

September 9, 2020

DECLARATION STATEMENT – MASIMO INSTRUMENT CLEANING

Re: Cleaning Masimo Instruments

The instructions for proper cleaning and disinfection for Masimo instruments are presented in each product's directions for use. In general, the instructions below apply to all models of the following Masimo instruments:

- Root®
- Radical-7®
- Rad-97®
- Radius-7®
- Rad-67™
- Rad-57®
- Rad-5® and Rad-5v®
- Rad-G™
- Rad-8®
- MightySat® and MightySat Rx
- Radical Docking Stations RDS®-1 and RDS-3
- SedLine® MOC-9® Module
- O3® Regional Oximeter MOC-9 Module
- NomoLine® ISA™ CO₂ MOC-9 Module

GENERAL CLEANING INSTRUCTIONS:

The outer surface of the instrument can be cleaned using a soft cloth dampened with a mild detergent and warm water solution. Do not allow liquids to enter the interior of the instrument and ensure that it is dry before use. The outer surface of the instrument can also be wiped down using a Masimo-approved cleaning solution.^{1,2}

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 Asepsi-Wipe® II Germicidal Wipes or PDI Super Sani-Cloth® Germicidal Wipes
- Accelerated Hydrogen Peroxide® Oxivir® Tb
- Cidex® Plus (3.4% glutaraldehyde)

CAUTIONS:

- Power off the instrument, disconnect the AC power cord (if equipped), and remove accessories before cleaning.
- Do not use petroleum-based or acetone solutions, undiluted bleach (5% - 5.25% sodium hypochlorite solution), or other harsh solvents. These substances affect the device's materials and instrument failure can result.
- Do not use different cleaning solutions to clean the same instrument. Unpredictable chemical reactions that may damage the instrument may occur.
- Do not touch, press, or rub the display panels with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could scratch the panel.
- Do not immerse the instrument in any liquid solution.
- Do not sterilize by irradiation, steam autoclave, or ethylene oxide.

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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