Reprocessing **overview**

stryker

Pulse oximeter sensors

Product availability: Stryker's Sustainability Solutions reprocessed pulse oximeter sensors are packaged in case quantities of 20 (Masimo®) and 24 (Nellcor®) units per corrugated cardboard box.

Receiving and visual inspection: Once pulse oximeter devices arrive to our reprocessing facility, they are removed from shipping containers, untangled and sorted. Pulse oximeters then undergo their first visual inspection. Devices are inspected for the presence of debris, contamination, stains, exposed wires and overall device integrity. Any device that does not meet Stryker's strict quality standards is rejected. Any device received with another reprocessor's identifier is also rejected. All devices approved for reprocessing are tallied and recorded.

Decontamination and cleaning: After the initial inspection is complete, the original tape and patient contact surfaces are removed. All cords, plugs and sensors are wiped down with medical grade cleaners and disinfectants.

Automated processes: We have implemented automated machines for assembly to increase speed, ensure quality and maximize the number of reprocessed devices we can return to a customer. These sophisticated machines are managed by an operations specialist and have regular maintenance and calibration schedules to keep them running at their best. On our automation machine (also known as PAM), the devices automatically move through a series of steps to assemble the device after being cleaned. The machines can assemble both woven or transpore style pulse oximeter sensors.

Assembly: The primary tape is dispensed and applied to the device and folded into its correct orientation. The secondary tape is also applied, and the final liner is placed onto the device*. All tape alignments are verified to ensure the device is functioning properly.

Performance testing: Every pulse oximeter sensor is tested for electrical continuity and signal output of the LED and photo detector. Any device that does not meet Stryker's strict quality standards is rejected. If applicable, devices with alarm recording capabilities are disabled to prevent data from being read/written during the device's next clinical use.

Device tracking: In addition to a Stryker logo, a unique barcode is applied to the proximal end of every device to track reprocessing cycles. Any device that has reached its maximum number of cleared reprocessing cycles is also rejected.

Auditing the process: Routine quality control audits are completed to ensure process integrity. Reports are provided to senior management for operating line performance and control. Additionally, finished product performance attributes, including cleaning end points, are routinely subjected to random sampling and inspection.

Documentation: Production support staff is required to sign off after performing each reprocessing step. Detailed documentation ensures traceability of critical steps performed. Records are maintained in accordance with FDA and ISO requirements.

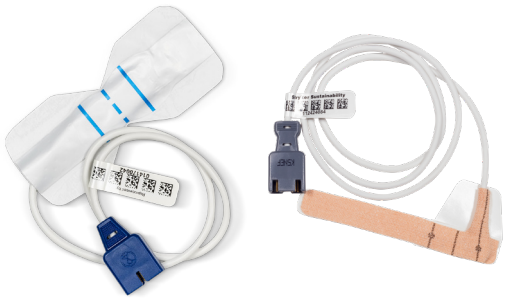
Packaging: Our packaging materials and sealing process for pulse oximeter sensors are validated in accordance with ISO 11607. Devices are packaged individually in two-toned printed Tyvek® peel pouches. Every pouch is inspected for debris, defects and overall integrity, then printed with a lot number. An expiration date is also printed if the devices are labeled as sterile. **Note**: Masimo and Nellcor devices are labeled as "non-sterile" and "sterile" respectively.

Vaporized Hydrogen Peroxide (VHP): All reprocessed pulse oximeter sensors are decontaminated within their final Tyvek pouches using VHP, except for Neonatal models that continue to use EO. VHP decontamination method is recognized by the FDA and is used by the healthcare industry to disinfect and eliminate microorganisms. VHP is considered a "green" sterilization modality; the active hydrogen peroxide vapor breaks down to oxygen and water vapor as byproducts to the process.

Recycling: Any devices that are rejected throughout the manufacturing line are collected and appropriately recycled through a third party.

***Masimo RD SET sensors**: Rather than a cable, OEM Masimo RD SET sensors are designed with a unique foam cord. During our reprocessing process, new foam tape is applied around the outside of the existing foam cord.

Masimo RD SET®



Masimo LNCS® and Nellcor OxiMax™

Sustainability Solutions **1 888 888 3433** **sustainability.stryker.com**