

DM000197378	REPROCESOR AUTOMAT PENTRU DEZINFECTAREA ENDOSCOAPELOR	MEDIVATORS® ISA®			Italia	CANTEL MEDICAL (ITALY) S.R.L.	F.C.P.C. DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	
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MEDIVATORS® ISA®

Endoscope Reprocessor



PRODUCT DATA SHEET

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 reprocessable 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 ($25 \pm 5^\circ \text{C}$). 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	<p>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:</p> <p>Detergent/Decontaminant:</p> <ul style="list-style-type: none"> - ISACLEAN™ Detergent; - INTERCEPT® PLUS Detergent; <p>High level disinfectant/ sterilant:</p> <ul style="list-style-type: none"> - ISASPOR® Single Shot Disinfectant; - RAPICIDE® PA Single Shot Disinfectant; <p>Detergent and High Level Disinfectant/Sterilant solutions are single-shot and are automatically dispensed.</p>
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: <ol style="list-style-type: none"> 1. Complete cleaning-disinfection cycle (20* min.); 2. Disinfection-only cycle (12 min.); 3. Self-Disinfection cycle (20 min.). <p>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</p>
Complete cleaning-disinfection cycle	Complete cleaning-disinfection cycle (20 min. long) <ol style="list-style-type: none"> 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.) <ol style="list-style-type: none"> 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.) <ol style="list-style-type: none"> 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	<p>Complete cycle 31 liters Disinfection cycle 17 liters Self-disinfection cycle 17 liters</p>

Water/air filtering system

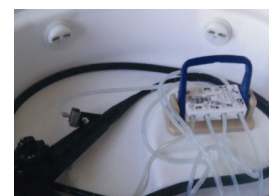
Water filters provided	<p>1st stage 0.45 µm filter 2nd stage 0.1 µm filter</p>
Water filter life cycle	6 months
Air filters	<p>0.2 micron N. 1 purging air filter 0.2 micron N. 1 leak test air filter</p>
Air filter life cycle	6 months
Monitoring filter life	Visualization of last change and time to the 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: <ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Endoscope hookup block connectors • Thermostatic Mixing valve • Air compressor • Kit medical device compliant to EN 1717 • Isopropyl 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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ISA™

Endoscope Reprocessor

Reprocess



EVOLUTIONARY PROCESS, REVOLUTIONARY SOLUTION

Cantel is dedicated to developing and providing innovative solutions in infection prevention control worldwide.

The ISA™ Endoscope Reprocessor represents a distinctive alternative for rapid, efficient reprocessing. The washer-steriliser ISA Endoscope Reprocessor has been designed for endoscopy units requiring an advanced technology and high quality standard.

Designed to be compliant to the standard UNI EN ISO 14937 the ISA Endoscope Reprocessor provides cold chemical sterilization with Sterility Assurance Level 10-6.

As a result of this process, the washer-disinfector and sterilizer ISA Endoscope Reprocessor ensures:

- High quality standards for the operator, endoscopes and patients
- Reduction of costs related to hospital infections



THE COMPLETE CIRCLE OF PROTECTION

As the global vanguard in infection prevention, **only Cantel delivers the Complete Circle of Protection**, a full-value, proactive partnership dedicated to helping you remove risk, streamline operational efficiencies and optimize your success.

REPROCESS High-level disinfection is the cornerstone of infection prevention. Reprocessing technologies from Cantel are designed to ensure patient safety by adhering to the strictest of standards for high level disinfection, optimize workflow efficiency, and deliver versatility by supporting a wide range of scopes.

ISA™ Endoscope Reprocessor

Assurance of the disinfection & sterilisation process
with a rapid and efficient solution

FAST & SIMPLE OPERATION FOR IMPROVED EFFICIENCY

- Sterilisation cycle in only 19 minutes with channel monitoring
- Full sterilisation cycle complete with cleaning in 25 minutes with channel monitoring
- Full disinfection cycle complete with cleaning in 25 minutes with channel monitoring
- Simple, user-friendly handling and operation
- Insertion of endoscopes and operation Information through RFID system — helps to avoid errors and save time



COMPACT & ERGONOMIC DESIGN FOR MAXIMUM USER COMFORT

- Compact size contributes to easy installation, operation and maintenance
- Large and easy to load basin accommodates all types of flexible endoscopes
- Intuitive interface assures fast and easy access to all the cycle information



ENSURING SAFETY FOR OPERATORS, PATIENTS & ENDOSCOPES

- Hands free operation and RFID-based technology for complete infection control
- Continuous monitoring of all channels and full leak test traceability through printed and electronic cycle documentation
- Validated process, fully compliant to the standards UNI EN ISO 14937, UNI EN ISO 15883-1/4 and UNI EN ISO 15883-5 Test Soil Annex Austrian (A), German (I/J) and France (F)

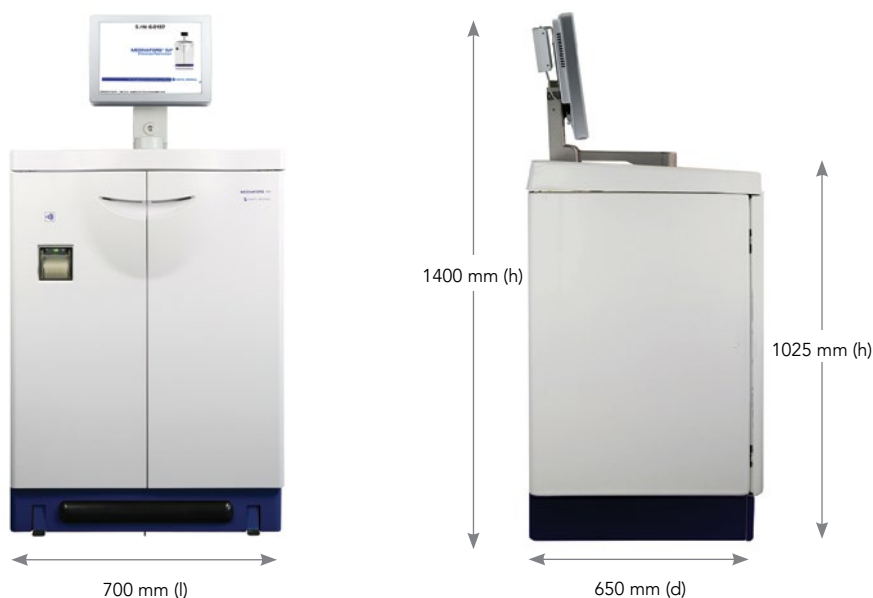


THE RIGHT FORMULA FOR THE BEST PERFORMANCE & RESULT

- Dedicated room temperature chemicals compatible with all types of flexible endoscopes
- Improved water and chemical consumption designed specifically for use with ISA Endoscope Reprocessor (sterilant compliant to the Chapter 5.3.1 of the UNI EN ISO 14937)



PRODUCT SPECIFICATIONS ISA™ DISINFECTOR & STERILISER
UNI EN ISO 14937 CERTIFIED



Dimensions

700 mm (l) x 1400 mm (h) x 650 mm (d) - monitor included

Weight

75 kg

Electrical Requirements

100 V-240 V, 50-60Hz

Operating Room Temperature

5° - 40° C

Humidity

20 - 80%

Reprocessing Time

25 minutes (complete disinfection cycle)

19 minutes (sterilization only cycle)

Process Capacity

1 endoscope per cycle

High Level Disinfectant/Sterilant

ISASPOR™ Single Shot Disinfectant/Sterilant, two parts, Peracetic acid and ISAZONE™ Activator

Detergent

ISACLEAN™ Detergent, multienzymatic detergent

ISA™ ENDOSCOPE REPROCESSOR ORDERING INFORMATION

PART NUMBER	DESCRIPTION	QUANTITY
500187	ISASPOR™ Single Shot High-Level Disinfectant/Sterilant	1 x 10L Sol. A+B
500188	ISASPOR Single Shot High-Level Disinfectant/Sterilant	1 x 5L Sol. A+B
500189	ISACLEAN™ Detergent	2 x 5L
500019	ISACLEAN Detergent	1L
93250-222	ISA™ CPC Filters	0,45µm + 0,1µm
ISAF01REV.1	ISA™ Water Filter	0,1µm
ISAF045REV.1	ISA Water Filter	0,45µm
ISA4400	ISA™ Air Filter	1
ISAROTS2	ISA™ Printer Roll	1

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MEDIVATORS IS NOW CANTEL

www.cantelmedical.eu

Medivators BV | p: +31 45 5 471 471 (customer service)

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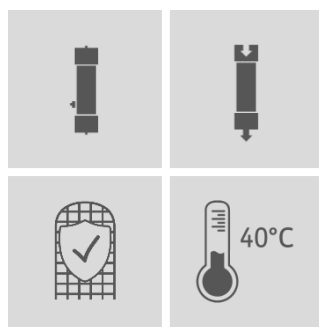


UFM filter

The UFM filter module provides automatic removal of bacteria (*Pseudomonas*, *E.coli*, *Legionella* etc.), particulate, viruses and sediment. The system employs hollow fibre ultrafiltration membrane technology to remove particulates as small as 0,02 microns independent of challenges in feed water composition. To maximize membrane capacity and membrane life an automated self-cleaning cycle functions periodically, to remove unwanted contaminants from the system.

The UFM filter module is an independently operating filter which can be used in healthcare, laboratory and as a prefilter for medical devices (Automatic Endoscope Reprocessors) and reverse osmosis. The UFM filter is available for both hot and cold water installations. The automatic flushing of the UFM filter combined with annual maintenance ensures a lifespan of 5 years.

PB Medical designs and builds modules with plug and play simplicity of operation. They are available in several sizes and configurations to meet your water treatment requirements. The unique engineering of module and membrane, makes it a trouble-free system.



"5 years experience in 5 states, 5 countries and 3 continents" (2019)

Art. nr.	Description	Max flow rate *		HxWxD (cm)
10362	UFM 90-750	10 L/min	2.6 GPM	123x28x14
10363	UFM 125-750	20 L/min	5.3 GPM	128x33x19
10364	UFM 160-750	30 L/min	7.9 GPM	131x36x23
10365	UFM 160-1000	40 L/min	10.6 GPM	159x36x23

* For drinking water at 16° C and water pressure of 2 bar.

Delivered inclusive:

- | | |
|--------------------------------------|--------------------|
| ✓ Drain valve and timer | ✓ Pre filter |
| ✓ Connection bij three-part coupling | ✓ Non return valve |
| ✓ Manual valves | ✓ Pipe clamps |
| ✓ Manometers | ✓ Power cord (2m) |

- Requires normal line pressure to operate
- Bacteria retention LOG6, virus retention LOG4
- Manual operation during loss of electrical power
- Extends life of downstream cartridge filters & equipment
- Self cleaning to extend life of system and reduce maintenance costs



September, 03rd 2021

To whom it may concern

STATEMENT LETTER

We, Cantel Medical (Italy) S.r.l., with a place of business and manufacturing facility at Via Laurentina, 169, 00071 Pomezia (RM), are the manufacturer of washer-disinfector & sterilizer for flexible & rigid scopes MEDIVATORS ISA.

Hereby we confirm, that ISA washing & disinfection basin has total volume of 30.14 L when closed with size 40 x 60 cm oval shaped. This allows to handle the most complex and biggest scopes with high ergonomics and avoid accidental damage of the scopes assuring the most efficient cleaning & disinfection performance.

Sincerely yours,
For Cantel Medical (Italy) S.r.l.
Mr Andre Kenik
International Sales Director

A handwritten signature in blue ink that reads "Kenik Andre".