part numbers, the observed costs of third-party reprocessed sensor failure, and the extra time spent troubleshooting failures. Critical costs that are not easily measured are those related to patient care, such as measurement accuracy and reliability in challenging conditions where the patient could be at risk.

WHO BEARS THE RESPONSIBILITY FOR THE CLINICAL PERFORMANCE OF A THIRD-PARTY REPROCESSED SENSOR?

Under federal law, third-party reprocessed sensor companies are responsible for the device performance and must label the device and packaging accordingly (Section 301 of MDUFMA). The FDA stipulates that reprocessing companies bear the responsibility of clinical performance. If performance is compromised, the question of liability could be raised. Masimo cannot guarantee system performance if third-party reprocessed sensors are utilized.

WHAT OTHER OPTIONS DOES A HOSPITAL HAVE TO REDUCE ITS SENSOR COSTS AND ENVIRONMENTAL WASTE?

Masimo offers reprocessed sensors at prices comparable to third-party reprocessors. Masimo reprocesses sensors in a very different manner than third-party reprocessors that ensures quality and performance. Moreover, only Masimo can guarantee the clinical performance of the instrument, cable, and sensor, which all function as a single system. Many hospitals have a hospital-wide contract for their pulse oximetry equipment and sensors; therefore working with Masimo can result in a reprocessing program that optimizes an existing or potential contract.

HOW ARE MASIMO REPROCESSED SENSORS DIFFERENT FROM THIRD-PARTY REPROCESSED SENSORS?

Although it could be to Masimo's financial advantage to reprocess in the same manner as third-party reproprocessors, Masimo believes that the resulting products would significantly compromise patient care. Therefore, Masimo reprocessed sensors are rebuilt using emitters, detectors, connecting elements, inner-wrap, and outer adhesive. The connector and cable can be reprocessed without performance compromise. Only Masimo reprocessed sensors are validated to perform the same as a completely new sensor. Even though the other components are only designed for single-patient use, third-party manufacturers generally only add or replace the outer wrap. Therefore, no matter what method is employed, reusing emitter, detector, and connecting elements cannot offer the same performance as new components.

For customers who wish to use single-patient-use sensors but recycle the components of their used sensors, Masimo offers a recycling program in which the sensors can be collected and returned to Masimo so the raw materials can be recycled.



MASIMO RESPONSABLE SENSORS – THE ULTIMATE SOLUTION FOR SUSTAINABILITY AND COST REDUCTION WHILE PRESERVING PERFORMANCE

To date, reprocessing and recycling have been the only options available to hospitals seeking sustainability and cost reduction. Masimo's new ReSposable Sensors offer customers the ultimate sensor solution for reducing pollution and waste in our world while also reducing costs. The ReSposable Sensor System combines the best features of disposable and reusable sensors into an innovative design. This design features a reusable optical sensor (ROS™), which can be used over multiple patients and a disposable optical sensor (DOS™) for single-patient-use. Masimo ReSposable Sensors have a lower carbon footprint and greater waste reduction than reprocessing – with equivalent performance and comfort as single-patient-use sensors and a similar sensor price-per-patient as using mixed third-party reprocessed and single-use sensors.



Figure 14. The ReSposable direct connect patient cable integrates the reusable optical sensor (ROS)



Figure 15. For each patient, a new disposable optical sensor (DOS) is used depending on the size of patient and sensor shape preference

RESPONSABLE – PERFECT FOR YOUR HOSPITAL'S GREEN INITIATIVES

Up to **90%** less waste vs. *only 34%* less waste with reprocessing*

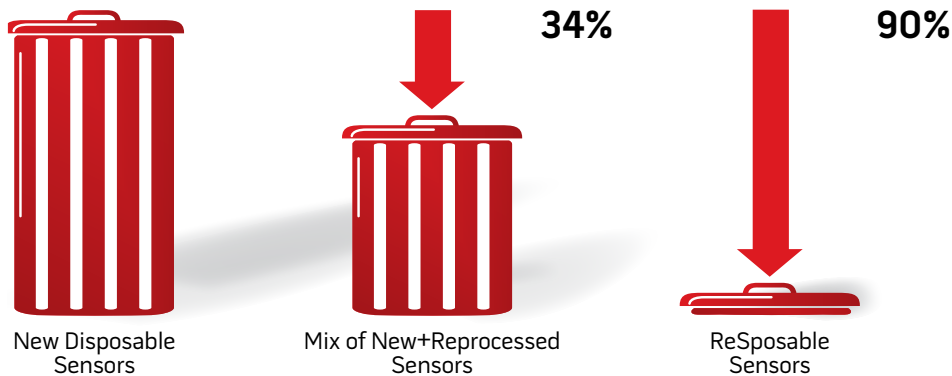


Figure 16. Comparison of waste generated by each type of sensor

Up to **41%** lower carbon footprint vs. *43% higher* carbon footprint with reprocessing*

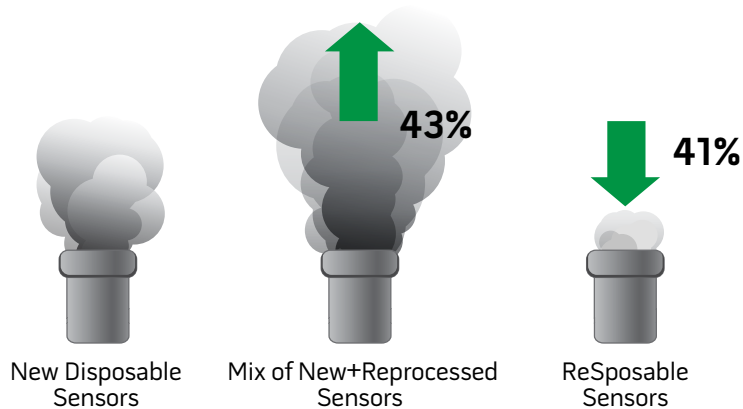


Figure 17. ReSposable sensors generate significantly less greenhouse gas emissions than reprocessed sensors. Reprocessed sensors have a higher carbon footprint than new sensors due to greater greenhouse gas emissions from transport, reprocessing, and decontamination procedures.

ReSposable sensors generate significantly less green house gas emissions than reprocessed sensors. Reprocessed sensors actually have a higher carbon footprint than new sensors, due to greater green house gas emissions from transport, reprocessing, and decontamination procedures.



Carbon footprint calculations validated by Carbonfund.org in November, 2011.

* Waste calculated by sensor weight for 40% reprocessed sensors with a mix of 80% Adult and Pediatric sensors, 20% Neo and infant sensors. Carbon footprint comparisons calculated by lbs. CO₂ emissions with same reprocess mix as waste.

REFERENCES

¹ Weinger S. Effective standards and regulatory tools for respiratory gas monitors and pulse oximeters: The role of the engineer and clinician. *Anesth Analg*. 2007;105: S95-99.