

## INTENDED PURPOSE

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Medical device intended for washing and cold chemical disinfection of rigid and flexible endoscopes.

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:

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- 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 with touch screen 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 Warranting 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 Warranting the complete sterility of the process, and dual filter system for the water feed (0.45 µm - 0.1 µm).
- Traceability of the processes in hardcopy 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.

## TECHNICAL SPECIFICATIONS

The basic specifications required for installation and operation of the MEDIVATORS™ ISA™ Reprocessor system are reported below:

Abbreviation	Description
Power Supply	100V–240V; 50-60 Hz
Power Consumption	300 VA
Compressed Air Pressure/Quality	4-6 Bar / oil free
Compressed Air Flow Rate	≥ 20 l/min
Water Supply Pressure	Max 4 Bar
Water Flow Rate	≥ 10 l/min
Water Quality	Potable water – Hardness 8 – 50 °F
Water Temperature	20°C - 40°C
Ambient Relative Humidity For Use	20 – 80%, condensate-free
Ambient Temperature For Use	5°C ÷ 40°C
Discharge Pipe Height	Max 510 mm
Environment	Emission-free closed circuit
Level of noise	< 55 dBA*
Environment Light Required	(215 ± 15) lx to (1 500 ± 15) lx
Heat Emission	60 KJ
Dimensions (LxHxP)	Dimensions: 70 cm x 140 cm x 65 cm
Weight	~ 75 kg (version STANDARD)
Altitude	up to 2000 m
Mains supply voltage fluctuations	up to ±10 % of the nominal voltage
Pollution degree	2

\* tested in accordance with ISO 3746:2010 as prescribed in the IEC 61010-1:2010 in an accredited laboratory.

## DISPOSAL

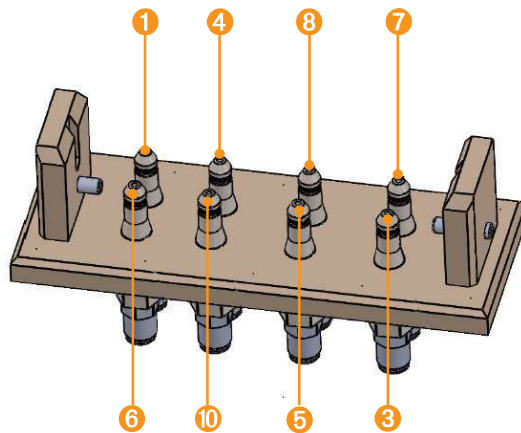
The MEDIVATORS™ ISA™ Automated Endoscope Reprocessor is categorised as an electric device. In accordance with Directive 2012/19/EU on Waste Electrical and Electronic Equipment, this symbol indicates that the product must not be disposed of as unsorted municipal waste, but should be collected separately.



Contact your supplier for return of the device and/or an available recycling collection system in your country.

## ENDOSCOPIC CHANNEL CONNECTION

The MEDIVATORS™ ISA™ Endoscope Reprocessor is fitted with a connection system in order to allow the rapid and unambiguous connection of the endoscope channels with the relevant connectors.



Position	Name in the software	Channel
1	Leak Test	Leak Test
3	Channel 7	Elevator Channel
4	Channel 2	Jet Channel
5	Channel 3	Water Channel
6	Channel 6	Extra Channel
7	Channel 4	Air 2 Channel
8	Channel 5	Biopsy Channel
10	Channel 1	Suction Channel

The mobile connection block supplied with the MEDIVATORS™ ISA™ Endoscope Reprocessor comes with a range of kits for connecting to endoscopes from the major manufacturers (OLYMPUS®, FUJIFILM™, PENTAX®, KARL STORZ etc.), supplied according to the client's needs.

## REMOVING THE ENDOSCOPES FROM THE BASIN

To correctly remove the endoscope from the basin, proceed as reported below:

1. Wear personal PPE.
2. Proceed with operator recognition by bringing the operator tag close to the RFID A reader as reported below.
3. Disconnect the connecting tubes from the relevant endoscope channels.
4. Disconnect the mobile interconnection block from that fixed to the basin by turning the red lever on the mobile interconnection block clockwise until open.
5. Remove the endoscope from the basin.
6. Close the basin cover using the pedal (black band present on the lower part of the equipment). This will be followed by a short acoustic signal confirming the command has been implemented.

RFID A-OPERATOR TAG



## ENDOSCOPE TREATMENT CYCLES

The MEDIVATOR<sup>SM</sup> ISA<sup>SM</sup> Endoscope Reprocessor has numerous cycles that are validated for the treatment of endoscopes, as reported in the following table (Table 1).

The self-disinfection cycle refers to sterilization of the circuit and the water filters.

Cycle	Duration	Description
Complete Disinfection	20 min	Washing and disinfection cycle
Complete Double Clean Disinfection	25 min	Double Washing and disinfection cycle
Complete Disinfection Austrian	50 min	Intensive Washing and disinfection cycle
Disinfection	12 min	Disinfection cycle only, with no cleaning
Self-Disinfection	20 min	Internal circuit sterilization cycle

Table 1. The MEDIVATORS<sup>SM</sup> ISA<sup>SM</sup> Endoscope Reprocessor pre-set cycles

It is also possible to perform a final drying cycle using isopropyl alcohol (optional).

## STEPS IN THE “COMPLETE DISINFECTION CYCLE”

1. Initial leak test (with monitoring throughout the entire cycle)
2. Water and detergent loading
3. Cleansing
4. Discharge
5. Water loading
6. Rinsing
7. Water discharge
8. Water and disinfectant solution loading
9. Disinfection
10. Solution discharge
11. Water loading
12. Rinsing
13. Water discharge
14. Endoscope channel drying

duration:  
20 minutes



## STEPS IN THE “COMPLETE DOUBLE CLEAN DISINFECTION CYCLE”

1. Initial leak test (with monitoring throughout the entire cycle)
2. Water and detergent loading
3. Cleaning
4. Drain
5. Water loading
6. Rinsing
7. Water Drain
8. Water and detergent loading
9. Cleaning
10. Drain
11. Water loading
12. Rinsing
13. Water Drain
14. Water and disinfectant solution loading
15. Disinfection
16. Solution Drain
17. Water loading
18. Rinsing
19. Water Drain
20. Endoscope channel drying

duration:  
25 minutes



▶ Type of alarm	▶ Cause	▶ Solution
JET/AUX CHANNEL DISCONNECTED ALARM	<ol style="list-style-type: none"> <li>1. Jet/Aux channel disconnected from the endoscope</li> <li>2. Hook-up Jet/Aux tube broken</li> <li>3. Hook-up not correctly fix on the basin</li> <li>4. Channel separator not correctly fixed on the endoscope.</li> <li>5. Wrong endoscope selection</li> <li>6. Jet/Aux flowmeter FT9 fault</li> <li>9. Suction valve V9 fault</li> <li>8. Flow reducer R2 fault</li> <li>9. In line check valve VR8 fault</li> </ol>	<ol style="list-style-type: none"> <li>1. Check Endoscope selection</li> <li>2. Check hook-up and tube</li> <li>3. Check channels separator</li> <li>4. Restart the cycle</li> <li>5. Contact your Cantel Service Representative</li> </ol>
JET/AUX CHANNEL BLOCKED ALARM	<ol style="list-style-type: none"> <li>1. Jet/Aux channel blocked on the endoscope</li> <li>2. Hook-up Jet/Aux tube kinked</li> <li>3. Wrong endoscope selection</li> <li>4. Jet/Aux flowmeter FT9 fault</li> <li>5. Jet/Aux valve V9</li> <li>6. Main pump P1 fault</li> <li>7. Drain valve V3 fault</li> <li>8. Flow reducer R2 fault</li> <li>9. In line check valve VR8 fault</li> </ol>	<ol style="list-style-type: none"> <li>1. Check Endoscope selection</li> <li>2. Check kinked tube</li> <li>3. Restart the cycle</li> <li>4. Contact your Cantel Service Representative</li> </ol>
WATER CHANNEL DISCONNECTED ALARM	<ol style="list-style-type: none"> <li>1. Water channel disconnected from the endoscope</li> <li>2. Hook-up Water tube broken</li> <li>3. Hook-up not correctly fix on the basin</li> <li>4. Channel separator not correctly fixed on the endoscope.</li> <li>5. Wrong endoscope selection</li> <li>6. Water flowmeter FT8 fault</li> <li>7. Suction valve V8 fault</li> <li>8. Flow reducer R2 fault</li> <li>9. In line check valve VR8 fault</li> </ol>	<ol style="list-style-type: none"> <li>1. Check Endoscope selection</li> <li>2. Check hook-up and tube</li> <li>3. Check channels separator</li> <li>4. Restart the cycle</li> <li>5. Contact your Cantel Service Representative</li> </ol>
WATER CHANNEL BLOCKED ALARM	<ol style="list-style-type: none"> <li>1. Water channel blocked on the endoscope</li> <li>2. Hook-up Water tube kinked</li> <li>3. Wrong endoscope selection</li> <li>4. Jet/Aux flowmeter FT8 fault</li> <li>5. Water valve V8</li> <li>6. Main pump P1 fault</li> <li>7. Drain valve V3 fault</li> <li>8. Flow reducer R2 fault</li> <li>9. In line check valve VR8 fault</li> </ol>	<ol style="list-style-type: none"> <li>1. Check Endoscope selection</li> <li>2. Check kinked tube</li> <li>3. Restart the cycle</li> <li>4. Contact your Cantel Service Representative</li> </ol>

▶ Type of alarm	▶ Cause	▶ Solution
AIR CHANNEL DISCONNECTED ALARM	1. Air channel disconnected from the endoscope 2. Hook-up Air tube broken 3. Hook-up not correctly fix on the basin 4. Channel separator not correctly fixed on the endoscope. 5. Wrong endoscope selection 6. Air flowmeter FT7 fault 7. Suction valve V7 fault 8. Flow reducer R2 fault 9. In line check valve VR8 fault	1. Check Endoscope selection 2. Check hook-up and tube 3. Check channels separator 4. Restart the cycle 5. Contact your Cantel Service Representative
AIR CHANNEL BLOCKED ALARM	1. Air channel blocked on the endoscope 2. Hook-up Air tube kinked 3. Wrong endoscope selection 4. Air flowmeter FT7 fault 5. Extra valve V7 6. Main pump P1 fault 7. Drain valve V3 fault 8. Flow reducer R2 fault 9. In line check valve VR8 fault	1. Check Endoscope selection 2. Check kinked tube 3. Restart the cycle 4. Contact your Cantel Service Representative
BIOPSY CHANNEL DISCONNECTED ALARM	1. Biopsy channel disconnected from the endoscope 2. Hook-up Biopsy tube broken 3. Hook-up not correctly fix on the basin 4. Channel separator not correctly fixed on the endoscope. 5. Wrong endoscope selection 6. Biopsy flowmeter FT6 fault 7. Biopsy valve V6 fault 8. Flow reducer R2 fault 9. In line check valve VR8 fault	1. Check Endoscope selection 2. Check hook-up and tube 3. Check channels separator 4. Restart the cycle 5. Contact your Cantel Service Representative
BIOPSY CHANNEL BLOCKED ALARM	1. Biopsy channel blocked on the endoscope 2. Hook-up Biopsy tube kinked 3. Wrong endoscope selection 4. Biopsy flowmeter FT6 fault 5. Suction valve V6 6. Main pump P1 fault 7. Drain valve V3 fault 8. Flow reducer R2 fault 9. In line check valve VR8 fault	1. Check Endoscope selection 2. Check kinked tube 3. Restart the cycle 4. Contact your Cantel Service Representative

▶ Type of alarm	▶ Cause	▶ Solution
EXTRA CHANNEL DISCONNECTED ALARM	1.Extra channel disconnected from the endoscope 2.Hook-up Extra tube broken 3. Hook-up not correctly fix on the basin 4. Channel separator not correctly fixed on the endoscope. 5. Wrong endoscope selection 6. Extra flowmeter FT5 fault 7. Extra valve V5 fault 8. Flow reducer R2 fault 9. In line check valve VR8 fault	1. Check Endoscope selection 2. Check hook-up and tube 3. Check channels separator 4. Restart the cycle 5. Contact your Cantel Service Representative
EXTRA CHANNEL BLOCKED ALARM	1.Extra channel blocked on the endoscope 2.Hook-up Extra tube kinked 3. Wrong endoscope selection 4. Extra flowmeter FT5 fault 5. Extra valve V5 6. Main pump P1 fault 7. Drain valve V3 fault 8. Flow reducer R2 fault 9. In line check valve VR8 fault	1. Check Endoscope selection 2. Check kinked tube 3. Restart the cycle 4. Contact your Cantel Service Representative
ELEVATOR CHANNEL DISCONNECTED ALARM	1.Elevator channel disconnected from the endoscope 2.Hook-up Elevator tube broken 3. Hook-up not correctly fix on the basin 4. Channel separator not correctly fixed on the endoscope. 5. Wrong endoscope selection 6. Elevator pressure transducer TP7 fault 7. Elevator valve VPP1 fault 8. Main pump P1 fault 9. Flow reducer R2 fault 10. In line check valve VR8 fault	1. Check Endoscope selection 2. Check hook-up and tube 3. Check channels separator 4. Restart the cycle 5. Contact your Cantel Service Representative
ELEVATOR CHANNEL BLOCKED ALARM	1.Elevator channel blocked on the endoscope 2.Hook-up Elevator tube kinked 3. Wrong endoscope selection 4. Elevator pressure transducer TP7 fault 5. Elevator valve VPP1 6. Main pump P1 fault 7. Drain valve V3 fault 8. Flow reducer R2 fault 9. In line check valve VR8 fault	1. Check Endoscope selection 2. Check kinked tube 3. Restart the cycle 4. Contact your Cantel Service Representative