



September 9, 2020

DECLARATION STATEMENT – MASIMO REUSABLE SENSOR AND CABLE CLEANING

Re: Cleaning Masimo Reusable Sensors and Cables

Masimo reusable sensors and cables are provided in non-sterile conditions. The instructions for proper cleaning and disinfection (for sensors and cables) are presented in each product's directions for use and supplemented as follows:

GENERAL CLEANING INSTRUCTIONS:

For Reusable Sensors:

1. Remove the sensor from the patient and disconnect it from the patient cable.
2. Saturate a cloth or gauze pad with a Masimo-approved cleaning solution.^{1,2}
3. Wipe all surfaces of the sensor and cable.
4. If using 70% IPA as the cleaning solution, allow the sensor to dry thoroughly prior to placement on a patient.
5. If using a cleaning solution other than 70% IPA, saturate another cloth or gauze pad with sterile or distilled water and wipe all surfaces of the sensor and cable.
6. Dry the sensor and cable with a clean cloth or dry gauze pad.

For Cables:

1. Remove the cable from the instrument and remove any attached sensors or adapters.
2. Follow steps 2 through 4 above to clean all surfaces of the cable.

¹ Masimo-approved cleaning solutions:

- 70% Isopropyl Alcohol (IPA)
- 10% bleach/water solution (~0.5% sodium hypochlorite solution)
- Up to 55% alcohol/0.5% quaternary ammonium chloride solution, such as Ecolab Asepti-Wipe® II Germicidal Wipes or PDI Super Sani-Cloth® Germicidal Wipes
- Accelerated Hydrogen Peroxide® Oxivir® Tb
- Up to 2.5% glutaraldehyde solution, such as Metrex MetriCide™ 28
- Chlorhexidine 4%

CAUTIONS:

- Do not use undiluted bleach (5% - 5.25% sodium hypochlorite solution).
- Do not immerse the sensor or connectors in any liquid solution.
- Do not attempt to sterilize by any method.

² CLEANING SOLUTIONS OTHER THAN MASIMO-APPROVED CLEANING SOLUTIONS:

Masimo has not tested cleaning solutions and wipes containing chemicals other than those listed above, and cannot guarantee that other cleaning solutions containing different chemicals will be safe for use on all Masimo products. Masimo chemical tests determine if the product material appears to be visibly damaged or the labeling rendered unreadable based on short term exposure to the cleaning agents. Masimo has not conducted testing of repeated long-term exposure and assumes no responsibility for any long-term damage that may result from the use of any cleaning agent other than those listed in this letter, the Masimo user manual, or directions for use.

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