The facility should ensure that the level of bacterial endotoxins in the final rinse water are controlled and monitored within the limits specified in national regulations depending upon the intended site of use of the endoscope (e.g. sterile body site).

INTENDED USE OF THE MEDIVATORS™ ISA™ ENDOSCOPE REPROCESSOR

The MEDIVATORS™ ISA™ Endoscope Reprocessor is a medical device designed for the cold chemical washing and disinfection of rigid and flexible endoscopes and endoscopic accessories.

The MD must NOT be used for any purposes not envisaged by the manufacturer and/or NOT reported in the present manual.

THE MAIN CHARACTERISTICS OF THE MEDIVATORS™ ISA™ ENDOSCOPE REPROCESSOR INCLUDE:

- Configuration conforming with the current European regulations and international standards EN ISO 15883-1/4 and CEN ISO/TS 15883-5.
- PC All in one dedicated to the user interface and recording of the cycle parameters.
- A spacious basin for the reprocessing of endoscopes and/or endoscopic accessories.
- The possibility to have a drying cycle with alcohol (optional).
- The use of safe and validated single shot detergent and sterilizing/disinfectant chemical solutions, compatible with the various brands of endoscope available on the market.
- A validated process (equipment and chemicals) for use at room temperature.
- Continuous monitoring of the channel pressure, the flow rates in the channels and the general parameters throughout the entire cycle.
- A rapid and unique interconnecting system for the endoscope channel connectors Warrantying the proper control of flow rates in the endoscope channels.
- Operator and endoscope recognition system using RFID (Radio-Frequency Identification).
- The possibility to perform the self-disinfection cycle using programmable automatic start-up.
- Air filtration system capable of Warrantying the complete sterility of the process, and dual filter system for the water feed (0.45µm - 0.1µm).
- Traceability of the processes in hard-copy format (using the integrated printer) and electronic format (using complete traceability management software).
- Opening of the lid by pedal (hands-free).
- Capable of adapting to all hospital situations, even in small spaces, thanks to compact size.
- Acoustic and visual alarm signals with a description of the type of fault to allow the operator to immediately identify the type of problem.
- Tanks for the detergent/decontaminant and high level sterilizing/disinfectant solutions A and B, that are safe with no harmful emissions.

The equipment must only be used by qualified personnel and only after having attended a training course organized by the manufacturer or by personnel authorized by the manufacturer.

REGULATORY COMPLIANCE

MEDIVATORS™ ISA™ Endoscope Reprocessor is a class IIb medical device, complying with the Medical Devices Directive 93/42/EEC and upgrades.

THE MEDICAL DEVICE IS COMPLIANT WITH THE FOLLOWING STANDARDS:

- EN ISO 15883-1
  “Endoscope Reprocessors - Part 1: General requirements, terms and definitions and tests”.
- EN ISO 15883-4
  “Endoscope Reprocessors - Part 4: Requirements and tests for endoscope Reprocessors employing chemical disinfection for thermolabile endoscopes”.
- CEN ISO/TS 15883-5
  “Endoscope Reprocessors - Part 5: Test soils and methods for demonstrating cleaning efficacy”.
- CEI EN 61010-1
  “Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements”.
- CEI EN 61010-2-040
  “Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and Endoscope Reprocessors used to treat medical materials”.
- CEI EN 61326-1
  “Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements”.
- CEI EN 62366
  “Medical devices - Application of usability engineering to medical devices”.

DESCRIPTION OF THE VALIDATED CHEMICAL SOLUTIONS

The MEDIVATORS™ ISA™ Endoscope Reprocessor uses specific and validated chemical solutions in order to obtain an effective cleaning and disinfection process.

In particular:

FOR THE CLEANSING PHASE:

ISACLEAN™ Multienzyme Detergent/Decontaminant:

ISACLEAN™ Multienzyme Detergent/Decontaminant is available in 1 L tanks or 5 L tanks.

- A 1 L tank of ISACLEAN™ Multienzyme Detergent/ Decontaminant allows the execution of approx. 62 cycles.
- A 5 L tank of ISACLEAN™ Multienzyme Detergent/ Decontaminant allows the execution of approx. 312 cycles.

ISACLEAN™ AER Detergent/Decontaminant:

ISACLEAN™ AER Detergent/Decontaminant is available in 1 L or 5 L tanks.

- ISACLEAN™ AER Detergent/ Decontaminant specific for the removal of microbial biofilms.
- A 1L tank of ISACLEAN™ AER Detergent / Decontaminant allows the execution of approx. 62 cycles.
- A 5 L tank of ISACLEAN™ AER Detergent/ Decontaminant allows the execution of approx. 312 cycles.

PROTEAZONE™ PLUS Detergent & Cleaner:

- PROTEAZONE™ PLUS Detergent & Cleaner, specific for the removal of microbial biofilms.
- PROTEAZONE™ PLUS Detergent & Cleaner is available in 5 L tanks.
- A 5 L tank of PROTEAZONE™ PLUS Detergent & Cleaner allows the execution of approx. 147 cycles.

FOR THE DISINFECTION PHASE:

ISASPOR™ SINGLE SHOT High Level Disinfectant/Sterilizing solution:

- ISASPOR™ Single Shot High Level Disinfectant/ Sterilant is available in 10 L tanks (10 L Solution A + 10 L Solution B) or in 5 L tanks (5 L Solution A + 5 L Solution B).
- A 5 L tank of ISASPOR™ Single Shot High Level Disinfectant/Sterilant allows the execution of approx. 26 cycles.
- A 10 L tank of ISASPOR™ Single Shot High Level Disinfectant/Sterilant allows the execution of approx. 52 cycles.

FOR THE DISINFECTION PHASE:

To aid with the proper connection of the aspiration nozzle to the relevant product tanks, the cap for sol. A (5 liter tank) has a different shape from the cap for sol. B sterilizer/disinfectant (5 liter tank).

In order to guarantee the efficacy of the process, only use the chemical solutions reported above, as recommended by the manufacturer.

The use of detergent and disinfectant products that are NOT validated and NOT authorized by the manufacturer does NOT guarantee process efficacy. Further, compatibility with the equipment and with the endoscopes is NOT guaranteed.

The tanks for the chemical solutions are housed in the lower, front compartment of the device to allow easy access (by opening the hatches) and at the same time prevents any potential dispersion outside of the equipment.

On completion of the disinfection cycle, the used and exhausted solutions are discharged directly into the waste water system without further treatment, in accordance with the applicable regulations.

▶ It is necessary to use personal protective equipment (PPE) during handling and disposal of the chemical solutions (detergent and high level sterilizer/disinfectant), always referring to the material safety data sheet for the products.

▶ The decontaminant and high level disinfectant/sterilizing solutions must be used in compliance with the instructions prescribing their use, safety and shelf life.

▶ Should there be any leakage of a chemical solution, please refer to the manufacturer‘s instructions prior to proceeding with its removal.