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 cosmetic blemishes. 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 testing.

Class II devices under the Code of Federal Regulations (21 CFR 870.2700), which requires FDA pre-market notification.
Documentation: Technicians are required to sign off after performing each reprocessing step. Detailed documentation assures traceability of critical steps performed. Records are maintained in accordance with FDA and ISO requirements.

Performance Testing: A simulator is used to test every pulse oximeter sensor for electrical continuity, signal output (LED) and photo detection. If applicable, devices with alarm recording capability are electronically altered 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 and expiration date.

Sterilization: Ethylene oxide sterilization is validated as per ANSI/AAMI/ISO 11135 to a sterility assurance level of 10^{-6}. Ethylene oxide 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.

* Savings estimates are based on best-demonstrated practices at a hospital with an average of 250 beds. A hospital’s true savings potential is not realized immediately; rather, savings may increase over time as reprocessing is continuously embraced by staff as a standard best practice.

The third-party trademarks used herein are trademarks of their respective owners.