TECHNICAL BULLETIN

Reprocessed Pulse Oximetry Sensors: What Every Hospital Needs to Know

HOW ARE PULSE OXIMETRY SENSORS REPROCESSED BY A THIRD PARTY?

Third-party pulse oximetry sensor reprocessors typically decontaminate the returned sensor, remove the old outer adhesive, and apply a new adhesive on top of the inner adhesive wrap which encases the electronic components. Reprocessing techniques that use tape overwraps yield sensors that are materially thicker. This additional bulk and corresponding stiffness may lead to unreliable readings in use, less comfort, and possibly more pressure to the tissue. Unreliable readings may lead to more false alarms and missed true alarms, which may impact timely and accurate diagnosis and treatment.

The FDA's own expert on pulse oximetry has written: ***"It is essential that users understand that the performance of reprocessed sensors might be different from that of the original sensor."***[1] These differences could lead to compromised care. Because of these concerns with patient safety, original manufacturer warranties expressly exclude use of sensors that have been altered through reprocessing.

EXAMPLES OF PERFORMANCE ISSUES IN THIRD-PARTY REPROCESSED PULSE OXIMETRY SENSORS

1

Internal tape layer is not removed from the components.

2

Extra tape layers can add bulk and stiffness to the sensor that can impact the comfort and performance of the sensor.

3

When the components are not removed from the original tape, it makes it difficult to align the components with the opening in the outer tape. This results in partially occluded components, compromising performance of the sensor.

HOW DOES A THIRD-PARTY REPROCESSOR VALIDATE THE PERFORMANCE AND COMPONENTS OF REPROCESSED SENSORS FOR USE WITH PULSE OXIMETER DEVICES?

The FDA 510k process requires only that the reprocessing entity state in writing that the reprocessed medical device is "substantially equivalent" to the original equipment, but the reprocessing entity is not required under FDA regulations to inspect and, as needed, replace aging wiring, connectors, or electronic components. Aging components may degrade performance and increase failure rates. Third-party reprocessors do not appear to guarantee that their reprocessed sensor will provide the same clinical performance as a new sensor through a range of conditions. Many reprocessed sensors are also not easily distinguishable in their packaging compared to a new sensor, which may lead to confusion over the source of any questionable sensor.

WHAT OTHER COSTS ARE ASSOCIATED WITH THE USE OF REPROCESSED SENSORS?

In addition to the price, hospitals may wish to critically assess the personnel costs associated with the reprocessing program administration itself, the observed costs of reprocessed sensor failure (users of reprocessed pulse oximeter sensors have reported higher failure rates than new sensors), and the extra time spent troubleshooting failures. Critical costs not easily measured are those related to patient care.

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

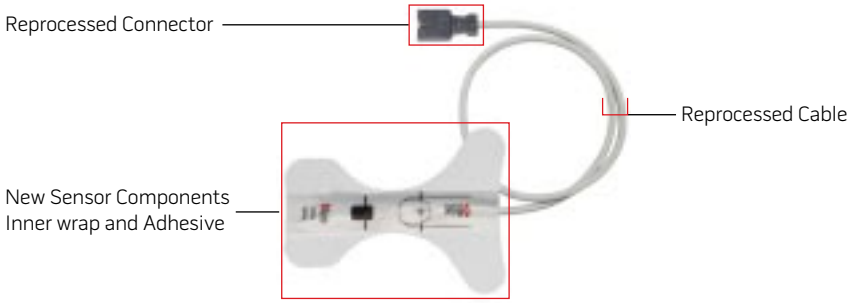
Third-party reprocessed sensor companies are responsible under federal law for the device performance and must label the device and packaging accordingly (Section 301 of MDUFMA). The FDA stipulates that reprocessing companies bear the responsibility of clinical performance. If performance is compromised, the question of liability may be raised.

WHAT OTHER OPTIONS DOES A HOSPITAL HAVE IF IT WANTS TO REDUCE ITS SENSOR COSTS AND/OR REDUCE 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 and uses new electronic components. Importantly, only Masimo can back the clinical performance of both the pulse oximeter and the pulse oximeter sensor. Many hospitals have a hospital-wide contract for their pulse oximetry equipment and sensors, so working with Masimo can result in a reprocessing program that optimizes an existing or potential new contract.

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

Masimo reprocessed sensors are "rebuilt" using new emitters, detectors, connecting elements, inner-wrap, and outer adhesive. Only Masimo reprocessed sensors are validated to perform the same as a new sensor. Third-party manufacturers generally only add or replace the outer wrap, even though the other components are only designed for use with one patient. Therefore, no matter what method is employed, reusing emitter, detector, and connecting elements cannot consistently offer the same performance as new components.



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1 Weininger 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.

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