MEDIVATORS® ISA®

Endoscope Reprocessor

PRODUCT DATA SHEET

MEDIVATORS
A Cantel Medical Company

Technological categories

Supplying company	Medivators Inc.
Device model	MEDIVATORS® ISA® Endoscope Reprocessor
Manufacturer	Cantel Medical (Italy) S.r.l.
Year in which the model started production	2015
Year in which the model was first marketed	2015
Intended use	Room temperature chemical washer-disinfector for endoscopes and endoscope accessories

Certifications and regulations

The device complies with all European and international standards currently applicable indicated below:

Complies with the Medical Device Directive	93/42 EEC and updates
Medical device category in compliance with Directive 93/42/EEC and updates	II b
Complies with the following CEI standards	CEI EN 61010 CEI EN 61010-2-040 CEI EN 61326-1 CEI EN 62366
Complies with the following UNI standards	UNI EN ISO 15883-1 UNI EN ISO 15883-4 UNI CEN ISO/TS 15883-5
Notified Body and EC Certificate (Medivators ISA - DM EC 0051)	IMQ, Certificate Nb. 1812/MDD
Notified Body and EC Certificate (Chemicals - DM EC 0546)	CERTIQUALITY, Certificate Nb. 995/CE001/2
Certification of the Manufacturer's Quality System	Certiquality Certificate Nb. 1050 - UNI EN ISO 9001 Certificate Nb. 995 - UNI CEI EN ISO 13485

General characteristics of the system

Reprocessing chambers	MEDIVATORS® ISA® Endoscope Reprocessor has a large basin for the reprocessing of flexible or rigid endoscopes and endoscope accessories.
Number of reprocessible endoscopes	One flexible or a one rigid endoscope.
Endoscope brands compatibility	All brands of endoscopes on the market (Olympus, Pentax, Fujifilm, Karl Storz, etc.)
Endoscope loading type	Top loading
Operating conditions	Reprocessing is carried out at room temperature (25 ± 5° C). Temperature control is ensured by 2 PT-1000 probes located inside the basin.
Endoscope leak test	The system automatically carries out the leak test at the start of the cycle and checks that the correct pressure is maintained throughout the entire reprocessing cycle. If anomalies are found, the cycle is immediately interrupted, keeping the endoscope safe.
Inspection of channel connection and patency	Continuous and individual monitoring of flow in each single channel.
Type of endoscope connections	The device has an interlocked connection system that allows the endoscope to be connected to up to 6 channels + 1 auxiliary channel + leak test.
Contact with chemical products	Double washing/disinfection system: immersion and spraying (spray arm)
Self disinfection cycle	Manual self-disinfection cycle programmed with automatic start.
Isopropyl alcohol cycle	It is possible to select a full cycle or disinfection only cycle with alcohol.
User interface	15” touch-screen color monitor for the management of the user interface and cycle parameters input.
Printer	Built-in
Operator and endoscope recognition through RFID system	Yes, supplied as standard.
Basin opening and closing system	By foot switch control.
Alarm management system	Notification of alarms with a failure type description of and possible solutions to allow the operator to identify immediately the type of problem and if possible its resolution; all alarms are also entered at the end-of-cycle report to avoid usage of incorrect reprocessed instruments.
Moving the machine	The device is equipped with anti-static swivel casters for easy moving, facilitating cleaning, maintenance and transportation.

Used Chemical solutions

Description of validated chemical solutions	Tests carried out to validate the washing and disinfection processes in the MEDIVATORS® ISA® Endoscope Reprocessor confirm the efficacy of processes using only the following chemical solutions: **Detergent/Decontaminant:** - ISACLEAN™ Detergent; - INTERCEPT® PLUS Detergent; **High level disinfectant/ sterilant:** - ISASPOR® Single Shot Disinfectant; - RAPICIDE® PA Single Shot Disinfectant; Detergent and High Level Disinfectant/Sterilant solutions are single-shot and are automatically dispensed.
Detergent solution	ISACLEAN Detergent, Multi-enzymatic concentrated solution, active on microbial biofilm INTERCEPT PLUS Detergent, Non-enzymatic concentrated solution, active on microbial biofilm
Detergent tank capacity	ISACLEAN (1x10L); INTERCEPT PLUS (2x5L)
High level disinfectant sterilant	ISASPOR Single Shot Disinfectant; concentrated 5% peracetic acid solution (Sol. A) and ISAZONE® ingredient (Sol. B) RAPICIDE PA Single Shot Disinfectant; concentrated 5% peracetic acid solution (Sol. A) and (Sol. B)
High Level disinfectant/sterilant tank capacity	ISASPOR: 1x10L (Sol. A + Sol. B) or alternatively 1x5L (Sol. A + Sol. B) RAPICIDE PA: 2x5L (Sol. AA + Sol. BB) or alternatively, 1x5L (Sol. A + Sol. B)
Quantity of chemical solutions used per cycle	ISASPOR Solution A: 190ml of high level disinfectant/sterilant ISACLEAN: 16ml of detergent RAPICIDE PA Solution A: 190ml of high level disinfectant/sterilant INTERCEPT PLUS: 34ml of detergent
Recommended Process temperature	25 ± 5° C
Disposal of chemical solutions	At the end of every disinfection cycle, used and waste solutions are discharged directly in the sewage system without need for further treatment, in accordance with the existing standards.

Description of cycles

Type of selectable cycles	**Standard cycles:** 1. Complete cleaning-disinfection cycle (20* min.); 2. Disinfection-only cycle (12 min.); 3. Self-Disinfection cycle (20 min.). Additional cycles can be added to provide changes only to non-critical parameters and/or if a final alcohol purging phase (optional) is required. *In optimal operating conditions
Complete cleaning-disinfection cycle	**Complete cleaning-disinfection cycle (20 min. long)** 1. Initial leak test 2. Water and detergent load 3. Cleaning 4. Draining 5. Water load 6. Rinsing 7. Draining 8. Water and disinfectant solution load 9. Disinfection 10. Draining 11. Water load 12. Rinsing 13. Draining 14. Purge of endoscope channels
“Disinfection cycle”	**Disinfection cycle (12 min.)** 1. Initial Leak test 2. Water and disinfectant solution load 3. Disinfection 4. Draining 5. Water load 6. Rinsing 7. Draining
Auto-disinfection cycle	**Self-disinfection cycle (20 min.)** 1. Initial Leak test 2. Water and disinfectant solution load 3. Sterilization 4. Draining 5. Water load 6. Rinsing 7. Draining 8. Purging
Volumes of water used per cycle	Complete cycle 31 liters Disinfection cycle 17 liters Self-disinfection cycle 17 liters

Water/air filtering system

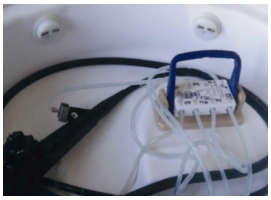
Water filters provided	1st stage 0.45 µm filter 2nd stage 0.1 µm filter
Water filter life cycle	6 months
Air filters	0.2 micron N. 1 purging air filter 0.2 micron N. 1 leak test air filter
Air filter life cycle	6 months
Monitoring filter life	Visualization of last change and time to the next change for each filter. The system will inform the operator for any expired filter through a “maintenance” alert.

Traceability

RFID system	The device guarantees the traceability of endoscopes, operators products through the RFID system.
Software for archiving and ensuring the traceability of washing/disinfection processes (electronic traceability)	Visual display monitoring of devices undergoing washing/ disinfection with attached count down to the end of cycle. For every cycle data are printed and stored in the PC internal memory. Data can be exported on an external drive.
Registering and printing washing/disinfection cycle data	**Parameters included in the print-out:** • Serial number of device • Date • Cycle starting and ending time • Progressive cycle number • Cycle type • Endoscope data (Model, serial number, ID etc.) • Physician (optional) • Patient (optional) • Operator starting the cycle • Cycle phases with relative contact times • Operator inserting the instrument • Cycle outcome • Operator taking out the endoscope

Operator safety

The device guarantees high standards of operator safety:	**1. Hands-free operation and RFID system:** Using an endoscope-operator RFID system reduces significantly or eliminates the chance of infection by contact, accelerates endoscope loading / unloading operations and reduces the possibility of errors.
	2. Substituting chemical solutions: The chemical solution substitution procedure does not require any handling by the operator of the chemical products used. As stated in the user manual, when changing product tanks, wear PPE clothing, gloves and protective goggles.
	3. Closed system: The device operates in a closed system and does not require air suction systems because it operates at room temperature and with low concentrations of peracetic acid. It is possible to connect the device to an air suction system by means of the appropriate duct placed on the back of the device.



Accessories

Accessories provided	1 Self disinfection connection kit
Accessories on demand	• Endoscope hookup block connectors • Thermostatic Mixing valve • Air compressor • Kit medical device compliant to EN 1717 • Isopropylic alcohol at 70%

DESCRIPTION OF THE TECHNICAL SPECIFICATIONS OF THE MEDIVATORS® ISA® ENDOSCOPE REPROCESSOR

- **Dimensions (LxHxP)**
  70 cm x 102,5 cm (140 cm with display) x 65 cm

- **Weight**
  ~ 75 kg

- **Electric power supply**
  The required electric power supply must be single-phase between 100V and 240V with a 50/60Hz frequency range.

- **Nominal power**
  Maximum power is 300W.

- **Compressed air**
  MEDIVATORS® ISA® Endoscope Reprocessor must be connected to an oil-free compressed air system with pressure between 4 and 6 bar and a minimum flow rate of 20 l/min.
  A stainless steel connection with a hose fitting for a 5mm diameter tube has been provided on the device as a standard accessory.
  Should there be no oil-free compressed air system, an oil-free medical compressor can be installed (optional).

- **Water supply**
  The water supply for the medical device must be “potable” with hardness values between 8°fH and 50°fH (4,5°–28°dH, 80–500 ppm) at a temperature between 20°C and 30°C (provided by means of a thermostatic water mixing valve) at a pressure of maximum 4 bar and with a flow rate of 10 l/min. A connection with 3/4” joint is provided. The filling tube is included with the WD. A back-siphonage prevention mechanism that complies with the requirements of IEC 61770 is included.

- **Draining the machine**
  The device is equipped with a hose fitting connection for the drainage tube to connect to the drainage system by means of a flexible tube provided as a standard feature.
  The maximum height above ground for the drainage duct must be 510 mm.

- **Operating ambient humidity**
  The accepted limit for proper use of the device should be less than 80% humidity (non-condensing).

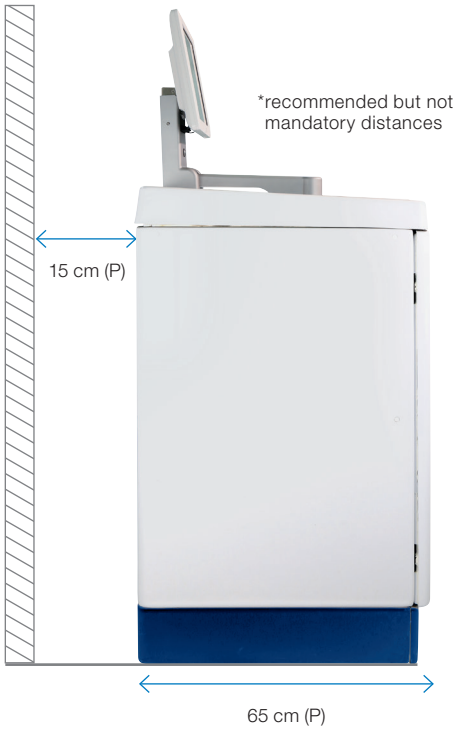
- **Operating temperature**
  The Room operating temperature of for MEDIVATORS ISA Endoscope Reprocessor cannot be less than 5°C or more than 40°C .
  For the system to function properly, it should must not be located close to heat sources.

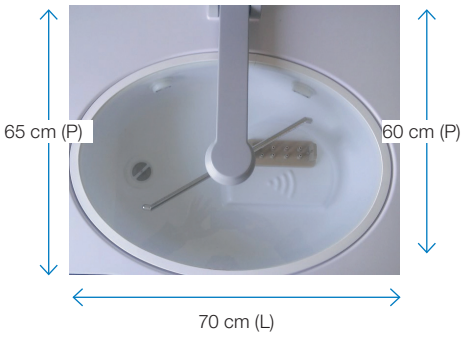
- **Environmental emissions**
  MEDIVATORS ISA Endoscope Reprocessor, which operates in as a closed circuit, does not release emissions into the environment. In any case, the emissions that may occur when replacing tanks or opening the basin do not have toxic or harmful effects on humans. It is recommended to install the device in rooms with adequate ventilation (10 air changes per hour)

- **Transportation and storage**
  MEDIVATORS ISA Endoscope Reprocessor must be maintained and stored in compliance with the following conditions: 5–40°C temperature, 20–80% humidity and 500–1060 hPa pressure

- **Drainage duct height**
  max. 51 cm

DIMENSIONS





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