Reprocessing **overview**

Pulse oximeters

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

Decontamination and cleaning: Reprocessed pulse oximeter sensors are initially inspected for visible damage such as exposed wires or gross contamination. Any device that does not meet Stryker's strict quality standards is rejected. Cords and plugs are wiped down with medical grade cleaners and disinfectants. The tape covering sensors and patient contact surfaces is removed and replaced with medical grade adhesive tape.

Device tracking: When Stryker receives pulse oximeter sensors, all quantities of approved devices are tallied and recorded. Any device received with another reprocessor's tracking identifier is rejected. A Stryker logo and unique barcode are 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.

Performance testing: Every pulse oximeter sensor is tested for electrical continuity and signal output of the LED and photo detector. If applicable, devices with alarm recording capability are disabled to prevent data from being read/written to during the device's next clinical use.

Visual inspection: Every pulse oximeter sensor is inspected throughout various steps of the production process. Devices are inspected for the presence of debris, contamination, stains and for overall device integrity. Any device that does not meet Stryker's strict quality standards is rejected.

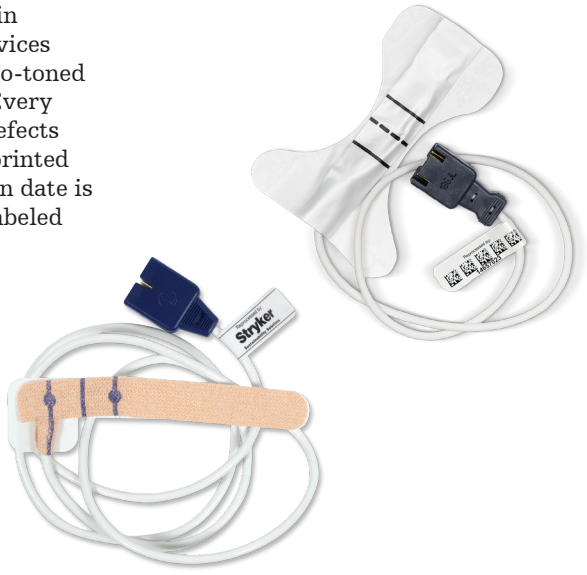
Packaging: Stryker's packaging materials and sealing process for pulse oximeter sensors are validated in accordance with ISO 11607. Devices are packaged individually in two-toned printed Tyvek® peel pouches. Every pouch is inspected for debris, defects and overall integrity and then printed with a lot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

Ethylene oxide exposure: Ethylene oxide (EO) exposure is validated utilizing ANSI/AAMI/ISO 11135 as a guideline for this bioburden reduction process. EO decontamination validation demonstrates the process and equipment are capable of consistently and reliably achieving a minimum six spore log reduction (SLR). EO residuals do not exceed maximum allowable limits of ANSI/AAMI/ISO 10993-7.

Note: Masimo and Nellcor devices are labeled as "non-sterile" and "sterile" respectively.

Product summary

- Class II devices under the Code of Federal Regulations (21 CFR 870.2700), which requires FDA pre-market notification
- All reprocessed pulse oximeters are visually inspected and performance tested to ensure functionality.



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

MKT8014 Rev. E 2028 | Stryker, 1810 West Drake Drive, Tempe, AZ 85283 USA | 888 888 3433 | Copyright © 2020 Stryker