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

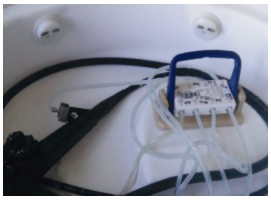
Water filters provided	1st stage 0.45 µm filter 2nd stage 0.1 µm filter
Water filter life cycle	6 months
Air filters	0.2 micron N. 1 purging air filter 0.2 micron N. 1 leak test air filter
Air filter life cycle	6 months
Monitoring filter life	Visualization of last change and time to the next change for 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).

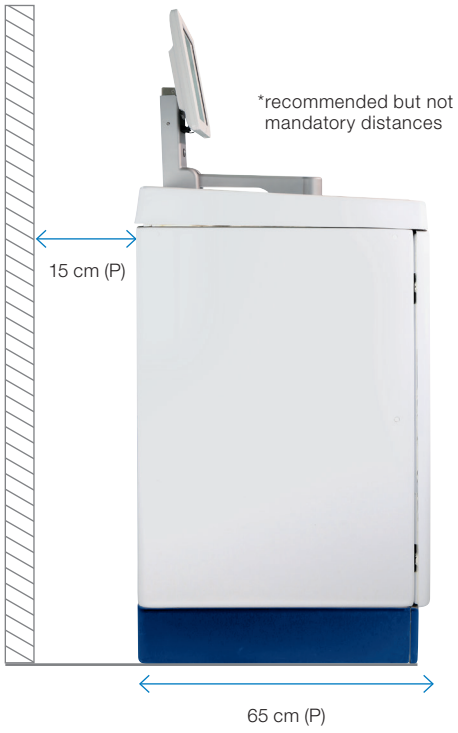
- **Operating temperature**
  The Room operating temperature of for MEDIVATORS ISA Endoscope Reprocessor cannot be less than 5°C or more than 40°C .
  For the system to function properly, it should must not be located close to heat sources.

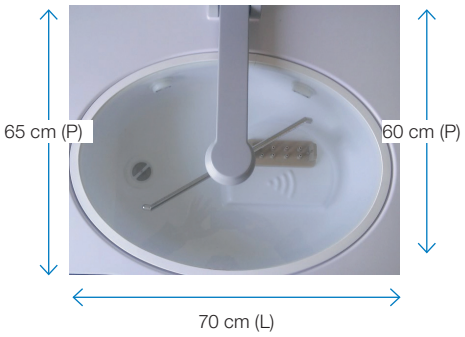
- **Environmental emissions**
  MEDIVATORS ISA Endoscope Reprocessor, which operates in as a closed circuit, does not release emissions into the environment. In any case, the emissions that may occur when replacing tanks or opening the basin do not have toxic or harmful effects on humans. It is recommended 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





MEDIVATORS
A Cantel Medical Company

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MEDIVATORS™ ISA™

Endoscope Reprocessor

SERVICE MANUAL

WASHER-DISINFECTOR

CANTEL

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is a trademark of Medivators Inc.

INTERCEPT™
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ISA™
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CONTENTS

USE OF THE MANUAL

This manual describes the characteristics of the MEDIVATORS™ ISA™ Endoscope Reprocessor, including the hardware, software, operations, safety, maintenance and problem resolution procedures.

It is important to follow the instructions provided in this manual in order to maintain the MEDIVATORS ISA Endoscope Reprocessor in the correct operational mode and to ensure that endoscopes are suitably disinfected.

This is not a technical support manual and does not provide detailed instructions for support apart from general maintenance. Please refer to the Service Manual for support instructions.

Contact the technical support representative on (+31) 45 5 471 444 for further information.

It is important that this manual be kept safe and in the same location as the equipment so that it may be consulted in the case of any hazard, and that its location be known to all personnel involved in reprocessing/maintenance/installation.

CHAPTER 1

INTRODUCTION

This chapter describes the MEDIVATORS™ ISA™ Endoscope Reprocessor safety notices, regulatory compliance, the validated chemical solutions and technical specifications.

SAFETY NOTICES

The purpose of the following notices is to reduce the risk to personnel and prevent the equipment from becoming unsafe due to improper use.

Therefore, both operators and maintenance personnel must follow the instructions in the user and service manual for the MEDIVATORS™ ISA™ Endoscope Reprocessor cold chemical endoscope Washer-Disinfector.

SYMBOLS

This symbol indicates that the operator must pay particular attention and consult the enclosed documentation.

This symbol indicates “open”, i.e. disconnected from the main power supply.

This symbol indicates “closed”, i.e. connected to the main power supply.

Warning symbol for the risk of electric shock.

Symbol of EER regulatory compliance.

Symbol indicating the year of manufacture.

Symbol indicating the manufacturer.

CE mark issued by the Notified Body in compliance with Directive 93/42/EEC and updates.

DEFINITIONS

Abbreviation	Description
PPE	Personal protective equipment
Manufacturer*	The physical or legal entity responsible for the design, manufacture, packaging and labelling of a device with regard to marketing in their own name, independently of the fact that these operations have been performed by an entity themselves or by a third party acting on their behalf.
MD – Medical Device**	Any instrument, equipment, system, software, substance or other product, used alone or in combination, including software intended by the manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for the correct operation of the device, intended by the manufacturer to be used in humans for diagnosis, prevention, control, therapy or attenuation of a disease; for diagnosis, control, therapy, attenuation or compensation of a wound or handicap; for study, replacement or modification of anatomy or a physiological process; for intervention in conception, where the product does not exert the main action, in or on the human body, for which it is intended, with pharmacological or immunological means, not by means of a metabolic process but whose function may be assisted by said means.
Accessory***	A product which, despite not being a device, is intended specifically by the manufacturer to be used with a device in order to permit its use as envisaged by the manufacturer themselves.
Intended use******	The use for which the device is intended in accordance with the instructions provided by the manufacturer in the labelling, the information leaflet or in the publicity materials.
Operator	A person instructed by personnel authorized by the manufacturer to use the equipment.
dB	Decibel (relative measurement of sound).
°fH/dH°	French/German Degrees (relative measurement of water hardness).
ppm	Parts per million Calcium Carbonate
RFID	(Radio Frequency IDentification); a technology for the automatic identification of objects, animals or people based on the ability to store and access said information using remote electronic devices (known as TAGs or transponders) capable of responding by communicating the stored information when queried.

*/**/***/****: IMPLEMENTATION OF DIRECTIVE 93/42/EEC and subsequent amendments and additions.

SAFETY NOTICES

Take care when opening the electrical panel and junction boxes labelled with the danger of electric shock sign.

Operators using the MEDIVATORS™ ISA™ Endoscope Reprocessor must be qualified for this activity and must have completed a training course organized by the manufacturer or personnel authorized by the manufacturer.

Maintenance and repair of the MEDIVATORS ISA Endoscope Reprocessor must be performed by technical staff, qualified and authorized by the manufacturer.

The MEDIVATORS ISA Endoscope Reprocessor work area must be kept clean in order to avoid hazardous situations due to the floor conditions.

The electricity supply must be disconnected prior to starting repair or maintenance operations on the MEDIVATORS ISA Endoscope Reprocessor.

The MEDIVATORS ISA Endoscope Reprocessor safety devices must not be altered or tampered with any way.

The MEDIVATORS ISA Endoscope Reprocessor panelling must be cleaned with a soft cloth and non-aggressive solutions.

Sharp pointed tools must not be used to insert or remove the machine‘s gaskets.

In the case of a cycle terminated due to an alarm, the operator must pay the utmost attention, adopting the precautions envisaged, so that the endoscope is reprocessed correctly.

OPERATOR SAFETY

In order to avoid biological contamination and/or chemical burning, PPE must be always be worn when handling the endoscope or the chemical solutions.

The chemical solutions must be used in compliance with the regulations prescribing their use, safety and shelf life. During handling of the chemical solutions, use the protective measures and devices reported in the material safety data sheet. In the case of leakage or the accidental spillage of chemical solutions, follow the material safety data sheets for the chemical solutions.

Do not attempt to open the machine basin cover during the operation cycle.

WARNINGS AND PRECAUTIONS

Wear protective clothing, gloves and eyewear. The manufacturer of the chemical solutions may recommend additional protective measures.

All endoscope connections must be checked periodically in order to make sure they are not damaged, and if that is the case, they must be replaced in order to avoid unfit endoscope reprocessing.

Prior to inserting the endoscope in the MD, make sure it is not damaged, using the instruments and methods envisaged for manual leak testing. Check that all connections to the endoscope are properly inserted. Otherwise there is a risk of the endoscope not being reprocessed correctly and consequently cannot be used on the patient.

WARNINGS AND PRECAUTIONS

Prior to removing the endoscope from the MD, check that all channel connections are inserted correctly. If an adapter is loose or disconnected, the cycle must not be considered valid, and must therefore be repeated.

Wear clean gloves in order to avoid fouling the reprocessed endoscope. If a cycle execution error is generated, the endoscope must not be used on a patient.

Never use chemical solutions beyond the expiration date indicated by the manufacturer.

Should it become necessary to replace the tanks containing the chemical solutions, always wear PPE.

Should it become necessary to replace the filters, always wear PPE.

If the equipment is used in a manner not specified by the manufacturer, the safety devices envisaged might be compromised.

Do not place objects on the glass cover.

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 UNI EN ISO 15883-1/4 and UNI 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 sterilising/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 (0.45 µm - 0.1 µm).
- 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 sterilising/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:

- **UNI EN ISO 15883-1**
  "Endoscope Reprocessors - Part 1: General requirements, terms and definitions and tests".
- **UNI EN ISO 15883-4**
  "Endoscope Reprocessors - Part 4: Requirements and tests for endoscope reprocessors employing chemical disinfection for thermolabile endoscopes".
- **UNI 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 10 L tanks or 5 L tanks.

- A 10 L tank of ISACLEAN Multienzyme Detergent/Decontaminant allows the execution of approx. 625 cycles.
- A 5 LT tank of ISACLEAN Multienzyme Detergent/ Decontaminant allows the execution of approx. 312 cycles.

INTERCEPT™ PLUS Detergent alchaline detergent /decontaminant:
INTERCEPT™ PLUS Detergent alchaline detergent /decontaminant is available in 5 LT tanks

- A 5 LT tank of INTERCEPT PLUS Detergent 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.

RAPICIDE™ PA High Level Disinfectant/Sterilising solution:

- RAPICIDE PA High Level Disinfectant/Sterilant is available in 5 L tanks (5 L Solution A + 5 L Solution B).
- A 5 L tank of RAPICIDE PA High-Level Disinfectant/Sterilizing allows the execution of approx. 26 cycles.
- The detergent and high level disinfectant/ sterilizing solution used for each cycle are single use (single shot).
- The medical device distribution system ensures that, for each cycle, the correct amount of concentrated product is withdrawn from the tanks and ensures that said products are injected into the basin containing the endoscope.

*molecule patented by Cantel Medical (Italy) S.r.l.

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.

HANDLING AND STORAGE OF 70% ISOPROPYL ALCOHOL

In the MEDIVATORS™ ISA™ Endoscope Reprocessor, it is possible to incorporate a final drying step after the cleaning cycles using 70% isopropyl alcohol (optional). The isopropyl alcohol solution is not supplied by Cantel Medical (Italy) S.r.l. but must be purchased by the client. The device has an internal compartment at the top right of the equipment where the alcohol bottle may be connected.

The following instructions must be followed for the handling and storage of 70% isopropyl alcohol:

- **Handling**
  Avoid spillage of the product and any prolonged and/or repeated contact with the skin. Extinguish any naked flames. Remove any sources of ignition and avoid the creation of sparks. Do not smoke. Take precautionary measures against static discharges. Connect all instruments to earth. Do not dispose of the product in the waste water system.
- **Handling temperature**
  Ambient temperature.
- **Storage**
  Keep out of direct sunlight and away from sources of heat or ignition. Do not smoke in storage areas. Keep the container tightly sealed and in a well-ventilated area.
- **Storage temperature**
  Ambient temperature.
- **Transfer of the product**
  Adopt precautionary measures against static discharges. Connect all instruments to earth.
- **Protection of the respiratory tracts**
  No special measures.
- **Eye protection**
  Single lens face mask.
- **Body protection**
  Standard work clothes. Safety footwear or boots resistant to chemical products.

MEDIVATORS™ ISA™ ENDOSCOPE REPROCESSOR CHANNEL CONNECTIONS

Endoscopes must be connected to the MEDIVATORS ISA Endoscope Reprocessor using the connectors provided by Cantel Medical (Italy) S.r.l. and following the instructions provided.

Any modifications to the connectors provided may compromise proper function of the system and irrigation of the endoscope channels, and hence the reprocessing cycle.

The connectors must NEVER be modified.

It is prohibited to use connectors other than those recommended by the manufacturer. To identify the type of connector required for your endoscope, contact the Cantel authorized representative

CHAPTER 2

TECHNICAL SPECIFICATIONS

This chapter describes the technical specification, parts and layout for the MEDIVATORS™ ISA™ Endoscope Reprocessor.

DIMENSIONS

Figure 1
Front Dimensions.

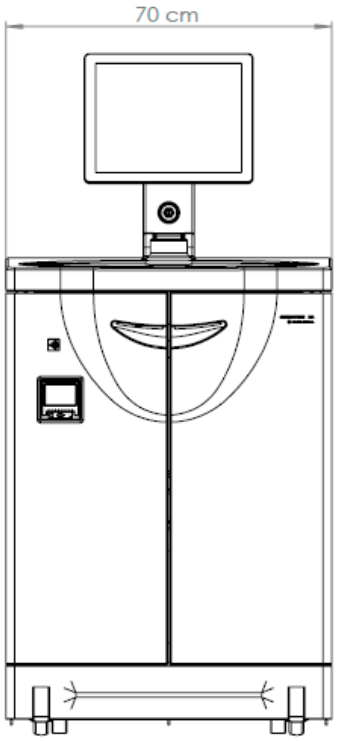
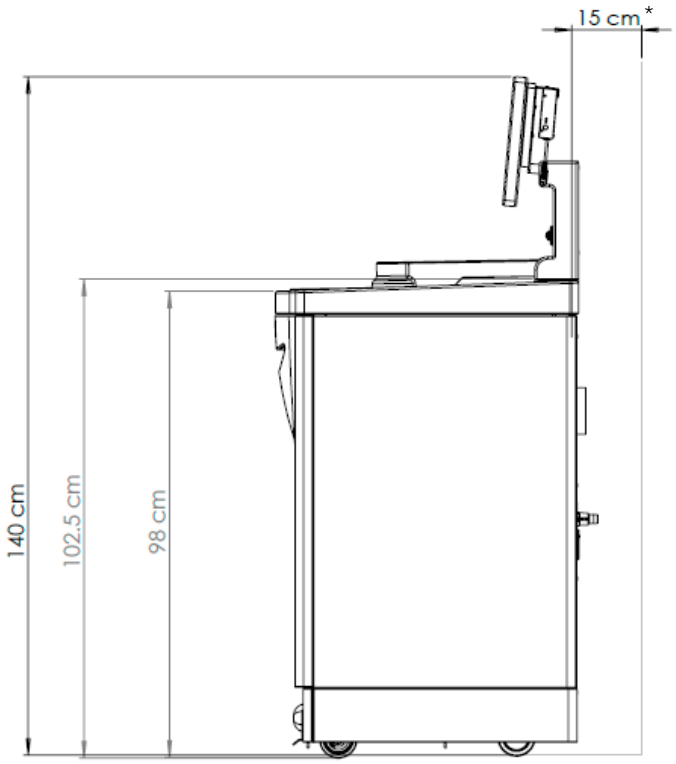


Figure 2
Side Dimensions and Spacing (cover closed).



*recommended but not mandatory distances.

DIMENSIONS

Figure 3
Side Dimensions and Spacing (cover open).

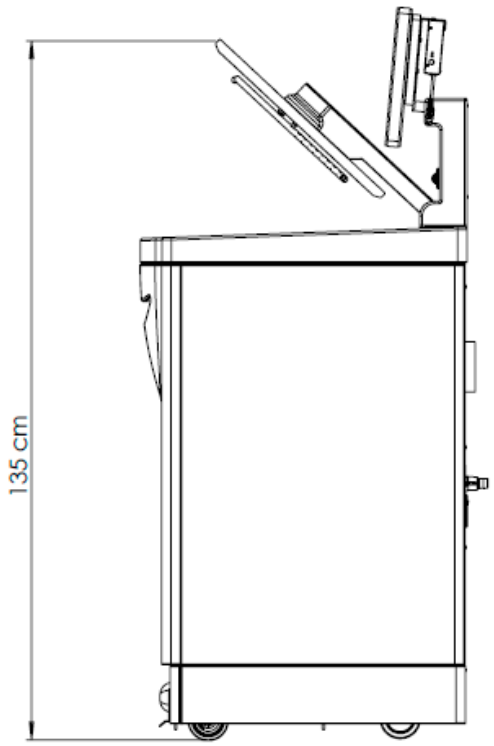
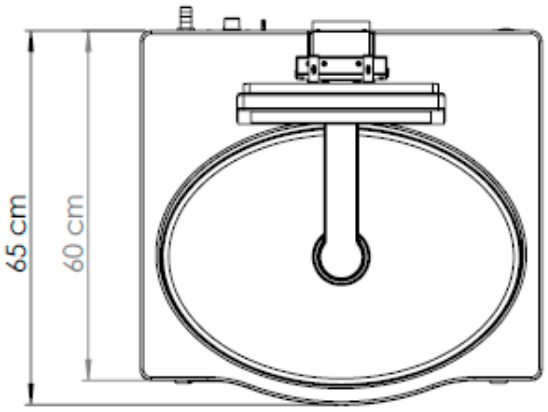


Figure 4
Basin dimensions.



TECHNICAL SPECIFICATIONS

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

Abbreviation	Description
Power Supply	100 V – 240 V; 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	25°C ± 5°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	< 65dBA
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)

DESCRIPTION OF THE TECHNICAL SPECIFICATIONS

- **Power supply**
  The required power supply is in the range between 100V and 240V with a frequency of 50/60Hz.

- **Nominal power**
  The maximum power consumption is 300W.

- **Compressed air**
  The MEDIVATORS™ ISA™ Endoscope Reprocessor requires oil-free compressed air with pressure between 4 and 6 bar and a minimum flow rate of 20 l/min.
  The device has a connector for a 3/8 mm tube, found in the accessories supplied with the equipment. In the case where hospital medical air is not available, an oil-free medical compressor is available (optional).

- **Water supply**
  The water supply for the MD must be of "potable" quality with a hardness between 8°fH and 50°fH (4,5°dH - 28°dH, 80–500ppm) supplied at a temperature of between 20°C and 30°C by connecting the hot and cold water supplies to a thermostatic water mixer (not included in the standard kit). The equipment has a 3/4" male connector and the relevant feed tube is included in the standard kit. There is an optional device for back flow prevention, conforming to the requirements of IEC 61770.

- **Machine discharge**
  The equipment has a stainless steel discharge connector, and a flexible tube is provided in the standard kit. The maximum height of the discharge tube to be connected to the MD is 510 mm.

- **Operating relative humidity**
  For correct use of the MEDIVATORS ISA Endoscope Reprocessor the relative humidity level must be less than 80% (condensation-free).

- **Operating temperature**
  The operating ambient temperature for the MEDIVATORS ISA Endoscope Reprocessor must be no less than 5°C and no greater than 40°C. For correct operation, the system must be located away from sources of heat.

- **Atmospheric emissions**
  The MEDIVATORS ISA Endoscope Reprocessor operates as a closed-circuit and there are no detectable environmental emissions. Any emissions due to changing the tanks or opening the basin are not toxic or harmful to human health.

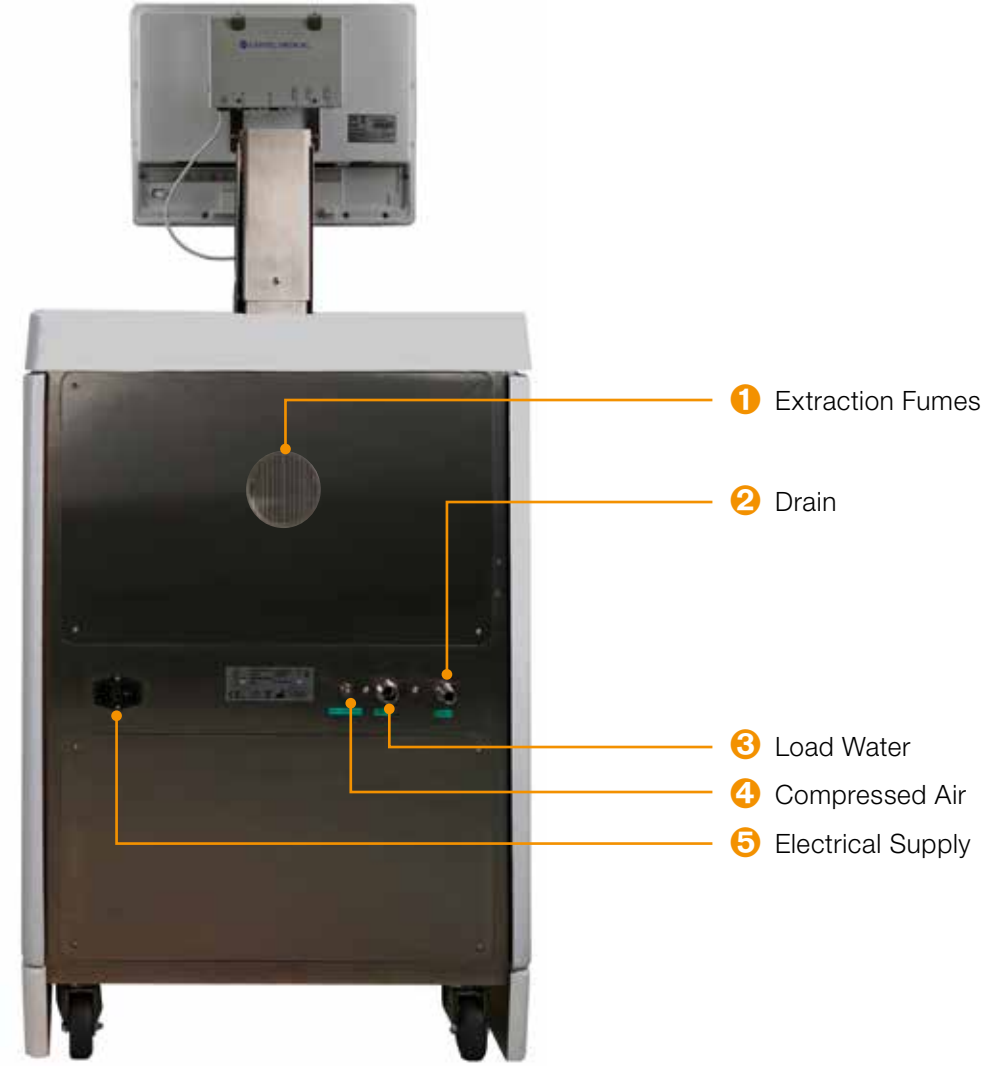
- **Ventilation of the environment**
  It is recommended that the equipment be installed in an environment with a ventilation system capable of providing 10 changes per hour. For the installation of several MEDIVATORS ISA Endoscope Reprocessor in the same room, it may be necessary to increase the number of exchanges per hour.

- **Transportation and storage**
  The MEDIVATORS ISA Endoscope Reprocessor must be stored and housed in compliance with the following conditions: temperature 5-40°C, relative humidity 20-80% and pressure of 500-1060 hPa. Prior to moving the equipment, make sure that the electrical cable, the discharge tube and the water supply system are disconnected, or that their lengths are sufficient to allow movement of the equipment.

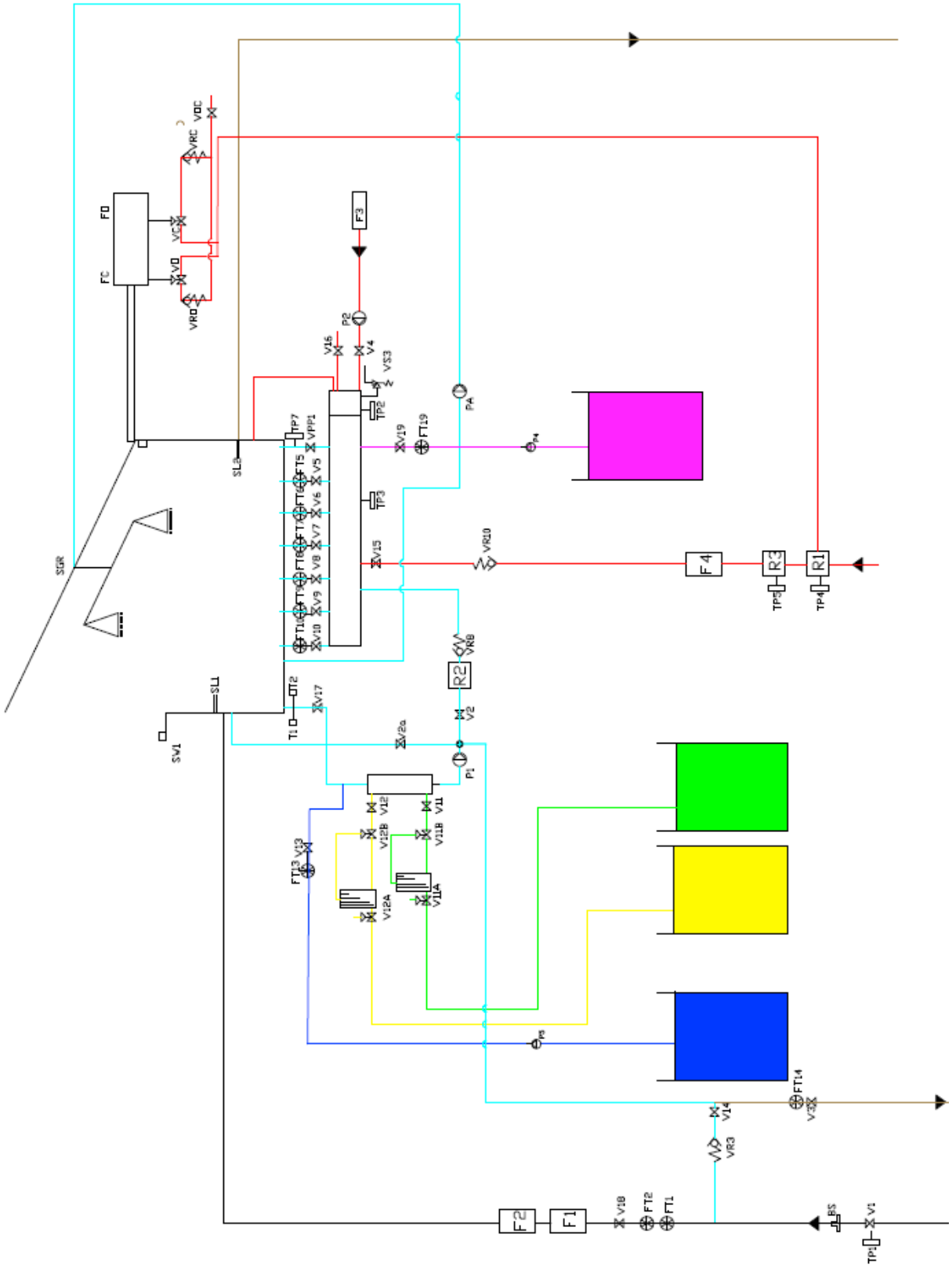
The technical specifications reported above ensure the correct operation of the MEDIVATORS ISA Endoscope Reprocessor. Failure to comply with the above alters the performance of the equipment and the efficacy of the cycle, and can result in damage not covered by the manufacturer's guarantee.

EXTERNAL CONNECTION SUPPLIES

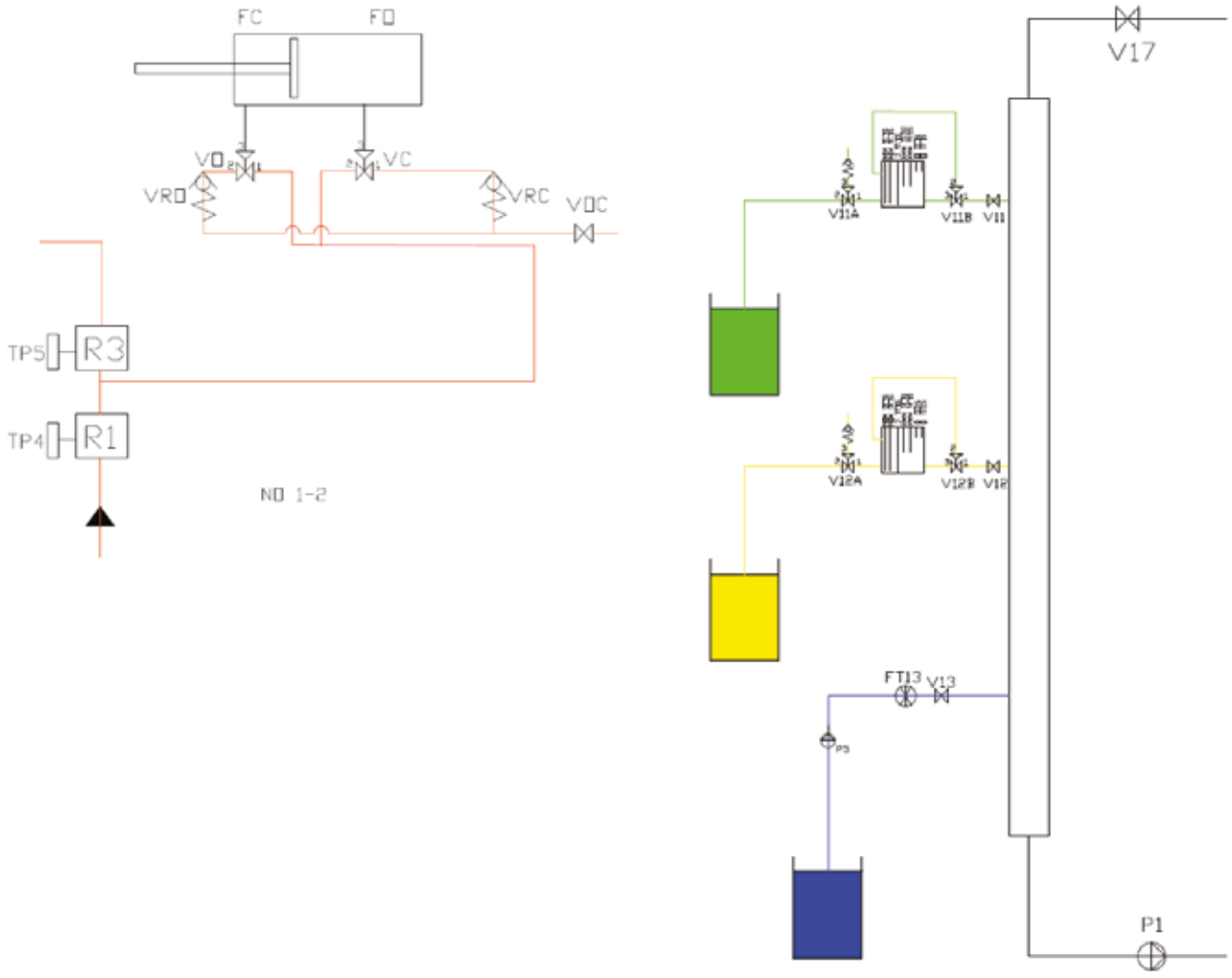
Figure 1
Rear view of the MEDIVATORS™ ISA™ Endoscope Reprocessor.



HYDRAULIC-PNEUMATIC CIRCUIT MEDIVATORS™ ISA™ ENDOSCOPE REPROCESSING SYSTEM



OPEN/CLOSED LID CIRCUIT



CODES USED FOR COMPONENTS

Tp	=	Pressure Transducer / Pressure Switch
T	=	Temperature Sensor
P	=	Electrical Pump
V	=	Electrical Valve
Ft	=	Flow Meter
Vpp	=	Electrical Valve For Elevator Channel
Vs	=	Safety Mechanical Valve
Vr	=	Check Valve
F	=	Filter
R	=	Pressure Regolator
Fc-Fo-Foc	=	Switch Control For Lid Movement
SL	=	Level Sensor

Table 1. Output

CODE	DESCRIPTION	TYPE
V11A	Valve for load dosing cylinder Sol. A	Electrical valve
V11B	Valve for drain dosing cylinder Sol. A	Electrical valve
V12A	Valve for load dosing cylinder Sol. B	Electrical valve
V12B	Valve for drain dosing cylinder Sol. B	Electrical valve
V11	Valve for dosing Sol. A	Electrical valve
V12	Valve for dosing Sol. B	Electrical valve
V13	Detergent Valve	Electrical valve
P5	Detergent Pump	Electrical pump
V19	Alcohol Valve	Electrical valve
P4	Alcohol Pump	Electrical pump
V1	Valve for load water	Electrical valve
V18	Valve for load water in the basin	Electrical valve
P1	Recirculation Pump	Electrical pump
V3	Drain Valve	Electrical valve
V2	Recirculation Valve	Electrical valve
V14	Self-Disinfection Valve	Electrical valve
V15	Air purge Valve	Electrical valve
V17	Drain basin Valve	Electrical valve
V5	Channel 1 Valve	Electrical valve
V6	Channel 2 Valve	Electrical valve
V7	Channel 3 Valve	Electrical valve
V8	Channel 4 Valve	Electrical valve
V9	Channel 5 Valve	Electrical valve
V10	Channel 6 Valve	Electrical valve
VPP1	Channel 7 Valve	Electrical valve
V16	Leak test drain Valve	Electrical valve
V4	Leak Test Valve	Electrical valve
P2	Leak Test Pump	Electrical pump
V2A	Load Solution Valve	Electrical valve
PA	Spray Arm Pump	Electrical pump
VO	Open Lid Valve	Electrical valve
VC	Close Lid Valve	Electrical valve
VOC	Valve for lid Mechanism	Electrical valve

Table 2. Input

CODE	DESCRIPTION	TYPE
SL11	Level Sensor Dosing Sol. A	Switch
SL12	Level Sensor Dosing Sol. B	Switch
FT-13	Detergent Flowmeter	Flow meter
FT-19	Alcohol Flowmeter	Flow meter
FT-1	Water load Flowmeter	Flow meter
FT-2	Water load Flowmeter	Flow meter
FT-14	Drain Flowmeter	Flow meter
FT-5	Channel 1 Flowmeter	Flow meter
FT-6	Channel 2 Flowmeter	Flow meter
FT-7	Channel 3 Flowmeter	Flow meter
FT-8	Channel 4 Flowmeter	Flow meter
FT-9	Channel 5 Flowmeter	Flow meter
FT-10	Channel 6 Flowmeter	Flow meter
TP4	Air Purge Pressure Transducer	Pressure transducer4…20mA
T1	Temperature Sensor	PT-1000
T2	Temperature Sensor	PT-1000
TP2	Leak Test Pressure Transducer	Pressure transducer4…20mA
SL1	Basin Level Sensor	Switch
SL2	Basin Level Sensor	Switch
SL3	Leakage Sensor	Pressure transducer4…20mA
TP7	Channel 7 Pressure Transducer	Reed Sensor
FC	Switch Sensor Closed Lid	Reed Sensor
FO	Switch Sensor Open Lid	Pressure transducer4…20mA
TP1	Pressure Switch Water	Switch
PED	Footswitch	Switch
TP5	Pressure Tranducer Compressed Air Lid	Pressure transducer4…20mA
SGR	Spray Arm Sensor	Magnetic Sensor

Table 3. Filters

CODE	DESCRIPTION
F1	First Stage Water Filter
F2	Second Stage Water Filter
F3	Leak Test Filter
F4	Air Purge Filter

Table 4. Regulators

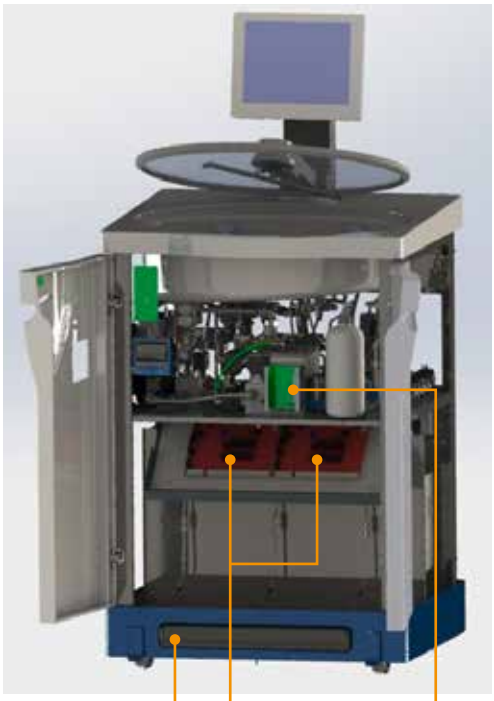
CODE	DESCRIPTION
R1	Cylinder Lid Regulator
R2	Channel Regulator
R3	Air Purge Regulator

Table 5. Other Parts

CODE	DESCRIPTION
VS3	Purge Air Leak Test
BS	Back Siphonage Valve

LAYOUT OF THE MEDIVATORS™ ISA™ ENDOSCOPE REPROCESSING SYSTEM

INTERNAL COMPONENTS



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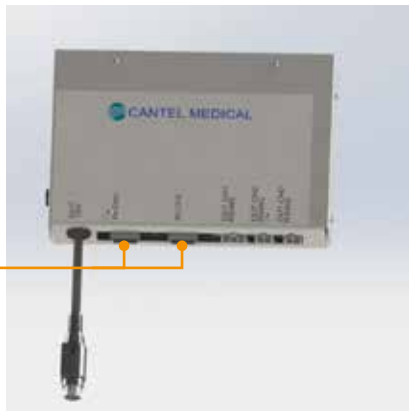

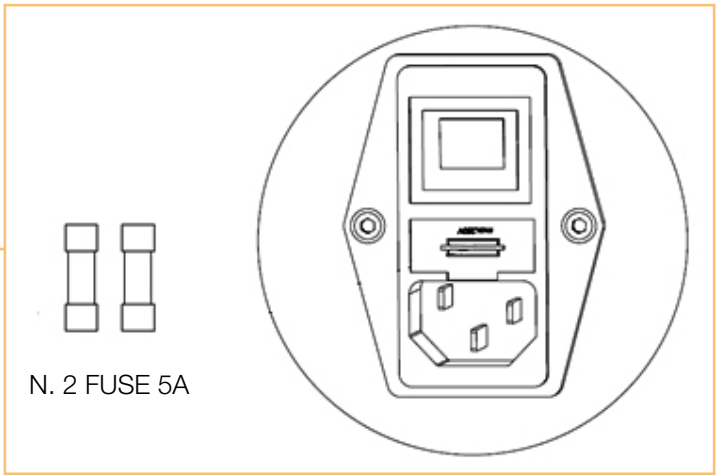

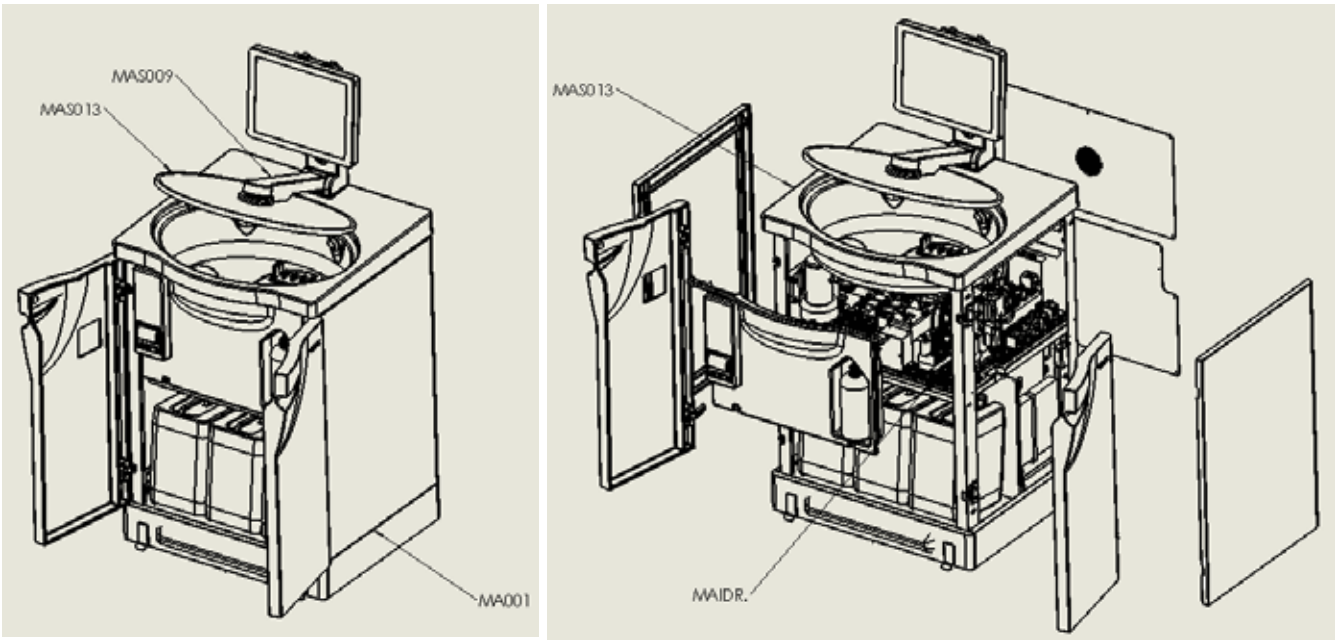
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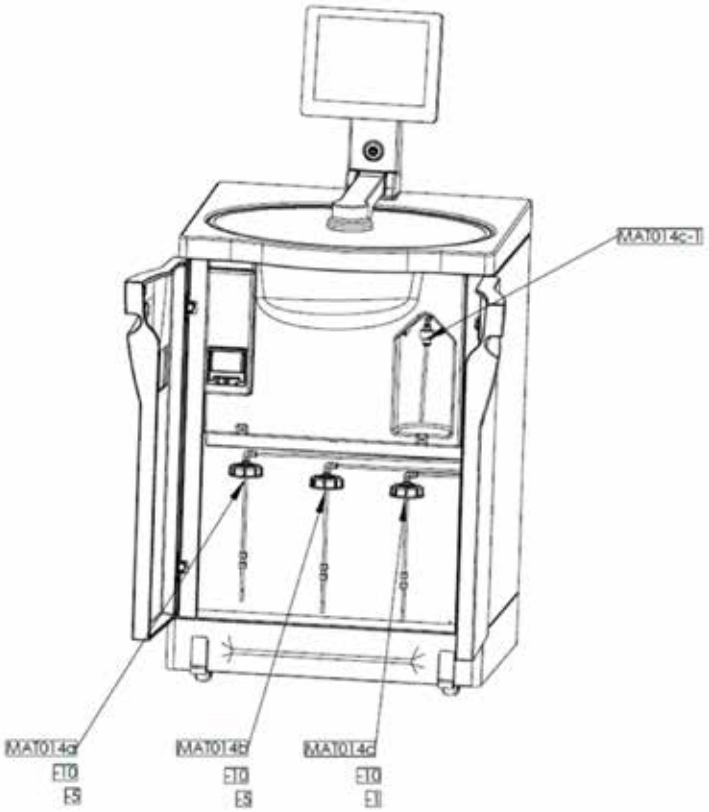
MAS013
MA001
MAS013
MAIDR.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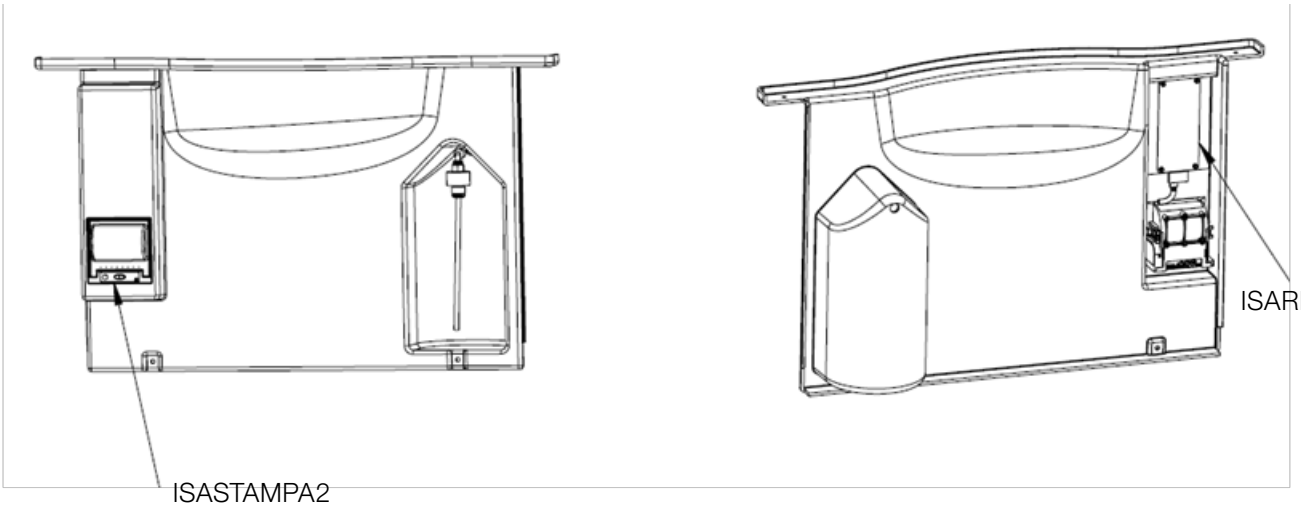
-T0
-S
MAT014c
-T0
-S
MAT014c
-T0
-S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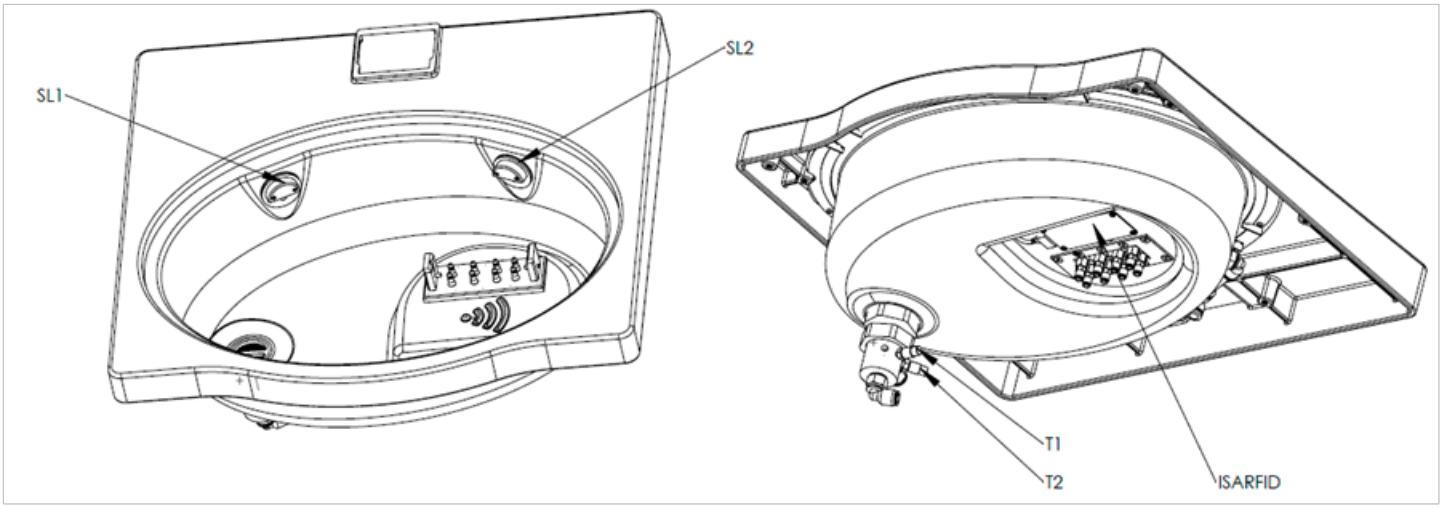
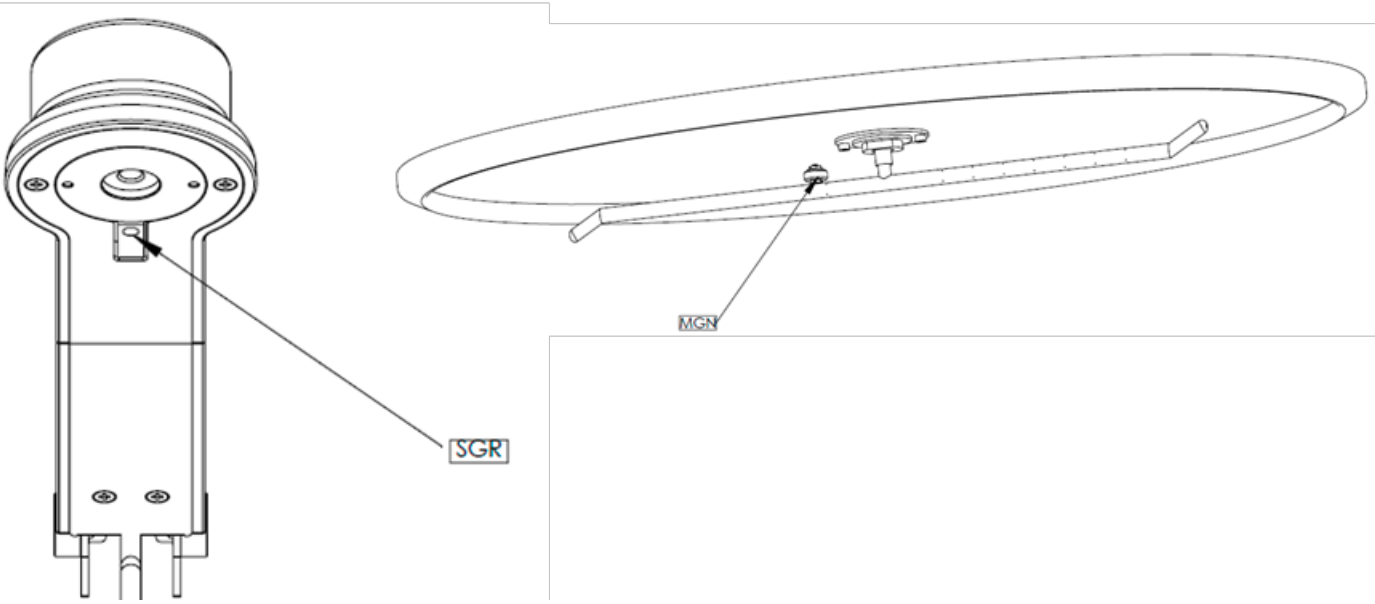
ISARFID


SL1
SL2
T1
T2
ISARFID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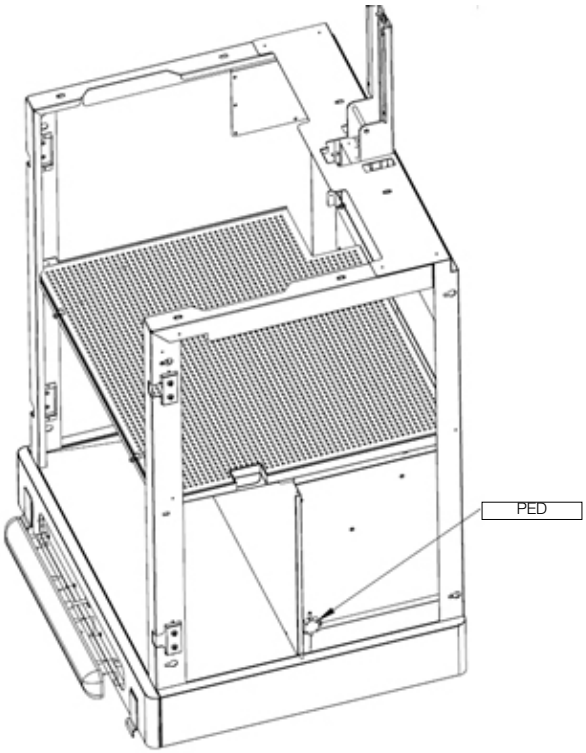
MGN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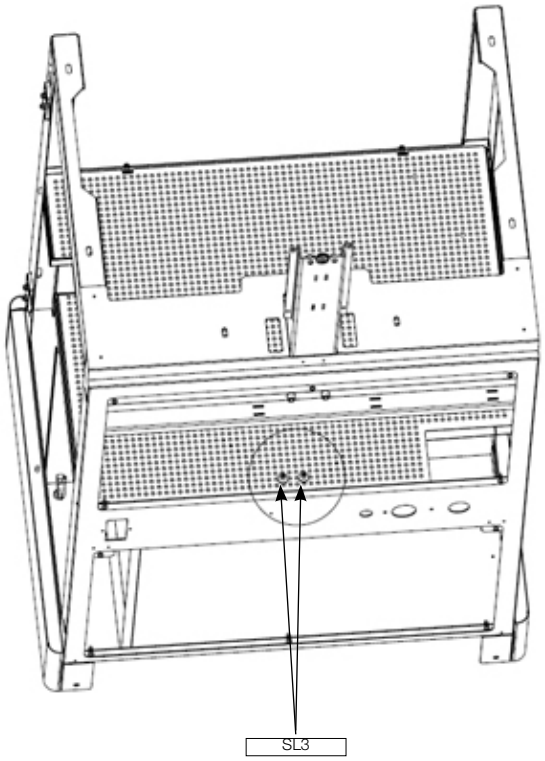
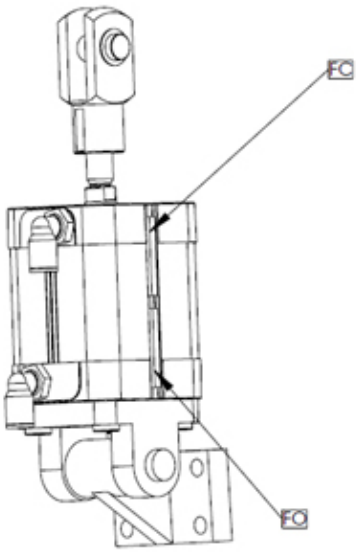
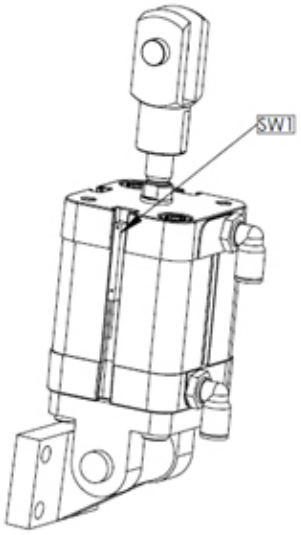
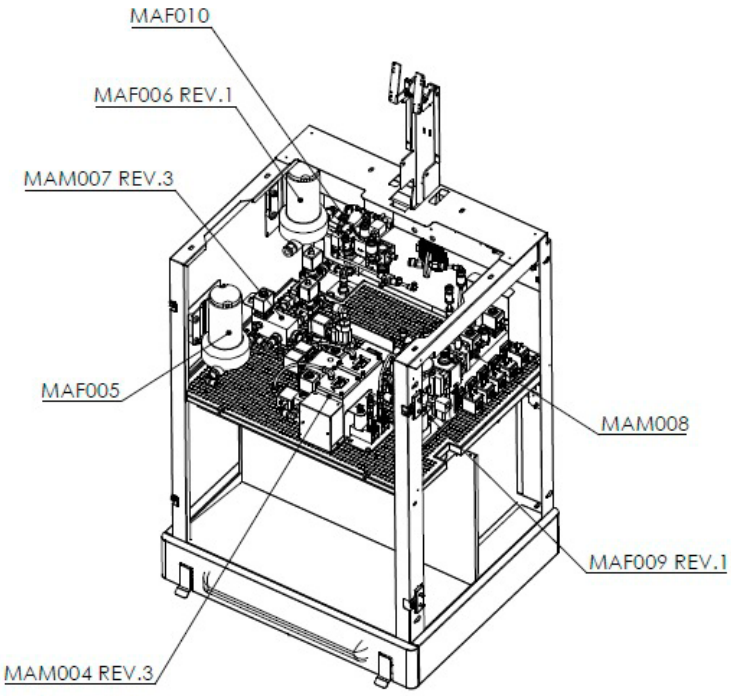
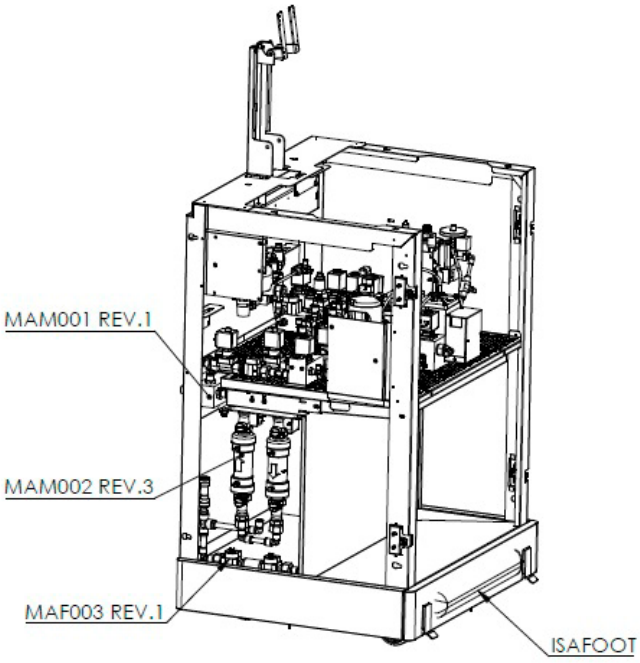

SL3

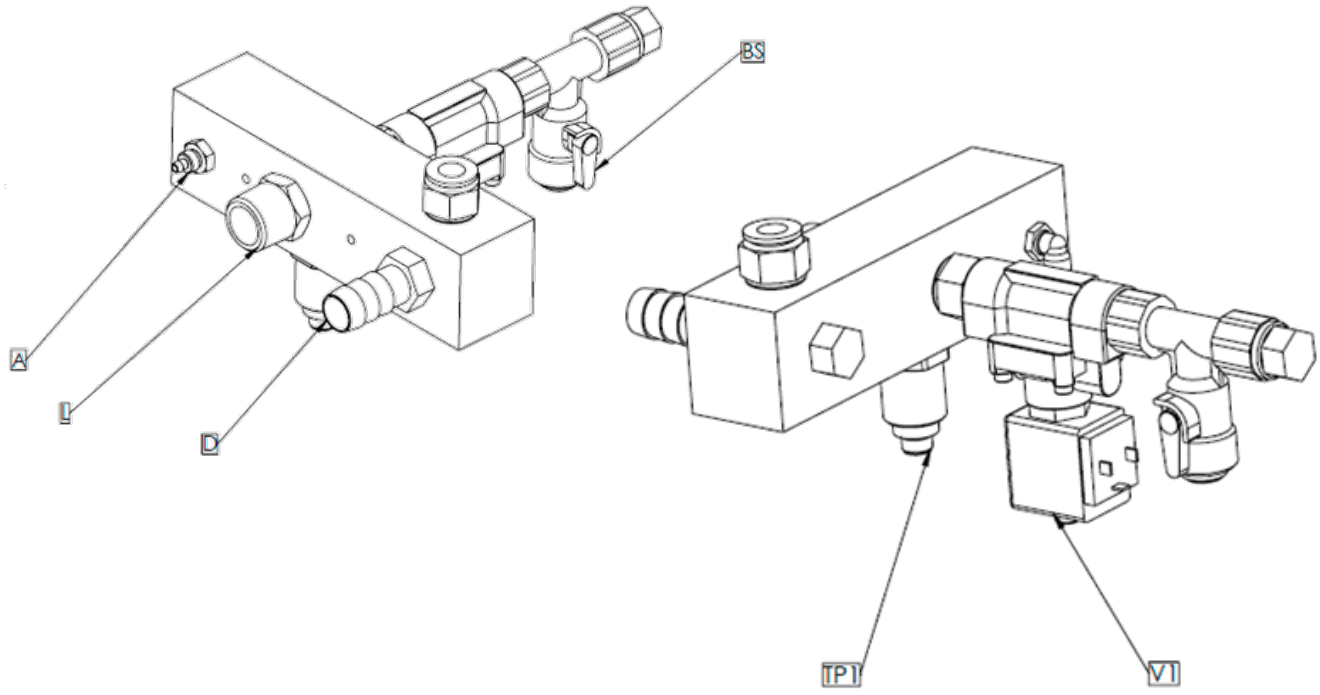

FC
FC


SW1

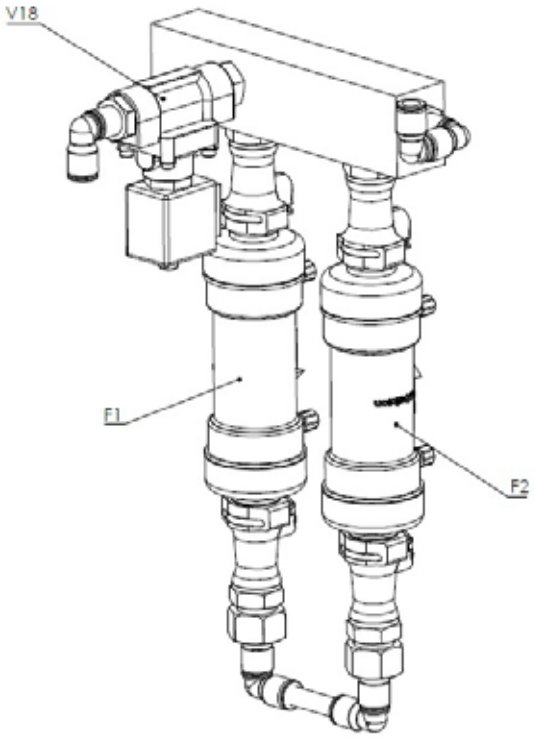




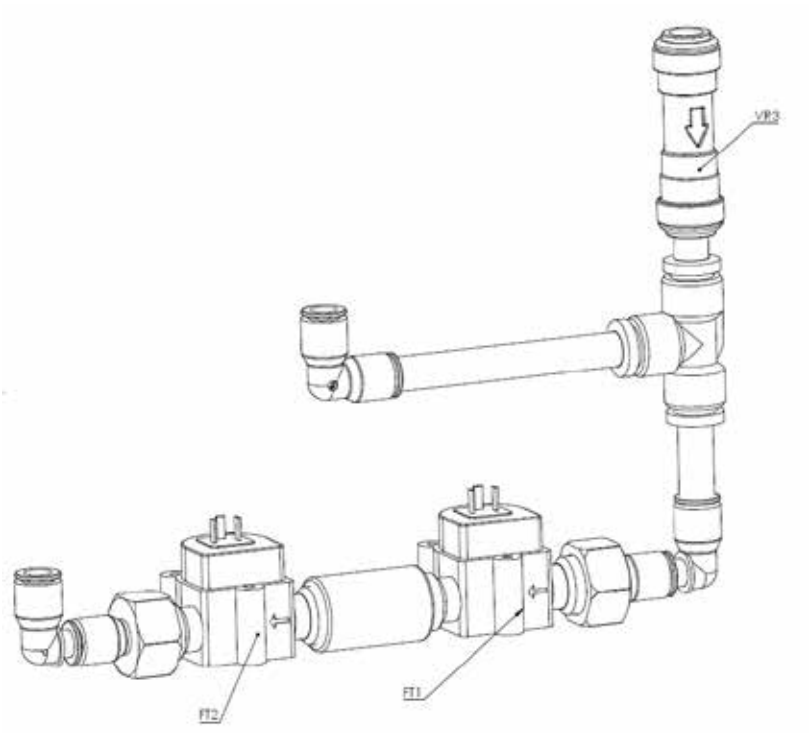
MAM001 ASSEMBLY EXTERNAL CONNECTIONS



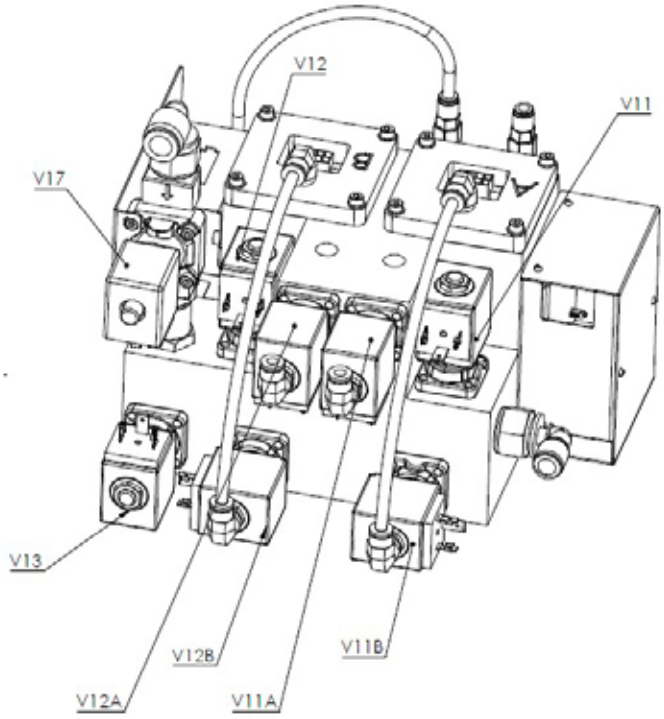
MAM002 ASSEMBLY FILTERS

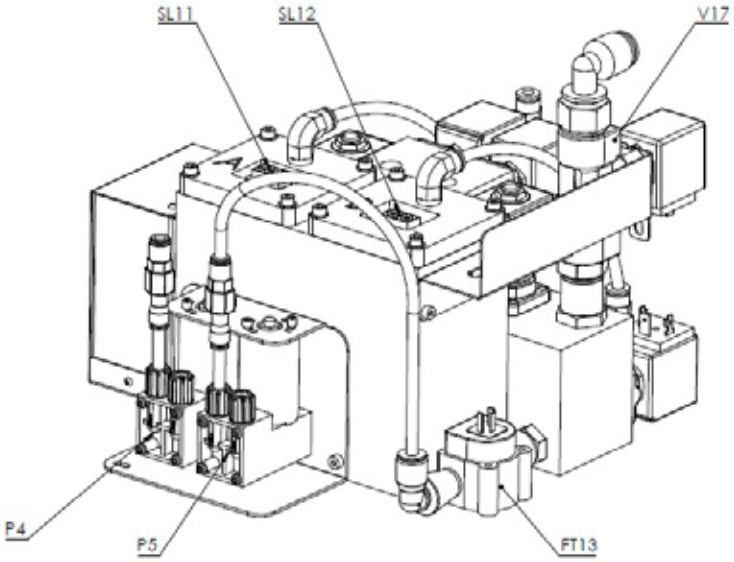


MAM003 ASSEMBLY WATER INLET FLOWMETERS

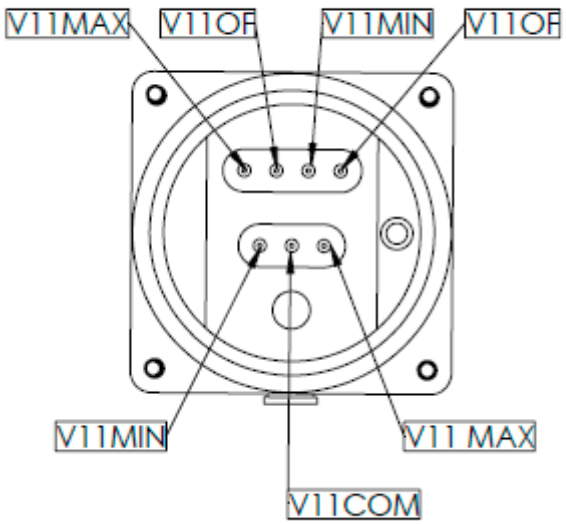


MAM004 ASSEMBLY DOSING SYSTEM

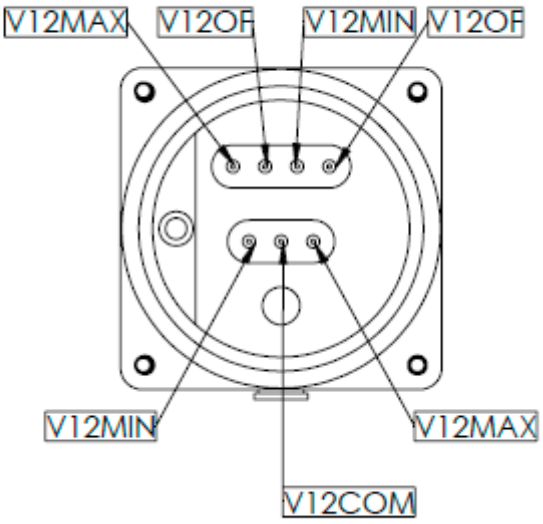




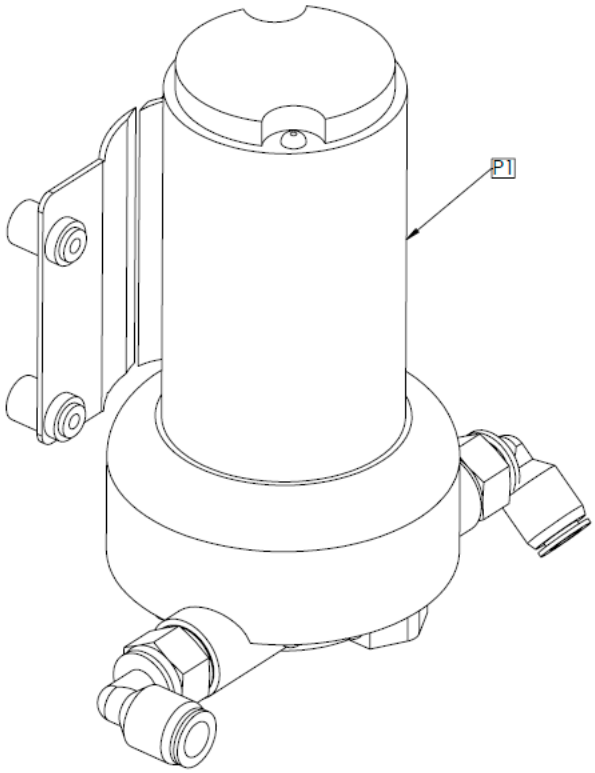
SL11



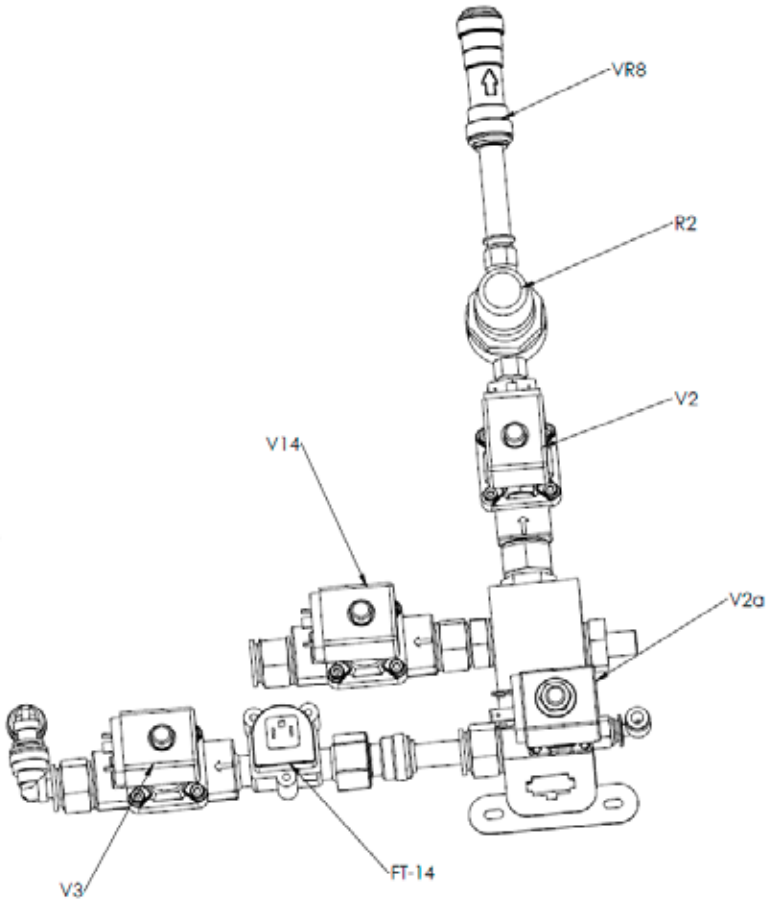
SL12



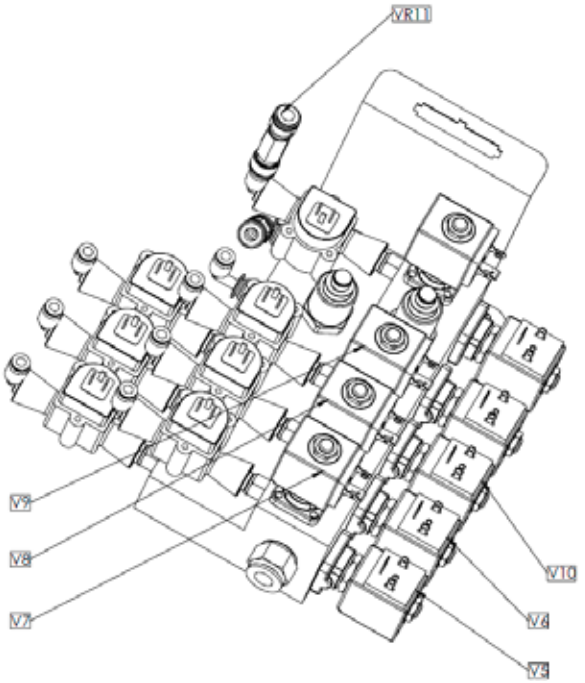
MAF005 ASSEMBLY DRAIN/CIRCULATION PUMP

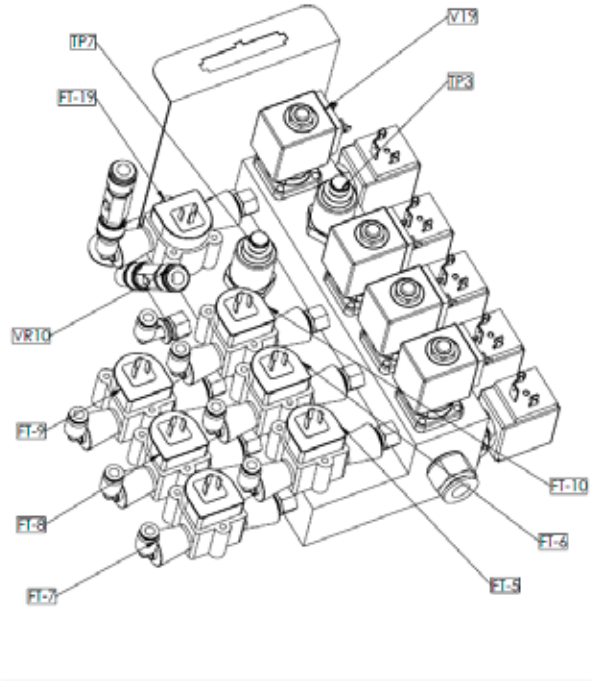


MAM007 ASSEMBLY VALVE DRAIN/RECIRC./SELF DISINFECTION

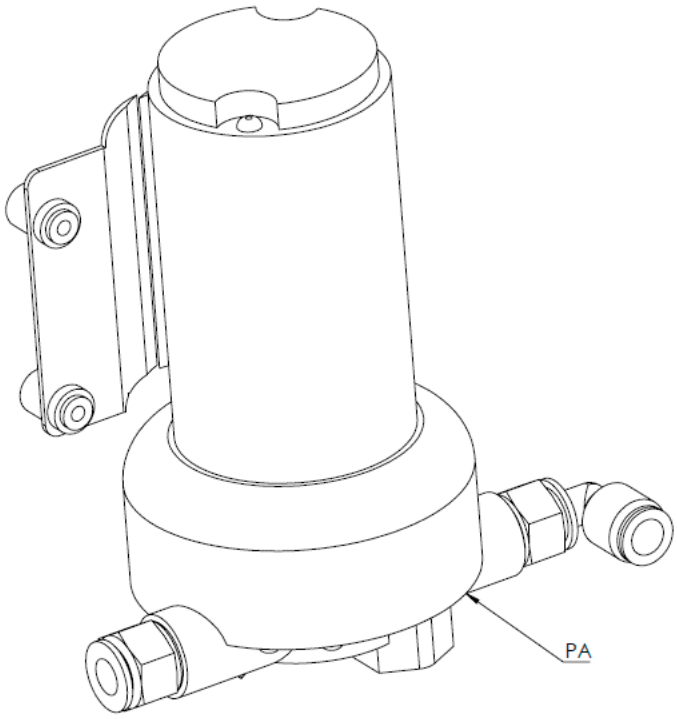


MAM008 ASSEMBLY COLLECTOR CHANNEL

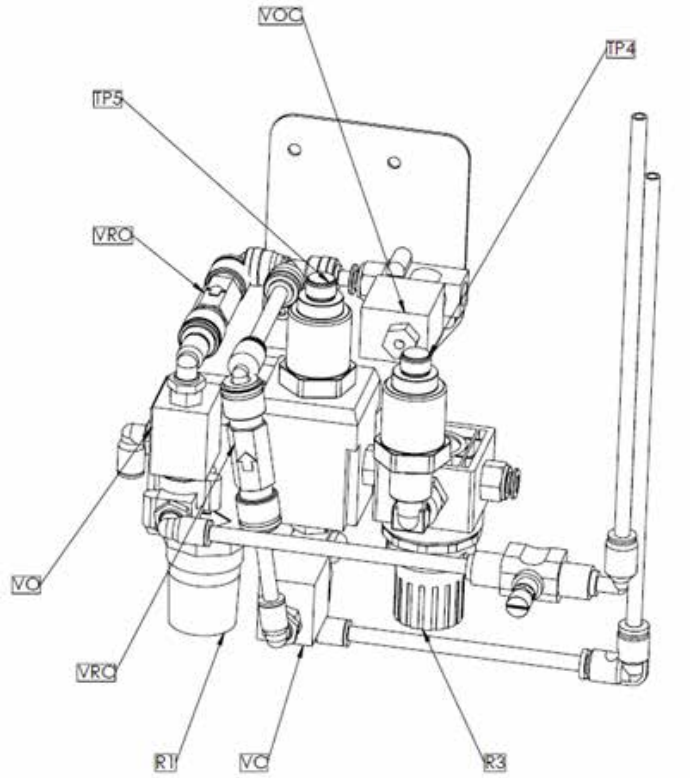




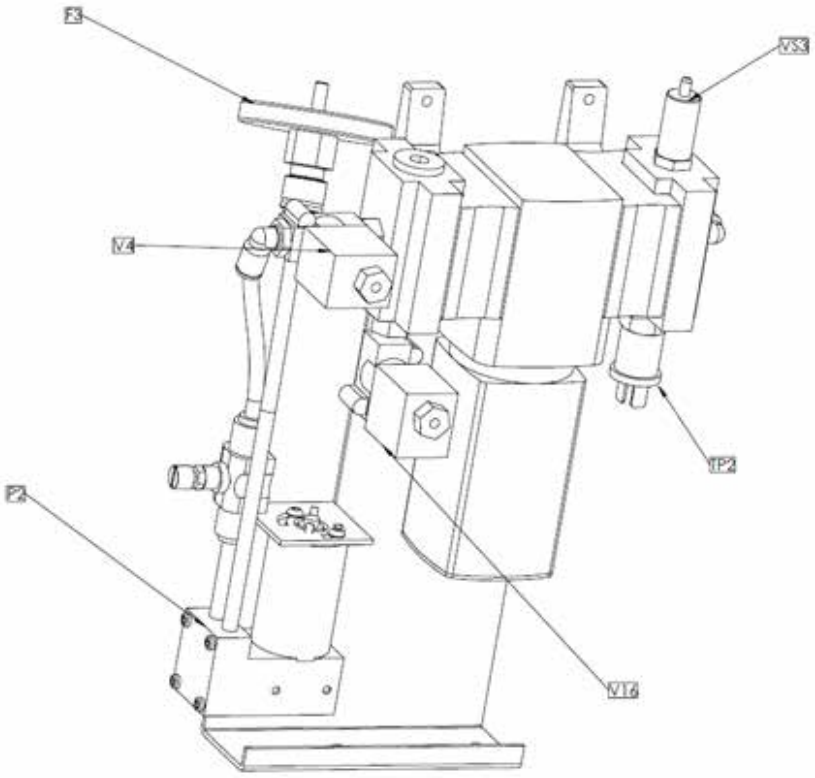
MAF006 ASSEMBLY SPRAY ARM PUMP



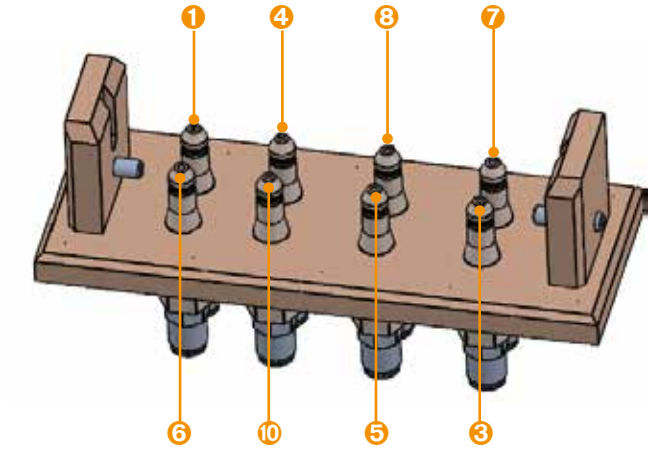
MAF010 ASSEMBLY AIR PRESSURE REGULATOR



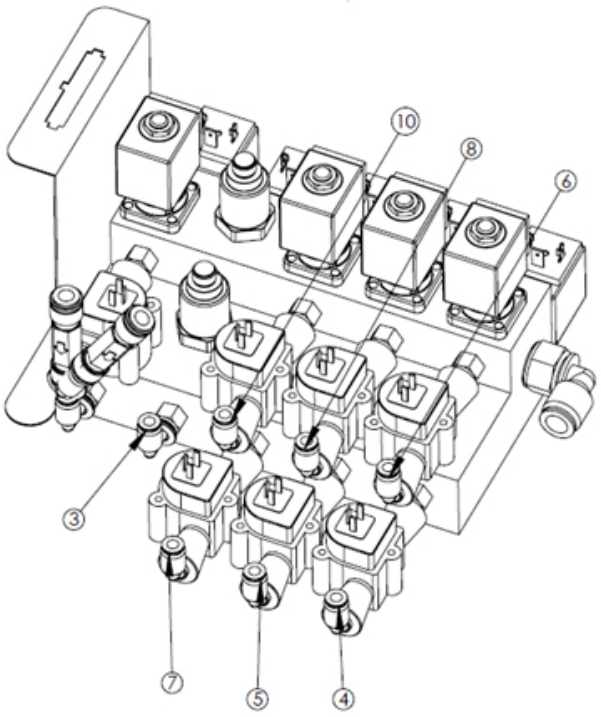
MAF009 ASSEMBLY LEAK TEST

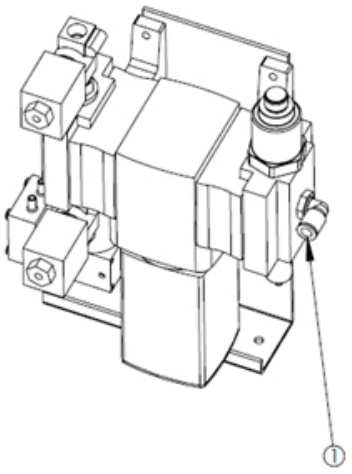


HOOKUP CONNECTION SCHEME



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





CHAPTER 3

SOFTWARE PROCEDURE TECHNICAL/ADMINISTRATOR FUNCTIONS

This chapter refers to the software functions dedicated to technicians (for operator functions refer to the specifications in the USER MANUAL) and Administrator.

START PROCEDURE

To access the functions of the PC, make sure that the equipment activation supply is on and if not, move the switch to the “I” position.

Figure 1 I Activation switch

First, set theactivation switch to “I”

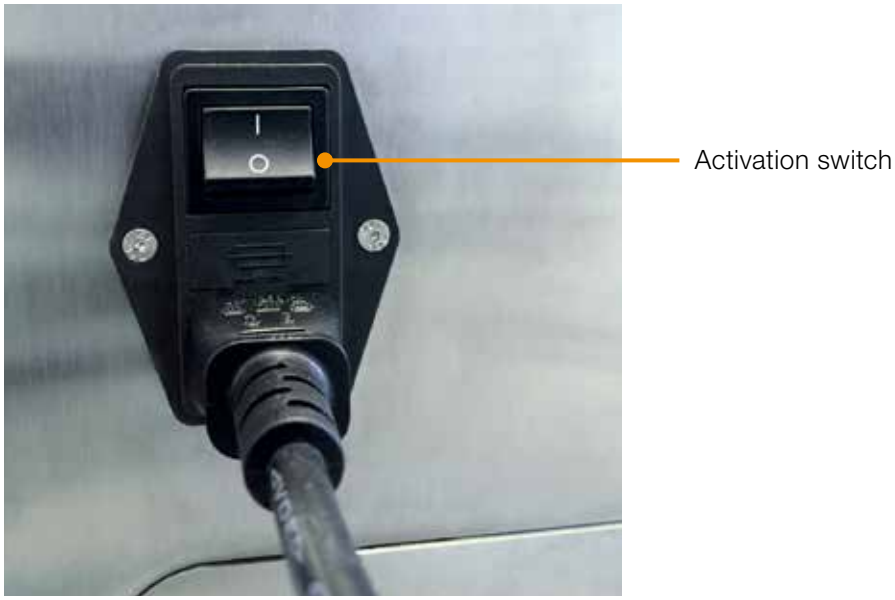
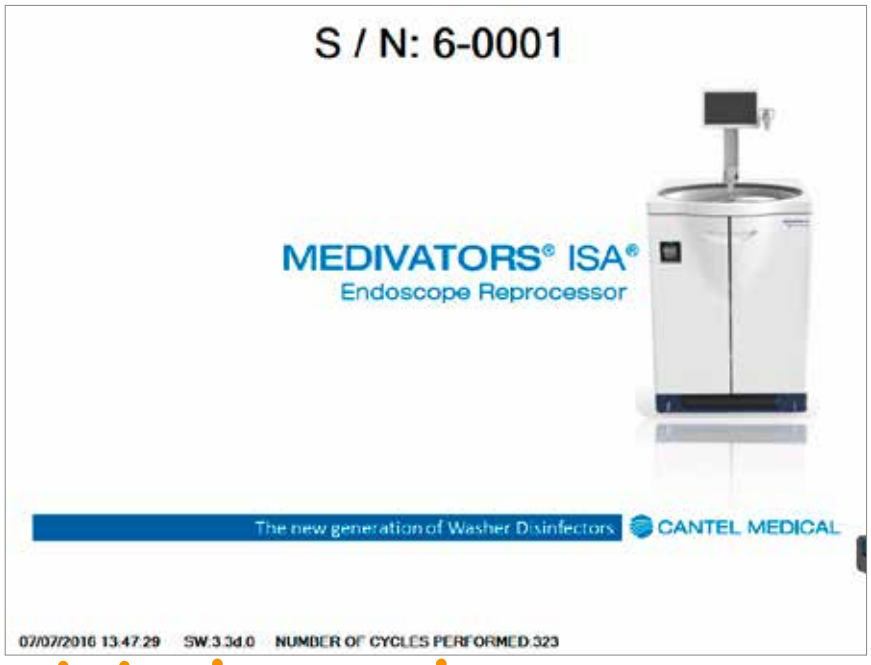


Figure 2 I PC on/off switch
Turn on the PC using the button located under the touch screen monitor

MEDIVATORS™ ISA™ ENDOSCOPE REPROCESSOR SOFTWARE PROCEDURES

This is the first screen that appears when the PC is switched on:

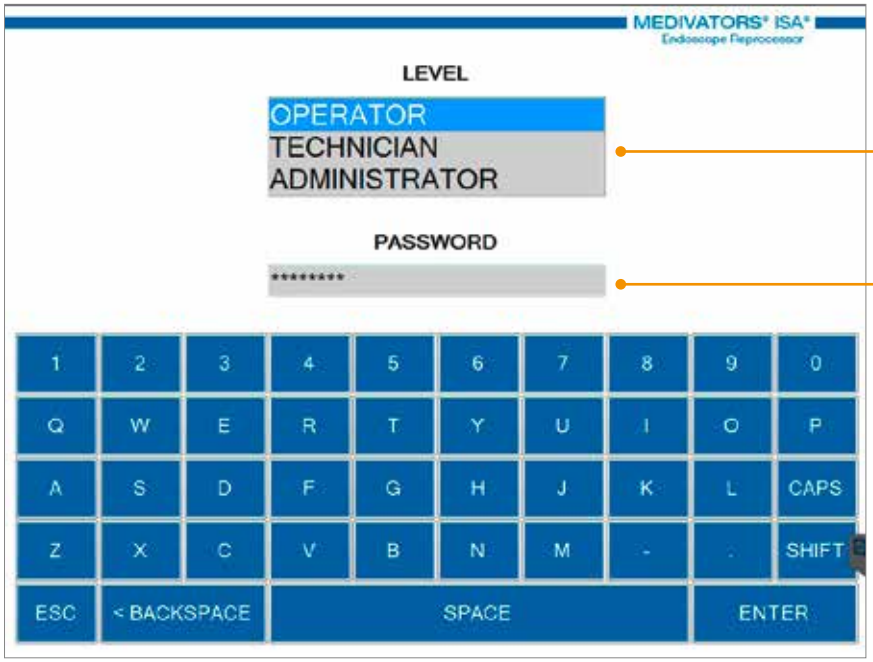


Date and time synchronized with the computer

Software revision

Cycle performed

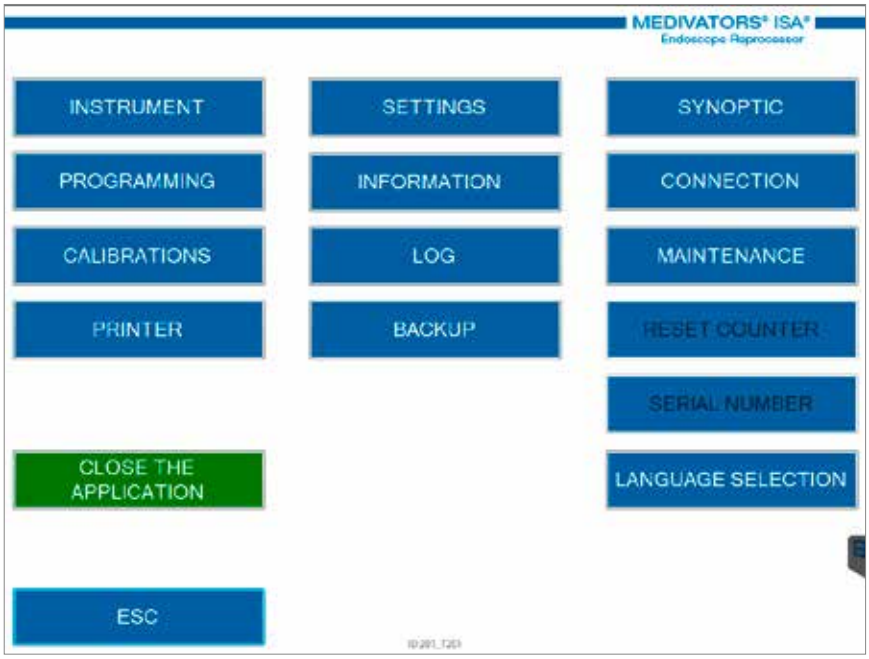
Type anywhere on the screen, to get the next screen to appear :



To continue press “ENTER”.

The main screen that will be showed is the follow:

Click on “TECHNICAL MENU” to access the following menu:

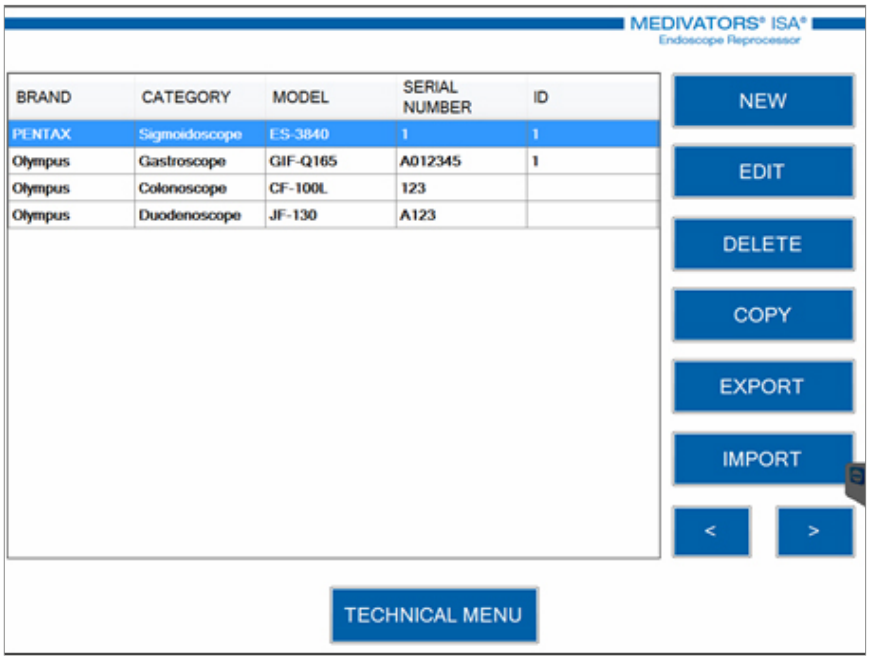


INSTRUMENT

This function is used to insert a new endoscope (with related control parameters) in the list of endoscopes process able with the equipment, or to modify existing ones, delete them from the list, make a copy of an existing ones (useful when you have endoscopes more of the same type) and finally to export and/or import a database from endoscopes and/or to another MEDIVATORS™ ISA™ Endoscope Reprocessor.

The two arrows at the bottom of the screen are used to scroll the list down (right arrow) or upwards (left arrow).

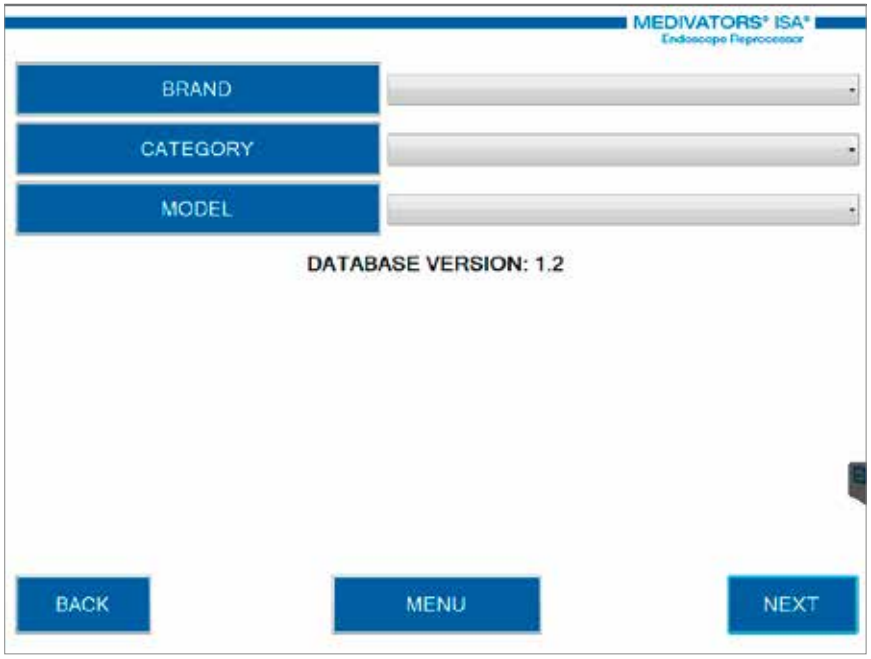
Finally, to return to the previous page type the TECHNICAL MENU button.



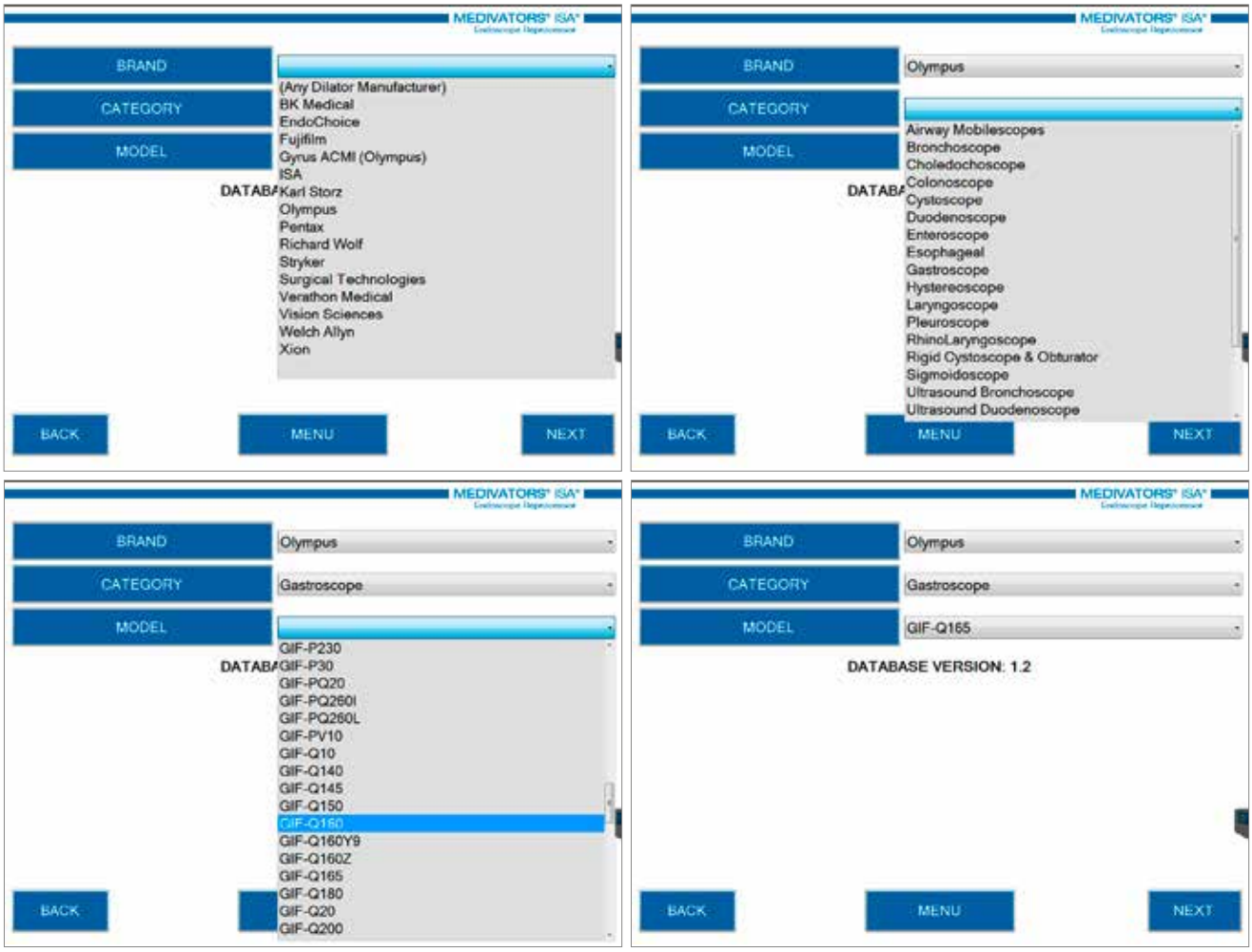
Consider you want to insert a new endoscope in the list (to the following inclusion will be displayed in the list on the left button):

Enter the NEW button.

The screen that will be displayed:

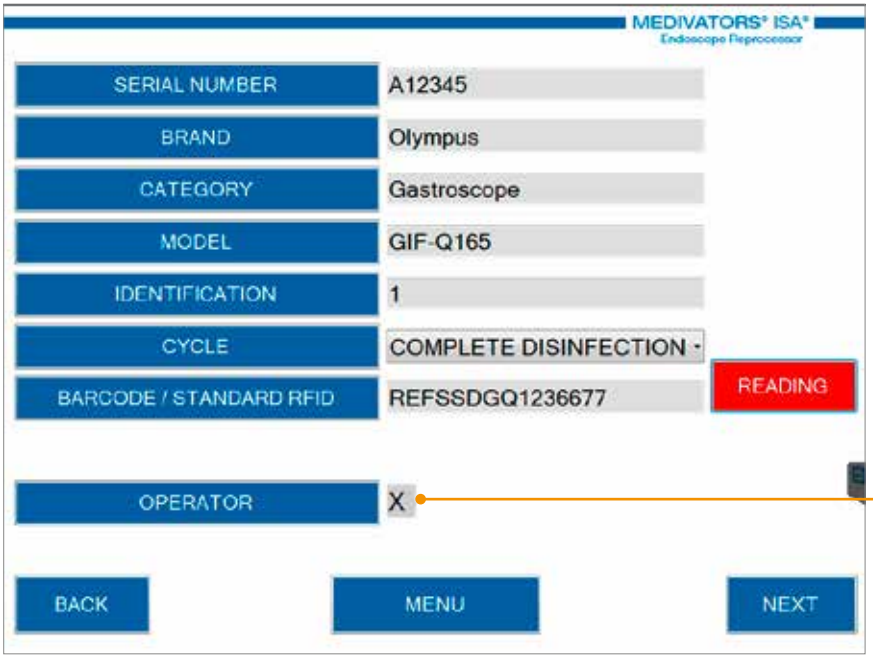


It means that you can load the endoscopes from an internal database, divided by Brand, Category and Model:



Selecting next, the page that will appear is:

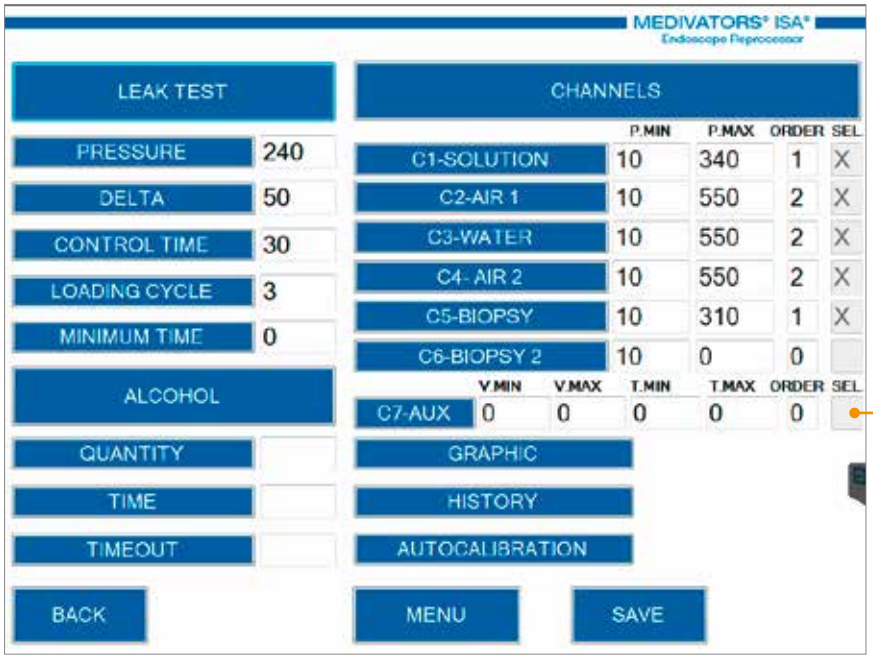
Consider that it has completed the required data on the previous page with sample data:



When the upload data, type the SCAN button and pull the tag endoscope to the card: This procedure associates the tags assigned to the endoscope.

Flag for visualization of this endoscope for OPERATOR users

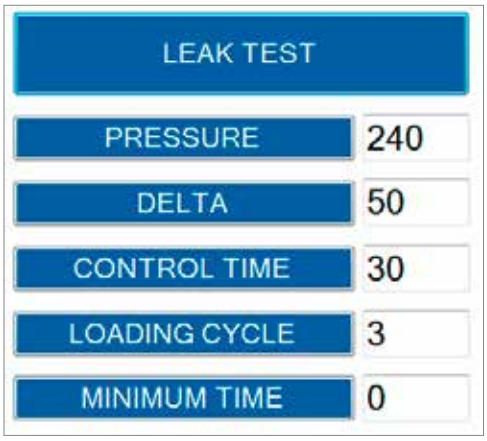
After entering the data on this page, you can move to the next page using the NEXT button or return to the previous screen with either button BACK - MENU



Selection of channel is blocked

Consider this page divided by 4 section:

LEAK TEST



Set Pressure

Maximum Admissible Leakage

Check Time (SEC)

Number of cycle for air loading*

Minimum time for filling the scope**

* Necessary in the case of large sized endoscopes, where only one loading cycle would cause an excessive loss of pressure, due to the non-complete filling of the endoscope.

** Useful to verify that the pressure read is actually relative to the endoscope and that the tube of the connector seal test has not suffered bottlenecks (in this case the filling would be carried out in less time, as the size would be lower).

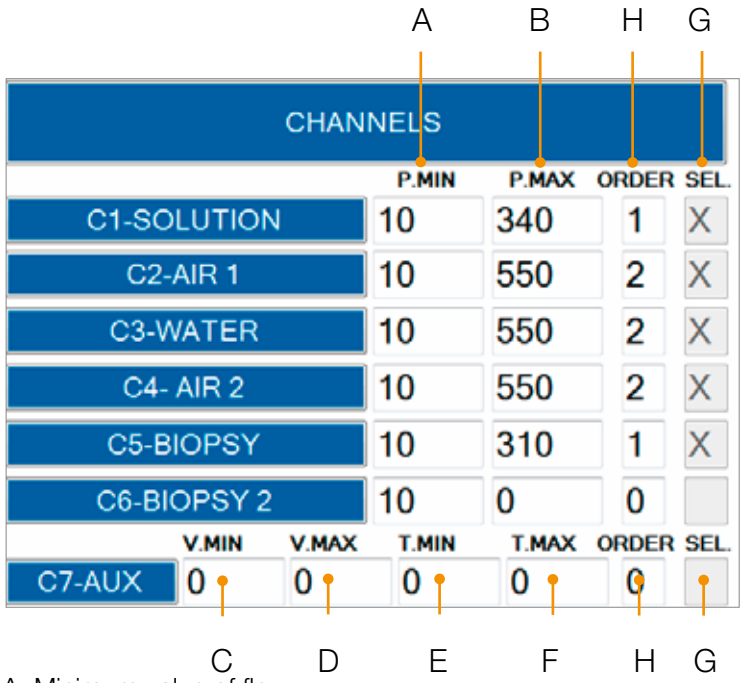
ALCOHOL

Set volume of Alcohol

Time of purge with Alcohol

Time out to load Alcohol

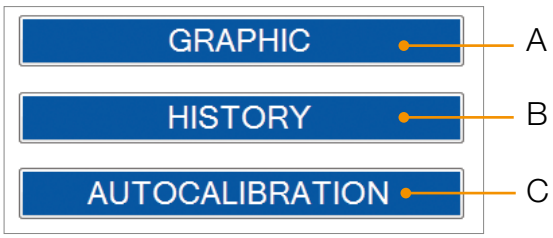
CHANNELS PARAMENTS



A. Minimum value of flow;
B. Maximum value of flow;
C. Minimum pressure in channel 7 (elevator channel);
D. Maximum pressure in channel 7 (elevator channel);
E. Time for decrease pressure to minimum pressure value with channel valve 7 closed;
F. Time for increase pressure to maximum pressure value with channel valve 7 opened;
G. Flag for select channel to check;
H. Order control channel *.

* If you insert '0' the check will be continuous.

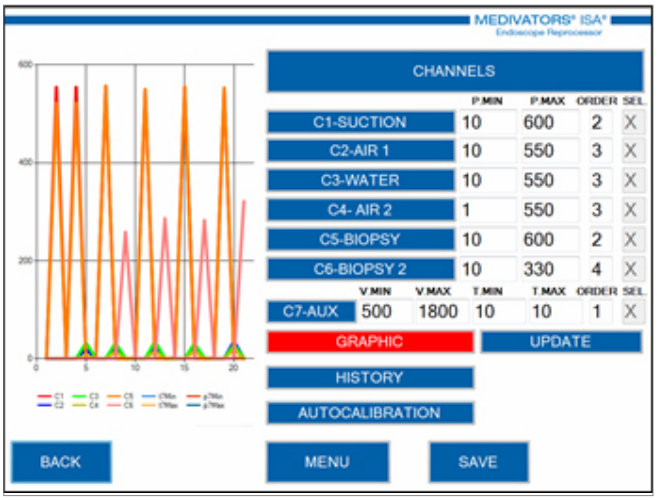
CALIBRATION FUNCTIONS

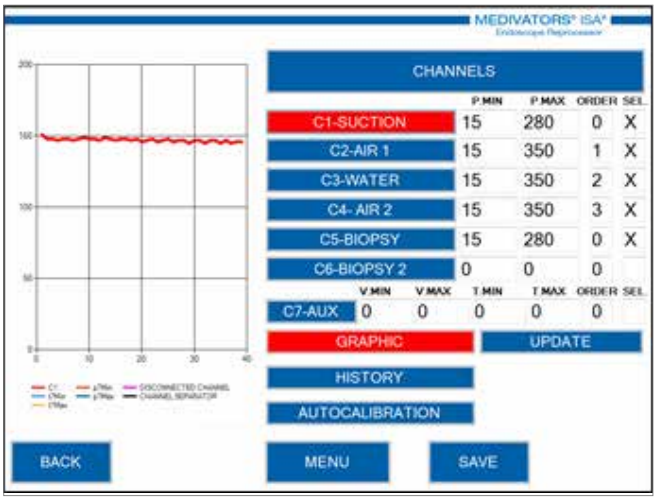


These functions, which will be detailed in the relevant chapter, are used for flow calibration of the endoscope channels.

In particular:

A. It is used to check the progress of the flows in the channels (considering them all together or requiring the chart for the specific channel: in the latter case, you select the channel, which is highlighted in red):

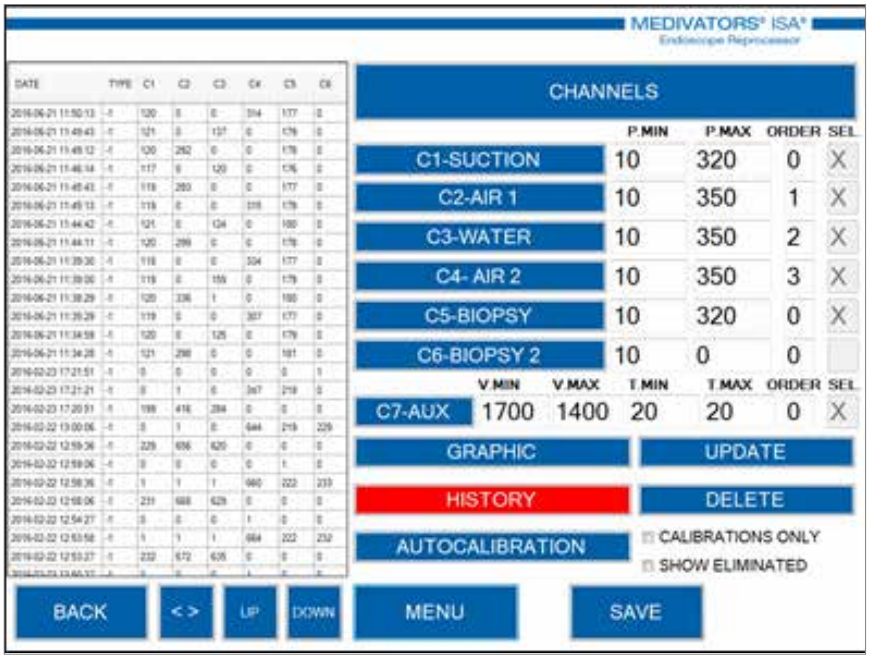




When enabling this feature, another button will appear:

If you type UPDATE, values encountered are updated and in this case, will affix them in the chart.

B. It is used for show historical value of flow per channel:

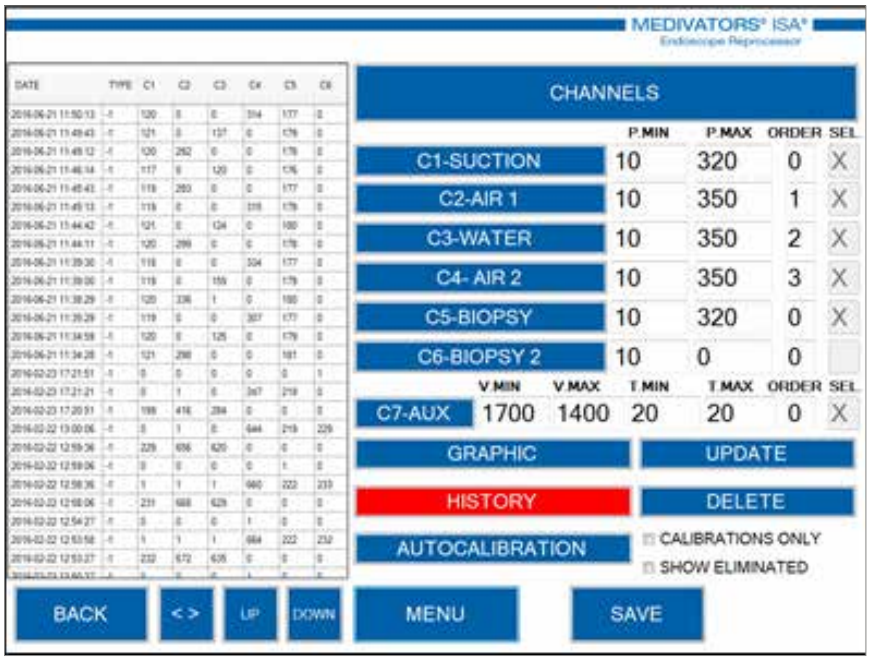


Enabling this function, activate buttons UPDATE and DELETE. The latter will be used to delete the line concerning one or more controls that you do not want to consider.

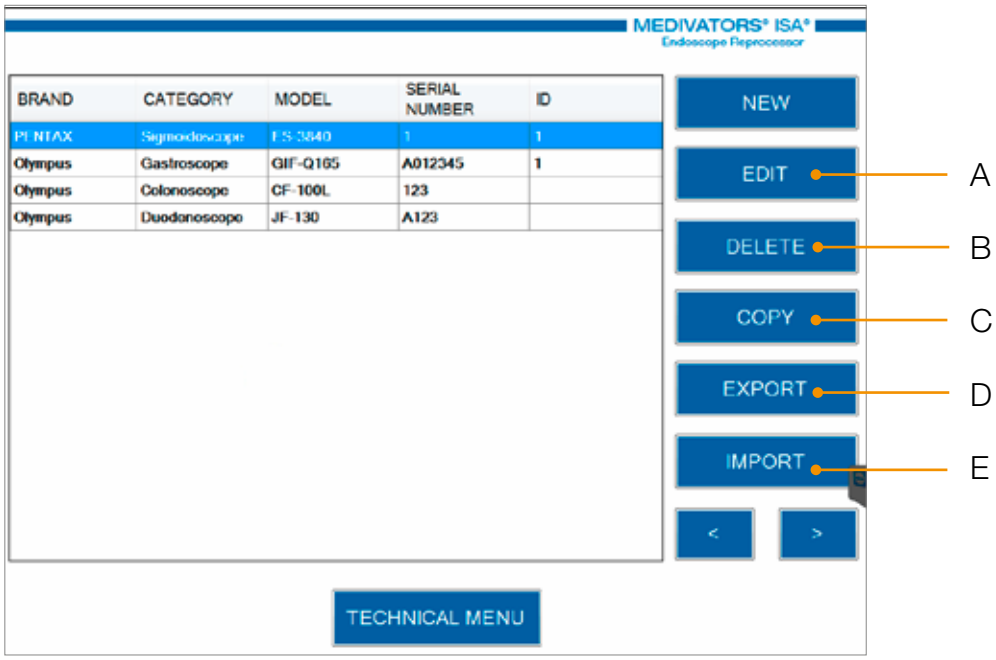
There are also two flags:

- ONLY CALIBRATIONS: if selected, it displays only the data relating to calibrations;
- SHOWS CANCELLED: shows the values previously deleted (if any).

C. This button, typed after calibration endoscope assigns values to cells corresponding to the flows of endoscopes. For example:



Returning to the page for endoscopes:



A. Will be used to make changes on the endoscope selected (it will highlight in blue);

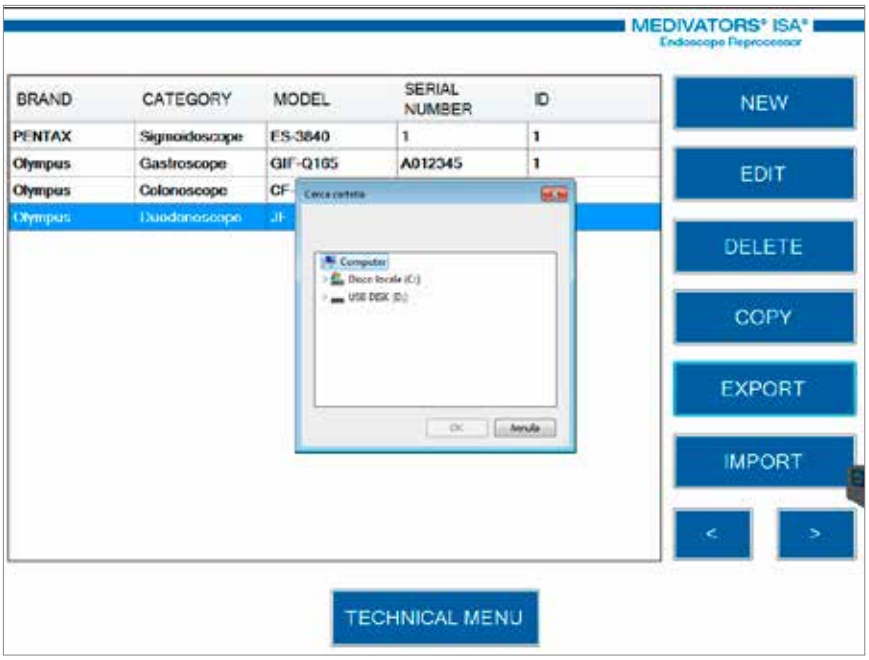
B. Will be used to delete the selected endoscope (it will highlight in blue);

C. Will be used to make a copy of the endoscope selected (it will highlight in blue);

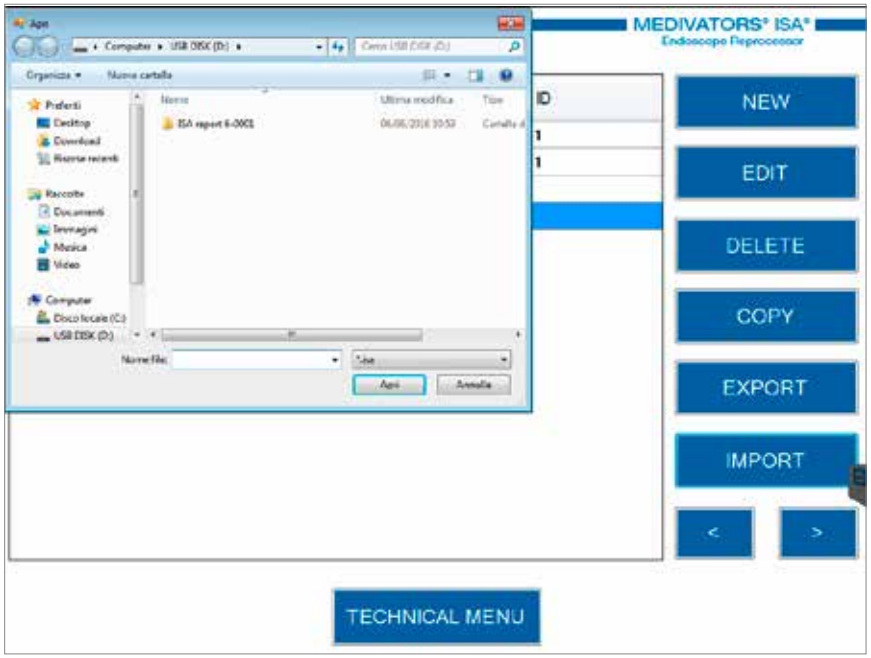
D. You will be selected to export the database for endoscopes. Typing on the button will open the screen, where it will request the drive to export the data:

E. Will be selected to import a database of endoscopes. Typing on the button will open the screen, where the unit will be required to import the data:

EXPORT



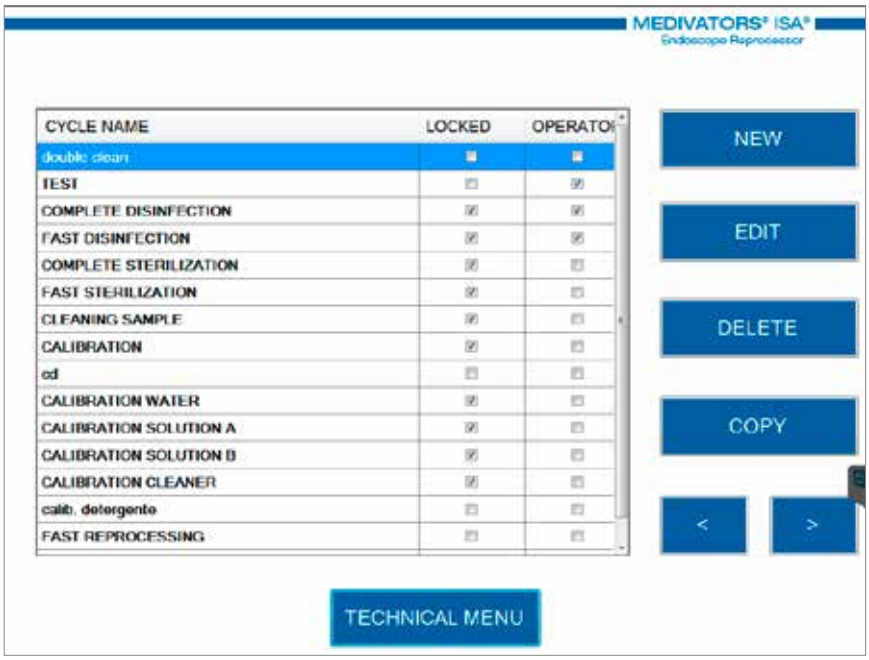
IMPORT



Proceeding in TECHNICAL MENU, you enter the page relative to program the cycles, through pulsed PROGRAMS.

This function can be used to enter a new cycle, modify an existing, delete from the list, and finally to make a copy of an existing one.

The two arrows at the bottom of the screen are used to scroll the list down (right arrow) or upwards (left arrow). Finally, to return to the previous page type on TECHNICAL MENU.

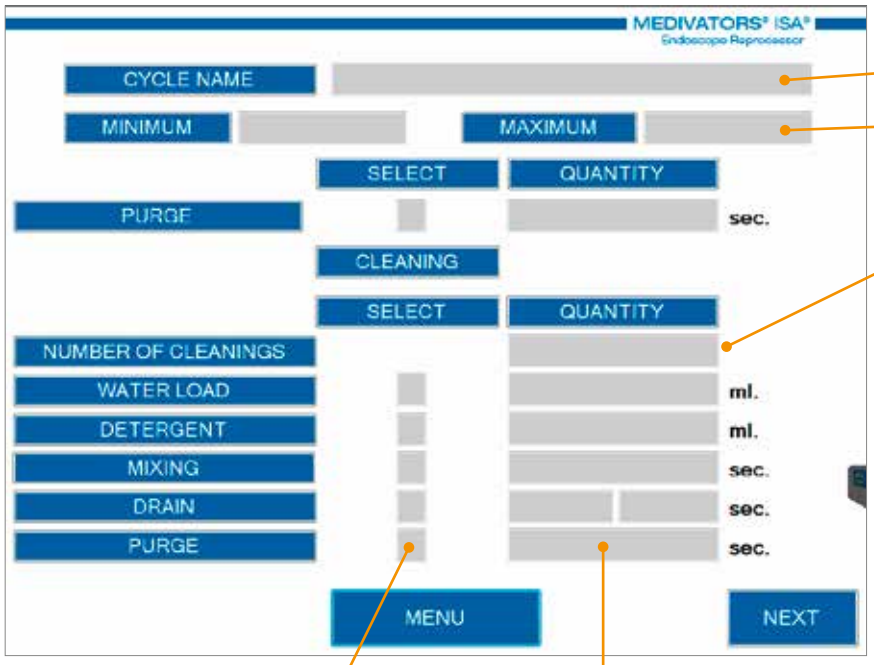


PROGRAMMING

* The cycles present are the only validated cycles for MEDIVATORS™ ISA™ Endoscope Reprocessor. The amendments may include the time of discharge, the purge time (can be increased) and the number of rinses. The other parameters are fixed and even if modified, the changes are deleted at the time that you save.

In the following pages shows the pages in the program menu, specifying the function of each of the panels - no flag.

Page 1 - CLEANING



Cycle name

Temperature value

Number of cleaning stage (cleaning and rinse) to perform for each cycle

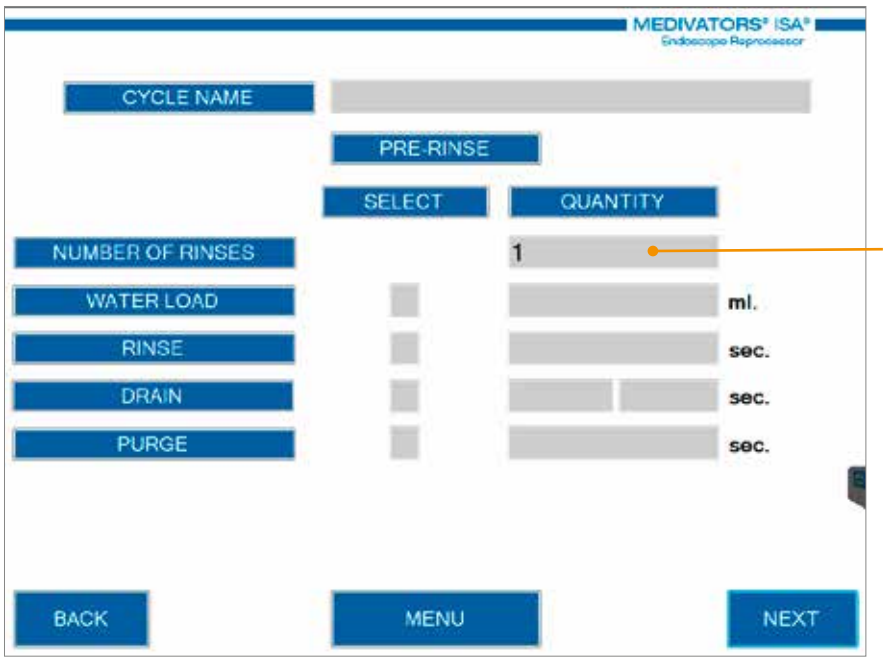
By entering a value in this framework adds a purge during drain.

In this case the drain takes for 60 seconds, of which the last 10 with the addition of air.

Flag for selection phase.

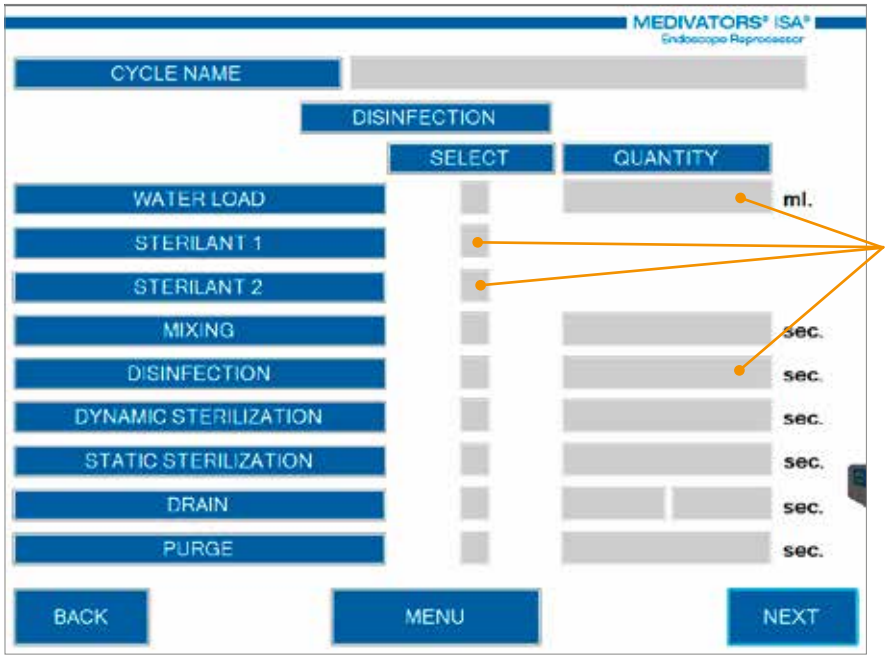
Box to enter a value:
The units of measure are specified to the right of the pane.

Page 2 - RINSE AFTER CLEANING



Number of consecutive rinse (default value is 1)

Page 3 - DISINFECTION

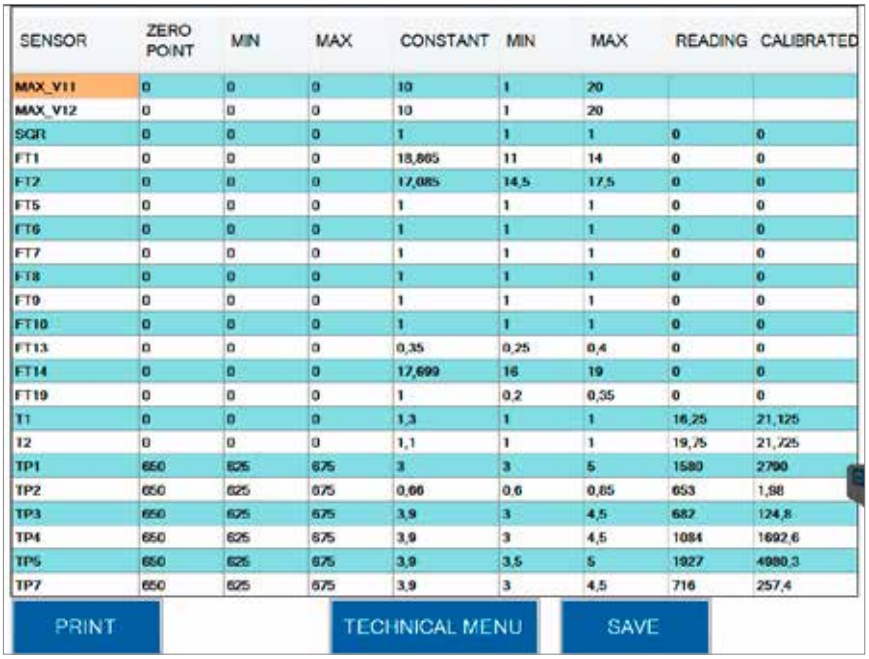


Page 4 - FINAL RINSE

* If you don't set this , it will be automatically be calculated.

Returning to the main screen of PROGRAMS, typing DELETE, will ask you to confirm deletion before proceeding:

CALIBRATIONS



SENSOR	ZERO POINT	MIN	MAX	CONSTANT	MIN	MAX	READING	CALIBRATED
MAX_V11	0	0	0	10	1	20		
MAX_V12	0	0	0	10	1	20		
SQR	0	0	0	1	1	1	0	0
FT1	0	0	0	18,865	11	14	0	0
FT2	0	0	0	17,085	14,5	17,5	0	0
FT5	0	0	0	1	1	1	0	0
FT6	0	0	0	1	1	1	0	0
FT7	0	0	0	1	1	1	0	0
FT8	0	0	0	1	1	1	0	0
FT9	0	0	0	1	1	1	0	0
FT10	0	0	0	1	1	1	0	0
FT13	0	0	0	0,35	0,25	0,4	0	0
FT14	0	0	0	17,699	16	19	0	0
FT19	0	0	0	1	0,2	0,35	0	0
T1	0	0	0	1,3	1	1	16,25	21,125
T2	0	0	0	1,1	1	1	19,75	21,725
TP1	650	625	675	3	3	5	1580	2790
TP2	650	625	675	0,66	0,6	0,85	653	1,98
TP3	650	625	675	3,9	3	4,5	682	124,8
TP4	650	625	675	3,9	3	4,5	1084	1692,6
TP5	650	625	675	3,9	3,5	5	1927	4980,3
TP7	650	625	675	3,9	3	4,5	716	257,4

PRINT TECHNICAL MENU SAVE

The following are specified commands and columns on the page:

A. Zero value of equation that describes the behavior of the sensor (editable within the limits MIN and MAX in columns b and c);

B. Minimum value assignable to the zero value of the equation that describes the behavior of the sensor (non- modifiable);

C. Maximum value assignable to the zero value of the equation that describes the behavior of the sensor (non- modifiable);

D. Constant value that describes the behavior of the sensor (adjustable within the limits set by MIN and MAX);

E. Minimum value assignable to the constant equation that describes the behavior of the sensor (fixed);

F. Maximum value assigned to the constant that describes the behavior of the sensor (fixed);

G. Value read by the sensor (eg. FT-1 has counted 100 pulses: 100 reads) (fixed);

H. Sensor value reported values to the desired (eg. FT-1 has counted 100 pulses: reads 100 * 16.5 = 1650) (modified);

I. Button to save the settings;

J. Button to return to the TECHNICAL MENU;

K. Button by which you can make a printout of the settings entered. For example, a report setting looks like this:

For example, a report setting looks like this:

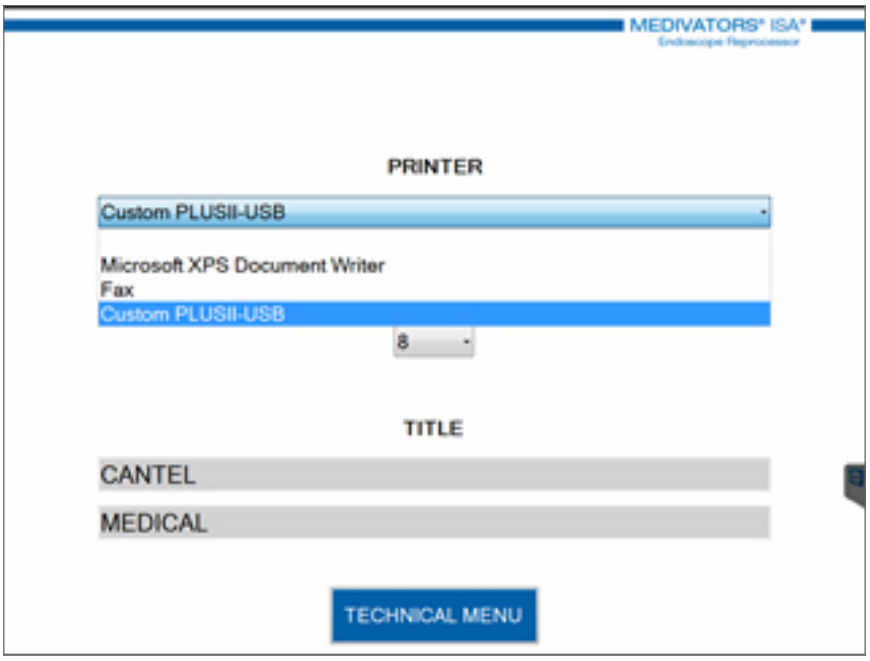
```
Medivators ISA

21/12/2015 12:45:04

MAX_V11 0      10
MAX_V12 0      10
SGR     0      1
FT1     0      16.5
FT2     0      16.5
FT5     0      1
FT6     0      1
FT7     0      1
FT8     0      1
FT9     0      1
FT10    0      1
FT13    0      0.9
FT14    0      16.5
FT19    0      1
T1      0      1
T2      0      1
TP1     650    4.2
TP2     650    0.66
TP3     650    3.9
TP4     650    3.9
TP5     650    4.2
TP7     650    3.9
```

Where the columns are reported in the press about the columns A and D of the screen.

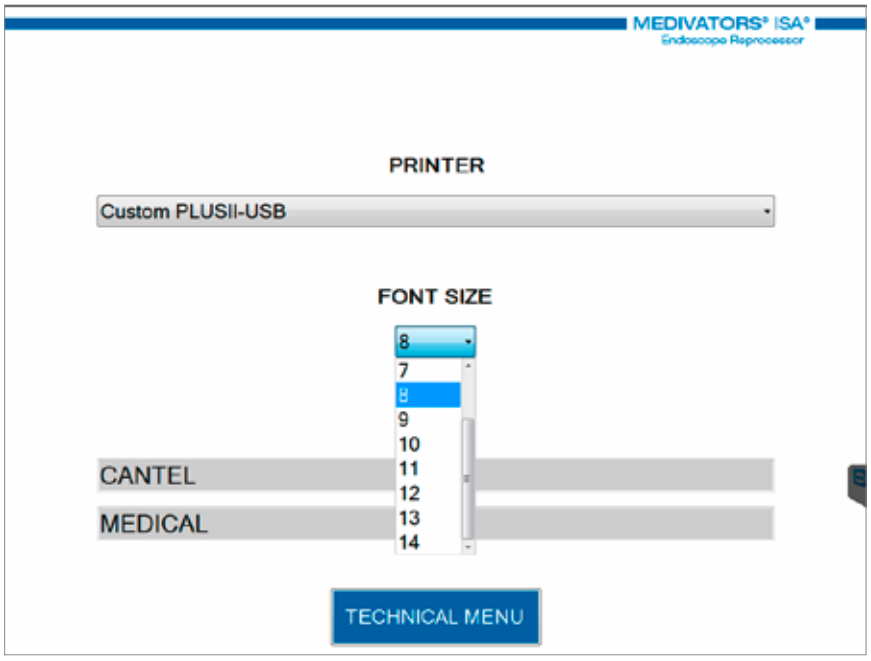
PRINTER

The printers displayed on this page have already been installed on PC.

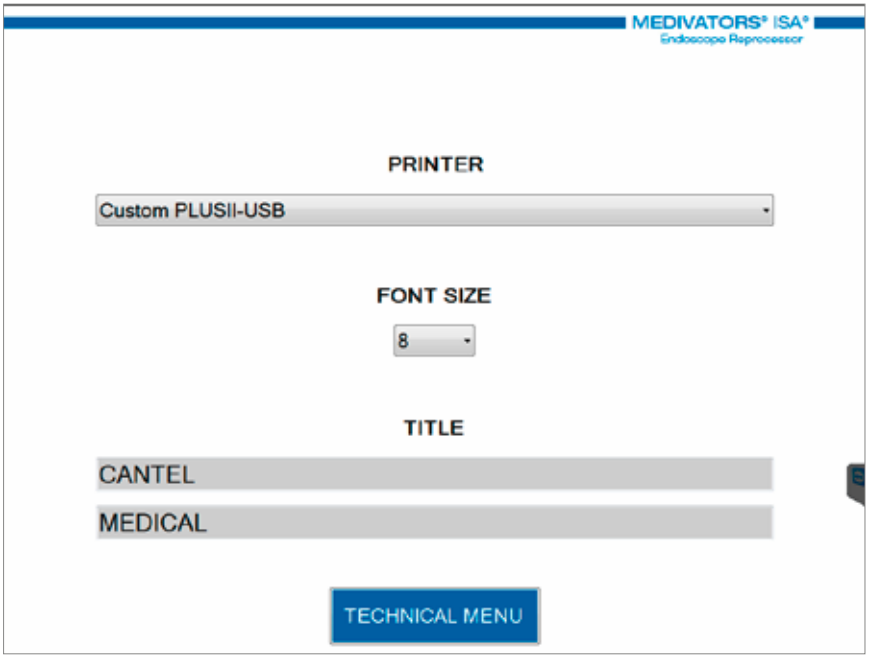
Select the printer from the list



Select font size



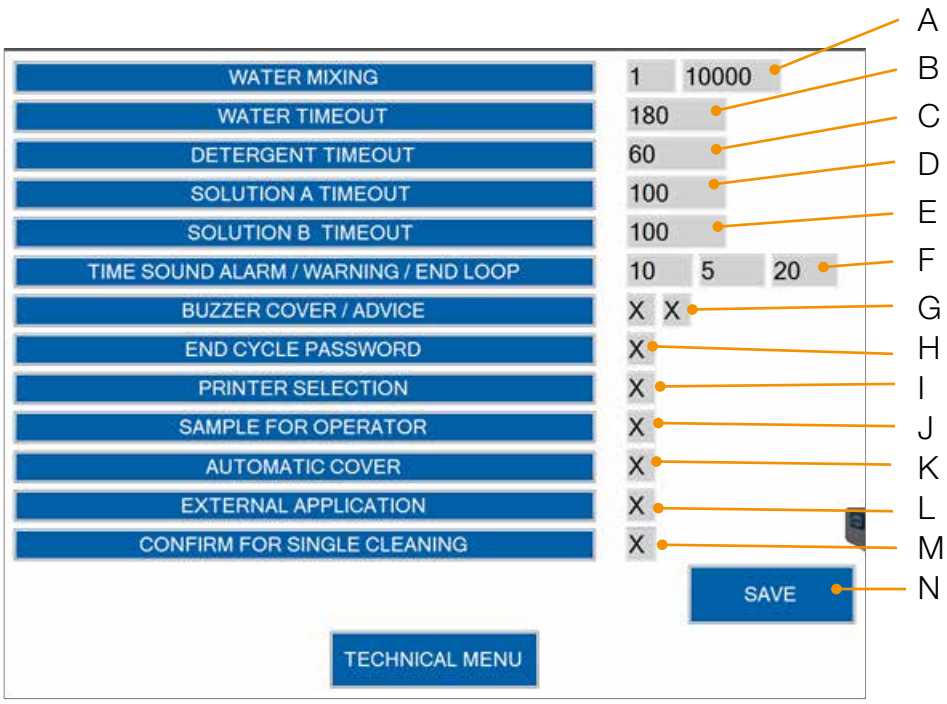
Insert the header that will be used on each report



To close the first column of the functions of the TECHNICAL MENU are:

- The command that closes the program and allows access to the windows screen: CLOSE THE APPLICATION;
- The command returns the screen to the MAIN PAGE: ESC.

In the central column of the TECHNICAL MENU, you find, starting from the top, the SETTINGS function, which gives access the following page:



A. The two columns represent: one, on the right, the quantity of water (in ml) as to get into the basin (with simultaneous drain) before signaling the temperature alarm, if the water temperature is not within the range 20-30°C; the other value, on the left, is the number of times that you want to repeat this attempt before giving the temperature alarm;

B. Maximum time (in seconds) beyond which the alarm is generated time out water load;

C. Time maximum (in seconds) beyond which the alarm is generated time out detergent load;

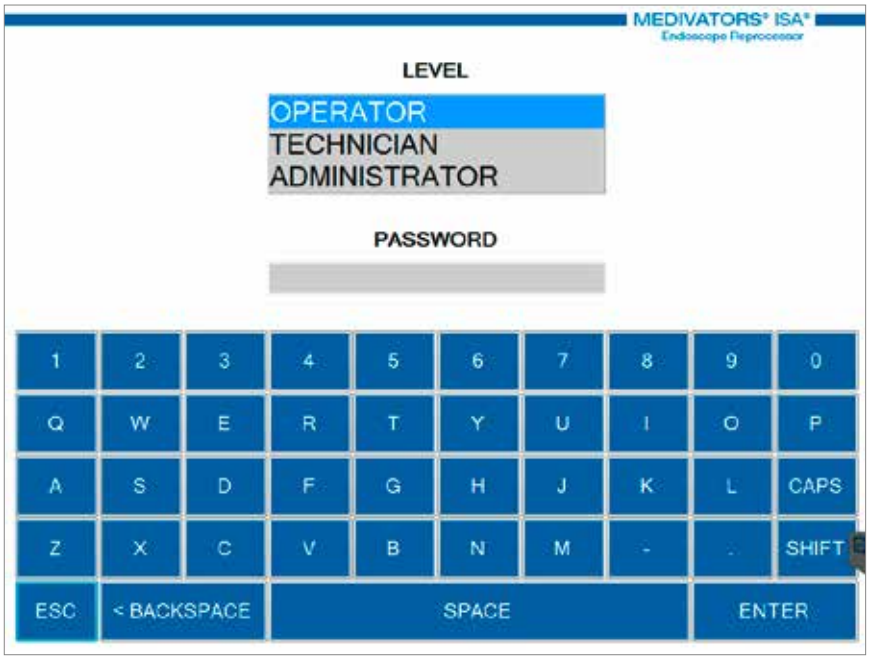
D. Time maximum (in seconds) beyond which the alarm is generated time out Solution A load;

E. Time maximum (in seconds) beyond which the alarm is generated time out Solution B load;

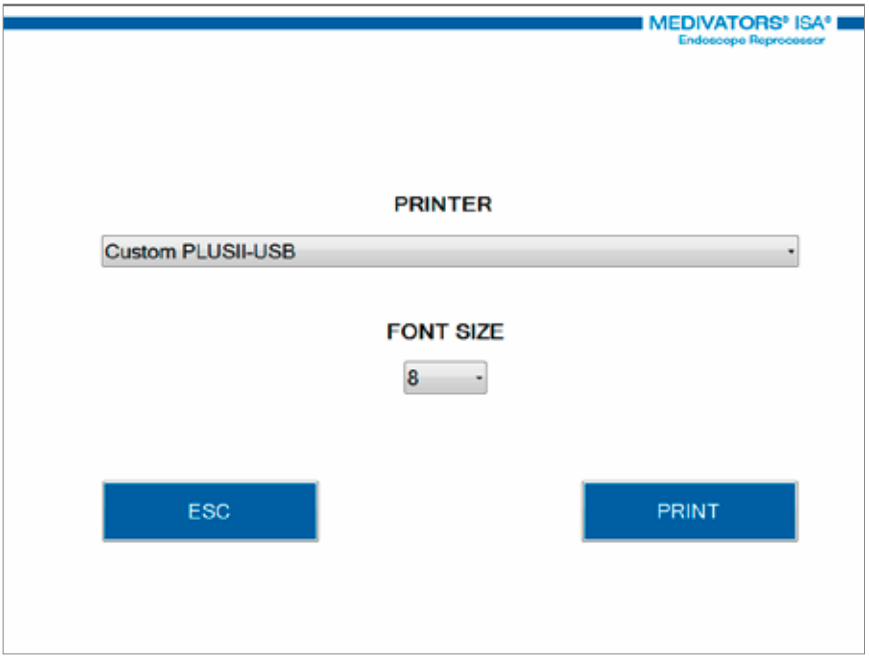
F. Time range that elapses between a sound and another in the three cases shown at the left;

G. Set beep in the present cases to the left;

H. Activation password request at the end of its re-processing: if activated does not allow the opening of the lid when it is done the user recognition. The page that is activated at the end of each cycle is:



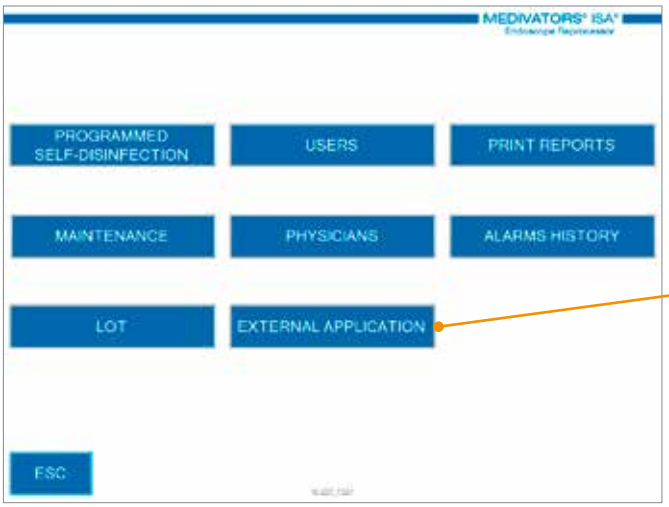
I. At the end of the cycle, it doesn't print by default but requires the printer on which to print the report and the size of the font. The page that appears is the following:

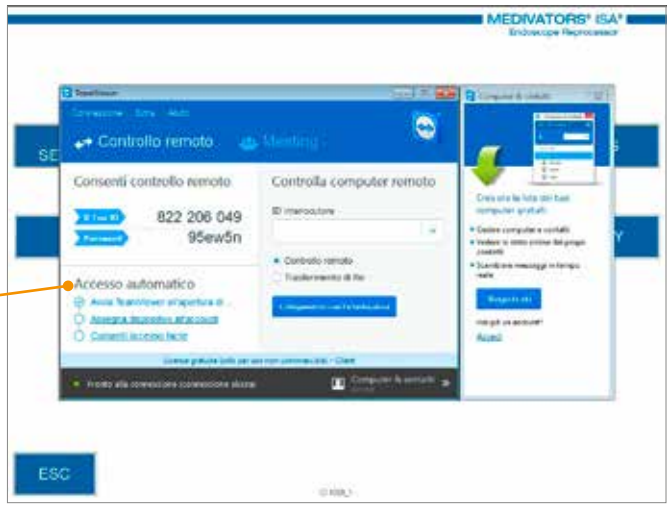


J. Activates the pickup for performance qualification of DM to users with operator level (The function will be explained in Chapter 4 - Performance Qualification);

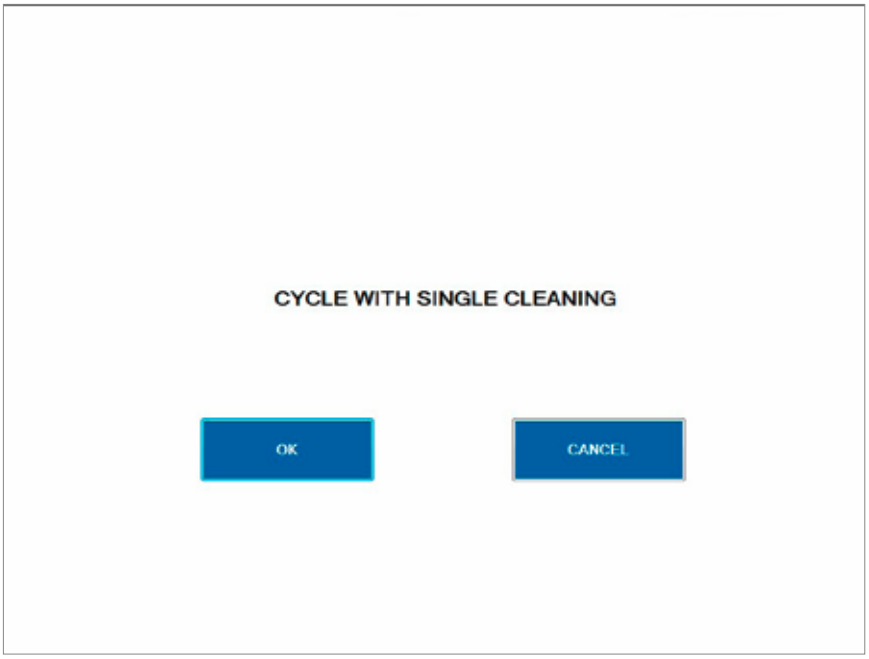
K. Activate the function of opening / closing of the lid by recognition RFID user tag;

L. Activate a button in the MENU' for connection with an external application. For example, if you choice tem viewer for remote control, when you'll digit on this button, the application will be open:



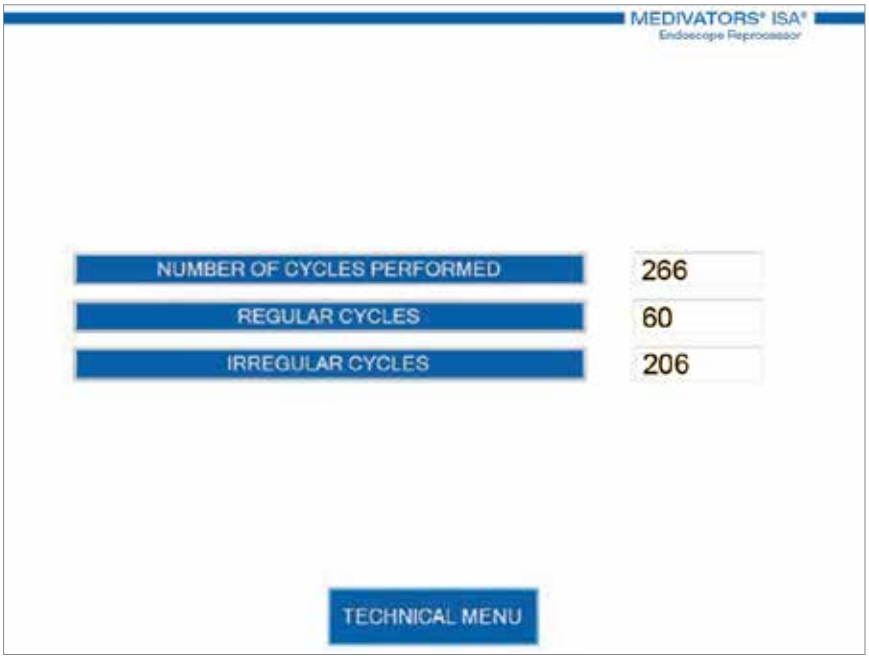


M. Acitvate a request when you select a cycle with a single wash:



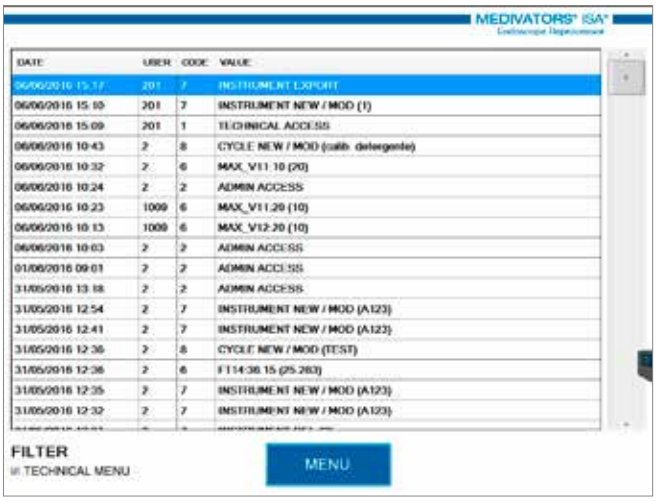
N. Save button for settings;

Continuing in the functions of the TECHNICAL MENU, there is the function INFORMATION, which displays the following page:



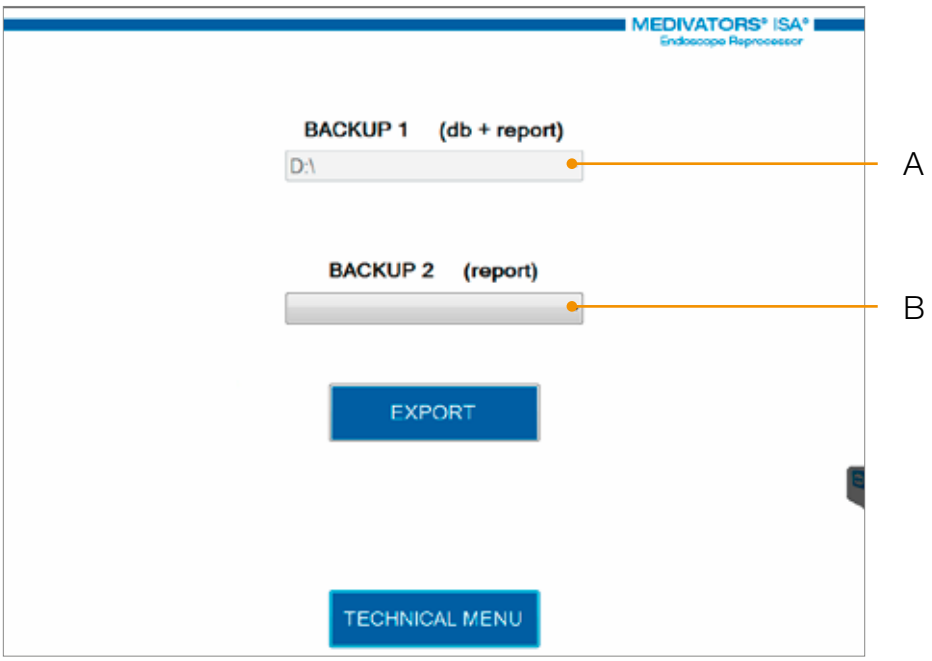
This page shows the cycles performed by the MEDIVATORS™ ISA™ Endoscope Reprocessor, the cycles performed regularly and those with no regular results.

The LOG button gives information on everything that has been done on the MEDIVATORS ISA Endoscope Reprocessor:



The flag on TECHNICAL MENU, if removed, does not show access operations to TECHNICAL MENU.

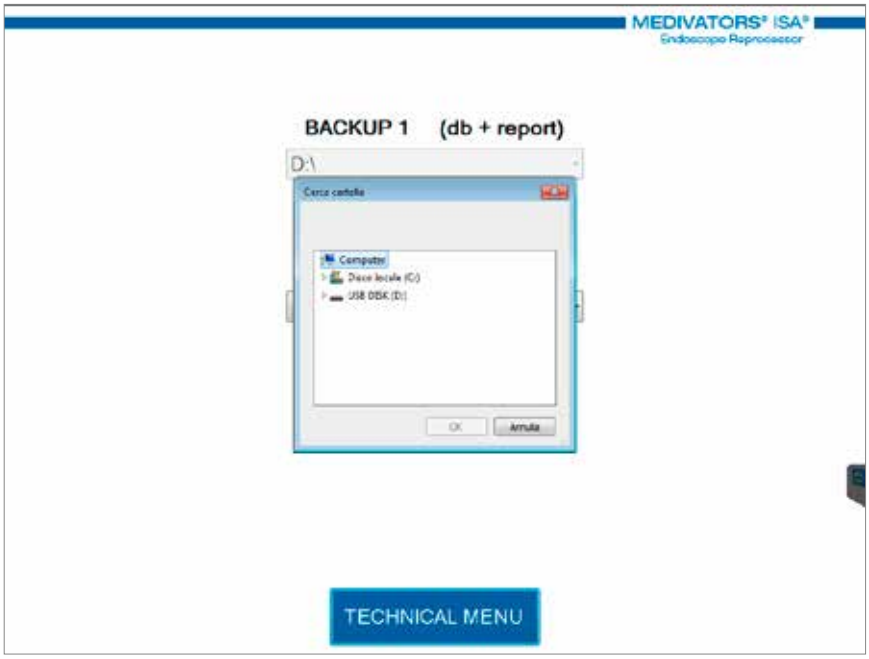
BACKUP button gives access to the following functions:



Where:

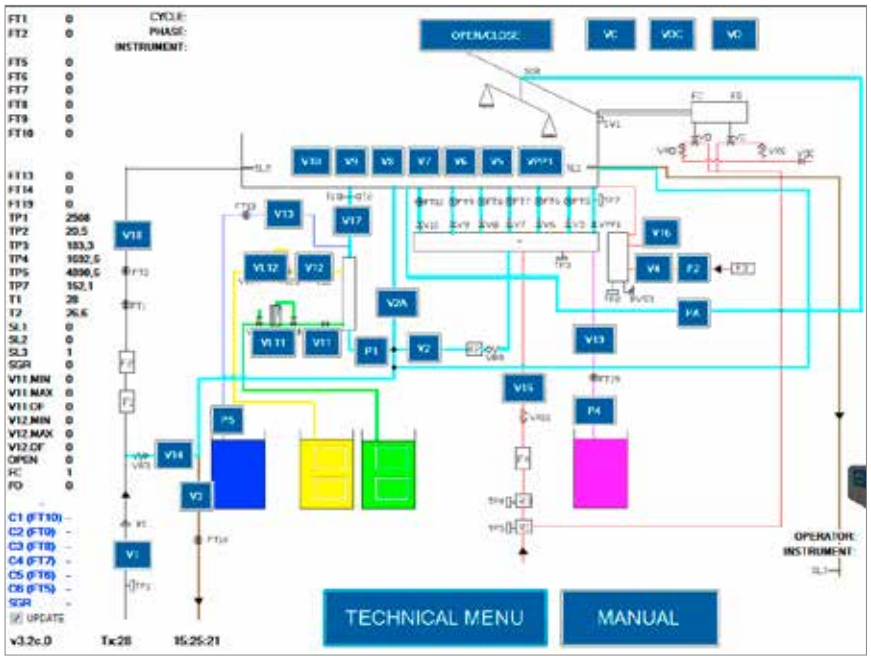
A. Select the drive on which you want to back up the database and reports (selected by the administrators);

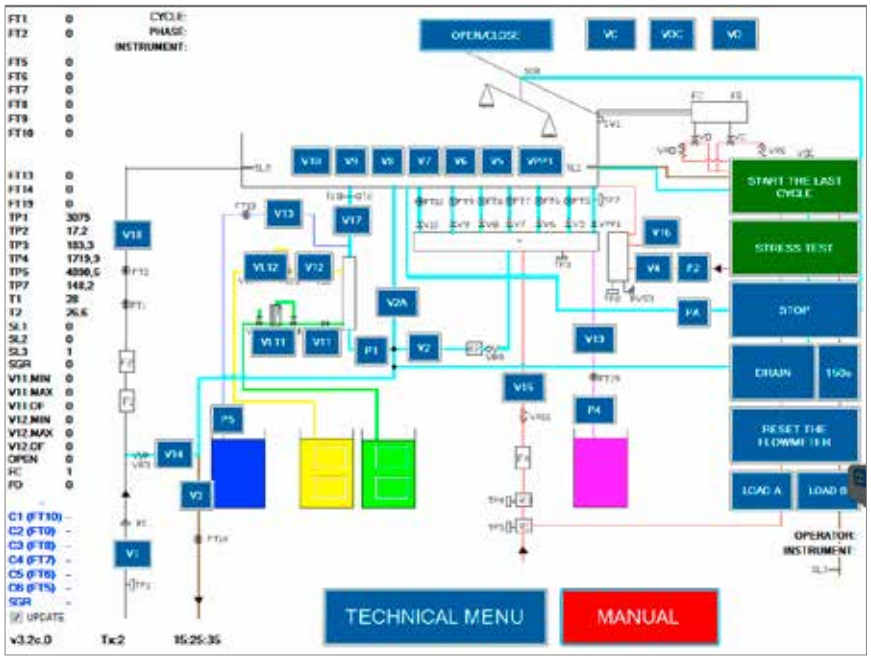
B. Select the drive on which you want to back up reports; Typing on the EXPORT button, you export the database to an external unit selectable from the dropdown shown below:



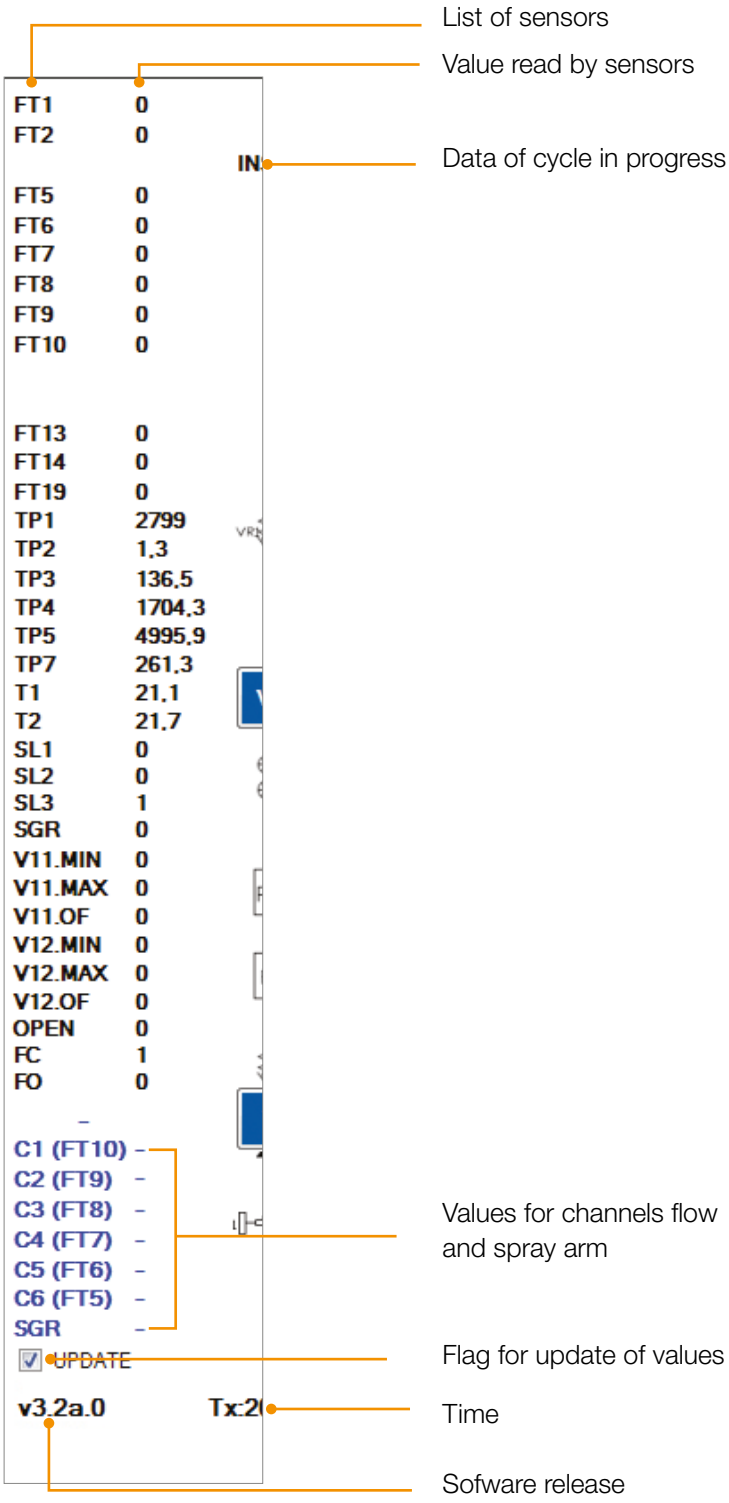
SYNOPTIC

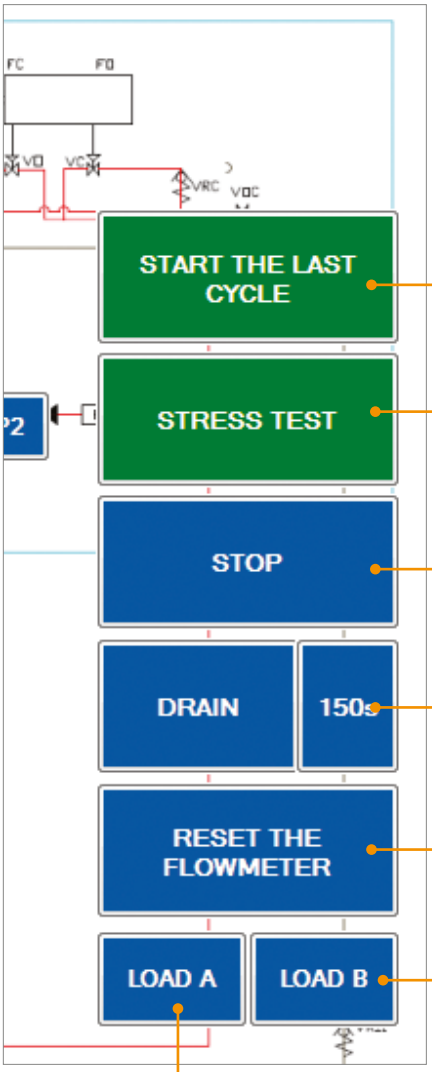
This page shows the hydraulic circuit of the MEDIVATORS™ ISA™ Endoscope Reprocessor, with output selectable manually with the command MANUAL (turn red).





Analyzing this page in detail, you have:





Button for to start the last cycle performed (with the last scope used)

Button to start STRESS TEST (testing the production procedure in the MEDIVATORS™ ISA™ Endoscope Reprocessor system)

Button to stop all operations

Button to start drain for 150s

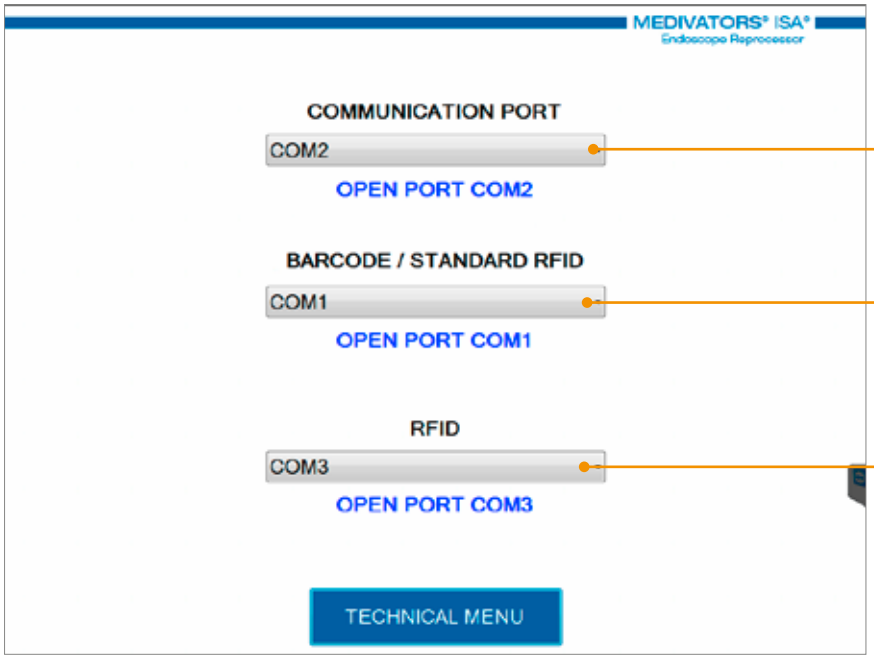
Button to reset flow and spray arm sensor value

Button to start procedure load solution B

Button to start procedure load solution A

Button to activate manual controls

CONNECTION

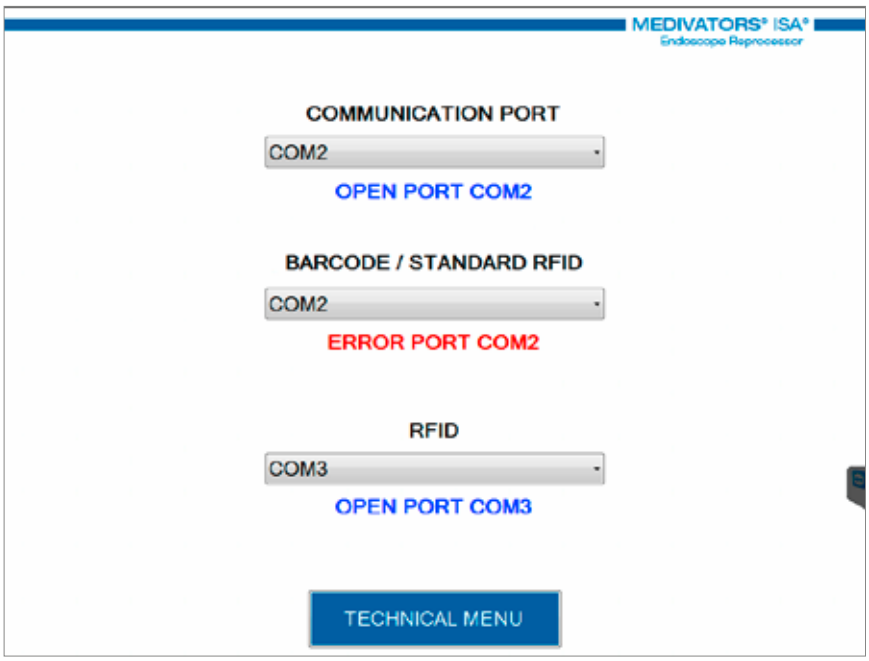


Communication port PC - Electronic boards

Communication port for - Barcode

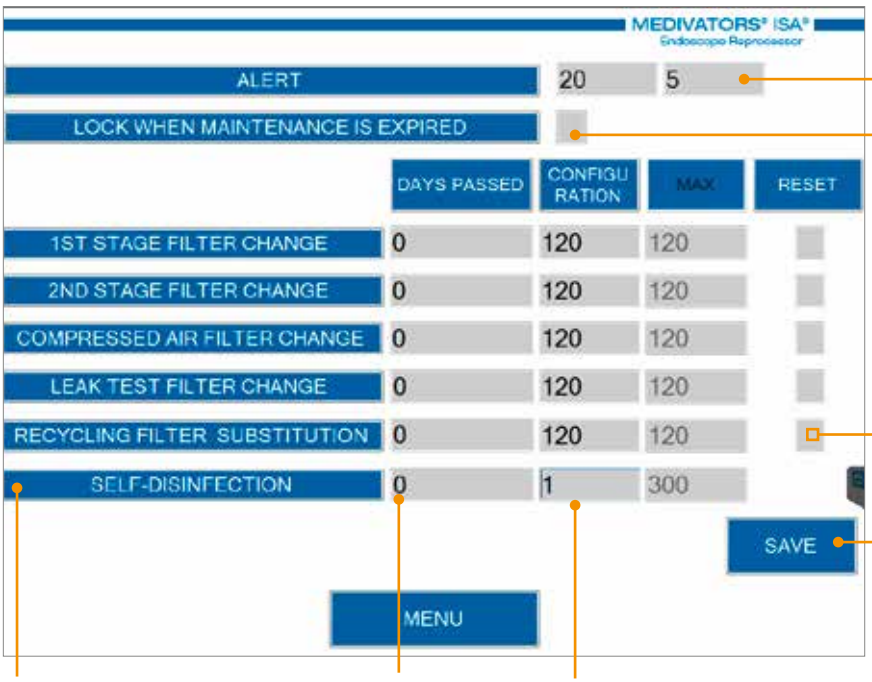
Communication port for - RFID boards

In the case where you select the same port for communications other than an error is generated, visible on the screen:



The last two functions of the TECHNICAL MENU usable by users with operator level are MAINTENANCE and SELECT LANGUAGE.

As regards MAINTENANCE, the screen accessible to the technical level is the following:



Day notice expiration Maintenance * , **

Flag to select for stop machine after expiration maintenance

Flag for reset maintenance

Button to save changes

List of programmed maintenance

Day passed after the last maintenance

Setting days

Maximum setting time*

* They can only be modified by a user with Administrator level;

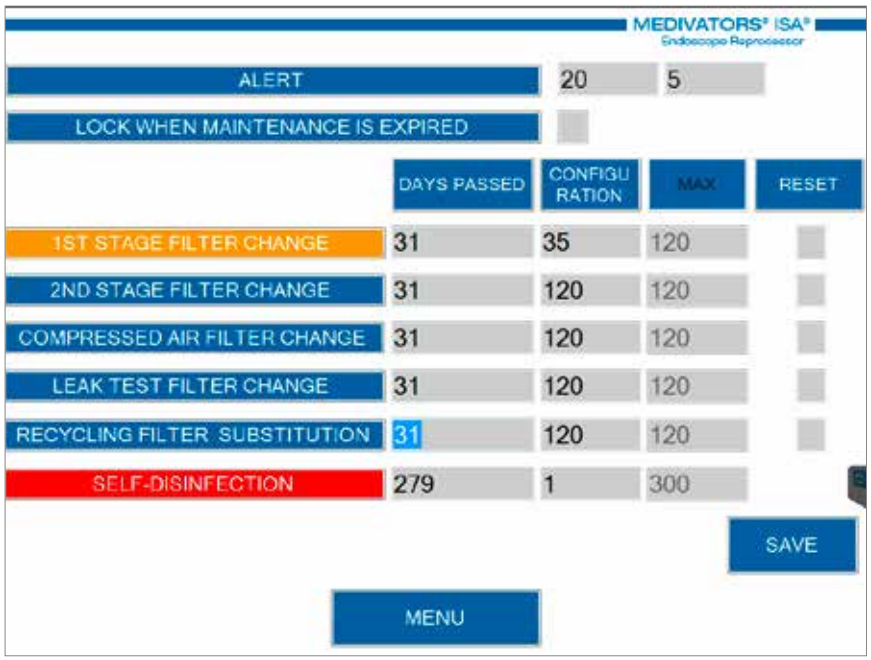
** The two boxes indicate:

*** The value can be set at the maximum equal to the value in the column MAX.

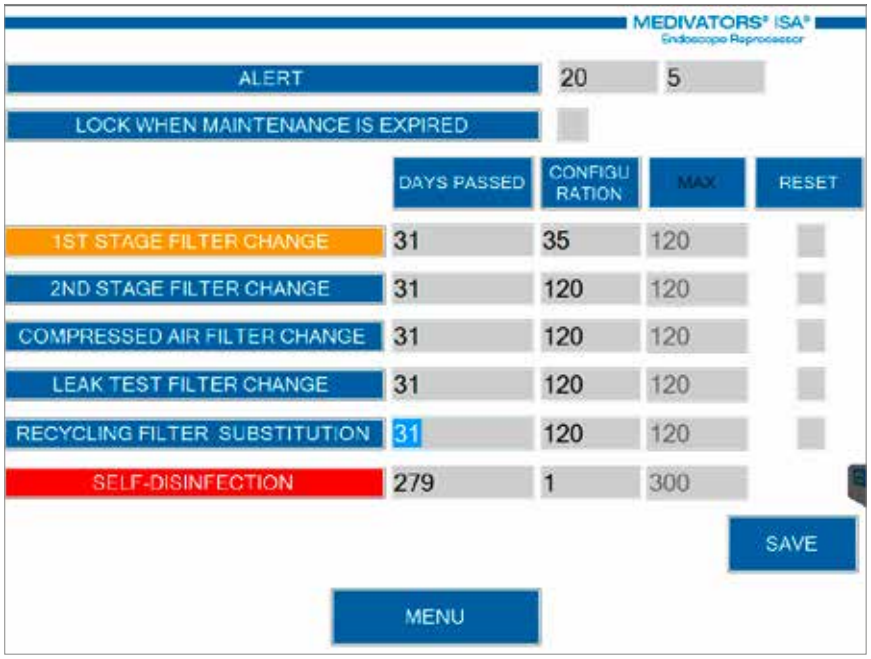
Days set for reporting on the main page expiration maintenance

Days set for flashing warning expiration maintenance before the cycle

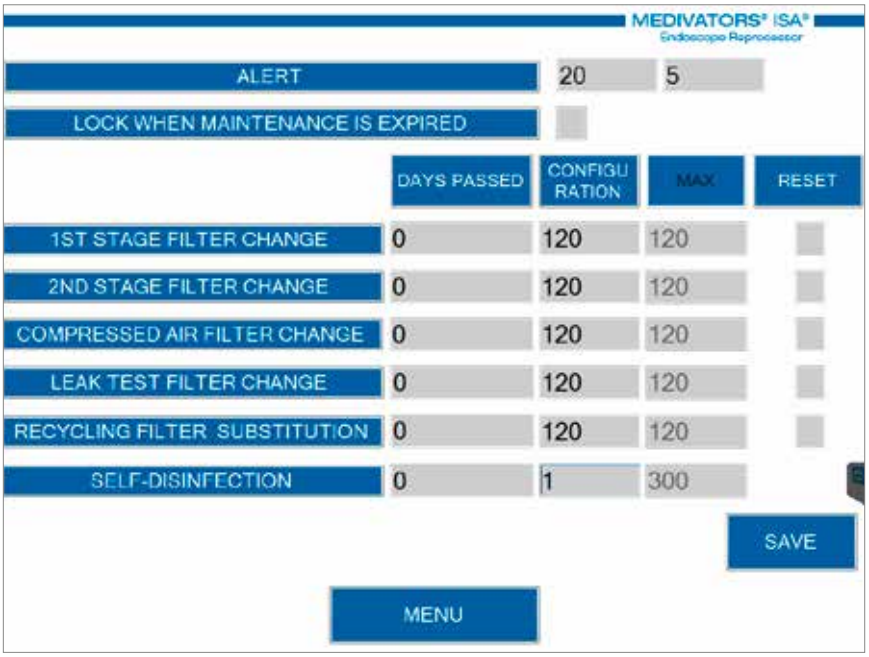
We consider there is a maintenance notice expired (in red) and in expiration (yellow): in this case is not activated lock machine.



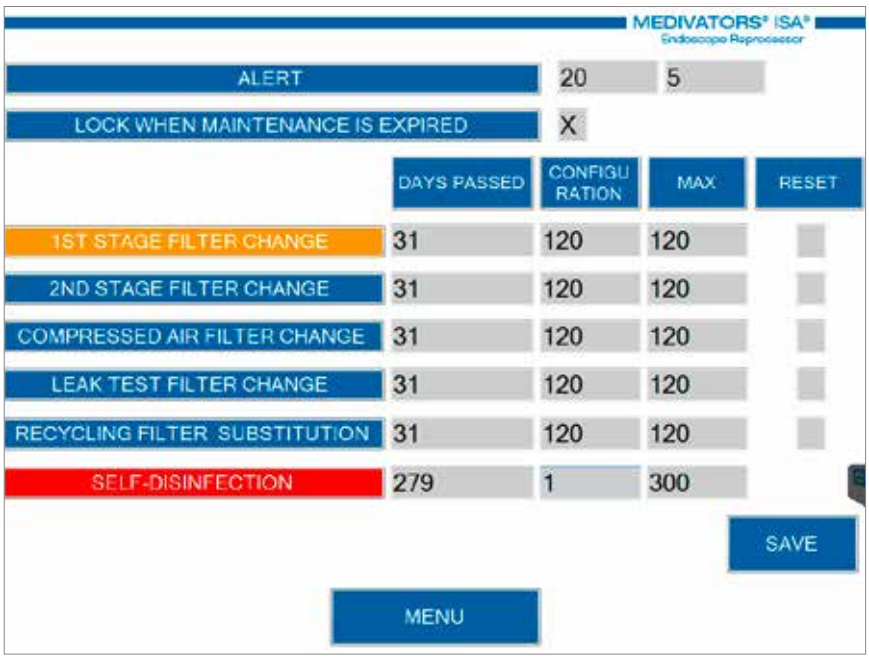
Being self-disinfection, maintenance expired cannot be reset except by starting a cycle of self-disinfection:



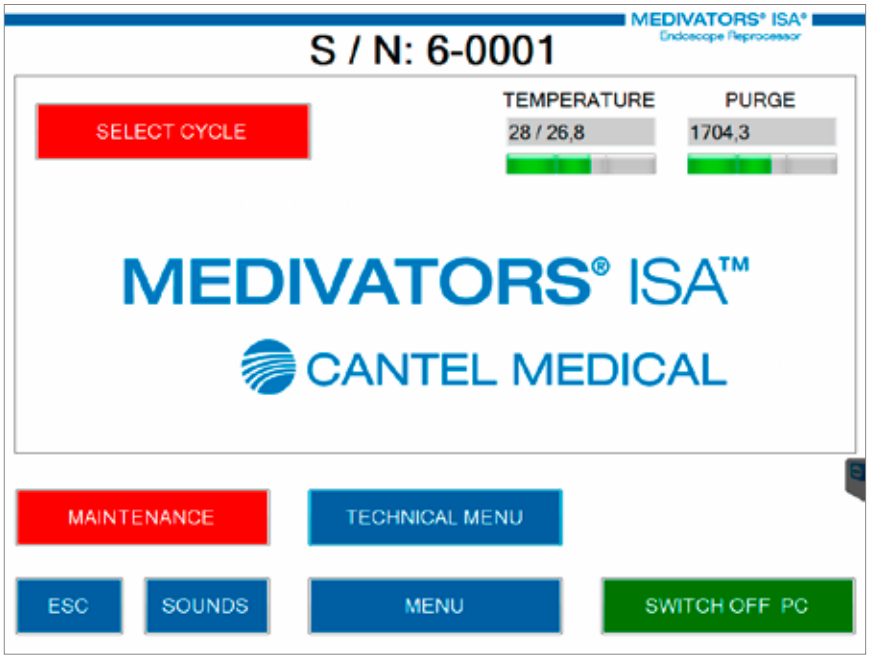
and, after entering the SAVE button, the screen will appear as follows:



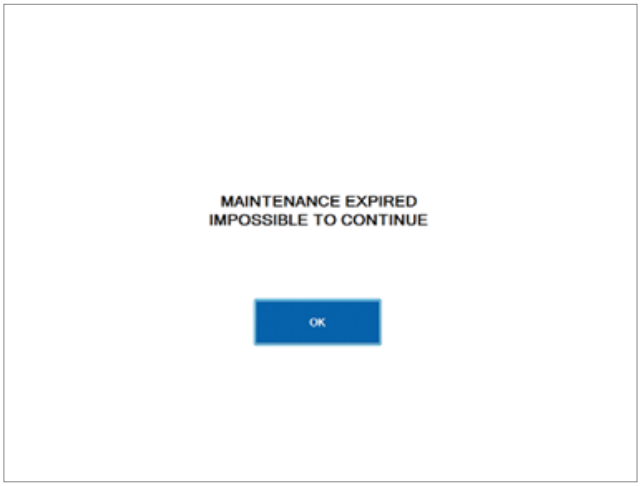
Staying in this menu, with access as ADMINISTRATOR, will be possible by activating the flag described above, lock the machine when maintenance is/are expired:



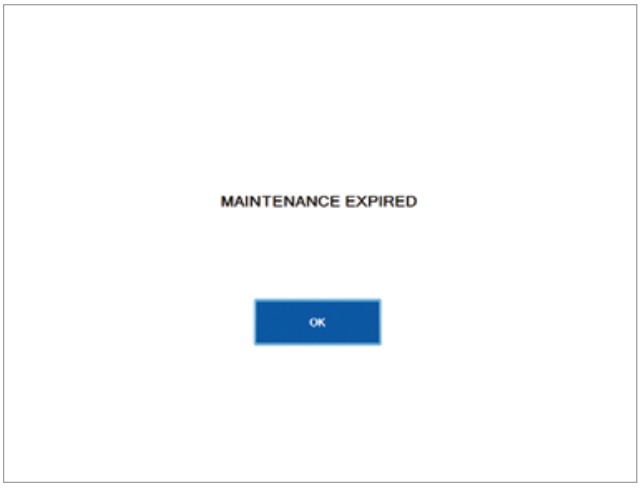
With this option enabled, the main page will appear as below:



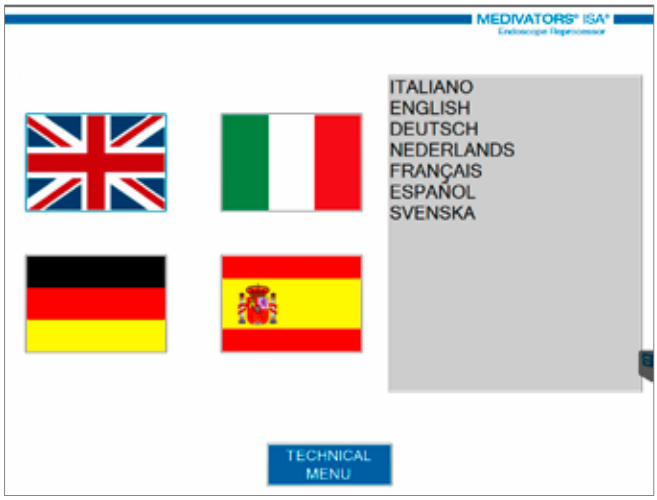
and to attempt to start the cycle, the screen will appear:

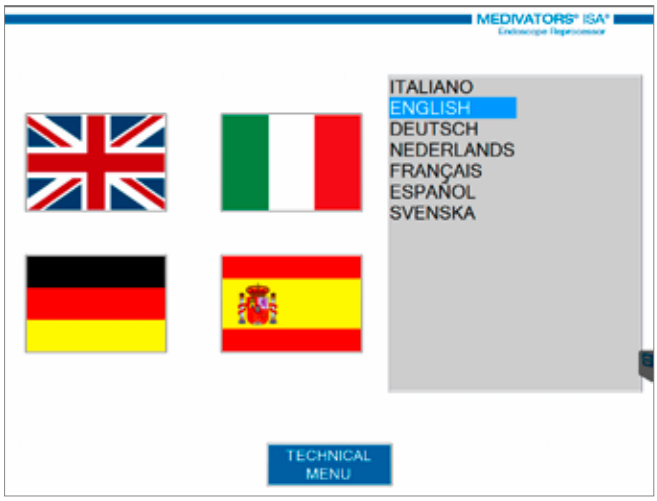


In the case instead, the flag had not been selected, the page would have been:

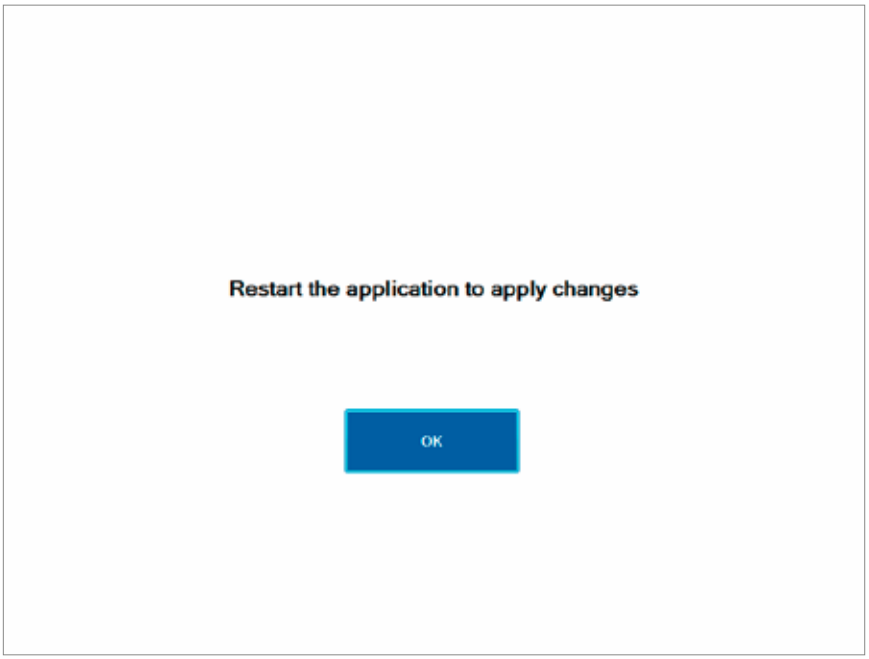


Finally, for what concerns the TECHNICAL MENU, SELECT LANGUAGE is the function, allowing you to change the language of the software *.

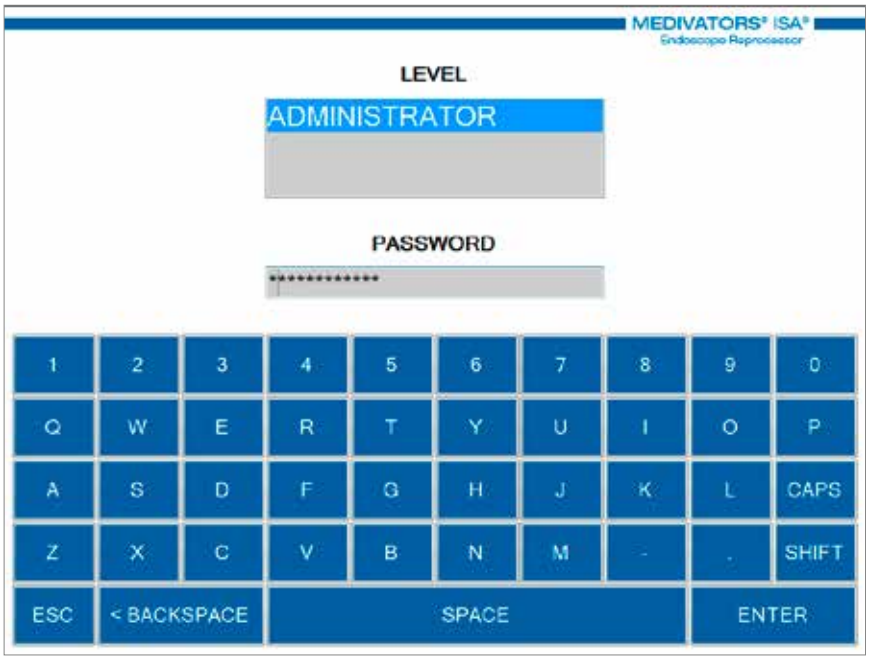




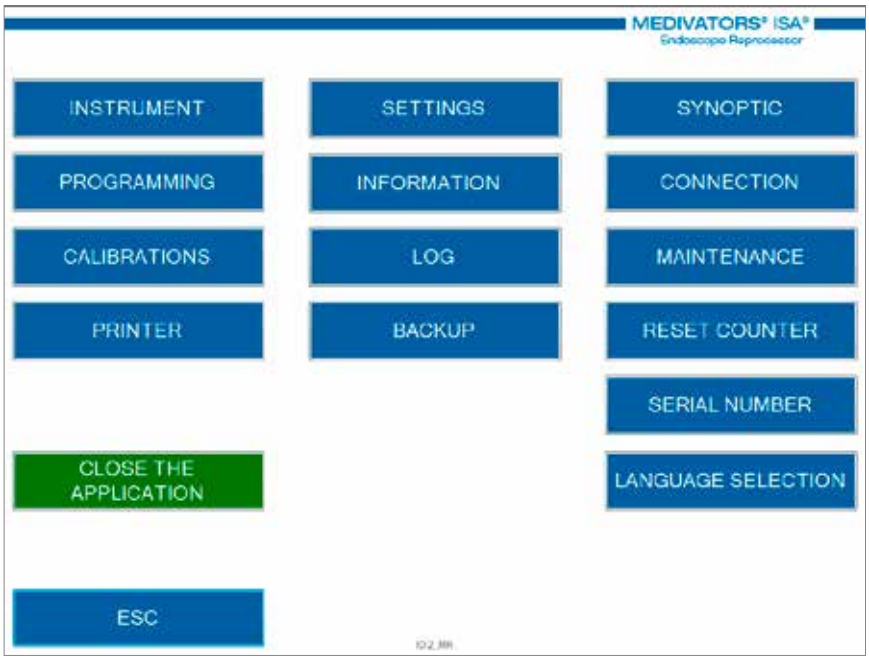
* To make the change necessary to close and restart the software.



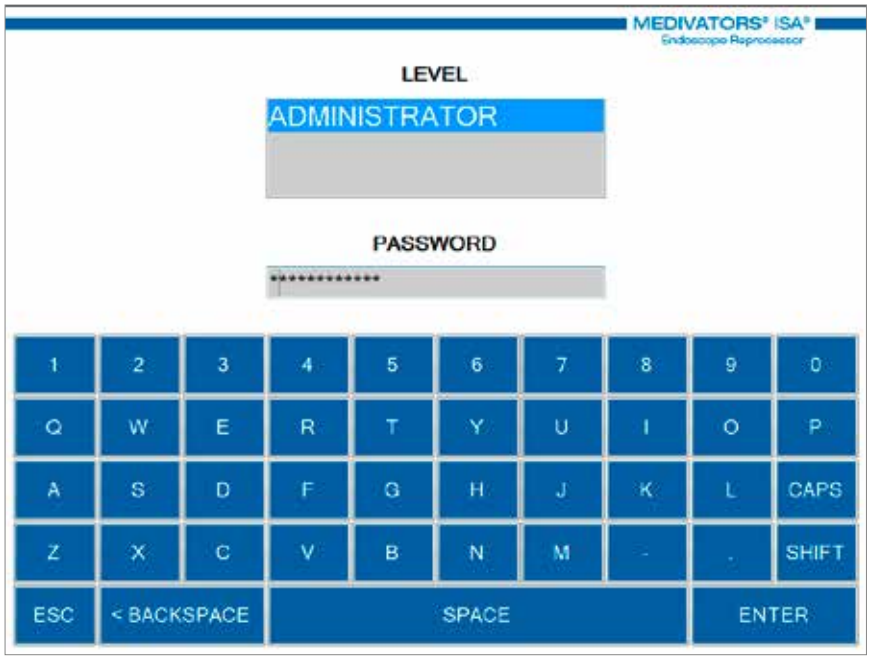
Consider, now, access to the TECHNICAL MENU, with level ADMINISTRATOR:



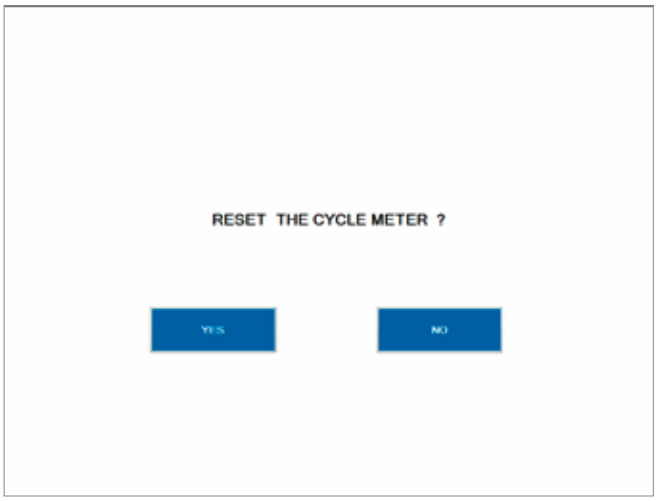
This time, all functions will be accessible, including the functions of COUNTER and RESET input of the SERIAL NUMBER of the MEDIVATORS™ ISA™ Endoscope Reprocessor.

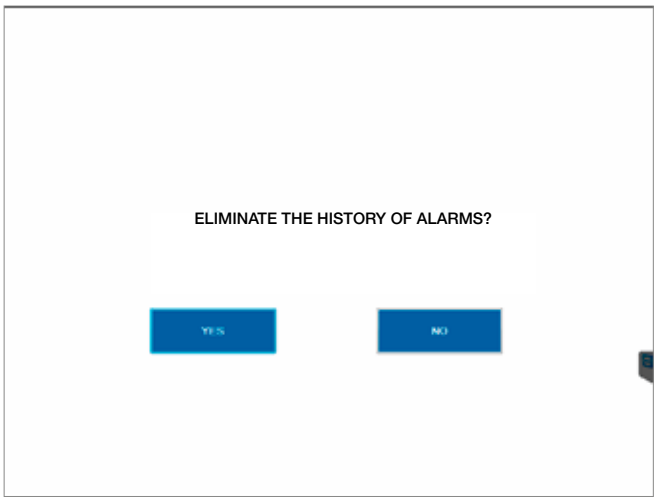


By accessing the RESET COUNTER, you are asked to identify the user accessing the RESET COUNTER, it prompts the user identification:

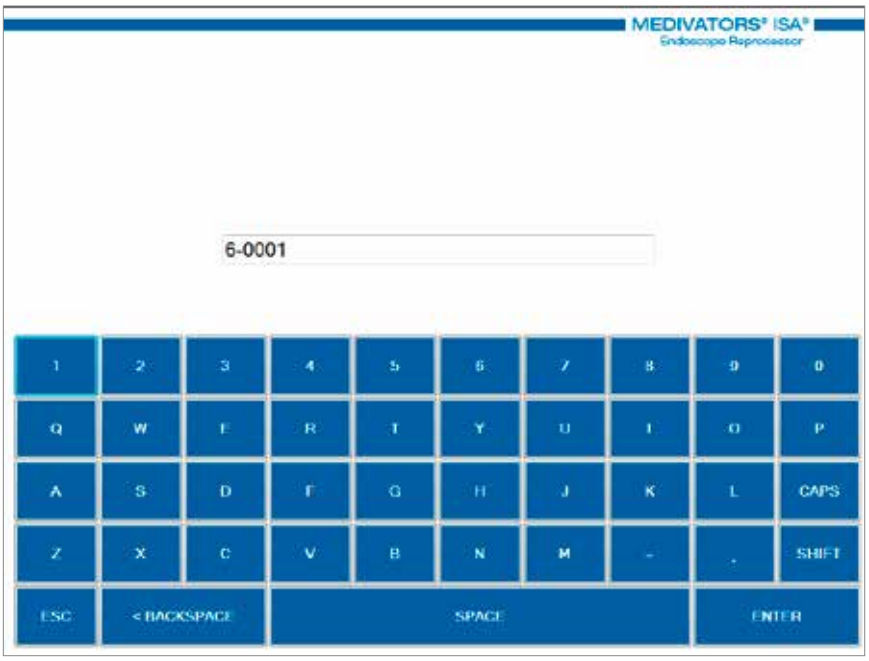


and then you will be asked what is meant reset:

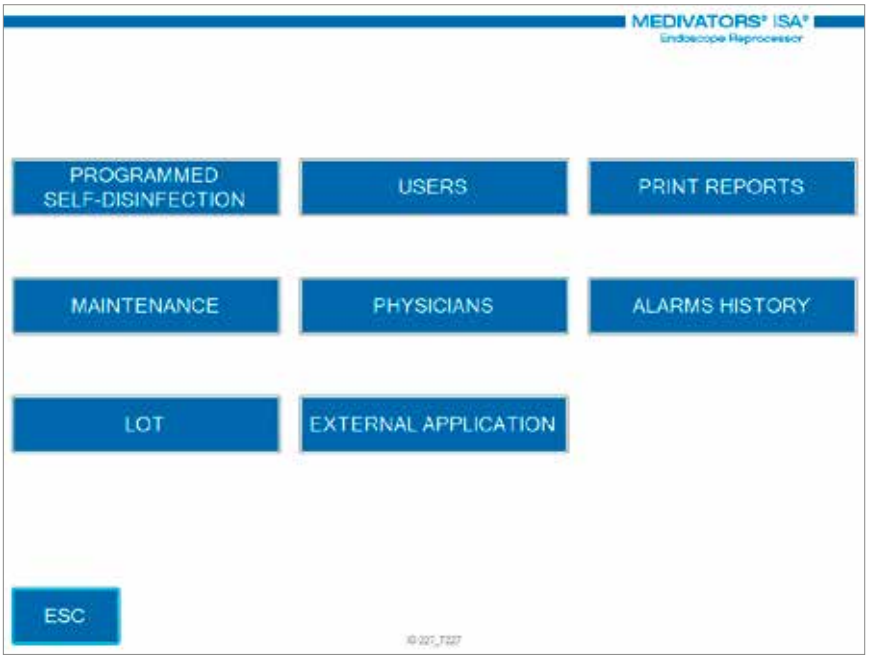




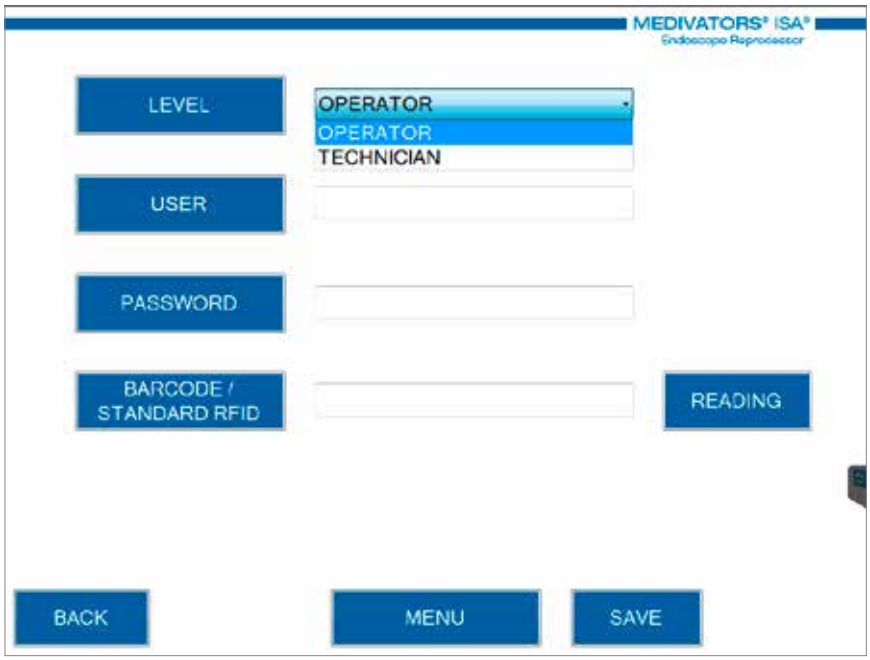
Finally, accessing the function SERIAL NUMBER, after recognition identification, you can enter the serial number of the MEDIVATORS™ ISA™ Endoscope Reprocessor:



The last feature with exclusive access in the MENU:



The level TECHNICAL be enabled with enter with level access and TECHNICAL OPERATOR:



CHAPTER 4

INSTALLATION

This chapter refers to the proper removal from packaging and the setting up of the MEDIVATORS™ ISA™ endoscope reprocessor.

WARNING! The follows operations can only be completed by technicians that are able to do and authorized from manufacturer.

Before installing the MEDIVATORS™ ISA™ Endoscope Reprocessing system carefully read and following the series of steps as described below:

Removal of the primary packaging containing the equipment, and the secondary, containing the accessories for the operation;

1. Position the MEDIVATORS ISA Endoscope Reprocessor in the area it will be installed and used (Installation Qualification);
2. Execution of the settings for the correct operation of the MEDIVATORS ISA Endoscope Reprocessor (Operational Qualification);
3. Carrying out the calibration of endoscopes (if they are not present in the list of the equipment in the database).
4. Verification of the effectiveness of the processes of re-processing (Performance Qualification);
5. Implementation of training for users who will use the equipment;
6. Running a cycle of self-disinfection;
7. The MEDIVATORS ISA Endoscope Reprocessor is ready for use.

ACCESSORIES FOR INSTALLATION MEDIVATORS ISA ENDOSCOPE REPROCESSOR

To enable the correct installation, correct operation and proper use of the MEDIVATORS ISA Endoscope Reprocessor the following list of components is provided:

DESCRIPTION

1. Water intake hose 2 mt. with threaded 3/4 inch.

2. Exhaust pipe extended to 2 meters
   Diameter of the drain connection 19 / 26mm.

3. Power cord with plug type Schuko length 1.5 m.

4. Compressed air hose screened dato 2 mt.

5. Compressed air and No.2 ties squeeze-tube

6. Connection for self-disinfection

7. User Manual.
8. Service Manual.

9. Tag RFID operator.
10. Tag RFID endoscope.

11. Connections for endoscopes

12. Uptake tubes

13. Water Filters

14. OPTIONAL- BreakTank.

15. External air compressor.

16. Water mixer

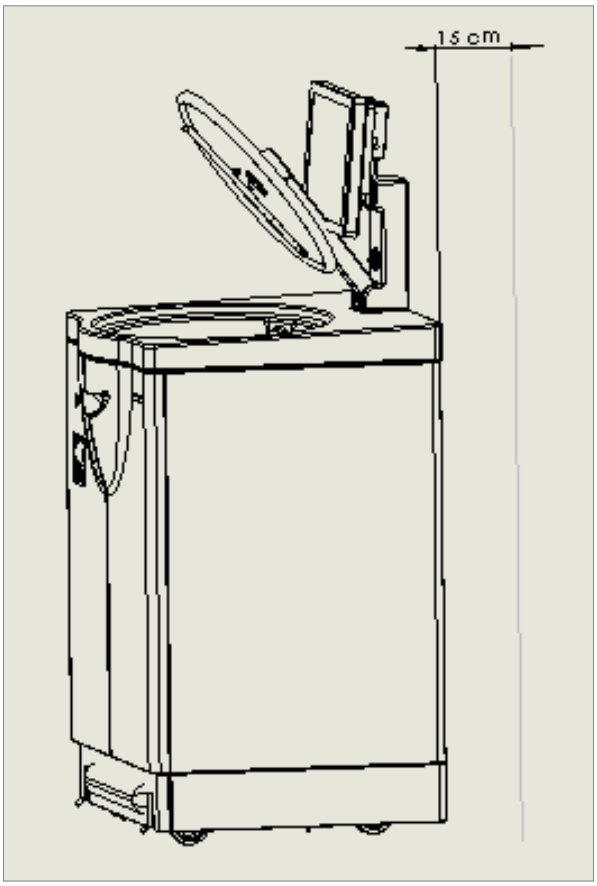
INSTALLATION PROCEDURE FOR THE MEDIVATORS™ ISA™ ENDOSCOPE REPROCESSING SYSTEM

After removing the primary packaging, release the brakes on the frontal wheels and move the machine in the chosen location:

Lever down = locked wheels

Lever up = unlocked wheels

Considering the following minimum requirement for installation:



1. Make the following connections:

Nº.	Connection	Point	Accessories (Description N.)
1	Load Water	1	1
2	Drain	2	2
3	Compressed Air	3	4+4a
4	Electrical Supply	4	3
5	Extraction Fumes	5	OPTIONAL

2. Turn on the electrical power:

3. Turn on the PC and wait for the MEDIVATORS™ ISA™ Endoscope Reprocessor software program to start;

4. Open the valves of the water and adjust the mixer until obtaining a water temperature between 20°C and 30°C.

5. Open the valves of the compressed air and check on the main page that the pressure of the drying air is in the required range:

6. To connect chemical solution tanks.

SETTINGS FOR MEDIVATORS™ ISA™ ENDOSCOPE REPROCESSOR

The settings of MEDIVATORS ISA Endoscope Reprocessor consist of a series of operations, made to verify that the sensors deputies to check the success of the operations are set correctly.

To carry out the operations, make sure to have the following equipment, properly calibrated and working:

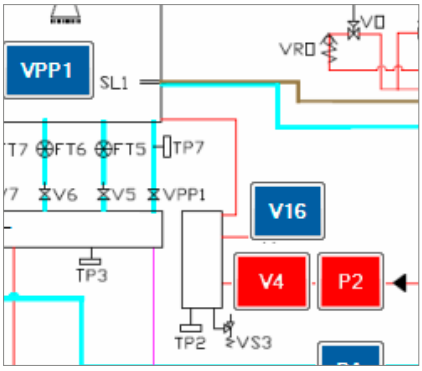
EQUIPMENT FOR CHECK
TEMPERATURE PROBE
ELECTRONIC SCALE
DIGITAL MANOMETER

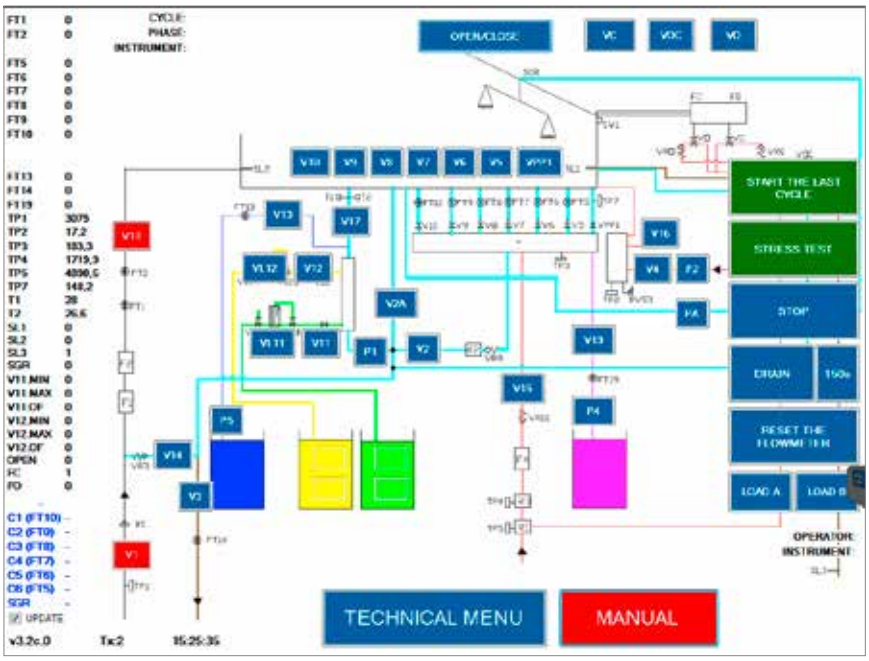
To proceed, turn on the device and access the TECHNICAL MENU, following the instructions in Chapter 3, using the functions SYNOPTIC and CALIBRATIONS and using (when required) the menu SELECT CYCLE.

TP2 CALIBRATION: LEAK TEST PRESSURE TRANSDUCER

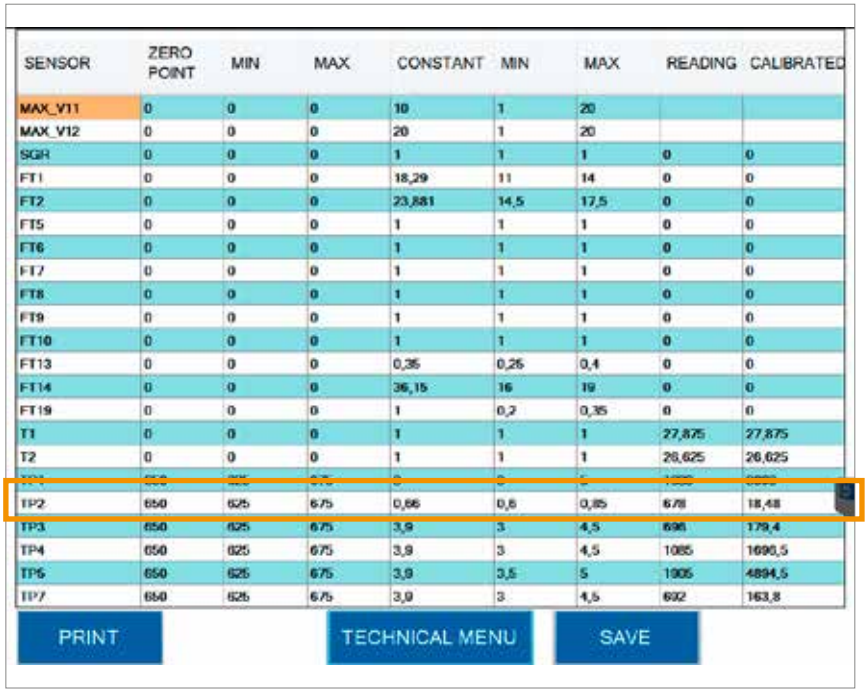
a. Connect the digital pressure manometer to the leak test line.

b. In the Synoptic screen push MANUAL button to activate manual mode (red button is active) and manually activated valve V4 and pump P2 (in this sequence) and then after TP2 reach 240mbar press STOP button.

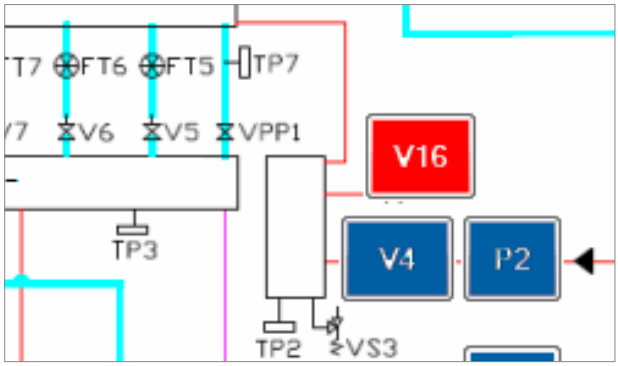




c. Check if TP2 pressure transducer indicated the allowed ± 10 % range value of digital pressure manometer. If not, change the value in the CALIBRATION screen (CALIBRATED columns) as digital manometer indicate and then push SAVE button.



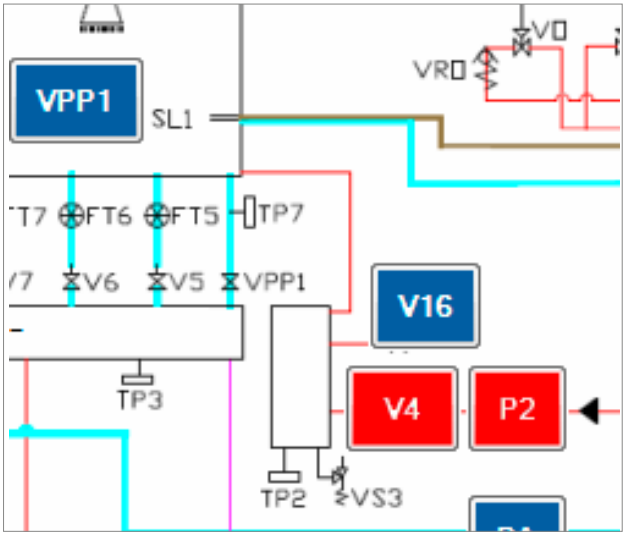
d. Activate valve V16 to drop the air pressure in the leak test line and press STOP button. Check again TP2 pressure transducer starting from point b.



LEAK TEST RELIEF VALVE CHECK

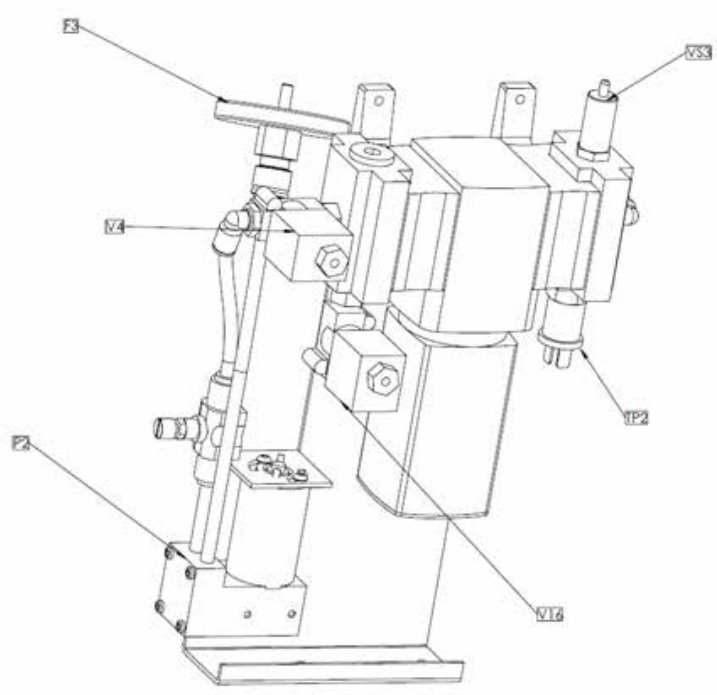
a. Connect the 78401-444 hookup (self-disinfection hookup) into the basin

b. In the Synoptic screen push MANUAL button to activate manual mode (red button is active) and manually activated valve V4 and pump P2 (in this sequence).



c. When the TP2 pressure transducer is over 500 mbar push STOP button and check, after 10/15 seconds, if the pressure indicated by TP2 transducer is above 450mbar. If the pressure is under 500mbar (e.g. 480mbar) it is good anyway.

e. Activate valve V16 to drop the air pressure in the leak test line and press STOP button.

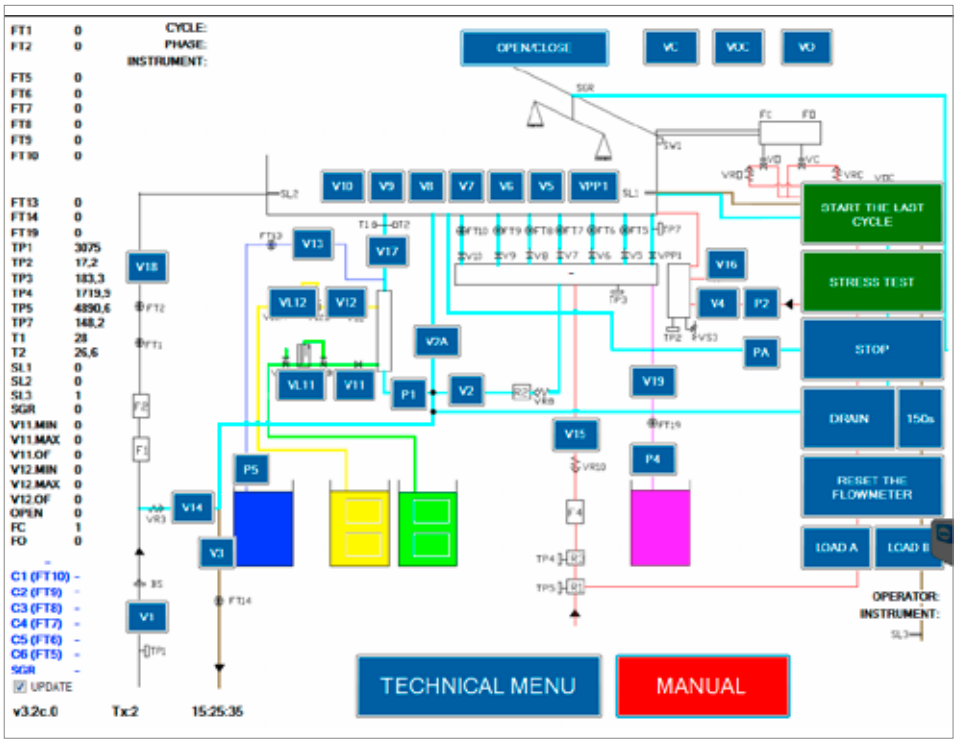


f. Check relief pressure again starting from point b.

PRESSURE TRANSDUCER CALIBRATION: TP3 (CHANNEL PRESSURE), TP4 (AIR PURGE PRESSURE), TP7 (ELEVATOR CHANNEL TRANSDUCER)

a. Connect the digital pressure manometer to the elevator channel line .

b. In the Synoptic screen push MANUAL button to activate manual mode (red button is active) and manually activated valve VPP1 (elevator valve) and then valve V15 (air purge valve)



c. Check if TP3, TP4 and TP7 pressure transducer indicated the allowed ± 10 % range value of digital pressure manometer.

d. If not, change the value in the CALIBRATION screen (CALIBRATED columns) as digital manometer indicate and then push SAVE button.

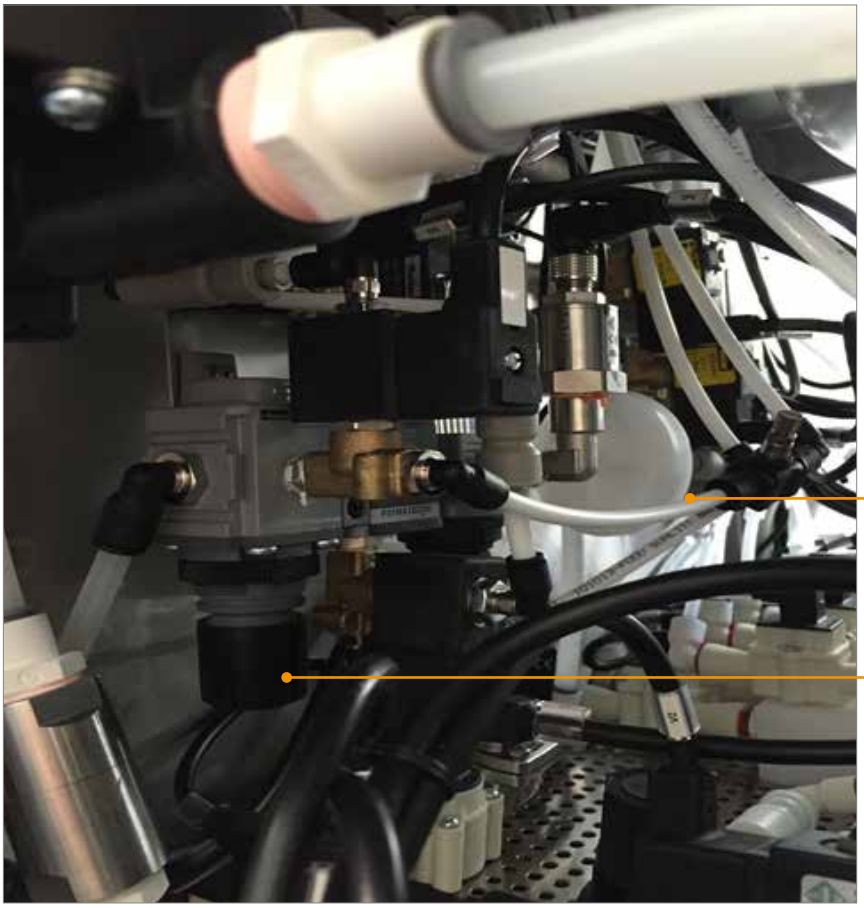
SENSOR	ZERO POINT	MIN	MAX	CONSTANT	MIN	MAX	READING	CALIBRATED
MAX_V11	0	0	0	10	1	20		
MAX_V12	0	0	0	20	1	20		
SGR	0	0	0	1	1	1	0	0
FT1	0	0	0	18,29	11	14	0	0
FT2	0	0	0	23,881	14,5	17,5	0	0
FT5	0	0	0	1	1	1	0	0
FT6	0	0	0	1	1	1	0	0
FT7	0	0	0	1	1	1	0	0
FT8	0	0	0	1	1	1	0	0
FT9	0	0	0	1	1	1	0	0
FT10	0	0	0	1	1	1	0	0
FT13	0	0	0	0,35	0,25	0,4	0	0
FT14	0	0	0	36,15	16	19	0	0
FT19	0	0	0	1	0,2	0,35	0	0
T1	0	0	0	1	1	1	27,875	27,875
T2	0	0	0	1	1	1	26,625	26,625
TP1	650	625	675	3	3	5	1680	3090
TP2	650	625	675	0,66	0,6	0,85	678	18,48
TP3	650	625	675	3,9	3	4,5	696	179,4
TP4	650	625	675	3,9	3	4,5	1085	1696,5
TP5	650	625	675	3,9	3,5	5	1905	4894,5
TP7	650	625	675	3,9	3	4,5	692	163,8

PRINT TECHNICAL MENU SAVE

e. Check again TP3, TP4 and TP7 pressure transducer starting from point b

PRESSURE TRANSDUCER TP5 CALIBRATION - LID AIR PRESSURE

a. With the lid close, disconnect the tube from the open lid valve (as indicated in the picture below) and connect the digital pressure manometer at the valve output black coupling



b. In the synoptic screen, push manual command and, manually, activate VC and VB valves

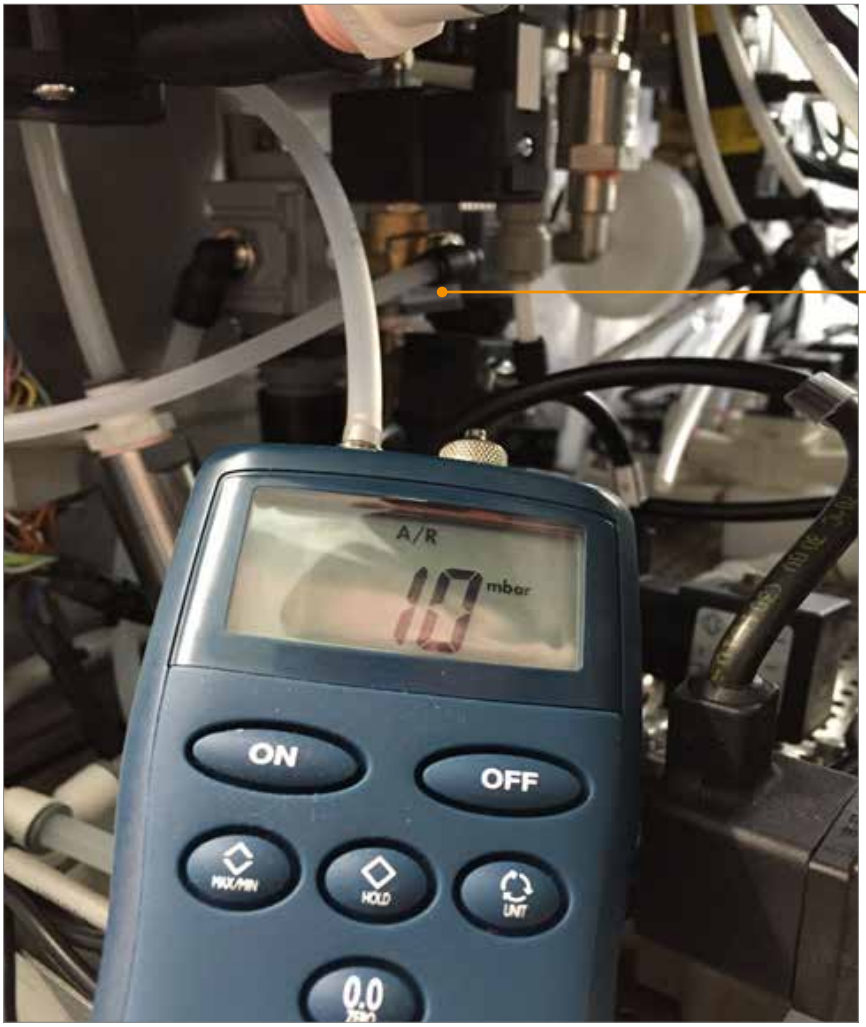
c. The lid air pressure must be between 4000 mbar and 6000 mbar (static pressure)

d. Set the pressure about 5000 mbar using the R1 regulator (remember to fix the regulator cap after the setting)

e. If necessary de-activate VB valve and activate it again after few seconds, to check pressure again

f. Check the value on the digital manometer pressure and then set TP5 with the same value in the CALIBRATION screen (CALIBRATED columns) then push SAVE button.

g. Restore air line connection as originally positioned



Connect The Digital Manometer To The Output Lid Valve Coupling And Push The Foot-Switch To Check The Incoming Pressure

SENSOR	ZERO POINT	MIN	MAX	CONSTANT	MIN	MAX	READING	CALIBRATED
MAX_V11	0	0	0	10	1	20		
MAX_V12	0	0	0	20	1	20		
SGR	0	0	0	1	1	1	0	0
FT1	0	0	0	18,29	11	14	0	0
FT2	0	0	0	23,881	14,5	17,5	0	0
FT5	0	0	0	1	1	1	0	0
FT6	0	0	0	1	1	1	0	0
FT7	0	0	0	1	1	1	0	0
FT8	0	0	0	1	1	1	0	0
FT9	0	0	0	1	1	1	0	0
FT10	0	0	0	1	1	1	0	0
FT13	0	0	0	0,35	0,25	0,4	0	0
FT14	0	0	0	36,15	16	19	0	0
FT19	0	0	0	1	0,2	0,35	0	0
T1	0	0	0	1	1	1	27,875	27,875
T2	0	0	0	1	1	1	26,625	26,625
TP1	650	625	675	3	3	5	1680	3090
TP2	650	625	675	0,66	0,6	0,85	678	18,48
TP3	650	625	675	3,9	3	4,5	696	179,4
TP4	650	625	675	3,9	3	4,5	1085	1696,5
TP5	650	625	675	3,9	3,5	5	1905	4894,5
TP7	650	625	675	3,9	3	4,5	682	163,8

PRINT TECHNICAL MENU SAVE

R3 CALIBRATION: AIR PURGE PRESSURE REDUCER

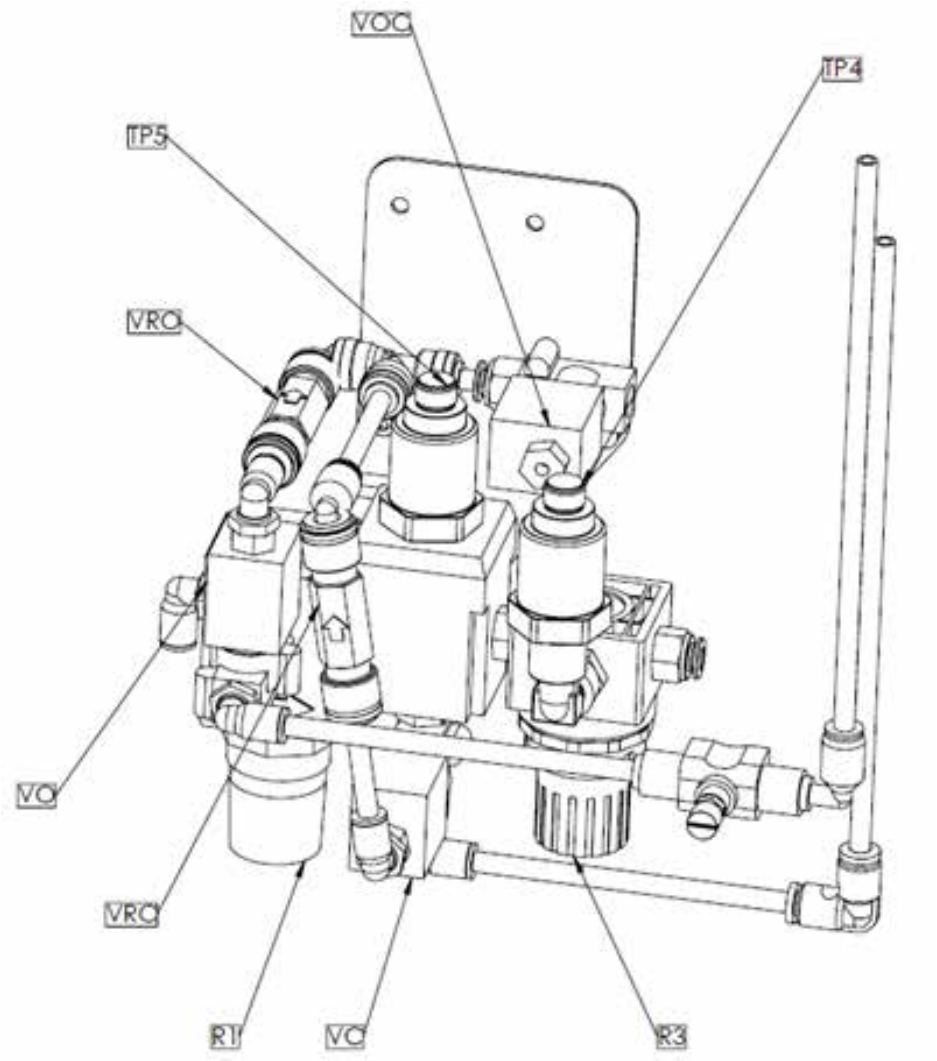
a. Connect the 78401-444 hookup (self-disinfection hookup) into the basin

b. In the Synoptic screen push MANUAL button to activate manual mode (red button is active) and manually activated valve V15 (air purge valve), open and close few times valve VVP1 (elevator valve) and check the TP4 transducer value when VPP1 is closed.

c. The TP4 (air purge transducer) value must be at 1700mba ± 10%

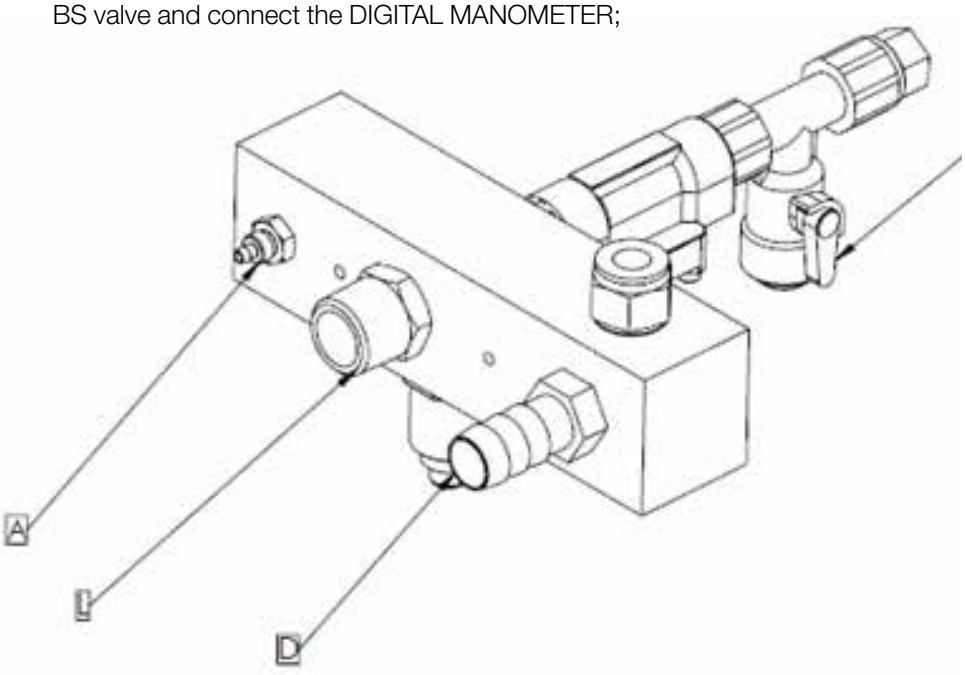
d. If the TP4 value is not correct, open and close manually for few times valve VPP1 to set the correct value using the R3 air regulator (located in the inlet air manifold). With valve VPP1 open, calibrate the air regulator with valve VPP1 close check the TP4 pressure transducer.

e. After the regulation, fix the regulator cap and push the STOP button



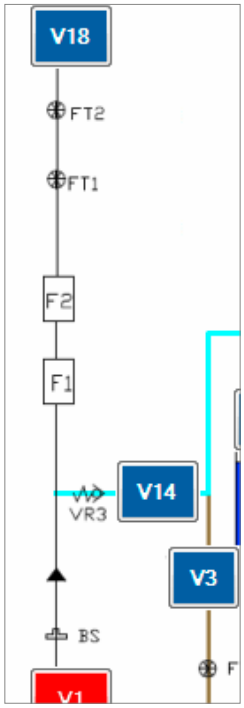
TP1 CALIBRATION: INLET WATER TRANSDUCER

a. Disconnect the tube 3/8” out of Back Siphonage BS valve and connect the DIGITAL MANOMETER;



Disconnect The Tube From The Back Siphonage Output Coupling

b. In the Synoptic screen push MANUAL button to activate manual mode (red button is active) and manually activated the water inlet valve V1, wait few second and push STOP button.



c. The inlet water pressure must max 4000 mbar.

d. Check the pressure of the incoming water on the digital manometer and set the TP1 value in CALIBRATION SCREEN (CALIBRATED columns) as digital manometer indicate and then push SAVE button.

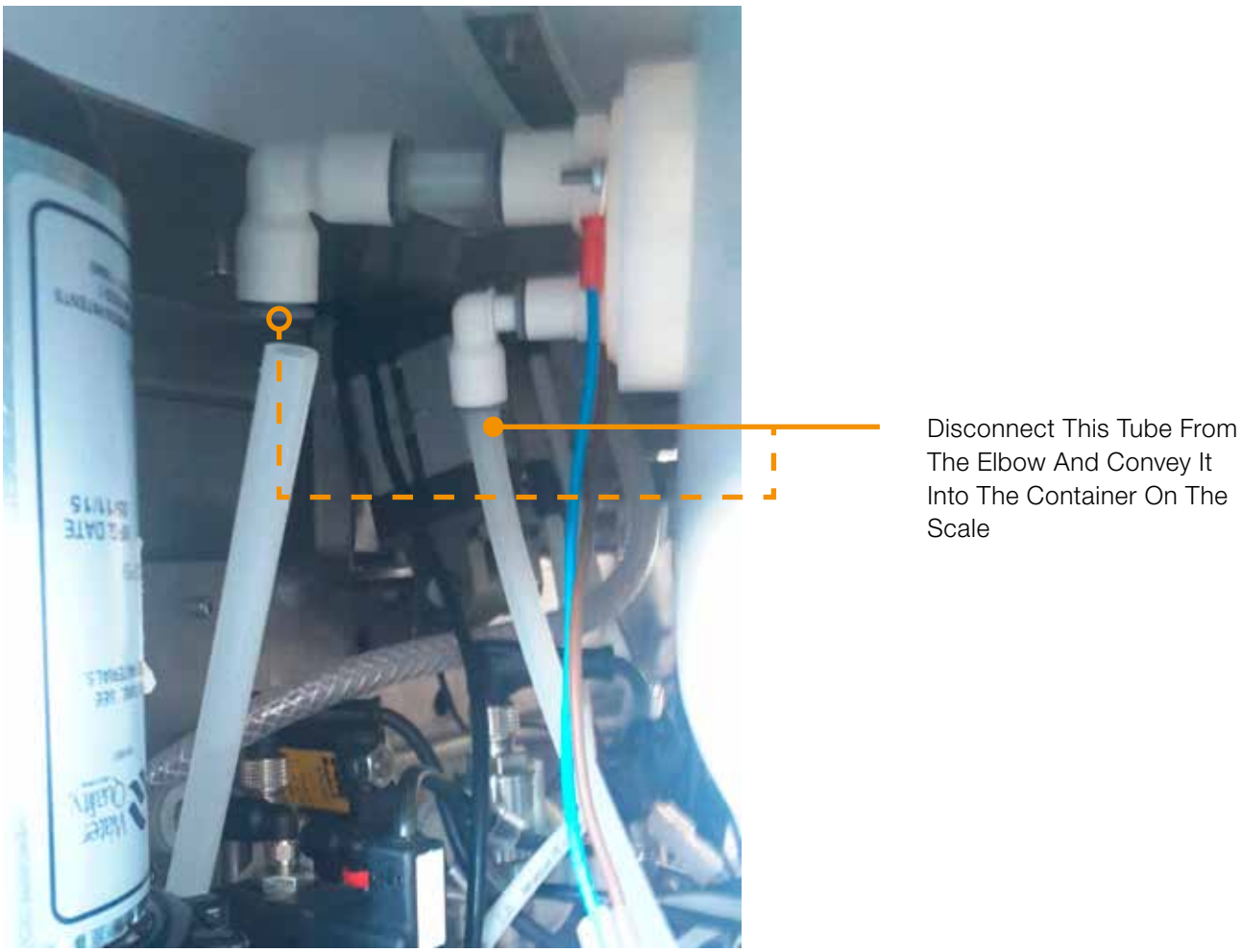
e. If the incoming pressure is much more than 4000mbar, must be installed a water pressure reducer in the incoming water line

SENSOR	ZERO POINT	MIN	MAX	CONSTANT	MIN	MAX	READING	CALIBRATED
MAX_V11	0	0	0	10	1	20		
MAX_V12	0	0	0	10	1	20		
SGR	0	0	0	1	1	1	0	0
FT1	0	0	0	18,885	11	14	0	0
FT2	0	0	0	17,085	14,5	17,5	0	0
FT5	0	0	0	1	1	1	0	0
FT6	0	0	0	1	1	1	0	0
FT7	0	0	0	1	1	1	0	0
FT8	0	0	0	1	1	1	0	0
FT9	0	0	0	1	1	1	0	0
FT10	0	0	0	1	1	1	0	0
FT13	0	0	0	0,35	0,25	0,4	0	0
FT14	0	0	0	17,699	16	19	0	0
FT19	0	0	0	1	0,2	0,35	0	0
T1	0	0	0	1,3	1	1	16,25	21,125
TP1	650	625	675	3	3	5	1580	2700
TP3	650	625	675	3,9	3	4,5	682	124,8
TP4	650	625	675	3,9	3	4,5	1084	1892,6
TP5	650	625	675	3,9	3,5	5	1927	4980,3
TP7	650	625	675	3,9	3	4,5	718	257,4

PRINT TECHNICAL MENU SAVE

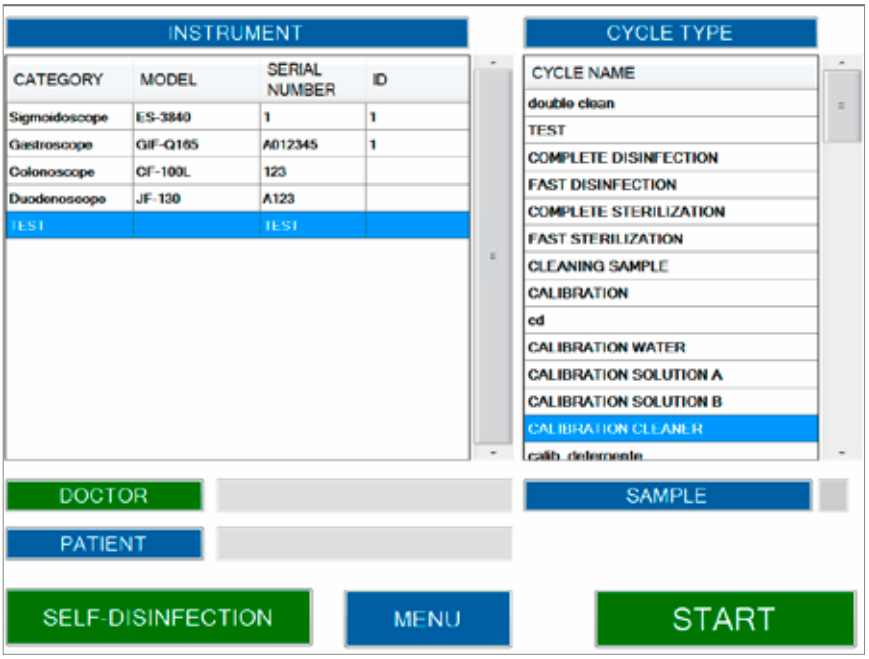
FT1 & FT2 CALIBRATION: INLET WATER FLOWMETERS

a. Disconnect the inlet water tube incoming into the basin and connect a tube to it to convey water out towards a 10 litres container located on the scale.



b. Reset the scale

c. Start the SET WATER cycle (available on the technical menu only)

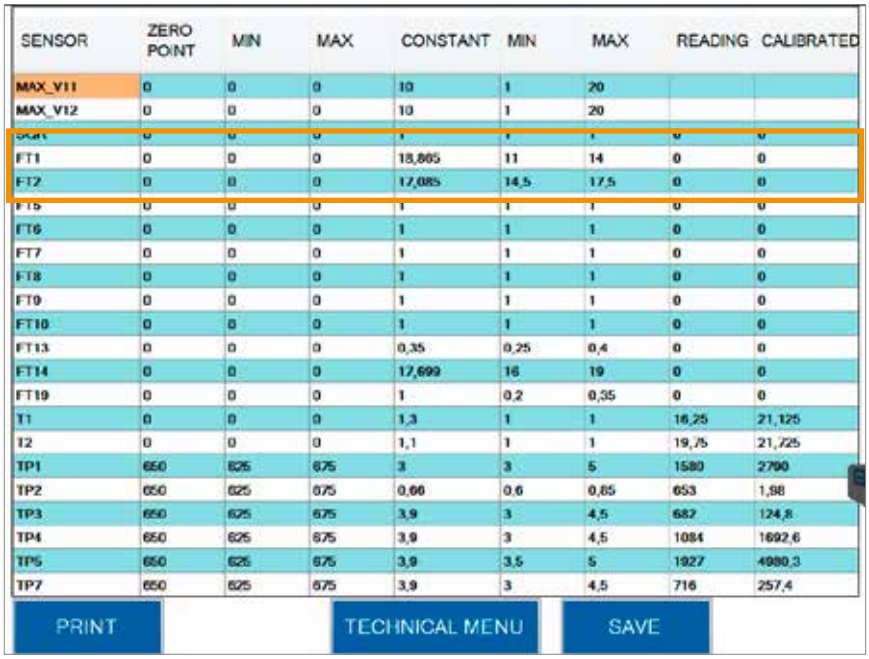


d. At the end of the cycle (green screen on the monitor with OK button) check the scale value and if necessary set it for FT1 and FT2 flowmeters in the CALIBRATION screen (CALIBRATED columns)

e. The allowed range between Scale, FT1 and FT2 is ± 5% (remember: the allowed range between FT1 and FT2 flowmeters during a cycle is ± 10%)

f. Push OK button on the screen, empty the water container located on the scale and drain the water from the basin using the synoptic screen. Push MANUAL button to activate manual mode (red button is active) and manually activated DRAIN button, when the basin is empty push the STOP button.

g. Repeat the procedure from point b at least three times with correct values



SENSOR	ZERO POINT	MIN	MAX	CONSTANT	MIN	MAX	READING	CALIBRATED
MAX_V11	0	0	0	10	1	20		
MAX_V12	0	0	0	10	1	20		
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
FT1	0	0	0	18,865	11	14	0	0
FT2	0	0	0	17,085	14,5	17,5	0	0
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
FT6	0	0	0	1	1	1	0	0
FT7	0	0	0	1	1	1	0	0
FT8	0	0	0	1	1	1	0	0
FT9	0	0	0	1	1	1	0	0
FT10	0	0	0	1	1	1	0	0
FT13	0	0	0	0,35	0,25	0,4	0	0
FT14	0	0	0	17,699	16	19	0	0
FT19	0	0	0	1	0,2	0,35	0	0
T1	0	0	0	1,3	1	1	16,25	21,125
T2	0	0	0	1,1	1	1	19,75	21,725
TP1	650	625	675	3	3	5	1580	2790
TP2	650	625	675	0,66	0,6	0,85	653	1,98
TP3	650	625	675	3,9	3	4,5	682	124,8
TP4	650	625	675	3,9	3	4,5	1084	1692,6
TP5	650	625	675	3,9	3,5	5	1927	4980,3
TP7	650	625	675	3,9	3	4,5	716	257,4

PRINT TECHNICAL MENU SAVE

FT14 CALIBRATION: DRAIN FLOWMETER

a. Connect the 78401-444 hookup (self-disinfection hookup) into the basin

b. With empty basin start the SET WATER cycle (available on the technical menu only) and wait the end of the cycle (green screen with OK button).

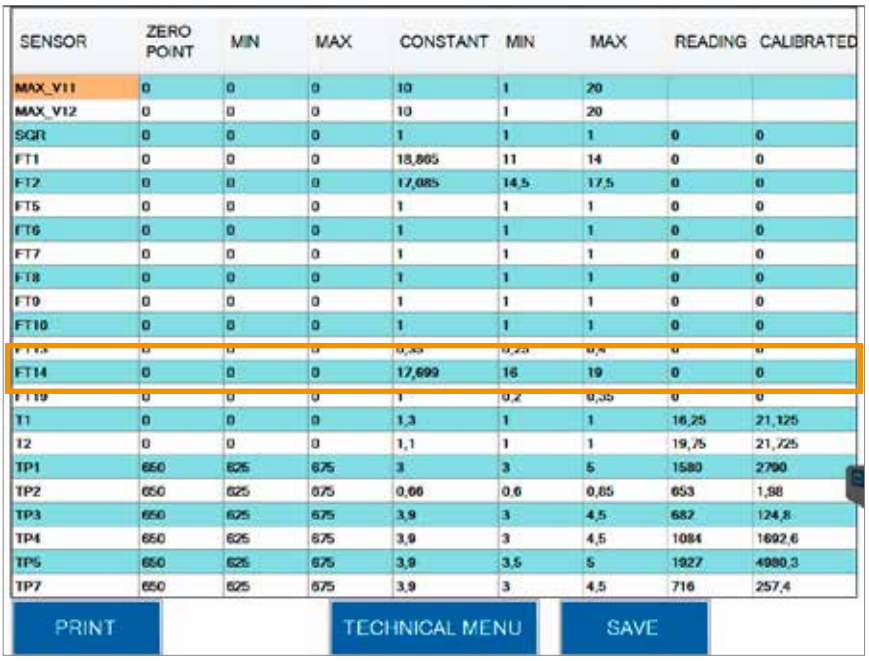
c. Push OK button on the screen.

d. In the synoptic screen push MANUAL button to activate manual mode (red button is active) and manually activated DRAIN button, when the basin is empty push the STOP button.

h. Check the FT1 and FT14 flowmeters values and if necessary set FT14 as FT1 value in the CALIBRATION screen (CALIBRATED columns)

i. The allowed range between FT1 and FT14 is ± 5%

j. Repeat the procedure from point b at least three times with correct values



SENSOR	ZERO POINT	MIN	MAX	CONSTANT	MIN	MAX	READING	CALIBRATED
MAX_V11	0	0	0	10	1	20		
MAX_V12	0	0	0	10	1	20		
SQR	0	0	0	1	1	1	0	0
FT1	0	0	0	18,865	11	14	0	0
FT2	0	0	0	17,085	14,5	17,5	0	0
FT5	0	0	0	1	1	1	0	0
FT6	0	0	0	1	1	1	0	0
FT7	0	0	0	1	1	1	0	0
FT8	0	0	0	1	1	1	0	0
FT9	0	0	0	1	1	1	0	0
FT10	0	0	0	1	1	1	0	0
FT14	0	0	0	17,699	16	19	0	0
T1	0	0	0	1,3	1	1	16,25	21,125
T2	0	0	0	1,1	1	1	19,75	21,725
TP1	650	625	675	3	3	5	1580	2790
TP2	650	625	675	0,66	0,6	0,85	653	1,98
TP3	650	625	675	3,9	3	4,5	682	124,8
TP4	650	625	675	3,9	3	4,5	1084	1692,6
TP5	650	625	675	3,9	3,5	5	1927	4980,3
TP7	650	625	675	3,9	3	4,5	716	257,4

PRINT TECHNICAL MENU SAVE

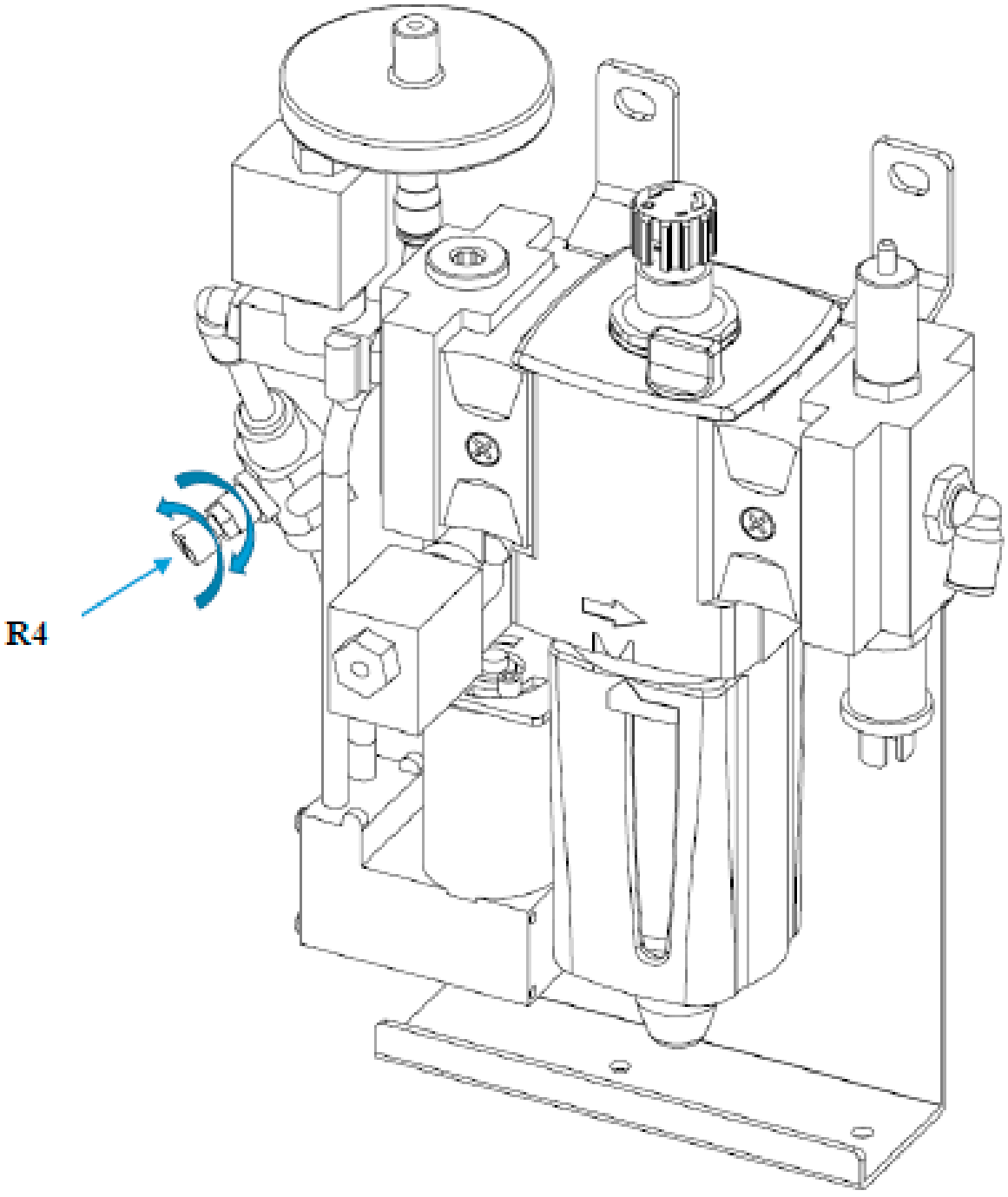
SETTING FLOW REDUCER FOR LEAK TEST R4

a. Connect the self-disinfection Hookup to the basin and start a cycle;

b. Act on the flow reducer R4 to reach a 240mbar pressure in 4 seconds;

c. Repeat this procedure at least 3 times and at the end block the pressure reducer.

d. Restart a cycle to be sure that the setting is still valid.



R2 CALIBRATION: RECIRCULATION CHANNEL REDUCER

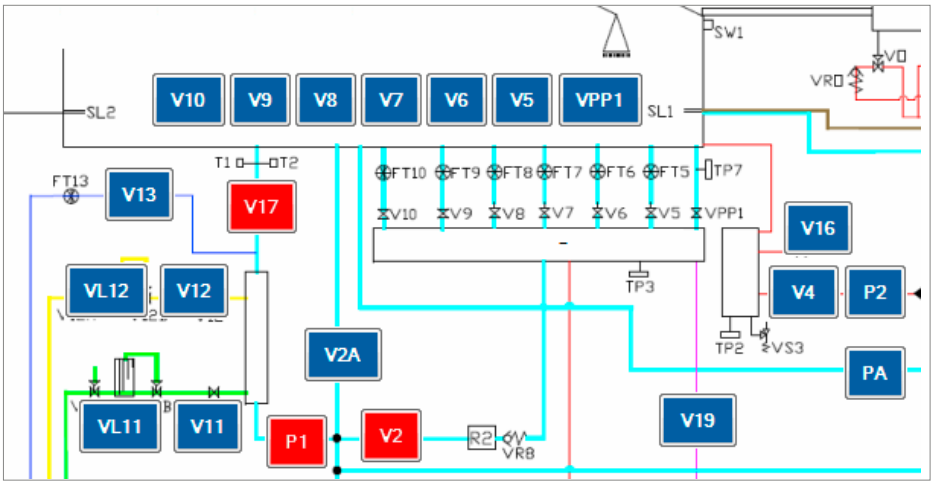
a. Connect the 78401-444 hookup (self-disinfection hookup) into the basin

b. Start the WATER CALIBRATION cycle (available on the technical menu only) and wait theend of the cycle (green screen with OK button).

c. Push OK button on the screen

d. In the synoptic screen push MANUAL button to activate manual mode (red button is active) and manually activated valves V10, V9, V8, V7, V6, V5 and VPP1.

e. Activate valves V2, V17 and pump P1 (in this sequence)



f. Wait few seconds and then close the valves V10, V9, V8, V7, V6, V5

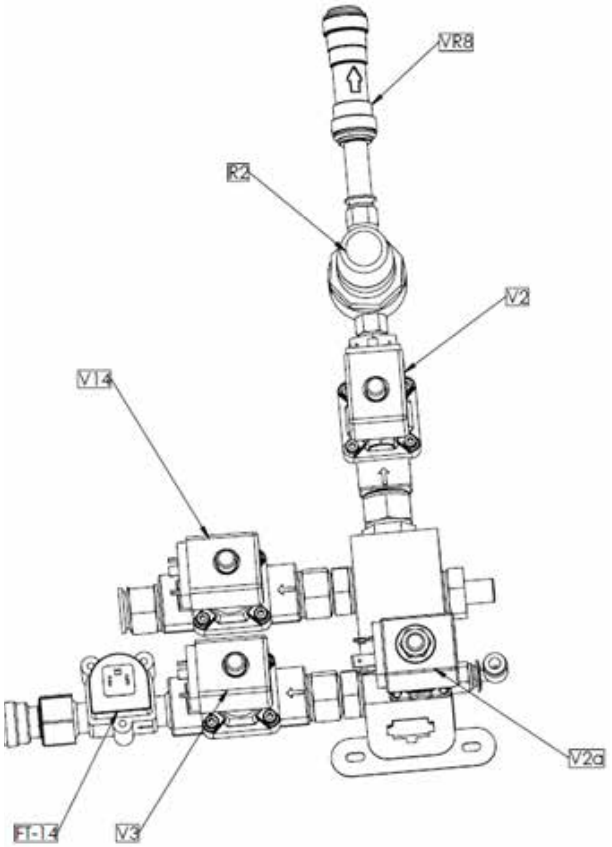
g. Leave P1, V17, V2 and VPP1 activate

h. Close VPP1 for few seconds and check TP3 value. Open VPP1 after to prevent pump damage

i. Check the pressure in the channel block using with TP3 transducer

j. TP3 pressure transducer value must be at 1900mbar -5%/+10%

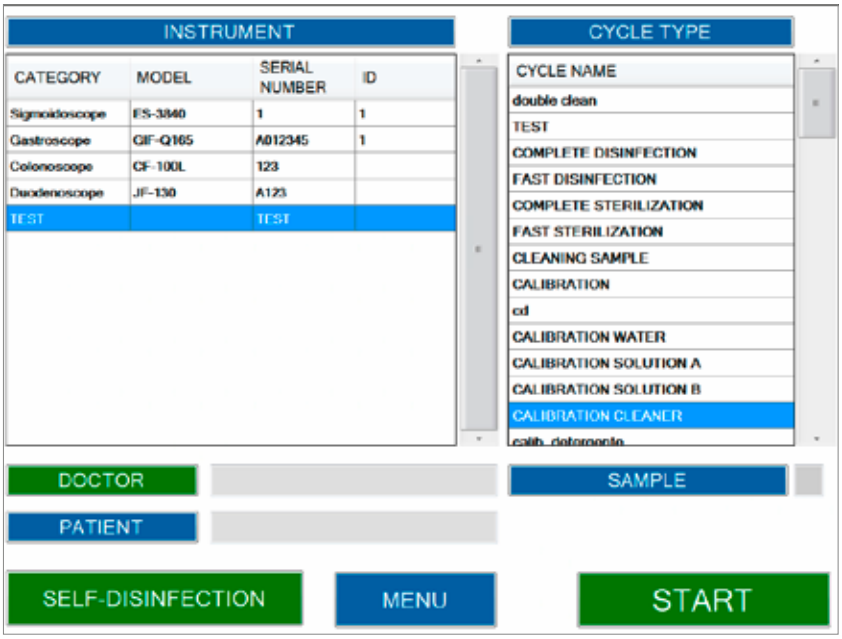
k. If the TP3 value is not correct open and close manually for few times all the valves (V10, V9, V8, V7, V6, V5 and VPP1) to set the correct value using the R2 channel regulator (With valves open calibrate the channel regulator, with valves close check the TP3 pressure)



FT13 CALIBRATION DETERGENT CALIBRATION

a. Connect the 78401-444 hookup (self-disinfection hookup) into the basin

b. Place the detergent container on the electronic scale, reset it and start the SET DETERGENT cycle (available on the technical menu only).



c. Wait the end of the cycle (green screen with OK button), and push OK button.

d. Check the scale and FT13 values and if necessary adjust FT13 value in the CALIBRATION screen (CALIBRATED columns)

e. The allowed scales range is min 16ml (ISACLEAN) or 34 ml (INTERCEPT PLUS)

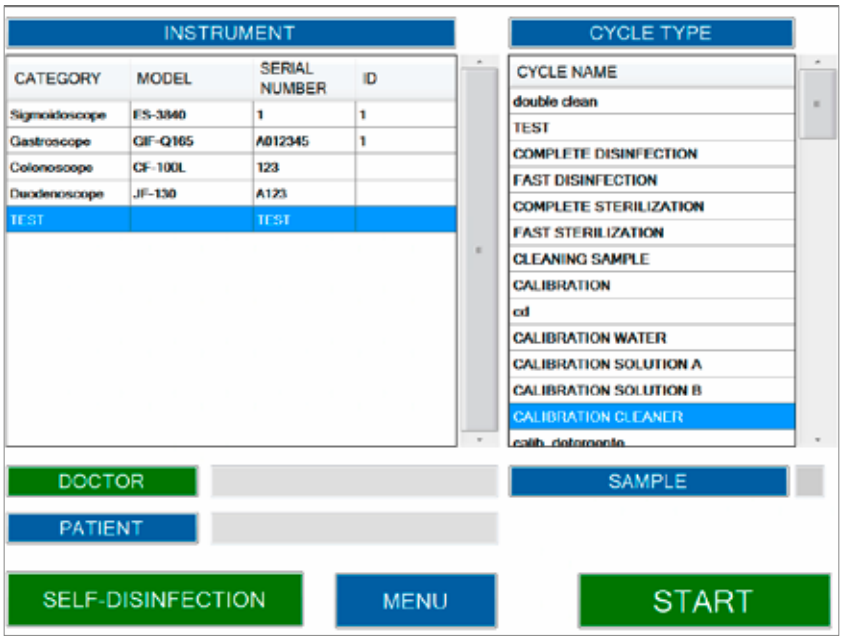
f. The allowed FT13 flowmeter is 16ml or 34 ml

g. Repeat the procedure from point at least three times with correct values

FT14 ALCOHOL CALIBRATION

a. Connect the 78401-444 hookup (self-disinfection hookup) into the basin

b. Place the Alcohol container on the electronic scale, reset it and start the SET ALCOHOL cycle (available on the technical menu only).



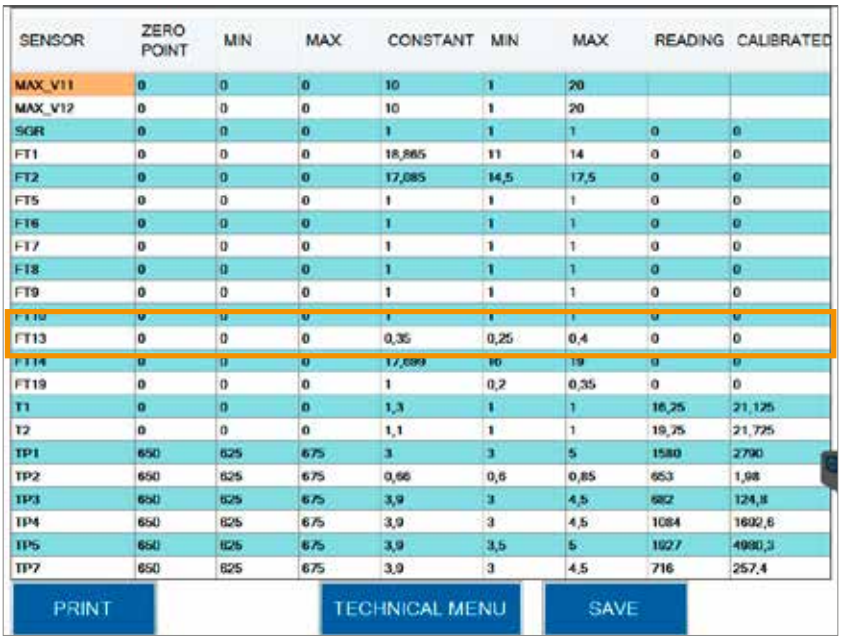
c. Wait the end of the cycle (green screen with OK button), and push OK button.

d. Check the scale value and if necessary adjust FT19 value in the CALIBRATION screen (CALIBRATED columns)

e. The allowed scales range is 50g ±10%

f. The allowed FT19 flowmeter is 50 ±10%

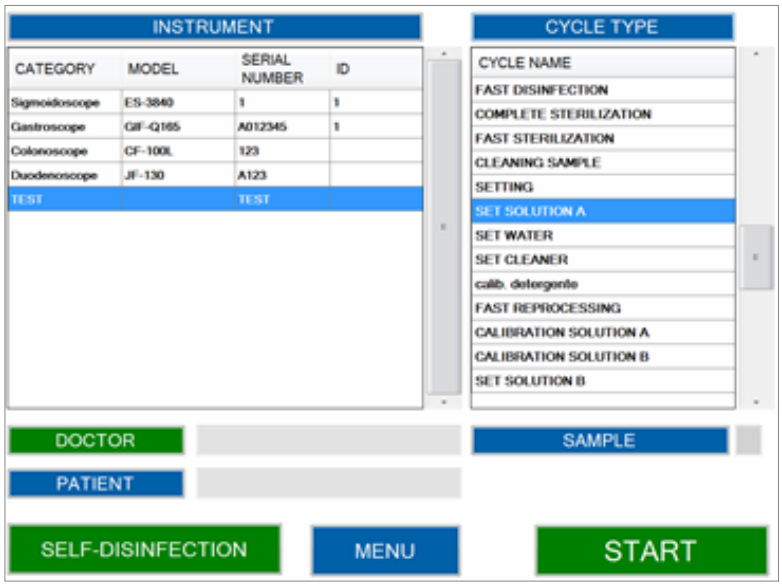
g. Repeat the procedure from point b at least three times with correct values



STERILANT/HLD SOLUTION A LOADING CALIBRATION

a. Connect the 78401-444 hookup (self-disinfection hookup) into the basin

b. Place the solution A bottle on the electronic scale, reset the weight value to zero and start the cycle SET SOLUTION A (available on the technical menu only)

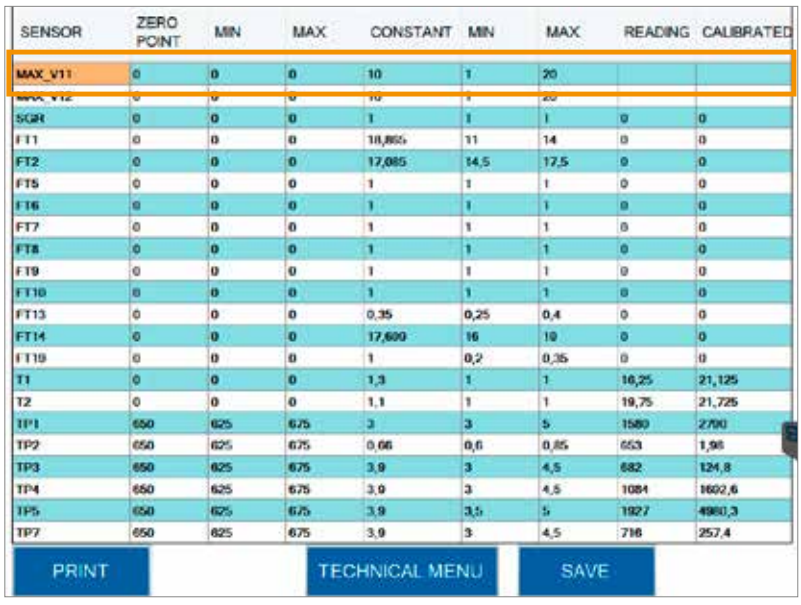


c. Wait the end of the cycle (green screen with OK button), and push OK button.

d. Check that the value read by the scale is within the SETTING range: SET value = 190 ml (± 5%)

e. If necessary, change the MAX_V11 COSTANT (K factor) in the CALIBRATION screen (CONSTANT column). Decrease K factor to reduce the Solution A amount or increase the K factor to increase the Solution A amount.

f. If necessary repeat the procedure from point b for correct values after MAX_V11 new setting



STERILANT/HLD SOLUTION B LOADING CALIBRATION

a. Connect the 78401-444 hookup (self-disinfection hookup) into the basin

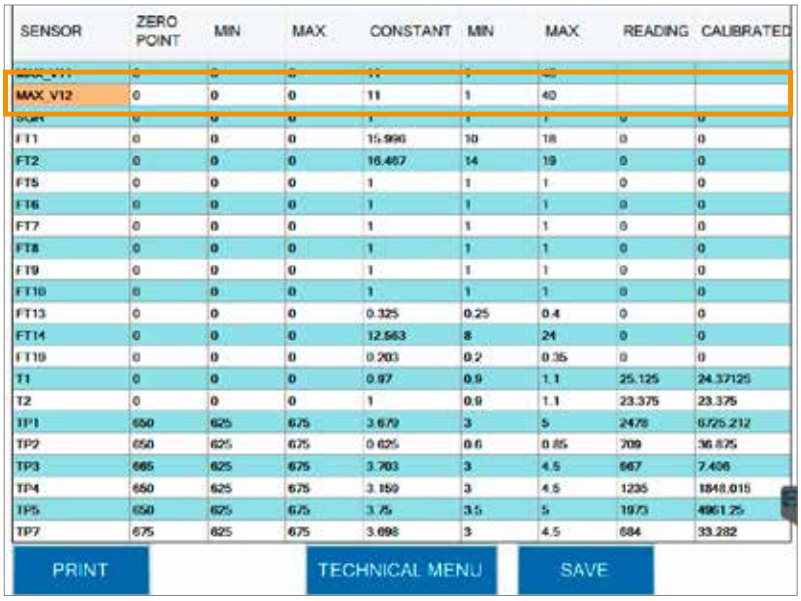
b. Place the solution B bottle on the electronic scale, reset the weight value to zero and start the cycle SET SOLUTIONS (available on the technical menu only)

c. Wait the end of the cycle (green screen with OK button), and push OK button.

d. Check that the value read by the scale is within the SETTING range: SET value = 190 ml (± 5%)

e. If necessary, change the MAX_V12 COSTANT (K factor) in the CALIBRATION screen (CONSTANT column). Decrease K factor to reduce the Solution B amount or increase the K factor to increase the Solution B amount.

f. If necessary repeat the procedure from point b for correct values after MAX_V12 new setting

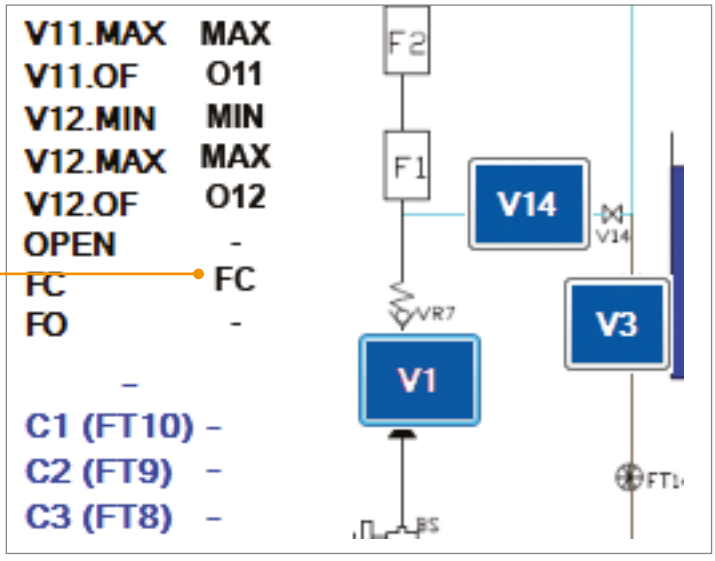


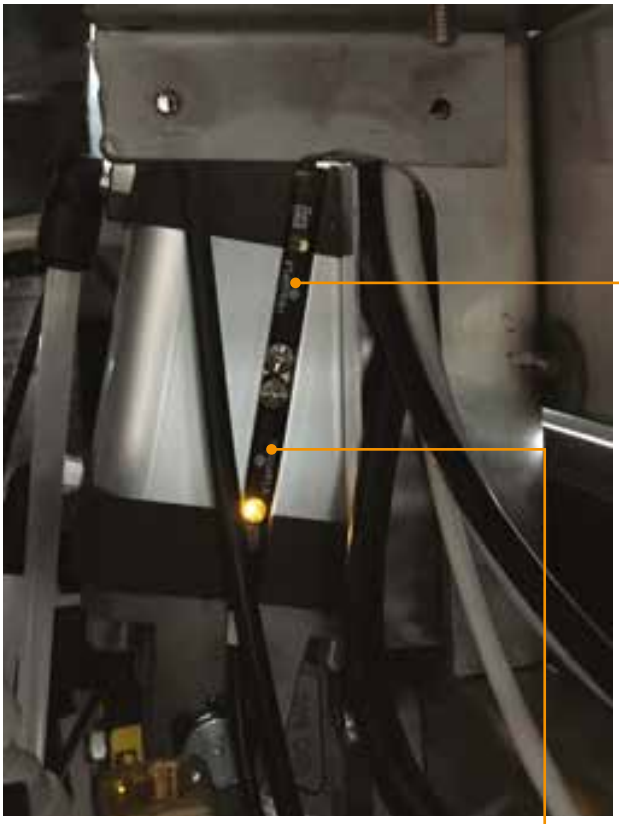
LID CALIBRATION

a. In the Synoptic screen, with lid open, activate manually OPEN/CLOSE button (to close the lid) and check if sensor FC become 1 when the lid is less than 1cm from the basin. If not, regulate the sensors on lid cylinder

b. In the Synoptic screen, with lid close, activate manually OPEN/CLOSE button (to open the lid) and check if sensor FC become 0 when the lid is over more than 1cm from the basin. If not, regulate the sensors on lid cylinder

FC=1 Lid Close
FC=0 Lid Open





OPEN LID SENSOR (RIGHT CYLINDER SIDE)

CLOSE LID FC SENSORS (BOTH CYLINDER SIDE)

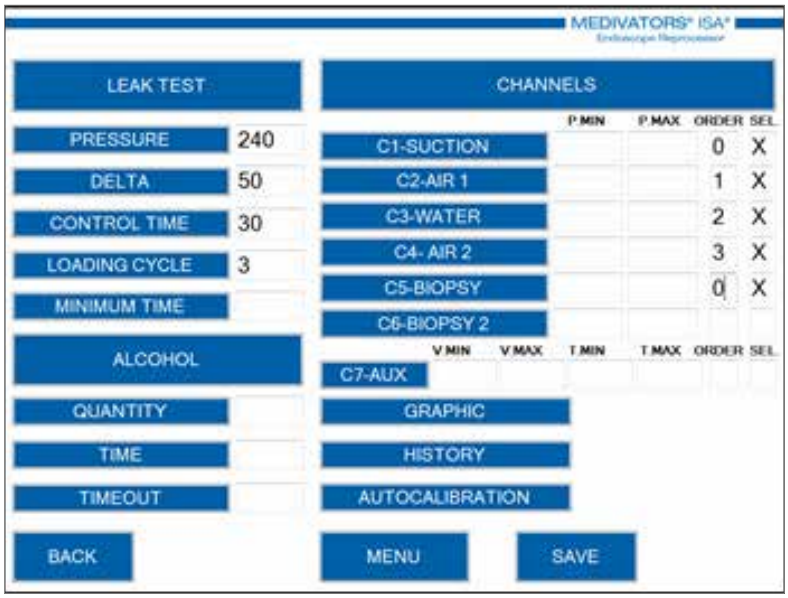
SET ENDOSCOPES PARAMETERS

To Set Parameter for endoscope channels, we can choose two ways:

1. The first one is to select the endoscopes from a list into the database (see Chapter 3 - INSTRUMENT);

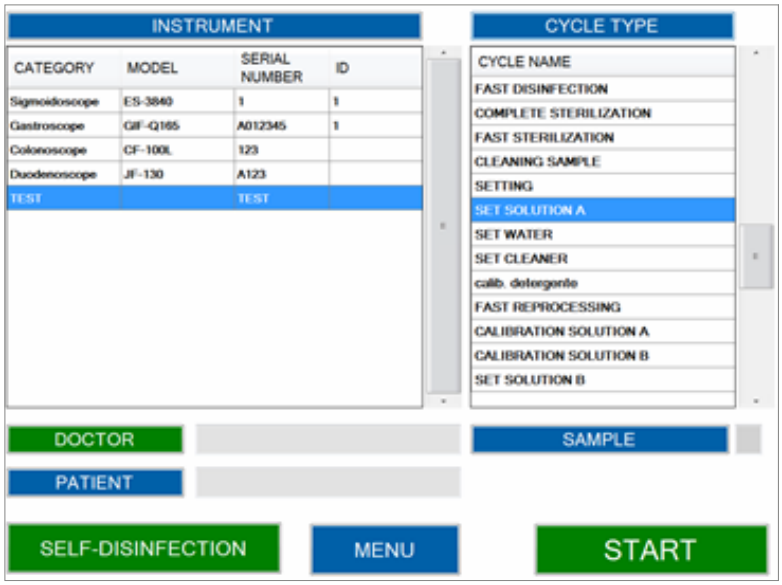
2. Proceed as below to set a new endoscope:

a. Insert the follow information in the page of endoscope that need to set:

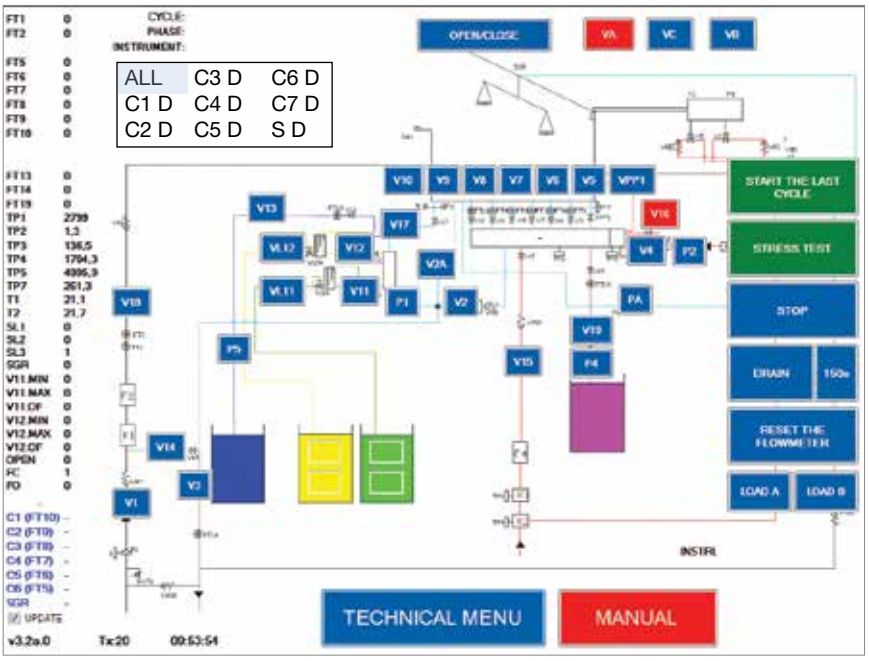


b. Insert the endoscope into the basin and connect the channel and leak test;

c. Start SETTING cycle;

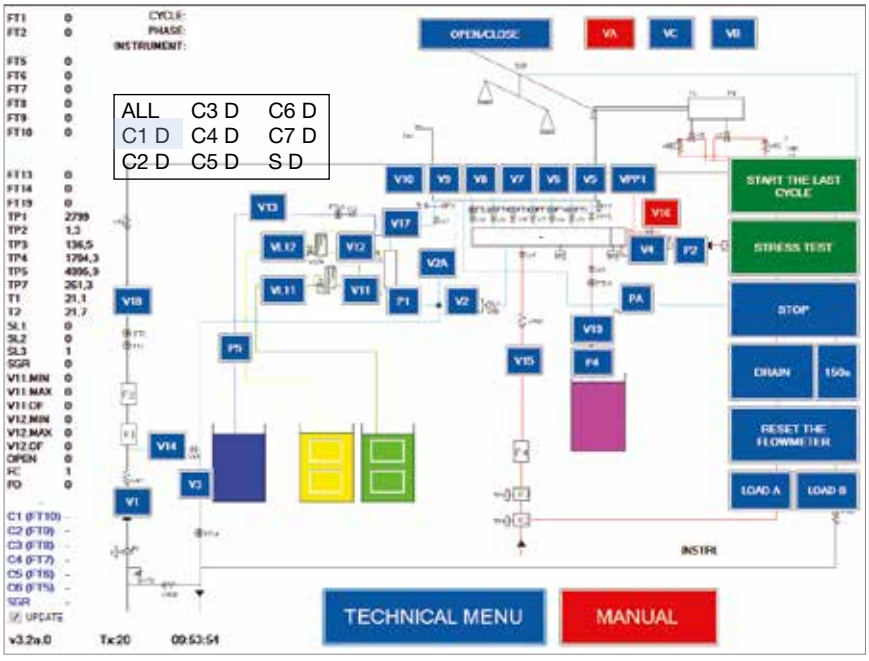


d. After START move to SYNOPTIC:



Box ALL, highlighted in blue, indicating that all channels are connected. After at least 3 cycles of recirculation (lasting 30 seconds), press STOP.

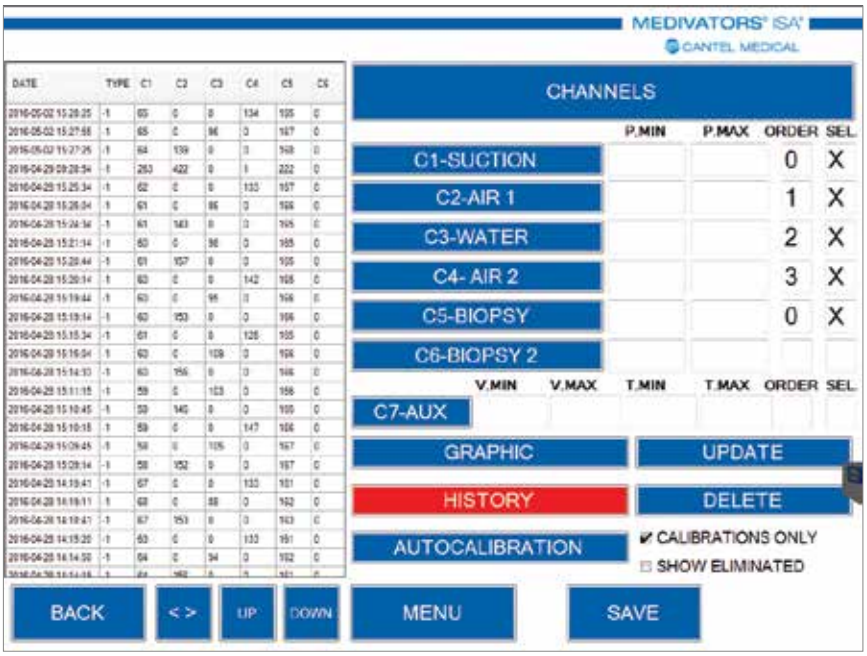
For example in the case of channel 1 disconnected:



and make another series of recirculation's (at least 3).
Repeat these operations for the other channels.

At this point, disconnect the connectors of the endoscope channels (including the sled) one at a time, highlighting each time the channel is disconnected in SYNOPTIC.

If you move on INSTRUMENTS and select the scope that you're setting. If you press on HISTORICAL you'll see all registered value of flow:



where , the values in column TYPE are referred to the corresponding disconnected channel. If this number is 0 it means that all channel are connected, if it's 8 the sled is disconnected.

After all tests, press on AUTOCALIBRATION and you'll have , automatically, by the software, the setted value for the flows

PERFORMANCE QUALIFICATION

The objectives of the Performance Qualification are the following:

- Check the cleaning efficacy of the test endoscope
- Check the disinfection efficacy of the test endoscope
- Check the microbial load of the last rinse water
- Checking the detection of non-connected channels
- Checking the detection of obstructed channels
- Check the Leak test

CHECK THE CLEANING EFFECTIVENESS

a. Insert the Hookup Connection 2-8-280 inside the basin and connect it to 2 supports Simicon RIBI-2-V2A containing two Simicon RI-EN tests
b. Start the CLEANING TEST CYCLE and at the end of the cycle, extract the indicator from the PCD and visually check the cleaning state comparing it with the Simicon evaluation table reported below.

Run n° 3 cycles and annex here below the photo of each test performed and print of every cycle as confirmation of the result obtained.

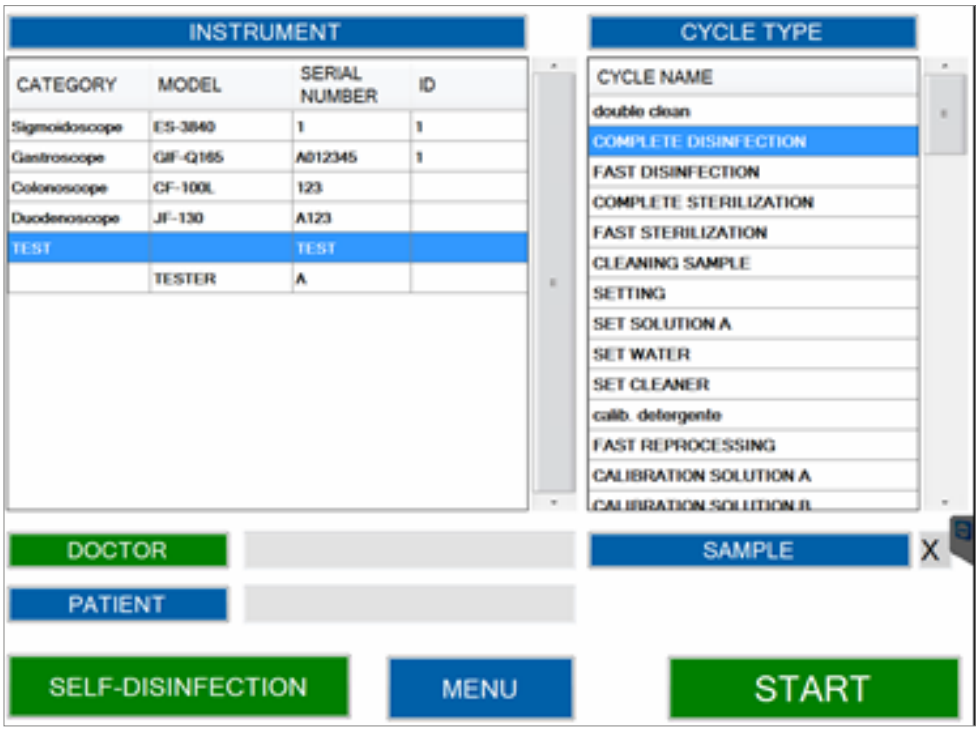
CHECK THE DISINFECTION EFFECTIVENESS MICROBIOLOGICAL TEST

a. Insert the Hookup Connection 2-8-280 inside the basin and connect it to 2 supports Simicon RIBI-2-V2A containing two Simicon Microbiological Tests
b. Start the COMPLETE CYCLE
c. Attach the Simicon instructions from which to extract the test and compile the forms and send the tests in analysis.
d. Attach the Simicon test report with the results obtained

CHECK THE LAST RINSING WATER - MICROBIOLOGICAL TEST

a. Insert the Hookup Connection 78401-444 inside the basin
b. Start the WATER SAMPLING CYCLE
c. Wait for the opening of the lid
d. Wear PPE
e. Sample rinsing water and fill the sterile containers as indicated by Simicon and send the test in analysis
f. Attach the Simicon test report with the results obtained

Alternatively, you can select from page for start cycles, the flag SAMPLES



In this case, a cycle will start and it will block:

1. After rinse post-cleaning, in order to check Cleaning Effectiveness;
2. After final rinse, but before the drain, in order to Check the last rinse water;
3. At the end of cycle, in order to check the Disinfection Effectiveness;

CHECK THE DETECTION OF NON CONNECTED CHANNELS

a. Start the CHANNEL TEST CYCLE using the TEST instrument (previously calibrated)
b. Leave the Channel 1 disconnected and check that the equipment emits an alarm
c. Add to the table the report of the disconnected channel
d. Repeat the test for every channel up to 7
e. Attach the printed report of the cycle for every test performed

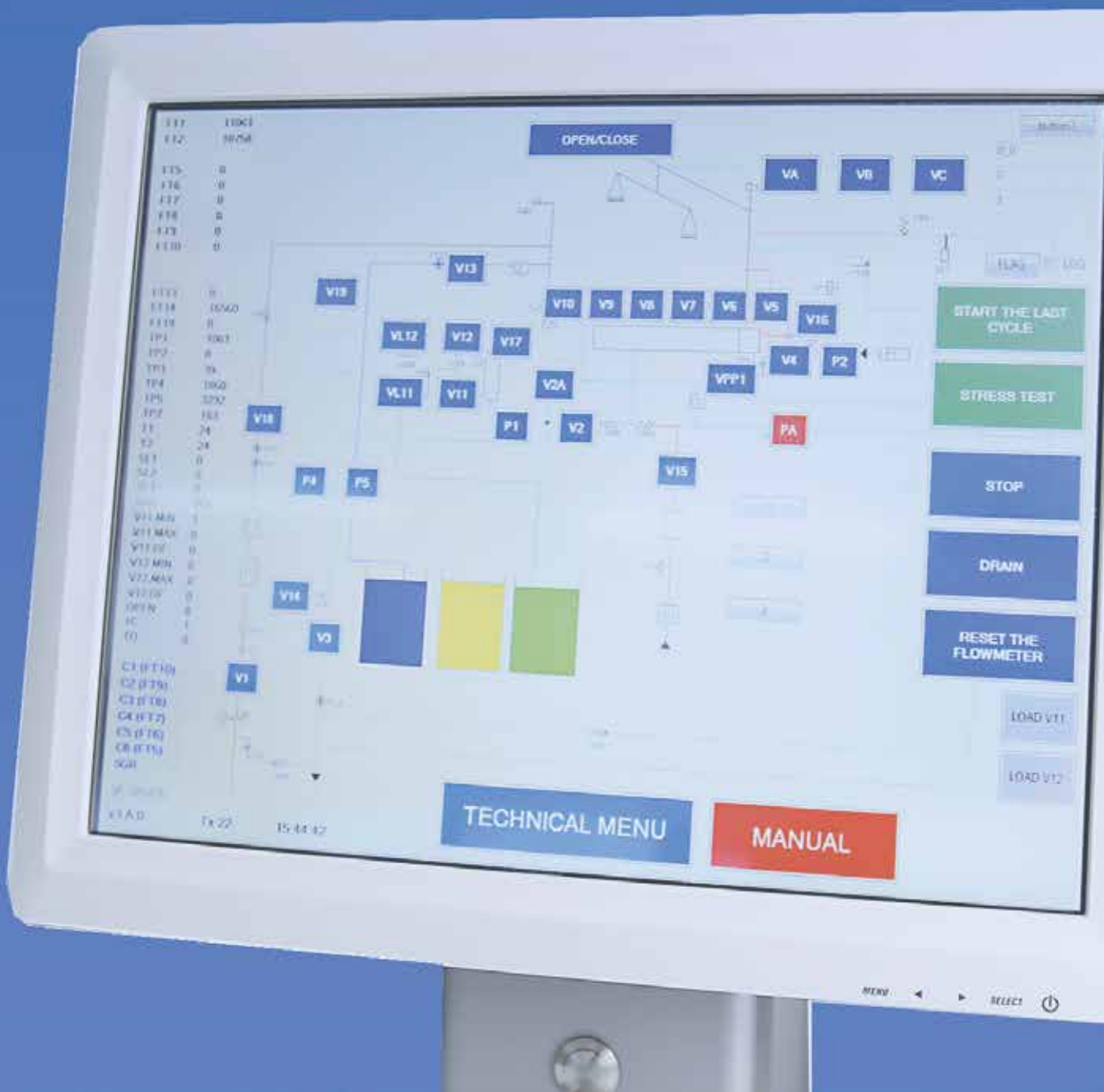
CHECK THE LEAK TEST

a. Start the COMPLETE CYCLE with the TEST instrument without inserting any Hookup Connection inside the basin
b. Check that the Leak Test alarm is correctly reported and that the equipment blocks

CHAPTER 5

MAINTENANCE

This chapter refers to the scheduled maintenance to be carried out on the MEDIVATORS™ ISA™ Endoscope Reprocessor.



CAUTION! FAILURE TO PERFORM SCHEDULED MAINTENANCE MAY PREVENT PROPER OPERATION AND SHORTEN THE LIFESPAN OF THE MD. THE CUSTOMER IS RESPONSIBLE FOR PERFORMING THE SCHEDULED MAINTENANCE OPERATIONS.

The table below refers to the operations to be carried out in accordance at the pre-established time intervals:

SCHEDULED MAINTENANCE OF MEDIVATORS™ ISA™ ENDOSCOPE REPROCESSOR

No.	OPERATIONS	DESCRIPTION	Reference
		6-month inspections and checks	
1	0.45 micron filter stage 1 water inlet	Water Filter replacement	Page 34, 91, 127
2	0.2 micron filter stage 2 water inlet	Water Filter replacement	
3	0.2 micron filter leak test air	Air Filter replacement	Page 129
4	0.2 micron filter compressed air	Air Filter replacement	Page 130
5	Leak test	Checking for leaks in hydraulic/ pneumatic circuit and fixing the same	-
		Annual inspection and checks	
1	Check calibration	Verification of correct operation of the measuring and control sensors.	See Chapter 4
2	Check of gaskets of interlocked connections	Check the state of wear and replace the gaskets of interlocked system that connect the endoscopic channels, if needed.	Page 131
3	Check tank lid gasket	Check the tightness of tank lid gasket	-
4	Annual maintenance kit	Replacing the parts Annual maintenance Kit	- IFU will be included into the kit

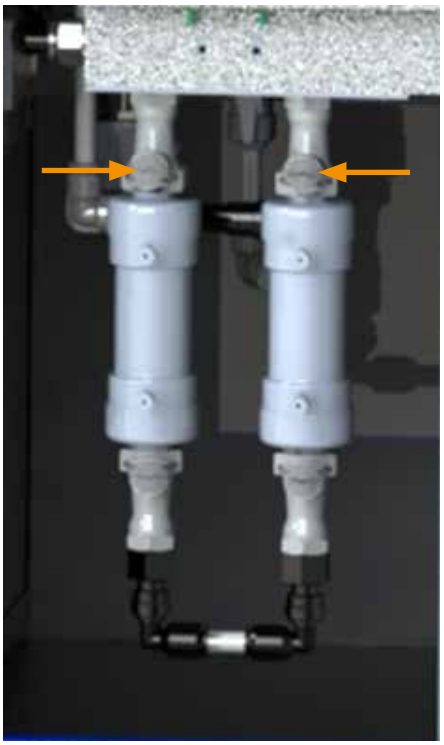
The filters fitted on MEDIVATORS ISA reprocessing equipment are provided solely by the manufacturer. Using different filters does not guarantee the effectiveness of washing and disinfection/ sterilization processes. The manufacturer denies all liability for problems arising from the use of filters different than those specified.

WATER FILTER REPLACEMENT

To replace the water filter of MEDIVATORS™ ISA™ Endoscope Reprocessor sterilizers proceed as follows:

1. Close the main water inlet;
2. Remove the left side cover (front view);
3. Open the relief valve on the filter to be replaced, turning it anti-clockwise and simultaneously collect the outgoing water with a container.
4. Push on the higher CPCs opening button for both filters (figure 1) and extract them:

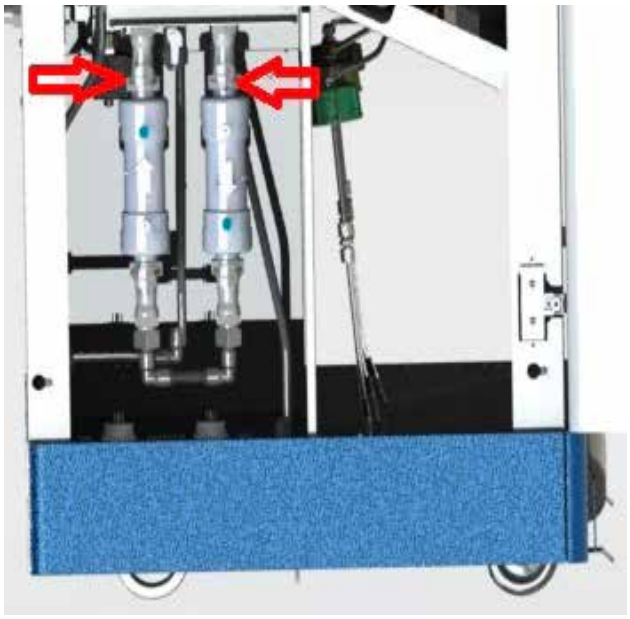
Figure 1 I Water Filter replacement



5. Push on the lower CPCs opening button for both filters (figure 2) and substitute;

6. Replace the filters into the MEDIVATORS™ ISA™ Endoscope Reprocessor:

Figure 2 I Water Filter replacement



AIR FILTER REPLACEMENT

Replacing the air filter for the leak test

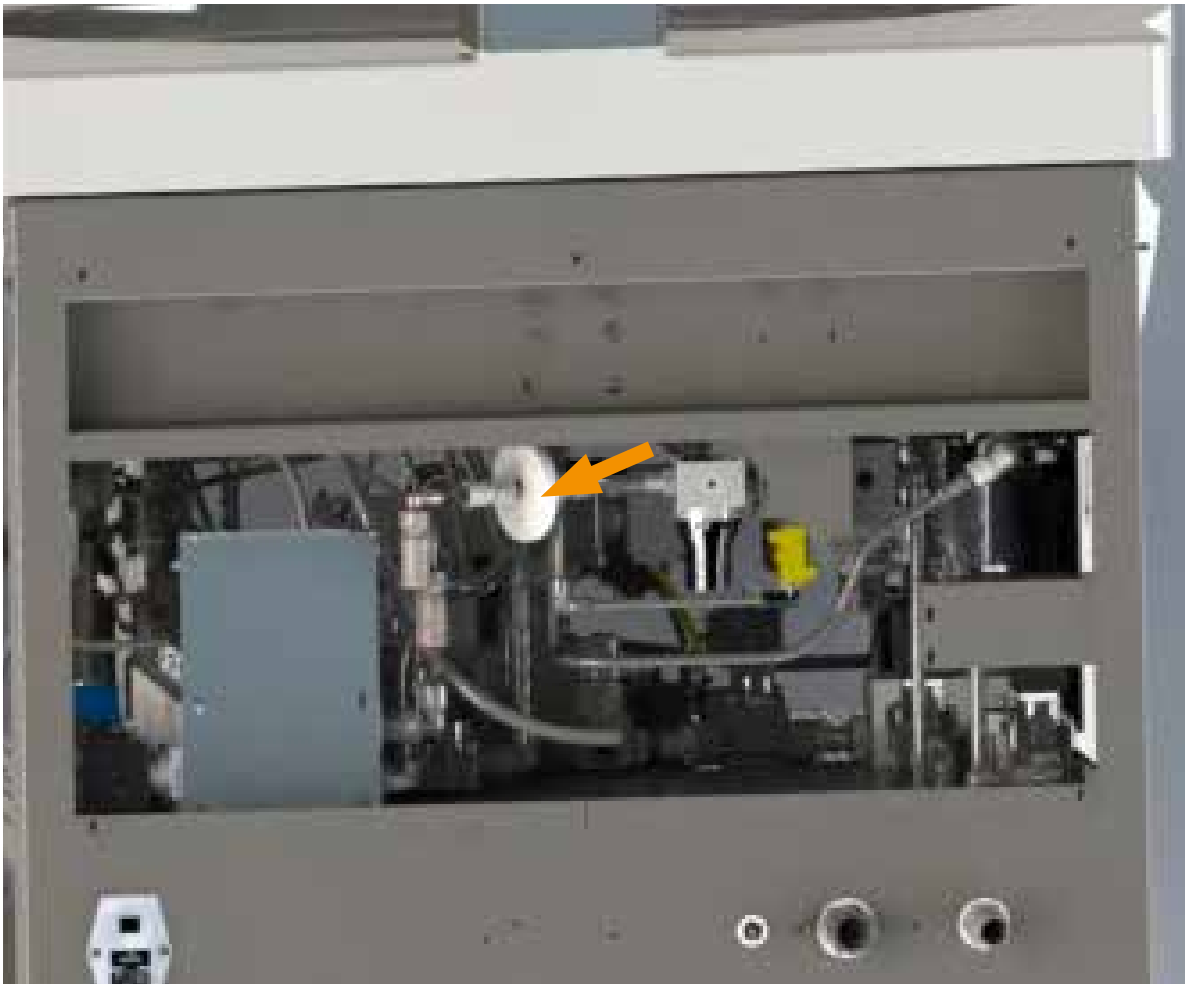
1. Remove the right side guard (front view) of MEDIVATORS™ ISA™ Endoscope Reprocessor;
2. Remove the leak test air filter from the hose;
3. Replace the leak test filter (figure 3) with a new one;
4. Dispose of the filter as provided by the authorized body;
5. Install the right side guard;

Figure 3 I Leak Test Air Filter Replacement

Replacing the drying air filter

1. Close the main air inlet;
2. Remove the top rear guard;
3. Remove the drying air filter from the hose;
4. Replace the drying air filter (figure 4) with a new one;
5. Dispose of the filter as provided by the authorised body;
6. Fit the top rear guard;
7. Open the main air inlet.

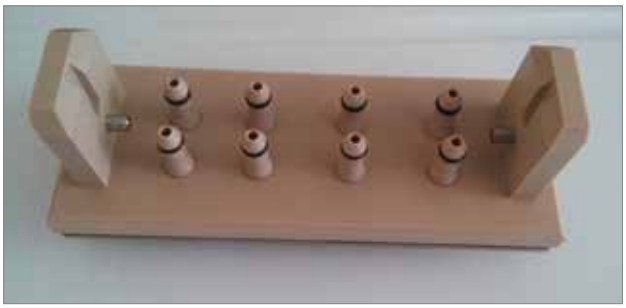
Figure 4 I Drying Air Filter replacement



REPLACEMENT OF INTERLOCKED ENDOSCOPIC CHANNEL CONNECTION GASKETS

1. Verify the intact state and the wear condition of every gasket fitted on the connection fittings (figure 5);

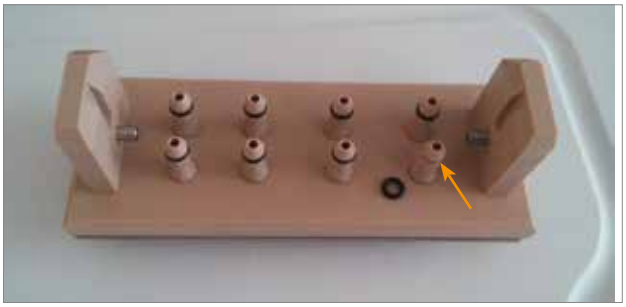
Figure 5 I Gasket replacement
Verify condition of gasket fittings



2. Remove the gasket from every connector (figure 6);

Figure 6 I Gasket replacement
Remove gasket from connectors

3. Place the new gasket taking care to insert it into the slot, preventing any leak.



CHAPTER 6

MAINTENANCE - ELECTRICAL

This chapter refers to additioanl scheduled maintenance to be carried out on the MEDIVATORS™ ISA™ Endoscope Reprocessor.

WARNING! THE OPERATION DESCRIBED IN THIS SECTION MUST BE CARRIED OUT BY QUALIFIED TECHNICICANS AUTHORIZED BY THE MANUFACTURER.

ELECTRICAL PROTECTIONS

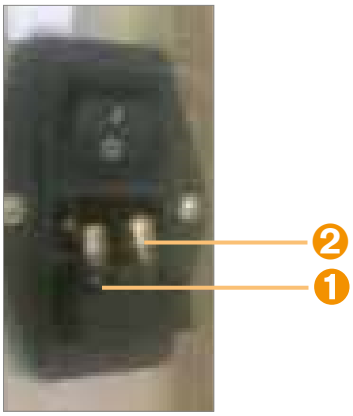
1. In the socket of the MEDIVATORS™ ISA™ Endoscope Reprocessor, there is a N.2 fuse for protection. In case of issues on power supply they will break.
2. In this case, to restore the operation, it is necessary to replace them.

FUSE REPLACEMENT

1. Turn off the line power supply, disconnecting the plug from the outlet of the equipment of the hospital;
2. Make sure the switch on the power outlet is placed in the OFF (0 - see figure 1);
3. Replace fuses placed inside the socket in the back of the device (see figure 2);.

Figure 1 I Fuses
Power switch is off

Figure 2 I Fuses
Replacing the fuses



FUSES	
1	Fuse 5A
2	Fuse 5A

CHAPTER 7

WARRANTY

This chapter describes the Warranty covering the MEDIVATORS™ ISA™ Endoscope Reprocessor and related parts.

EXCLUSION OF RESPONSIBILITY

Cantel Medical (Italy) S.r.l. warranties the perfect operation of the MEDIVATORS™ ISA™ Endoscope Reprocessor and the attainment of washing and disinfection results for the endoscopes reprocessed only if:

- The equipment is used in compliance with the procedures described in this manual and in accordance with the instructions provided by the manufacturer.
- Technical servicing is performed by technical personnel authorized by Cantel.
- Consumable products (filters, products, spare parts etc.) that are validated and supplied by the Manufacturer are used.

LIMITED WARRANTY

Cantel Medical (Italy) S.r.l. warranties that the MEDIVATORS ISA Endoscope Reprocessor complies with the specifications declared by Cantel and is warranted to be free from material and processing defects during normal use and maintenance for a period of fifteen (15) months from the date of dispatch from Cante or one (1) year from the date of installation, depending on which of the two situations should occur first.

Independently of all provisions to the contrary contained in the present document, the warranty period for consumables and accessories supplied by Cantel, including by way of non-limiting example, endoscope connectors, filters, printers, printer spare parts, accessories, is ninety (90) days from the date of installation or 120 days from the date of dispatch, depending on which of the two situations should occur first.

The warranty only includes any faults or manufacturing defects.

The warranty does not cover, and the Company shall have no obligation of warranty regarding damages to the Product caused by or associated with: (i) external causes, including, without limitation, accidents, acts of vandalism, natural disasters, acts of God, loss of electricity supply or power surges, (ii) abuse, negligence or improper use of the product by the client or third parties, or the use of unauthorized third party filters or other consumables or accessories or chemical substances not validated by the Company, (iii) use not in compliance with the Product instructions, (iv) lack of preventive maintenance requested by the client, or (v) unauthorized support and repairs.

LIMITATION OF RESPONSIBILITIES

At the discretion of the Company, the SOLE RESPONSIBILITY of the Company, with regard to the warranty, shall be the repair or replacement of defective Product(s) or the reimbursement or the issuing of credit to the value of the purchase price. This shall be the sole solution for the client for a defect covered by the warranty.

To obtain compensation under warranty, the client should inform the Company of the defect (describing the problem in a reasonably detailed way) before the expiration of the warranty period and within thirty (30) days of discovery of the defect.

After having received the official „return merchandise authorization“ (RMA) from the Company, the client should return the defective product immediately to the company itself (or to the support centre indicated in the RMA), paying transport and insurance in advance. The Company shall not be responsible for any damages occurring during transport.

LIMITATION OF THE WARRANTY

The above Warranty represents the entirety of the Warranty obligations of the company‘ towards the product purchaser. The company expressly declines all other warranties and conditions, expressed or implied, statutory or of any other nature, including, without limitation, warranties or conditions of commerciability and suitability for a particular purpose, in addition to warranties resulting from execution of an agreement and from commercial uses; the company does not declare nor Warranty that the products satisfy the needs of the client.

Within the legally permitted limits, and except in the case of gross negligence or malicious behaviour by the company, the company shall not be responsible to the client for indirect or consequential damages or for damages or other costs or passivity (whether foreseeable or not), even if advised of the possibility of said damages, resulting from the warranty or from the contract, from negligence or other illegal acts of another nature, including, without limitation, foreseeable commercial losses, loss of profits, loss of contracts or commercial opportunities, and dependant damages.

This New Product Limited Warranty provides the Product client with specific legal rights; the client themselves can also benefit from other rights which vary from one jurisdiction to another.

Within legally permitted limits, the Company‘s responsibilities cannot exceed the original purchase price of the Product covered by the warranty.

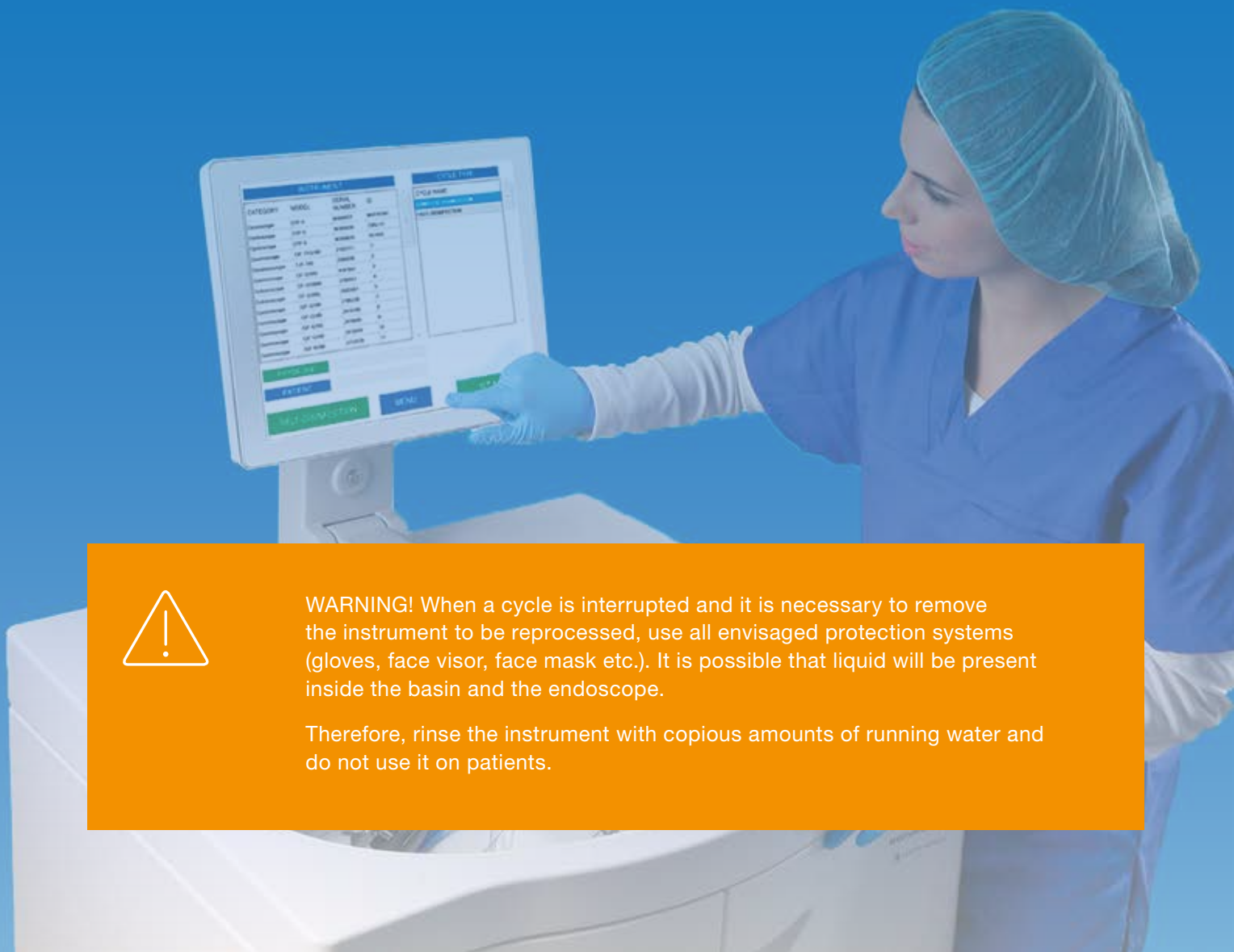
No Company representative or agent has the power to bind the Company to any other declaration or warranty with regard to the Products, and the client accepts that the Products are subject to all the aforementioned terms.

CHAPTER 8

TROUBLESHOOTING

This chapter deals with the resolution of problems affecting the MEDIVATORS™ ISA™ Endoscope Reprocessor, with regard to alarms indicated by the equipment and the potential actions of healthcare workers for the resolution of said problems.

Any other operations for the restoration of equipment function must be performed by staff that are qualified and authorized by the Manufacturer.



WARNING! When a cycle is interrupted and it is necessary to remove the instrument to be reprocessed, use all envisaged protection systems (gloves, face visor, face mask etc.). It is possible that liquid will be present inside the basin and the endoscope.

Therefore, rinse the instrument with copious amounts of running water and do not use it on patients.

TROUBLESHOOTING

Type of alarm	Cause	Solution
MINIMUM WATER PRESSURE	1. No mains water pressure 2. Failure in TP1	▶ Check the mains water supply is on. ▶ Check the inlet water pressure. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
MINIMUM AIR PRESSURE	1. No compressed air feed 2. Fault in R1 3. Fault in F4 4. Fault in TP4	▶ Check that the inlet air pressure is present and/or sufficient. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
MAXIMUM AIR PRESSURE	1. Fault in R1 2. Fault in TP4	▶ Check that the inlet air pressure is not too high. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISINFECTANT 1 LOADING TIME OUT ALARM	1. Component A tank empty 2. Aspiration nozzle not inserted in the tank or faulty 3. Fault in SL11 4. Fault in V11 5. Fault in V11a 6. Fault in V11b 7. Fault in V17 8. Fault in P1	▶ Replace the tank. ▶ Check that the cap is correctly inserted into the tank and that it is properly closed. ▶ Check that the nozzle tube is not kinked and is obstructing the passage of liquids. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISINFECTANT 2 LOADING TIME OUT	1. Component B tank empty 2. Aspiration nozzle not inserted in the tank 3. Fault in SL12 4. Fault in V12 5. Fault in V12a 6. Fault in V12b 7. Fault in V17 8. Fault in P1	▶ Replace the tank. ▶ Check that the cap is correctly inserted into the tank and that it is properly closed. ▶ Check that the nozzle tube is not kinked and obstructing the correct liquid flow. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
DETERGENT LOADING TIME OUT	1. Detergent tank empty 2. Aspiration nozzle not inserted in the tank 3. Fault in FT13 4. Fault in V13 5. Fault in P5	▶ Replace the tank. ▶ Check that the cap is correctly inserted into the tank and that it is properly closed. ▶ Check that the nozzle tube is not kinked and obstructing the correct liquid flow. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
ALCOHOL LOADING TIME OUT	1. Alcohol bottle empty. 2. Aspiration nozzle not inserted in the tank. 3. Fault in FT19 4. Fault in V19 5. Fault in P4	▶ Change the bottle. ▶ Check that the cap is correctly inserted into the tank and that it is properly closed. ▶ Check that the nozzle tube is not kinked and obstructing the correct liquid flow. ▶ Send technical intervention request.

TROUBLESHOOTING

Type of alarm	Cause	Solution
DISINFECTANT 1 DISCHARGE TIME OUT	1. Fault in SL11 2. Fault in V11 3. Fault in V11a 4. Fault in V11b 5. Fault in V17 6. Fault in P1	▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISINFECTANT 2 DISCHARGE TIME OUT ALARM	1. Fault in SL12 2. Fault in V12 3. Fault in V12a 4. Fault in V12b 5. Fault in V17 6. Fault in P1	▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISINFECTANT 1 MAX LEVEL ALARM	1. Fault in SL11 2. Fault in V11 3. Fault in V11a 4. Fault in V11b 5. Fault in V17 6. Fault in P1	▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISINFECTANT 2 MAX DISCHARGE LEVEL ALARM	1. Fault in SL12 2. Fault in V12 3. Fault in V12a 4. Fault in V12b 5. Fault in V17 6. Fault in P1	▶ Send technical intervention request.

Type of alarm	Cause	Solution
COVER CLOSURE ALARM	1. Cover open 2. Fault in SW1	▶ Check that the cover of the basin is closed. ▶ Check that nothing is obstructing correct cover closure. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
SPRAY TURNING SENSOR	1. Erroneous endoscope positioning. 2. Fault in SGR	▶ Check that the cover of the basin is closed. ▶ Check that nothing is obstructing the proper movement of the spray arm. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
LEAK TEST ALARM	1. Endoscope selected incorrectly. 2. Interblock connector connected incorrectly. 3. Endoscope connected incorrectly. 4. Endoscope damaged. 5. Fault on P2 6. Fault on V4 7. Fault on V16 8. Fault on TP2	▶ Check correct endoscope selection. ▶ Check proper endoscope seal by manual testing. ▶ Check the interblock connector is connected properly. ▶ Check the endoscope is correctly connected to the interblock connector. ▶ Send technical intervention request.

TROUBLESHOOTING

Type of alarm	Cause	Solution
LEAK TEST OVERPRESSURE ALARM	1. Endoscope selected incorrectly 2. Fault on V16 3. Fault on TP2	▶ Check correct endoscope selection. ▶ Check that the interblock connection leak test tube is positioned correctly. ▶ Check that the endoscope is correctly positioned inside the basin. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 1 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-5 7. Fault in V5 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 2 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-6 7. Fault in V6 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 3 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-7 7. Fault in V7 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 4 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-8 7. Fault in V8 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 5 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-9 7. Fault in V9 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

TROUBLESHOOTING

Type of alarm	Cause	Solution
CHANNEL 6 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-10 7. Fault in V10 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 7 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in TP7 7. Fault in VPP1	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 1 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2 5. Fault in FT-5	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 2 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2 5. Fault in FT-6	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 3 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2 5. Fault in FT-7	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 4 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2 5. Fault in FT-8	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

TROUBLESHOOTING

Type of alarm	Cause	Solution
CHANNEL 5 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2; 5. Fault in FT-9;	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 6 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2; 5. Fault in FT-10;	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 7 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel incorrectly connected 3. Endoscope channel connector fault 4. Fault in TP7 5. Fault in R2	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
MAXIMUM TEMPERATURE ALARM	1. Excessively high temperature 2. Fault in T1 and/or T2 3. Faulty connection in T1 and/or T2	▶ Check that the temperature is within the envisaged limits. ▶ Reduce the equipment inlet temperature. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
MINIMUM TEMPERATURE ALARM	1. Temperature not reached 2. Fault in T1 and/or T2 3. Faulty connection in T1 and/or T2	▶ Check that the temperature is within the envisaged limits. ▶ Reduce the equipment inlet temperature. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
WATER LOADING TIME OUT ALARM	1. No mains water supply 2. F1 filter fault 3. F2 filter fault 4. Basin water inlet connector fault 5. Fault in V1 6. Fault in V18 7. Fault in FT-1 and FT-2	▶ Check for water in the mains water feed. ▶ Check the water stopcock is opened correctly. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
WATER FLOW METER REDUNDANCY ALARM	1. Fault in FT-1 and/or FT-2;	▶ Send technical intervention request.

TROUBLESHOOTING

Type of alarm	Cause	Solution
BASIN LEVEL ALARM	1. Excessive basin liquid level 2. Fault in SL1 3. Fault in P1 4. Fault in FT-1 and/or FT-2 5. Fault in V3 6. Fault in FT-3	▶ Close the water inlet stopcock. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISCHARGE ALARM	1. Discharge pipe blocked 2. Fault in P1 3. Fault in V3	▶ Check that the basin discharge pipe is not blocked. ▶ Check the external waste water system is not blocked. ▶ Send technical intervention request

Type of alarm	Cause	Solution
COMMUNICATION ERROR	1. USB cable disconnected 2. USB cable faulty 3. Faulty circuit board	▶ Check and insert the USB cable into the PC if necessary. ▶ Turn the PC off then on again. ▶ Send technical intervention request.


S / N: 6-0107
MEDIVATORS® ISA®
Endoscope Reprocessor
SPOR
SPOR
CLEAN

CE
0051

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MEDIVATORS® ISA®

Endoscope Reprocessor

USER MANUAL

WASHER-DISINFECTOR

MEDIVATORS
A Cantel Medical Company

MEDIVATORS®
is a registered trademark of Medivators Inc.

ISA®
is a registered trademark of Cantel Medical (Italy) S.r.l.

ISASPOR®
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ISACLEAN™
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FUJIFILM™
is a trademark of Fujfilm Corporation.

OLYMPUS®
is a registered trademark of Olympus Corporation.

PENTAX®
is a registered trademark of Hoya Corporation.

50098-864-EN REV B

DEAR CUSTOMER,

Thank you for having chosen the MEDIVATORS® ISA® Endoscope Reprocessor, designed and manufactured by Cantel Medical (Italy) S.r.l.

This MEDIVATORS ISA Endoscope Reprocessor medical device has been manufactured to the highest standards in order to achieve the highest quality performance, ease of use and safety for reprocessing endoscopes.

Cantel Medical, present in various locations throughout the world, is the major PARTNER in the prevention and control of Hospital Infections, Warrantying clients excellent and innovative solutions in compliance with applicable standards and regulations.

Client satisfaction is OUR MISSION and the driving factor for the development of increasingly innovative and satisfactory solutions.

We ask that you read this manual carefully prior to performing any operations on medical equipment so as to Warranty performance and the safety of all personnel involved.

Besides compromising the cleansing/disinfection process, failure to comply (even partially) with the recommendations reported in this manual invalidates the Warranty and relieves the manufacturer from all responsibility.

For further information regarding this MEDIVATORS ISA Endoscope Reprocessor medical device, please contact your Cantel Medical/Medivators representative or Cantel Medical (Italy) S.r.l. customer services.

USE OF THE MANUAL

This manual describes the characteristics of the MEDIVATORS® ISA® Endoscope Reprocessor, including the hardware, software, operations, safety, maintenance and problem resolution procedures.

It is important to follow the instructions provided in this manual in order to maintain the

MEDIVATORS ISA Endoscope Reprocessor in the correct operational mode and to ensure that endoscopes are suitably disinfected.

This is not a technical support manual and does not provide detailed instructions for support apart from general maintenance. Please refer to the Service Manual for support instructions.

Contact the technical support representative on (+31) 45 5 471 444 for further information.

It is important that this manual be kept safe and in the same location as the equipment so that it may be consulted in the case of any hazard, and that its location be known to all personnel involved in reprocessing/maintenance/installation.

CONTENTS

CHAPTER 1

INTRODUCTION

This chapter describes the medical device for endoscope reprocessing MEDIVATORS® ISA® Endoscope Reprocessor, the safety notices, regulatory compliance, the validated chemical solutions and the technical specifications of the medical device.

SAFETY NOTICES

The purpose of the following notices is to reduce the risk to personnel and prevent the equipment from becoming unsafe due to improper use.

Therefore, both operators and maintenance personnel must follow the instructions in the user and maintenance manual for the MEDIVATORS® ISA® Endoscope Reprocessor cold chemical endoscope Washer-Disinfector.

SAFETY NOTICES

This symbol indicates that the operator must pay particular attention and consult the enclosed documentation.

Symbol of EER regulatory compliance.

This symbol indicates “open”, i.e. disconnected from the main power supply.

Symbol indicating the manufacturer.

This symbol indicates “closed”, i.e. connected to the main power supply.

Symbol indicating the year of manufacture.

Warning symbol for the risk of electric shock.

CE mark issued by the Notified Body in compliance with Directive 93/42/EEC and updates.

DEFINITIONS

Abbreviation	Description
PPE	Personal protective equipment
Manufacturer*	The physical or legal entity responsible for the design, manufacture, packaging and labelling of a device with regard to marketing in their own name, independently of the fact that these operations have been performed by an entity themselves or by a third party acting on their behalf.
MD – Medical Device**	Any instrument, equipment, system, software, substance or other product, used alone or in combination, including software intended by the manufacturer to be used specifically for diagnostic or therapeutic purposes and necessary for the correct operation of the device, intended by the manufacturer to be used in humans for diagnosis, prevention, control, therapy or attenuation of a disease; for diagnosis, control, therapy, attenuation or compensation of a wound or handicap; for study, replacement or modification of anatomy or a physiological process; for intervention in conception, where the product does not exert the main action, in or on the human body, for which it is intended, with pharmacological or immunological means, not by means of a metabolic process but whose function may be assisted by said means.
Accessory***	A product which, despite not being a device, is intended specifically by the manufacturer to be used with a device in order to permit its use as envisaged by the manufacturer themselves.
Intended use******	The use for which the device is intended in accordance with the instructions provided by the manufacturer in the labelling, the information leaflet or in the publicity materials.
Operator	A person instructed by personnel authorized by the manufacturer to use the equipment.
dB	Decibel (relative measurement of sound).
°fH/dH°	French/German Degrees (relative measurement of water hardness).
ppm	Parts per million Calcium Carbonate
RFID	(Radio Frequency IDentification); a technology for the automatic identification of objects, animals or people based on the ability to store and access said information using remote electronic devices (known as TAGs or transponders) capable of responding by communicating the stored information when queried".

*/**/***/****: IMPLEMENTATION OF DIRECTIVE 93/42/EEC and subsequent amendments and additions.

SAFETY NOTICES

Take care when opening the electrical panel and junction boxes labelled with the danger of electric shock sign.

Operators using the MEDIVATORS® ISA® Endoscope Reprocessor must be qualified for this activity and must have completed a training course organized by the manufacturer or personnel authorized by the manufacturer.

Maintenance and repair of the MEDIVATORS ISA Endoscope Reprocessor must be performed by technical staff, qualified and authorized by the manufacturer.

DThe MEDIVATORS ISA Endoscope Reprocessor work area must be kept clean in order to avoid hazardous situations due to the floor conditions.

The electricity supply must be disconnected prior to starting repair or maintenance operations on the MEDIVATORS ISA Endoscope Reprocessor.

The MEDIVATORS ISA Endoscope Reprocessor safety devices must not be altered or tampered with any way.

The MEDIVATORS ISA Endoscope Reprocessor panelling must be cleaned with a soft cloth and non-aggressive solutions.

Sharp pointed tools must not be used to insert or remove the machine‘s gaskets.

In the case of a cycle terminated due to an alarm, the operator must pay the utmost attention, adopting the precautions envisaged, so that the endoscope is reprocessed correctly.

OPERATOR SAFETY

In order to avoid biological contamination and/or chemical burning, PPE must be always be worn when handling the endoscope or the chemical solutions.

The chemical solutions must be used in compliance with the regulations prescribing their use, safety and shelf life. During handling of the chemical solutions, use the protective measures and devices reported in the material safety data sheet. In the case of leakage or the accidental spillage of chemical solutions, follow the material safety data sheets for the chemical solutions.

Do not attempt to open the machine basin cover during the operation cycle.

WARNINGS AND PRECAUTIONS

Wear protective clothing, gloves and eyewear. The manufacturer of the chemical solutions may recommend additional protective measures.

All endoscope connections must be checked periodically in order to make sure they are not damaged, and if that is the case, they must be replaced in order to avoid unfit endoscope reprocessing.

Prior to inserting the endoscope in the MD, make sure it is not damaged, using the instruments and methods envisaged for manual leak testing. Check that all connections to the endoscope are properly inserted. Otherwise there is a risk of the endoscope not being reprocessed correctly and consequently cannot be used on the patient.

WARNINGS AND PRECAUTIONS

Prior to removing the endoscope from the MD, check that all channel connections are inserted correctly. If an adapter is loose or disconnected, the cycle must not be considered valid, and must therefore be repeated.

Wear clean gloves in order to avoid fouling the reprocessed endoscope. If a cycle execution error is generated, the endoscope must not be used on a patient.

Use only the chemical solutions (detergent and high level sterilizer/disinfectant) declared and validated by the manufacturer. Never use chemical solutions beyond the expiration date indicated by the manufacturer.

Should it become necessary to replace the tanks containing the chemical solutions, always wear PPE.

Should it become necessary to replace the filters, always wear PPE.

If the equipment is used in a manner not specified by the manufacturer, the safety devices envisaged might be compromised.

Do not place objects on the glass cover.

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:

- **UNI EN ISO 15883-1**
  "Endoscope Reprocessors - Part 1: General requirements, terms and definitions and tests".
- **UNI EN ISO 15883-4**
  "Endoscope Reprocessors - Part 4: Requirements and tests for endoscope reprocessors employing chemical disinfection for thermolabile endoscopes".
- **UNI 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".

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 UNI EN ISO 15883-1/4 and UNI CEN ISO/TS 15883-5.
- A personal and touch-screen computer (PC) 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 (0.45 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.

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:

- For the cleaning cycle, MEDIVATOR ISA Endoscope Reprocessor uses ISACLEAN multienzyme detergent/decontaminant, a certified medical device (CE 0546) specific for the removal of microbial biofilms.
- ISACLEAN multienzyme detergent/decontaminant is available in 10 L tanks.
- A 10 L tank of ISACLEAN multienzyme detergent/decontaminant allows the execution of approx. 625 cycles.

FOR THE DISINFECTION PHASE:

ISASPOR® SINGLE SHOT high level Disinfectant/Sterilizing solution:

- For the disinfection cycle, the MEDIVATOR ISA Endoscope Reprocessor uses ISASPOR® Single Shot High Level Disinfectant/Sterilant, a certified medical device (CE0546).
- This device consists of a tank containing solution A (5% peracetic acid) and a tank containing solution B (containing ISAZONE®*) ingredient.
- 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.
- The detergent and high level disinfectant/sterilizing solution used for each cycle are single use (single shot).
- The medical device distribution system ensures that, for each cycle, the correct amount of concentrated product is withdrawn from the tanks and ensures that said products are injected into the basin containing the endoscope.

*molecule patented by Cantel Medical.

FOR THE DISINFECTION PHASE:

To aid with the proper connection of the aspiration nozzle to the relevant product tanks, the black cap for sol. A (5 liter tank) has a different colour and shape from the white cap for sol. B - ISASPOR® Single Shot High Level Disinfectant/Sterilant (5 liter tank).

The black cap only fits the tank for product A.

The white cap only fits the tank for product B.

In order to Warranty 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 Warranty process efficacy. Further, compatibility with the equipment and with the endoscopes is NOT Warrantyd

The tanks for the chemical solutions are housed in the lower, front compartment of the device so as 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.

HANDLING AND STORAGE OF 70% ISOPROPYL ALCOHOL

In the MEDIVATORS® ISA® Endoscope Reprocessor, it is possible to incorporate a final drying step after the cleaning cycles using 70% isopropyl alcohol (optional). The isopropyl alcohol solution is not supplied by Cantel Medical (Italy) S.r.l. but must be purchased by the client. The device has an internal compartment at the top right of the equipment where the alcohol bottle may be connected.

The following instructions must be followed for the handling and storage of 70% isopropyl alcohol:

- **Handling**
  Avoid spillage of the product and any prolonged and/or repeated contact with the skin. Extinguish any naked flames. Remove any sources of ignition and avoid the creation of sparks. Do not smoke. Take precautionary measures against static discharges. Connect all instruments to earth. Do not dispose of the product in the waste water system.
- **Handling temperature**
  Ambient temperature.
- **Storage**
  Keep out of direct sunlight and away from sources of heat or ignition. Do not smoke in storage areas. Keep the container tightly sealed and in a well-ventilated area.
- **Storage temperature**
  Ambient temperature.
- **Transfer of the product**
  Adopt precautionary measures against static discharges. Connect all instruments to earth.
- **Protection of the respiratory tracts**
  No special measures.
- **Eye protection**
  Single lens face mask.
- **Body protection**
  Standard work clothes. Safety footwear or boots resistant to chemical products.

MEDIVATORS® ISA® ENDOSCOPE REPROCESSOR CHANNEL CONNECTIONS

Endoscopes must be connected to the MEDIVATORS ISA Endoscope Reprocessor using the connectors provided by Cantel Medical (Italy) S.r.l. and following the instructions provided.

Any modifications to the connectors provided may compromise proper function of the system and irrigation of the endoscope channels, and hence the reprocessing cycle.

The connectors must NEVER be modified.

It is prohibited to use connectors other than those recommended by the manufacturer. To identify the type of connector required for your endoscope, contact the Cantel Medical or MEDIVATORS authorized representative

TECHNICAL SPECIFICATIONS OF THE MEDIVATORS® ISA® ENDOSCOPE REPROCESSOR

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

Abbreviation	Description
Power supply	100 V – 240 V; 50/60 Hz
Nominal version power consumption	300 W
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°fH (4,5° – 28°dH, 80–500ppm)
Water supply temperature	25°C ± 5°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
Dimensions (LxHxW)	Dimensions: 70 x 102.5 x 65 cm
Weight	~ 75 kg

DESCRIPTION OF THE TECHNICAL SPECIFICATIONS

- **Power supply**
  The required power supply is in the range between 100V and 240V with a frequency of 50/60Hz.

- **Nominal power**
  The maximum power consumption is 300W.

- **Compressed air**
  The MEDIVATORS® ISA® Endoscope Reprocessor requires oil-free compressed air with pressure between 4 and 6 bar and a minimum flow rate of 20 l/min.
  The device has a connector for a 3/8 mm tube, found in the accessories supplied with the equipment. In the case where hospital medical air is not available, an oil-free medical compressor is available (optional).

- **Water supply**
  The water supply for the MD must be of “potable” quality with a hardness between 8°fH and 50°fH (4,5°dH - 28°dH, 80–500ppm) supplied at a temperature of between 20°C and 30°C by connecting the hot and cold water supplies to a thermostatic water mixer (not included in the standard kit). The equipment has a 3/4“ male connector and the relevant feed tube is included in the standard kit. There is an optional device for back flow prevention, conforming to the requirements of IEC 61770.

- **Machine discharge**
  The equipment has a stainless steel discharge connector, and a flexible tube is provided in the standard kit. The maximum height of the discharge tube to be connected to the MD is 510 mm.

- **Operating relative humidity**
  For correct use of the MEDIVATORS ISA Endoscope Reprocessor the relative humidity level must be less than 80% (condensation-free).

- **Operating temperature**
  The operating ambient temperature for the MEDIVATORS ISA Endoscope Reprocessor must be no less than 5°C and no greater than 40°C. For correct operation, the system must be located away from sources of heat.

- **Atmospheric emissions**
  The MEDIVATORS ISA Endoscope Reprocessor operates as a closed-circuit and there are no detectable environmental emissions. Any emissions due to changing the tanks or opening the basin are not toxic or harmful to human health.

- **Ventilation of the environment**
  It is recommended that the equipment be installed in an environment with a ventilation system capable of providing 10 changes per hour. For the installation of several MEDIVATORS ISA Endoscope Reprocessor in the same room, it may be necessary to increase the number of exchanges per hour.

- **Transportation and storage**
  The MEDIVATORS ISA Endoscope Reprocessor must be stored and housed in compliance with the following conditions: temperature 5-40°C, relative humidity 20-80% and pressure of 500-1060 hPa. Prior to moving the equipment, make sure that the electrical cable, the discharge tube and the water supply system are disconnected, or that their lengths are sufficient to allow movement of the equipment.

The technical specifications reported above ensure the correct operation of the MEDIVATORS ISA Endoscope Reprocessor. Failure to comply with the above alters the performance of the equipment and the efficacy of the cycle, and can result in damage not covered by the manufacturer‘s Warranty.

DIMENSIONS

Figure 1
Front Dimensions.

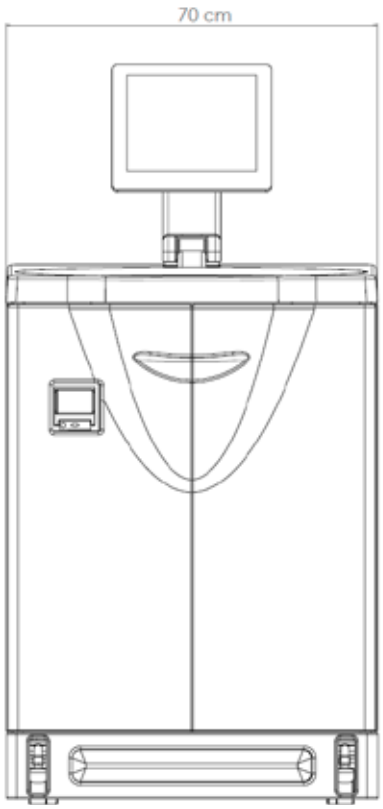
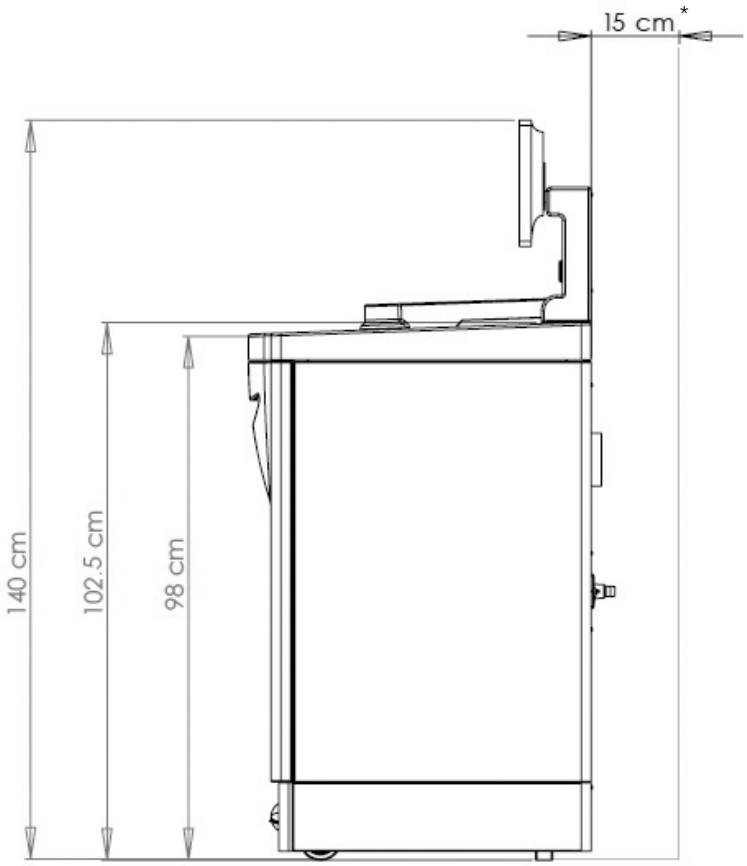


Figure 2
Side Dimensions and Spacing (cover closed).



*recommended but not mandatory distances.

DIMENSIONS

Figure 3
Side Dimensions and Spacing (cover open).

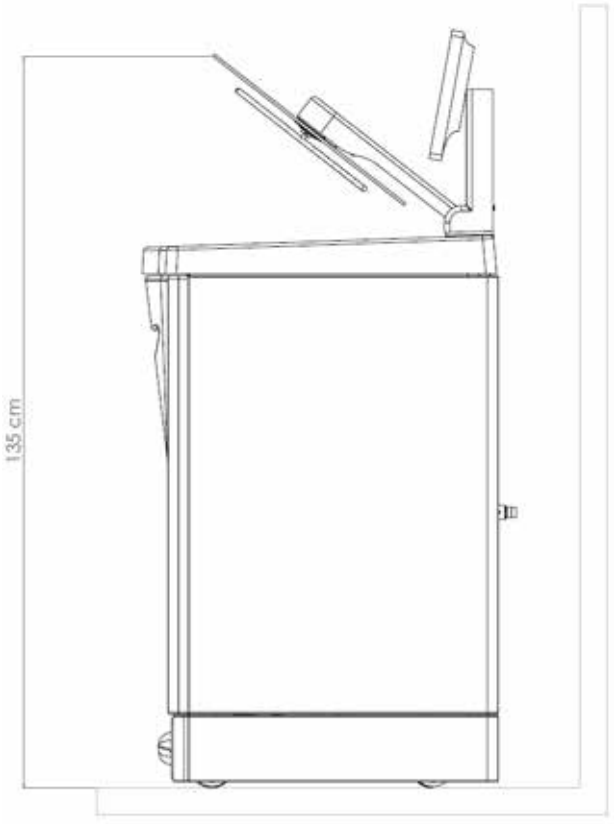
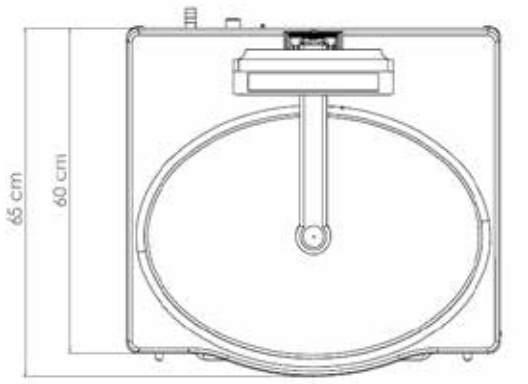


Figure 4
Basin dimensions.



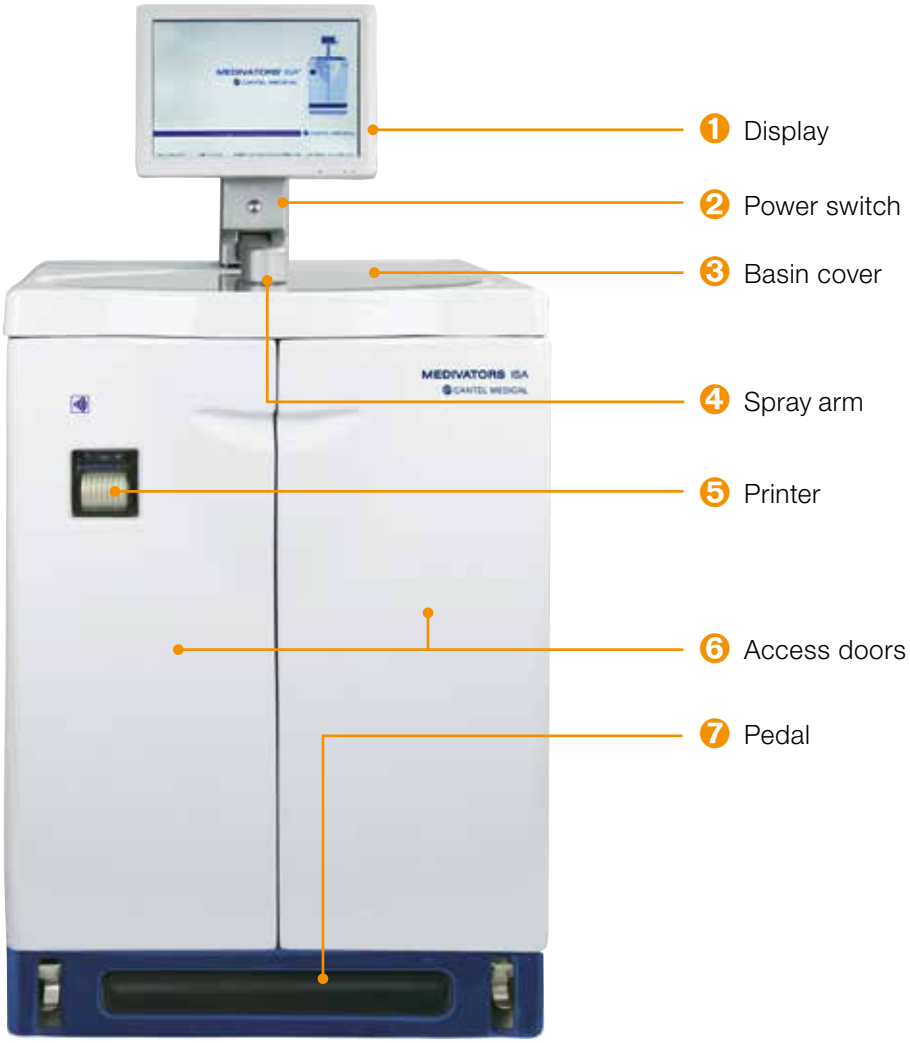
CHAPTER 2

MAIN COMPONENTS

This chapter describes the main components of the MEDIVATORS® ISA® Endoscope Reprocessor.

EXTERNAL COMPONENTS

Figure 1
Front view of the MEDIVATORS® ISA® Endoscope Reprocessor



EXTERNAL COMPONENTS

Figure 2
Rear view of the MEDIVATORS® ISA® Endoscope Reprocessor.

INTERNAL COMPONENTS

Figure 3
Viewed from above the basin of the MEDIVATORS® ISA® Endoscope Reprocessor.

INTERNAL COMPONENTS

Figure 4
Chemical solutions and alcohol (optional) of the MEDIVATORS® ISA® Endoscope Reprocessor.

1. Alcohol Bottle (optional): The alcohol bottle is located to the upper right inside the front housing.

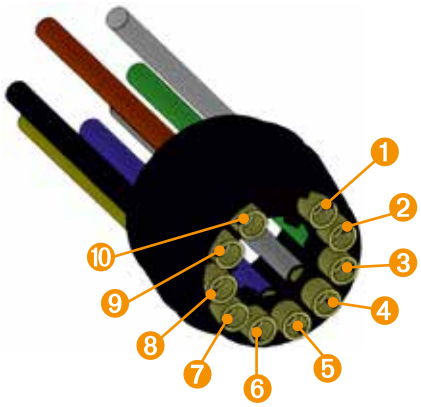
2. Tank for ISASPOR® SINGLE SHOT high level sterilizer/ disinfectant - Solution A: Contains Solution A of the ISASPOR single shot high level sterilizer/disinfectant, 5% peracetic acid. Component A uses a green coloured tank with a black cap, and is located on the left side inside the front housing.

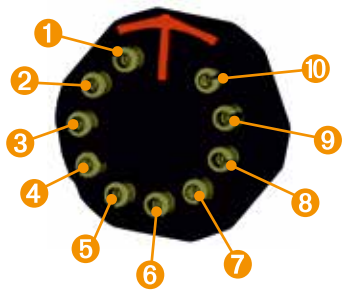
3. Tank for ISASPOR SINGLE SHOT high level sterilizer/ disinfectant - Solution B: It contains Solution B of ISASPOR single shot high level sterilizer/disinfectant, ISAZONE® ingredient. Component B uses a white coloured tank with a white cap, and is located in the centre position inside the front housing.

4. Detergent Tank: This contains the ISACLEAN™ detergent used in the washing process. The detergent uses a white coloured tank with a black cap (of a different size from those containing component B) and is located on the right side inside the front housing.

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.

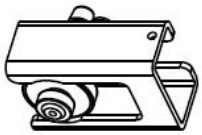
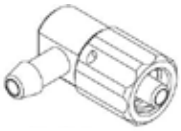




Position	Name in the software	Channel
1	**Leak Test Channel**	Leak Test
2	**Not used**	Not used
3	**Aux Channel 1**	Elevator Channel
4	**Channel 2**	Jet Channel
5	**Channel 3**	Water Channel
6	**Channel 6**	Extra Channel
7	**Channel 4**	Air Channel 2
8	**Channel 5**	Biopsy Channel
9	**Not used**	Not used
10	**Channel 1 (Kanal 1)**	Air Channel 2

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.

EXAMPLE OF CONNECTORS FOR ENDOSCOPE CHANNELS

Leak Test connection	
Biopsy channel connection	
Air channel connection	
Auxiliary or elevator channel connection	
Channel separator connection (buttons)	
Air-water connection	
Suction channel connection	

To identify the type of connector required to reprocess the various endoscope types, contact the Cantel Medical or Medivators authorized representative.

BASIN COVER CONTROL PEDAL

The control pedal allows the operator to open and close the lid without the use of hands, thus aiding easy insertion of the endoscope inside.

Once the pedal is pressed, the equipment emits an acoustic warning signal confirming the execution of the command.

PRINTER

The MEDIVATORS® ISA® Endoscope Reprocessor is equipped with an integrated printer fitted as standard, facing frontwards and located to the upper left of the device.

On completion of each reprocessing cycle, the device automatically prints a report containing the information relating to the cycle: cycle start date and time, endoscope ID code, medical operator (optional), patient (optional), type of cycle executed, all the various phases conducted, indicating the times and cycle outcome.

Reprocessing report

5 Printer

RFID RECOGNITION SYSTEM

An automatic recognition system is provided for the endoscope and the operator by means of TAGS, using an RFID data acquisition system.

The TAG recognition zones are positioned according to the layout proposed in the following figures:

RFID A = Operator TAG recognition

RFID B = Endoscope TAG recognition

RFID SYSTEM
OPERATOR- ENDOSCOPE RFID SYSTEM

Once the basin cover is opened using the control pedal, the automatic operator-endoscope RFID identification function allows the user to insert the endoscope into the basin and automatically recognize them by means of the related TAGS. Subsequently, having closed the lid using the control pedal, the user can proceed in two ways:

1. Proceed with user recognition and start the desired cycle using the manual on-screen commands;

2. Proceed with user recognition and automatic preset cycle start by holding your TAG on the reading strip for at least 3 seconds. At this point the cycle starts automatically without the need to press any of the buttons on the screen;

In the case where a password request has been set to remove the endoscope from the basin, on completion of the cycle, the user must ensure their tag is recognized and it will then be possible to open the cover.

FILTRATION SYSTEMS

The MEDIVATORS® ISA® Endoscope Reprocessor is equipped with a water and air filtration system capable of Warrantying the efficacy of the reprocessing cycles performed.

Water filter

- The device is equipped with a dual water filtration system:
- 0.45 micron water filter capsule;
- 0.1 micron water filter capsule;
- A pair of water filters are supplied with the equipment on installation.
- Replacement of both water filters is scheduled with a frequency of 4 months.
  However, the lifespan of the water filters might be less than expected due to poor water quality at the installation site.

	Code	Description
1	**ISAF01**	0.1 micron Water Filter Capsule
2	**ISAF045**	0.45 micron Water Filter Capsule

Replacement of the water filters must be performed by qualified technical staff authorized by the manufacturer. Otherwise the efficacy of the washing and sterilization processes is NOT Warrantyd.

Any damage resulting from failure to replace the water filters and/or the use of NON ORIGINAL filters and/or operations performed by NON authorized personnel will invalidate any type of Warranty. The use of filters other than those indicated by the manufacturer does NOT Warranty the efficacy of the washing and disinfection processes.

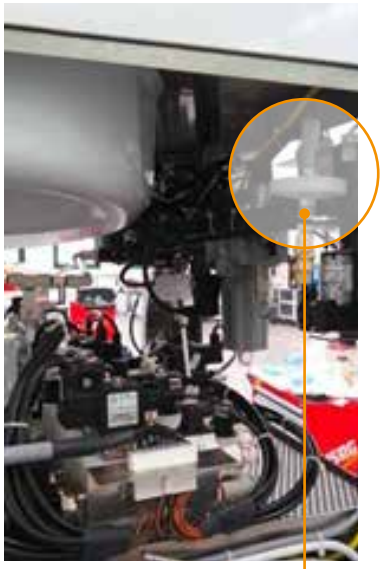
AIR FILTERS

The device is equipped with two air filters:

1. Leak test air filter;
2. Drying air filter.

A pair of air filters are supplied with the equipment on installation. Subsequently, they must be replaced with a frequency of 4 months.

1 ISA4400



2 ISA4400

	Code	Description
1	**ISA4400**	0.2 micron Leak Test Air Filter
2	**ISA4400**	0.2 micron Compressed Air Filter

Replacement of the AIR filters must be performed by qualified technical staff authorized by the manufacturer. Otherwise the efficacy of the washing and disinfection processes is NOT Warrantied.

Any damage resulting from failure to replace the air filters and/or the use of NON ORIGINAL filters and/or operations performed by NON authorized personnel will invalidate any type of Warranty. The use of filters other than those indicated by the manufacturer does NOT Warranty the efficacy of the washing and disinfection processes.

CHAPTER 3

INTRODUCTION

This chapter describes the processing to be performed on endoscopes subsequent to their use, starting from the manual pre-treatments up to the automatic reprocessing to be performed in the MEDIVATORS® ISA® Endoscope Reprocessor.

INSTRUMENTATION PREPARATION GUIDE

Reference to the “Extract from the GUIDELINES States: Cleaning and Disinfection in Endoscopy“

In order to be effective, the decontamination and disinfection process for endoscopes must be performed according to a pre-established and consistent sequence.

This consists of the following steps, none of which must be omitted or performed in a rush or in an approximate manner:

Decontamination and Disinfection process for instruments:

- Pre-cleaning
- Leak test
- Manual Cleaning
- Manual or Automatic disinfection or sterilization
- Final rinse
- Drying
- Storage

MANUAL ENDOSCOPE CLEANING STEPS

Pre-cleaning

a) On completion of the endoscopy examination, apply the cleaning valve.
b) Aspirate water and detergent through the channels inside the instrument.
c) Wipe the exterior of the instrument with a gauze moistened in the same solution.
d) Turn off the column.
e) Apply the video control cover cap to the light holder stem of the instrument (seal cap) for videoendoscopes.
f) Place the instrument inside a suitable container and take it to the wash room.

LEAK TEST

Prior to starting cleaning, it is necessary to check that the instrument has not suffered any damage during use (holes due to biting, assorted prosthetics, examination manoeuvres). Depending on the type of instrument, use the manual tester or immerse the instrument itself in water taking care to keep it in as extended a position as possible (not coiled) and after having connected the tester, turn on the tap. In the case any problems should be observed, send the instrument to a specialist company for repair, without attempting any manipulation that might be even more damaging for both the device itself and the Operator. **It should be remembered that certain endoscope washing machines have the ability to automatically check the instrument, but the manual method is the most certain and valid in that it avoids false negatives.**

Only move on to the subsequent step if the instrument is intact.

MANUAL CLEANING

a) Wear the appropriate PPEs.

b) Insert the leak test in the light source and connect it to the endoscopy device; it is recommended the leak test be inserted in order to keep the pressure constant and suitable inside the internal channels of the instrument for the entire time of manual washing.

c) Still connected to the leak test, immerse the instrument in the detergent solution, prepared in accordance with the manufacturer‘s instructions.
Never immerse the instrument prior to having connected it to the leak test: in the case of rupture this may cause further damage due to infiltration. The instrument must be immersed completely in the detergent solution.

d) Remove all the valves from the instrument.

e) Pass the short pipecleaner at least three times through the biopsy and aspiration channels.

f) Then use the long brush to clean all the channels inside the instrument at least three times.

   Make sure that this emerges from the opposite end of the instrument every time.

   The brush must be recleaned after each introduction, its bristles must be cleaned under running water in order to avoid retrograde recontamination.

   There are currently brushes on the market with more bristles, or systems with solutions other than bristles, for example small disks, or even microspheres that are aspirated through the channel together with detergent, thus removing the dirt.

   In the case of employing said alternative systems, it is recommended that the manufacturer‘s instructions be followed strictly.

g) Brush the ends of the instrument using a soft brush, paying particular attention to the air/water nozzle and the directional elevator (e.g. duodeno-scopes).

h) Clean the instrument externally using a soft sponge.

i) Apply the specific connectors for washing the operative-auxiliary channels (e.g. angled)

j) Insert the adapter by sliding it in and wash each channel separately by aspirating the detergent solution, ensuring that this passes through the channel from the inlet to the end section of the wash and aspiration channels, and the connection to the light source.

k) For the auxiliary channels, wash after having applied the adapter, using small syringes (e.g. 5 ml).

l) Rinse the instrument thoroughly, both internally and externally, using running water in order to remove any traces of detergent.

m) On completion of this operation, pat the instrument
dry using disposable swabs.

n) Proceed with disinfection.

DISINFECTION

All operations must be carried out using appropriate PPEs.

- Following manual cleaning, lodge the instrument in the disinfection basin of the endoscope reprocessor
- Connect all channels using the specific connectors so that the disinfectant floods them completely; follow the manufacturer‘s instructions
- Make sure all channels are connected
- Insert the valves and the accessories in the specific container, where available
- Remove gloves and close the endoscope reprocessor
- Select the appropriate program and start the machine
- On completion of the cycle, check that all operations have been completed according to the manufacturers parameters
- Open the cover and remove the endoscope. Dry the instrument thoroughly and place it in a dedicated cabinet along with its valves

DRYING AND STORAGE

The internal and external surfaces, valves and disinfection accessories must be dried completely so as to avoid the regrowth of microorganisms present in any residual water. Drying must be performed using filtered (0.2 micron filter) or medical grade air at a maximum pressure of 0.5 bar so as not to damage the internal channels of the instruments.

The majority of washers-disinfectors, even those with a drying step, do not Warranty the complete removal of water residues.

Therefore, prior to storing the instruments at the end of the working day, it is recommended they be dried manually and completely.

Drying can be more rapid between one examination and another: residual water is removed from the internal and external surfaces, and the valves and all parts of the light holder stem (electrical contacts) are dried.

The endoscopes, complete with their valves and disinfection accessories, must be stored vertically in a dry environment, in specific cabinets, possibly ventilated.

The valves and sealing cap must not be inserted in the instrument, but stored together with it.

During the drying and storage procedures and removal from the cabinets, gloves must be worn in order to avoid any recontamination from microorganisms present on the operators hands.

There are various type of cabinets available on the market fitted with filters and capable of maintaining such an environment (temperature, humidity) as to prevent the proliferation of pathogenic microorganisms during prolonged periods of storage.

There is no scientific evidence showing the need to process endoscopic devices at the start of each working day. providing these have been properly reprocessed, dried and stored. On the other hand, there is also no evidence available to support the need for reprocessing endoscopes even after storage for 48-72 hours.

Or rather, the few published works tend to confirm that, having performed the final reprocessing steps correctly, no regrowth of pathogens is observed several days later (Rejchrt 2004; Vergis 2007).

Failure to carry out the preliminary steps does NOT Warranty the efficacy of the process and correct reprocessing of the endoscope. Therefore, the manufacturer is exempt from all responsibility resulting from the failure to conduct the operations described.

Failure to carry out the preliminary steps may lead to the presence of residual organic matter capable of causing damage to the components of the instrument circuit: in this case, maintenance operations will NOT be considered to be covered by the Warranty.

CHAPTER 4

INTRODUCTION

This chapter describes the operation of the MEDIVATORS® ISA® Endoscope Reprocessor vice, and how to disinfect an endoscope.

COLD CHEMICAL ENDOSCOPE REPROCESSOR CYCLE START PROCEDURE

Prior to starting a reprocessing cycle on a MEDIVATORS® ISA® Endoscope Reprocessor, ensure that:

- The connections to the mains electricity, water and compressed air supplies are active.
- The tanks containing the detergent and high level disinfectant/sterilant chemical solutions are present in the specific compartment.
- The bottle of 70% isopropyl alcohol (optional) for MEDIVATORS ISA Endoscope Reprocessor is present.
- The main electricity power shut-off switch for the equipment, located on the rear panel of the equipment, is activated.
- Open the stopcocks for the water and air.

Figure 1 I Activation switch
To activate the power, move the switch to position

Figure 2 I PC on/off switch
Turn on the PC using the button located under the touch screen monitor

LOADING THE ENDOSCOPES INTO THE BASIN

To correctly load the endoscope into the basin, proceed as reported below:

1. Wear the personal protective equipment for transport of the endoscope to be reprocessed.
1. Open the lid of the basin using the pedal (Figure 3).

This will be followed by a short acoustic signal confirming the command has been implemented.

Figure 3 I Pedal
Black strip present on the lower part of the equipment

Figure 4
Basin connector

3. Connect the mobile interconnection block to the fixed the basin connector (Figure 4) and fix it by turning the red lever on it counterclockwise until it is locked.

Figure 5
RFID B-Endoscope TAG

Insert the endoscope inside the basin and perform recognition by passing the endoscope tag over the RFID B recognition zone, located close to the front of the island: a short confirmatory acoustic signal will follow.

N.B. Place the endoscope inside the basin, paying attention to locate it below the spray arm (rotating arm located on the cover). In addition, ensure that the endoscope connecting tubes do not interfere with rotation of the spray arm.

Figure 6
1. Connect all endoscope channels to the relevant interconnection block connectors.

Figure 7
2. Proceed with operator recognition by bringing the operator TAG close to the RFID A reading zone, as reported below:

3. Close the basin lid by 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.
4. Proceed with the cycle start procedure from the software, reported in this chapter.

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.

ENDOSCOPE TREATMENT CYCLES

The MEDIVATORS® ISA® 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
Disinfection	12 min	Disinfection cycle only, with no cleaning
Auto-Disinfection	20 min	Internal circuit sterilization cycle

Table 1. The MEDIVATORS ISA 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"

duration:
20 minutes

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

STEPS IN THE “DISINFECTION CYCLE”

duration:
12 minutes

1. Initial leak test (with monitoring throughout the entire cycle)
2. Water and disinfectant solution loading
3. Disinfection
4. Solution discharge
5. Water loading
6. Rinsing
7. Water discharge
8. Endoscope channel drying

STEPS IN THE “SELF-DISINFECTION“ CYCLE

duration:
20 minutes

1. Initial leak test (equipment circuits only, and with monitoring throughout the entire cycle)
2. Water and sterilizer loading
3. Mixing
4. Sterilization
5. Solution Discharge
6. Water Loading
7. Rinsing
8. Water discharge
9. Drying

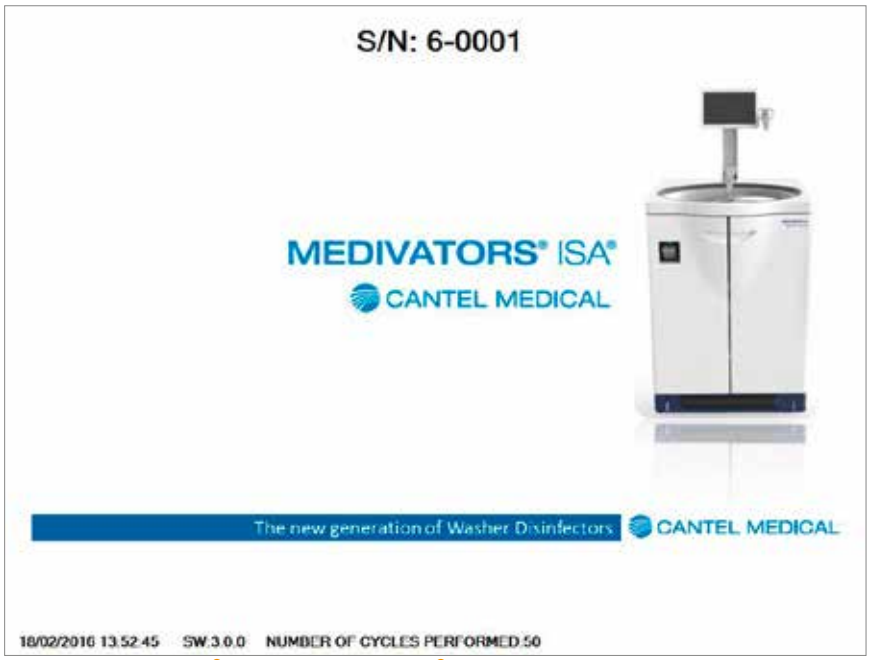
Cantel Medical recommends daily execution of the programmed auto-disinfection cycle in order to sterilize all internal fluid circuits and water filters in order to Warranty a higher level of safety with regard to infections.

VOLUME OF WATER USED PER CYCLE

- Complete Disinfection cycle: 31 litres
- Disinfection Cycle: 17 litres
- Self-disinfection Cycle 17 litres

MEDIVATORS® ISA® ENDOSCOPE REPROCESSOR SOFTWARE PROCEDURES

On start-up of the equipment management program, the following page appears:



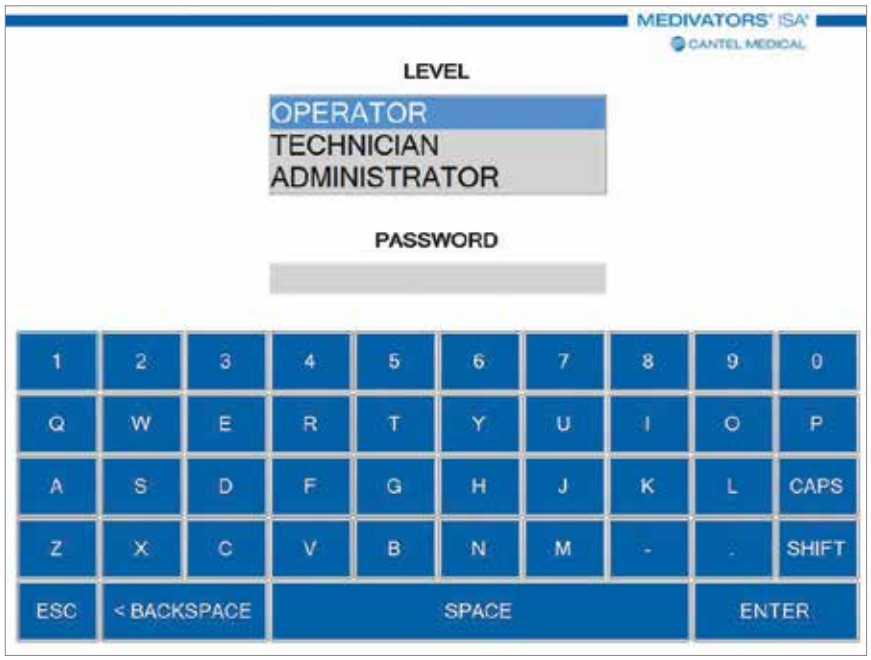
Date and time synchronized with the computer

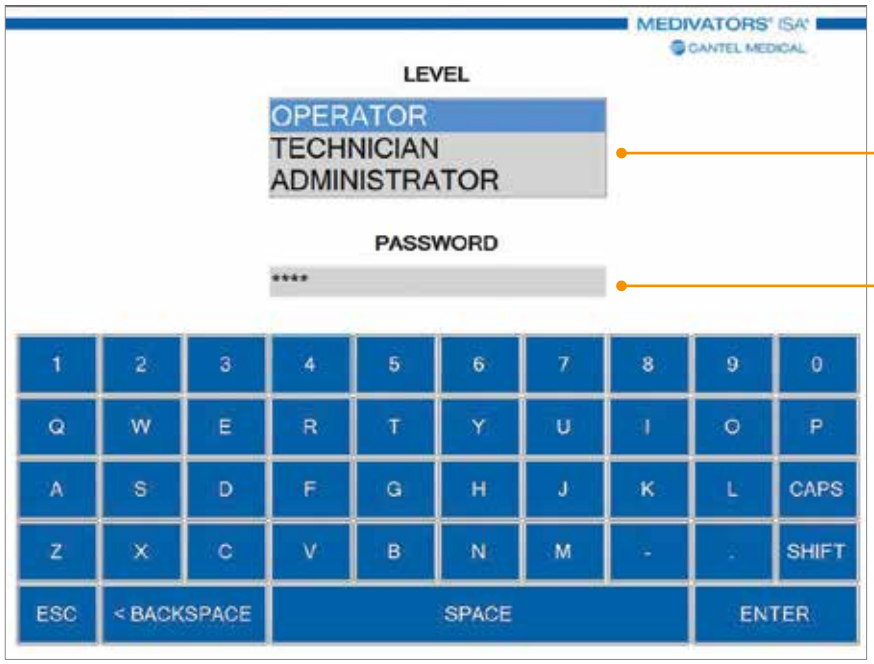
Software revision

Cycle counter

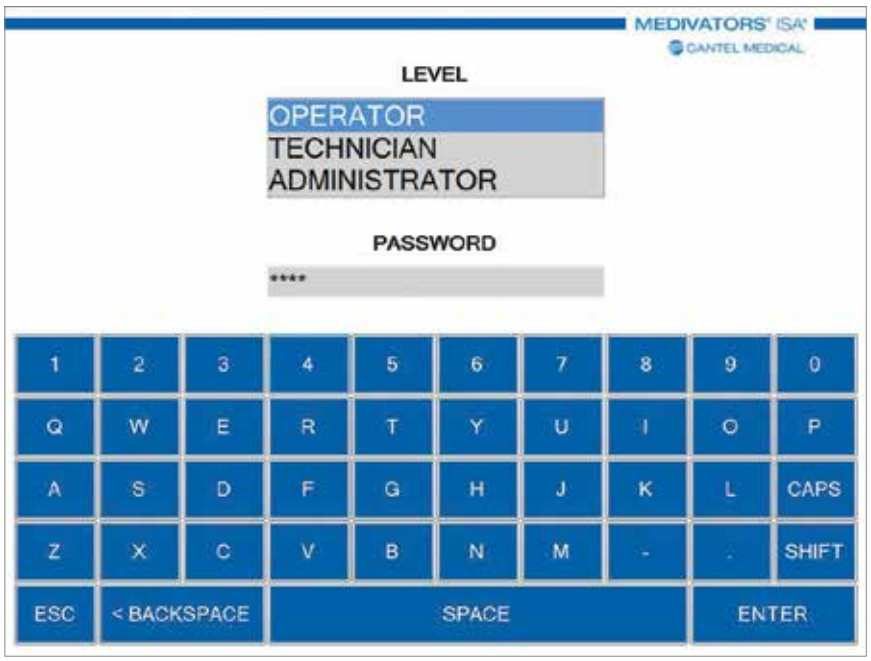
Touching any part of the screen accesses the following page, requiring authorization for access to the user interface functions, obtained by entering a personal ID code.

The line located under the LEVEL option represents a menu with the various software function access levels.

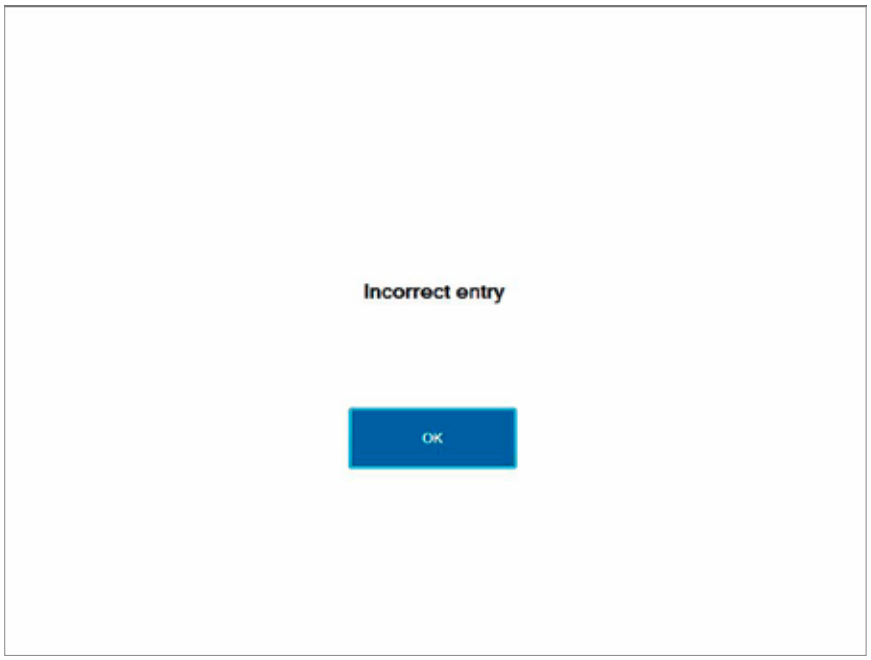




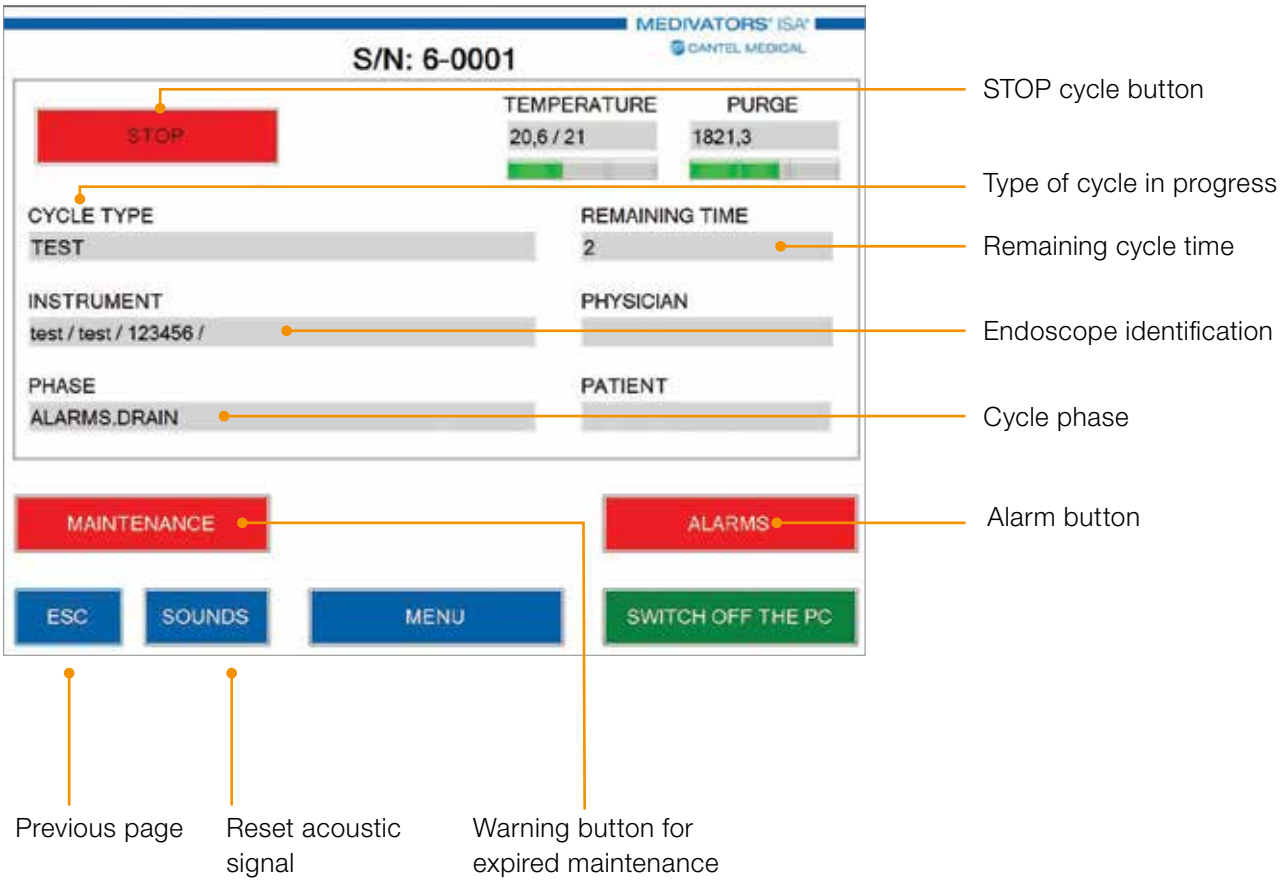
Your personal ID code should be entered in the strip under the PASSWORD option by clicking on the screen and using the keyboard to enter the alphanumeric code, which appears in “encrypted” form as a series of asterisks.



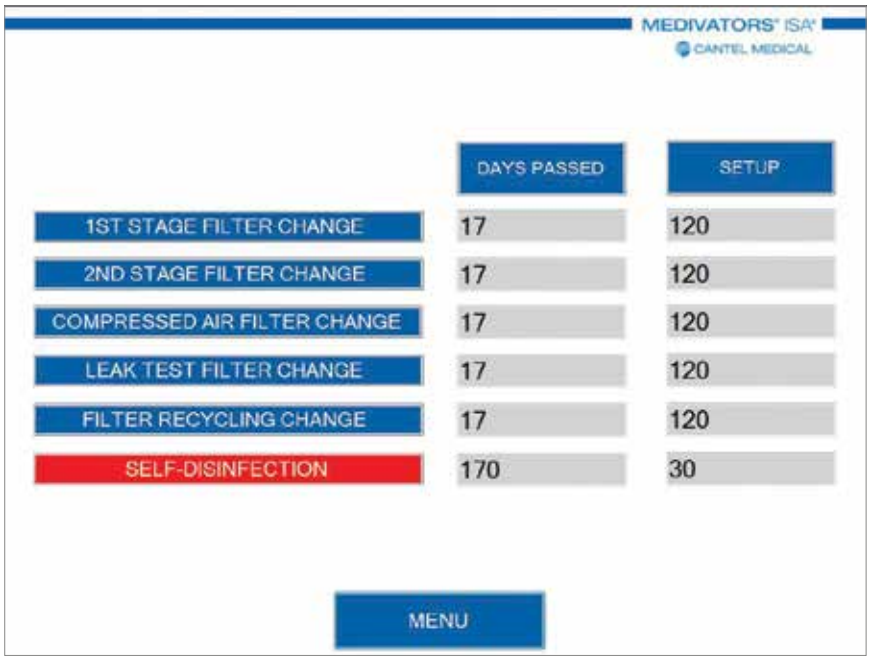
On completion of entry, click the ENTER button.
If an erroneous password is entered, the following error message will be displayed:



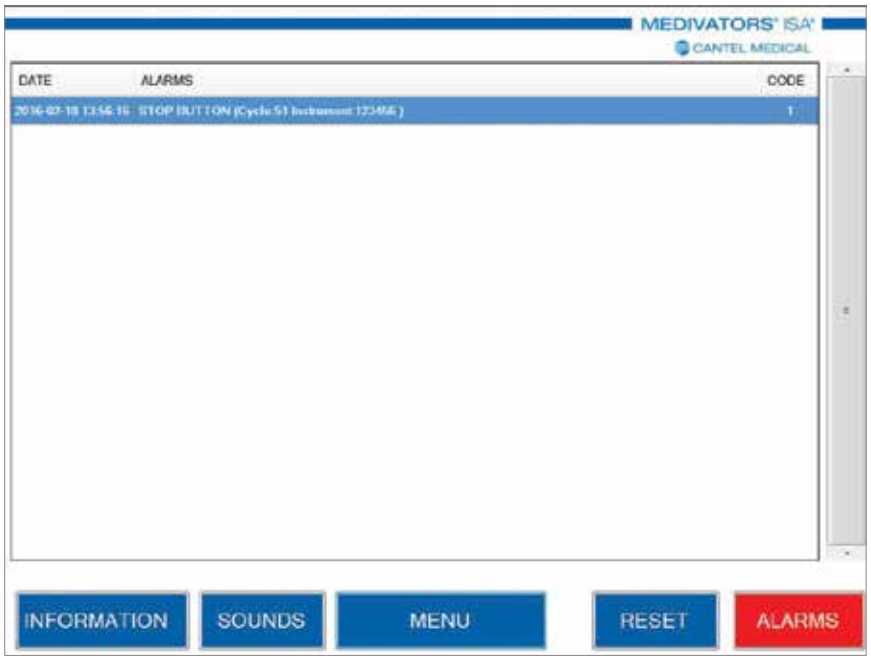
After having entered the LEVEL and PASSWORD, press the ENTER button. This will access the following page (in the most complete configuration possible, i.e. with an ongoing alarm and with the periodic maintenance warning expired):



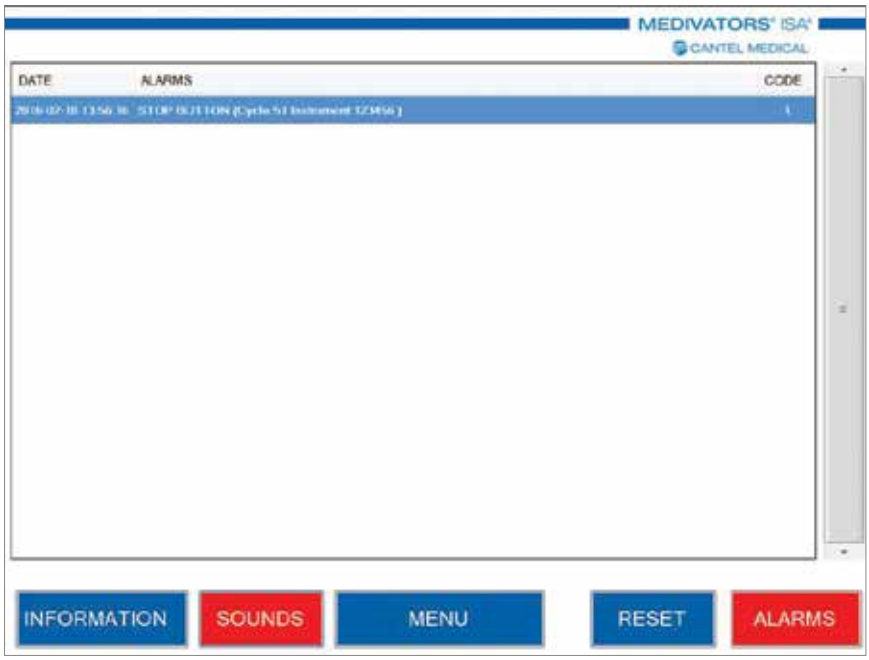
Typing on MAINTENANCE button, you can view the expired maintenance and especially the days spent by the installation of filters with an indication of the set-up (indicating the duration of the filters).



Typing on the ALARMS button, you can display the page the historian of alarms triggered:

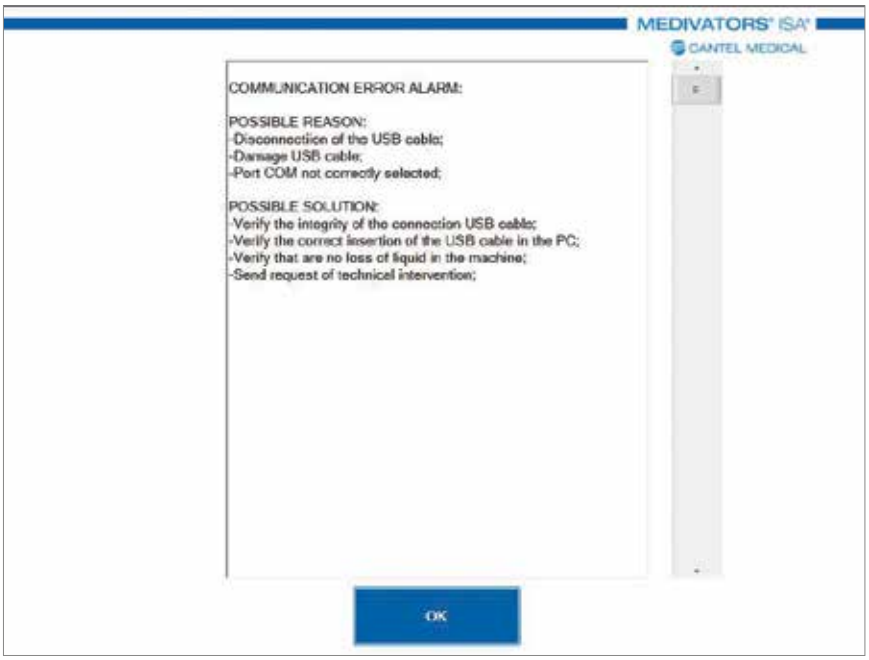


Pressing the SOUNDS button disables all acoustic signals (the button colour turns red):



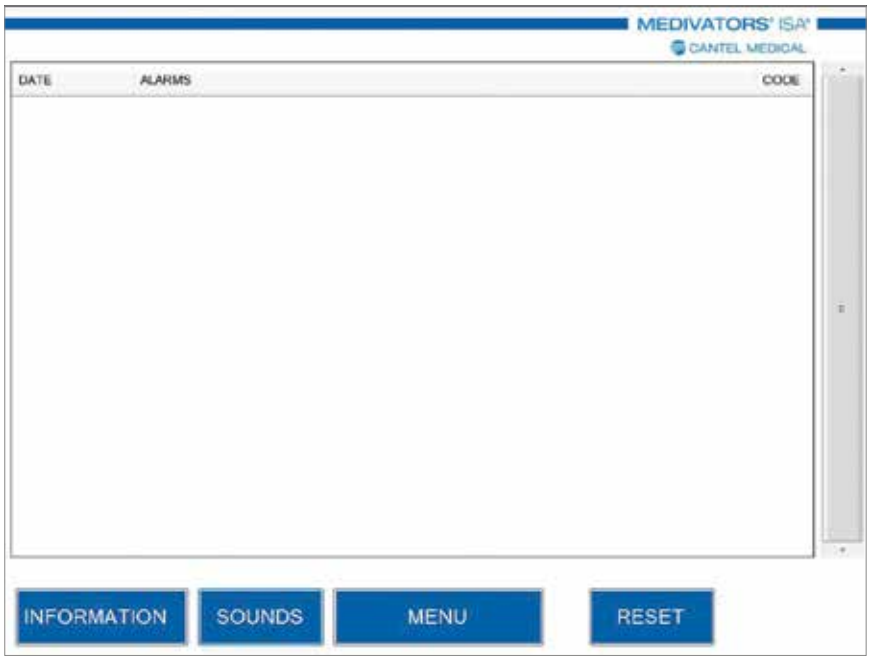
Pressing the INFORMATION button can allow viewing of the information relating to alarms in progress, and in particular, the potential causes and possible solutions.

Possible solutions are not displayed for all those types of alarms requiring the exclusive intervention of a specialized technician.

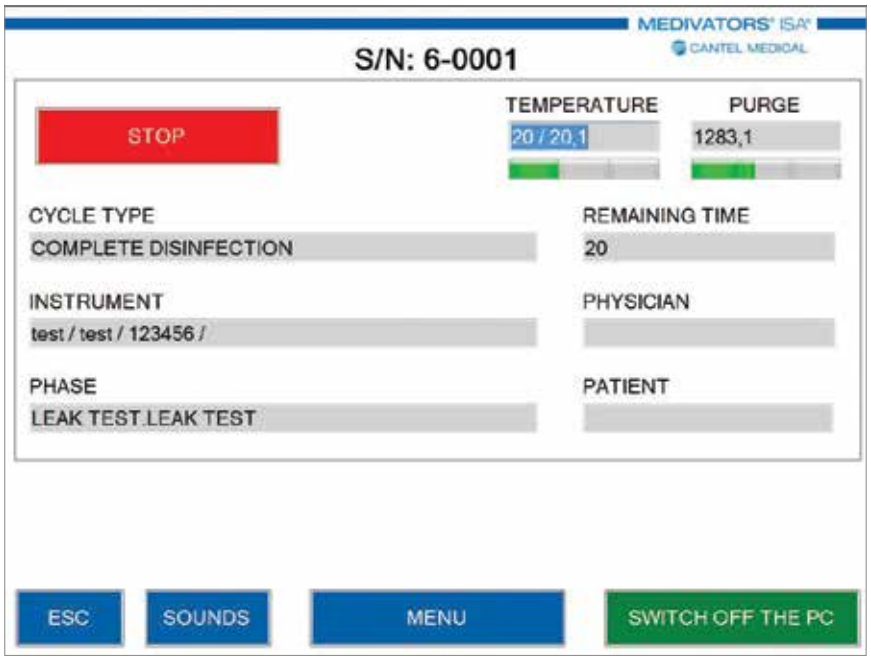


Pressing the RESET button resets the alarm in progress and the related acoustic signal.

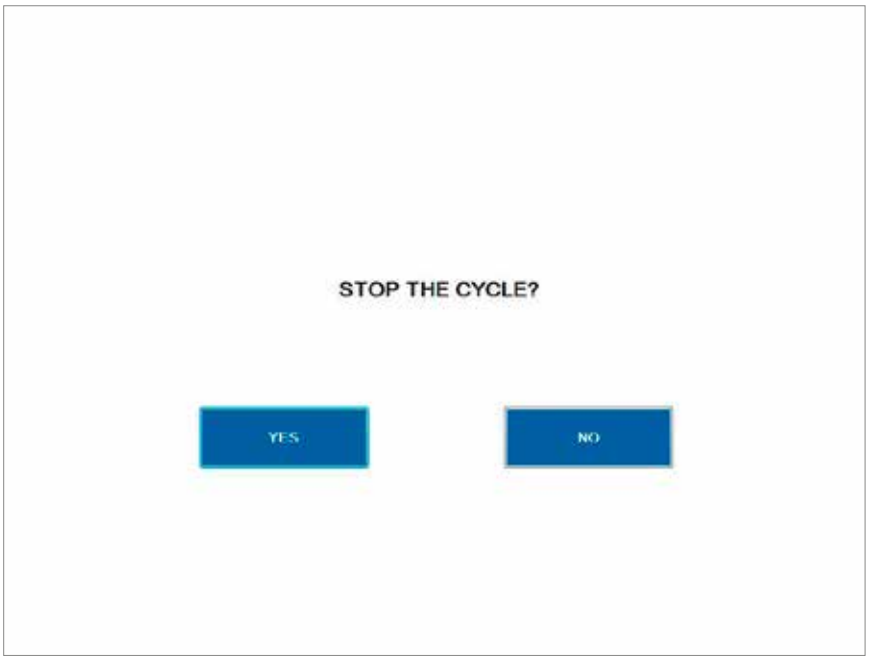
This operation indicates to the equipment that the user is aware that the cycle is in an alarm state.



Pressing the MENU button returns to the main page:



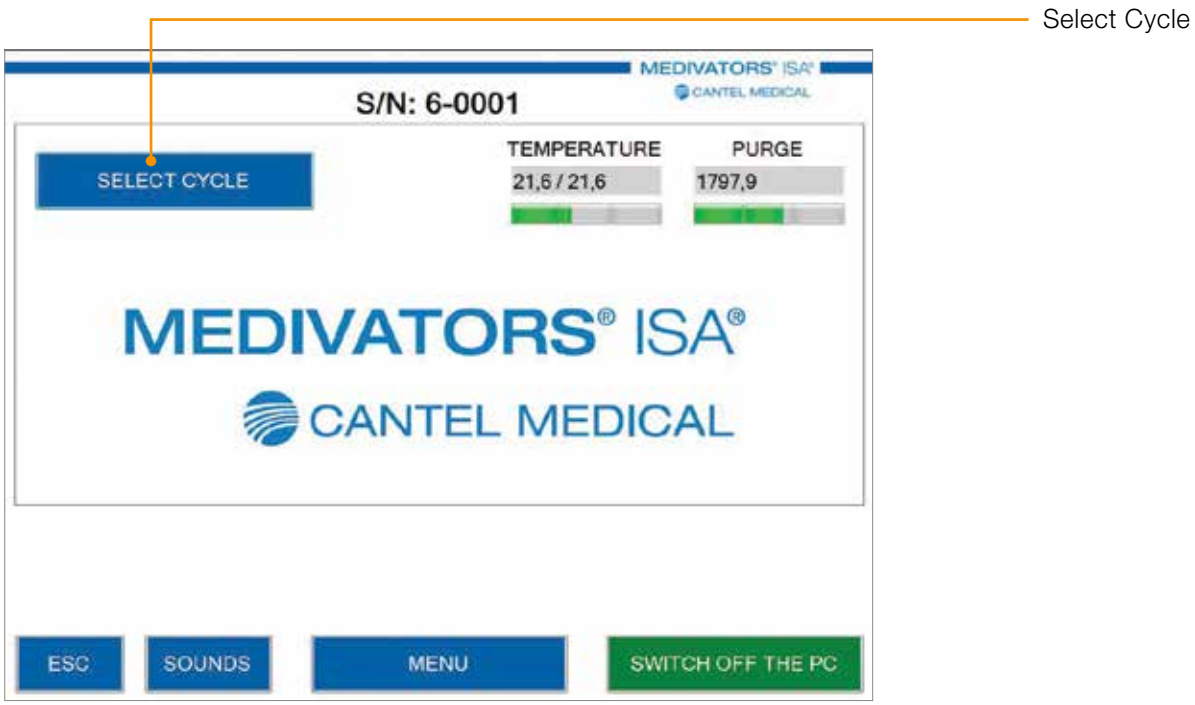
The STOP button can be used to interrupt the cycle at any time. After having pressed it, confirmation is required to stop the cycle in progress.



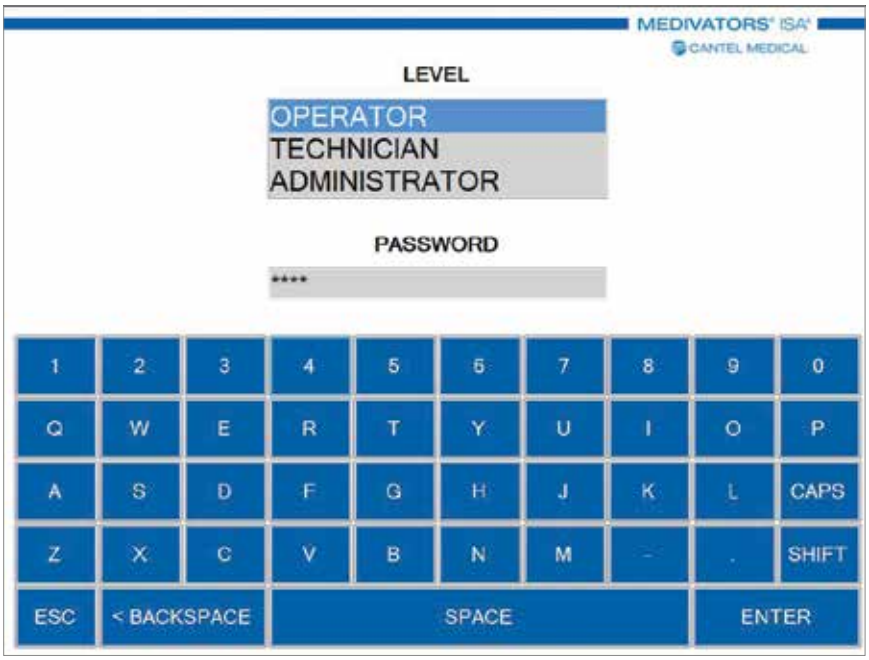
The main page normally appears as follows:

CYCLE START PROCEDURE

To start a cycle, press the MENU button.
This accesses the SELECT CYCLE page:



Pressing the SELECT CYCLE button opens the recognition request page:



Insert the personal ID code. This then opens the cycle select page:

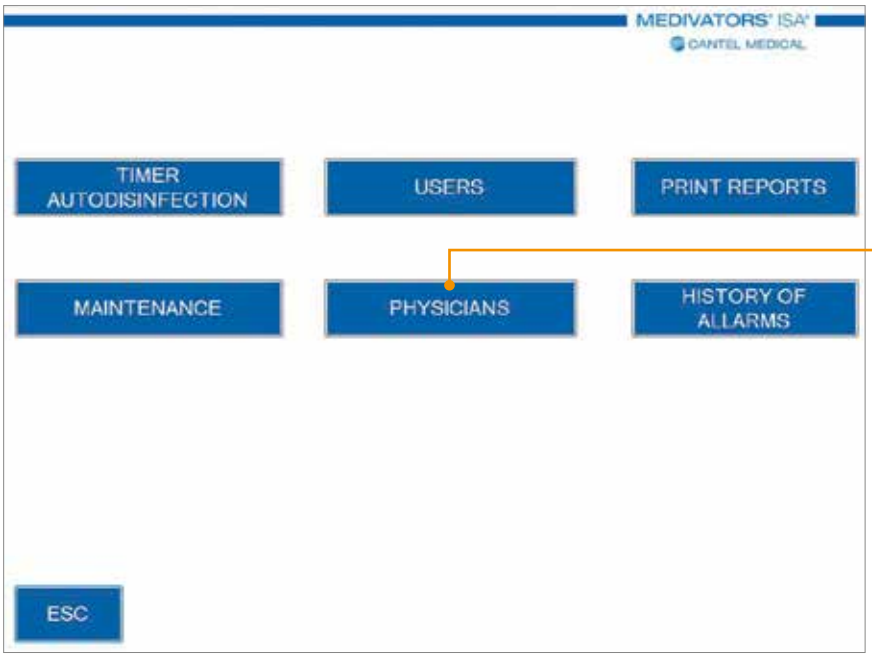
To select the type of cycle to be performed, press once above the name of the cycle to be run so as to display the corresponding line. Press the instrument to be reprocessed once so as to display the corresponding line.

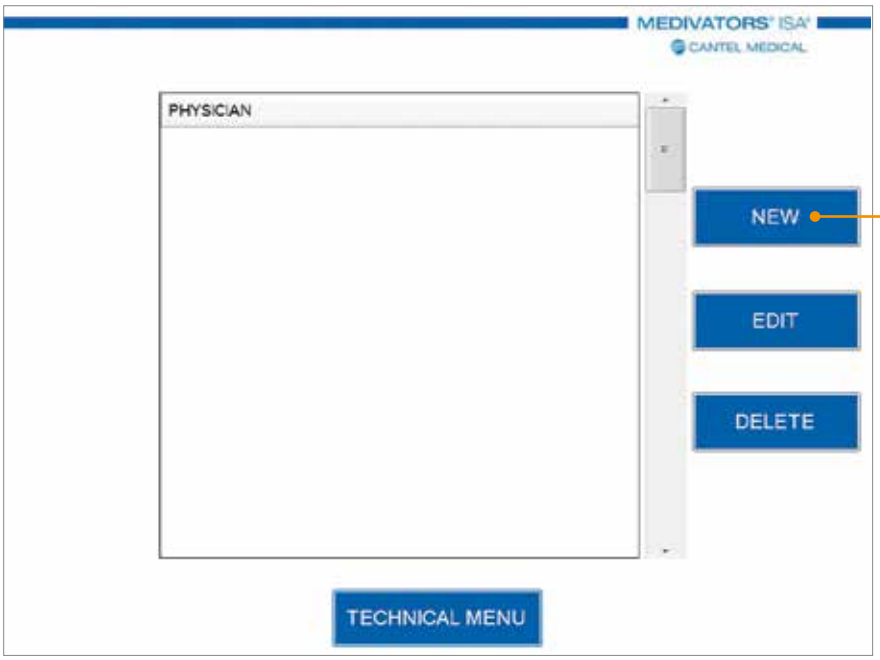
Once completed, press the START button to start the cycle.

On this page, there are two OPTIONAL panels indicating the physician and the patient, in the case of use, the text inserted here will be printed in the cycle report.

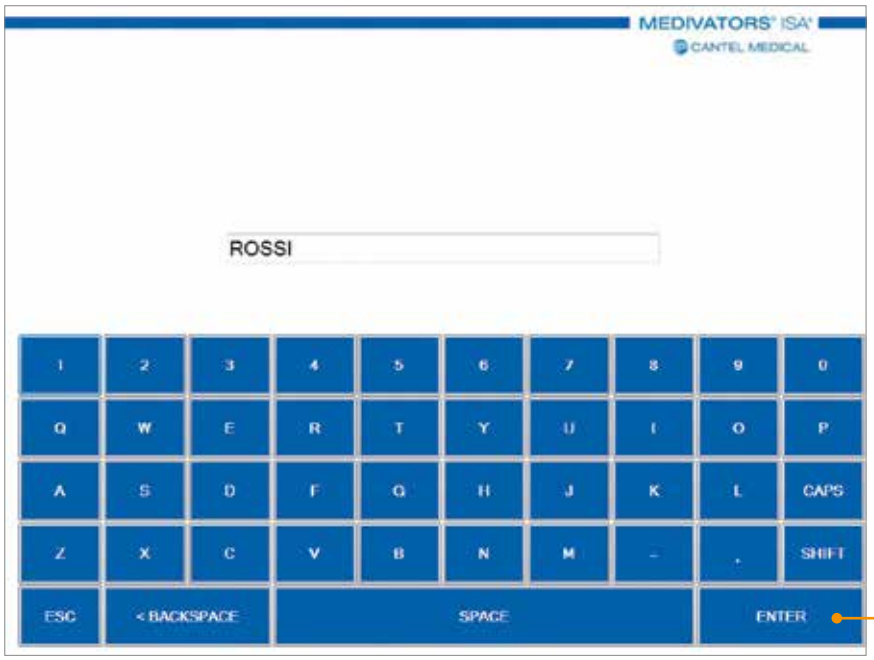
With regard to the PHYSICIAN, pressing the LIST button to the right of the white line makes it possible to select one of the options previously included in the list.

In the case where it is intended to insert a new physician not present in the list, simply click on PHYSICIAN, press the NEW button and enter the information on the page.

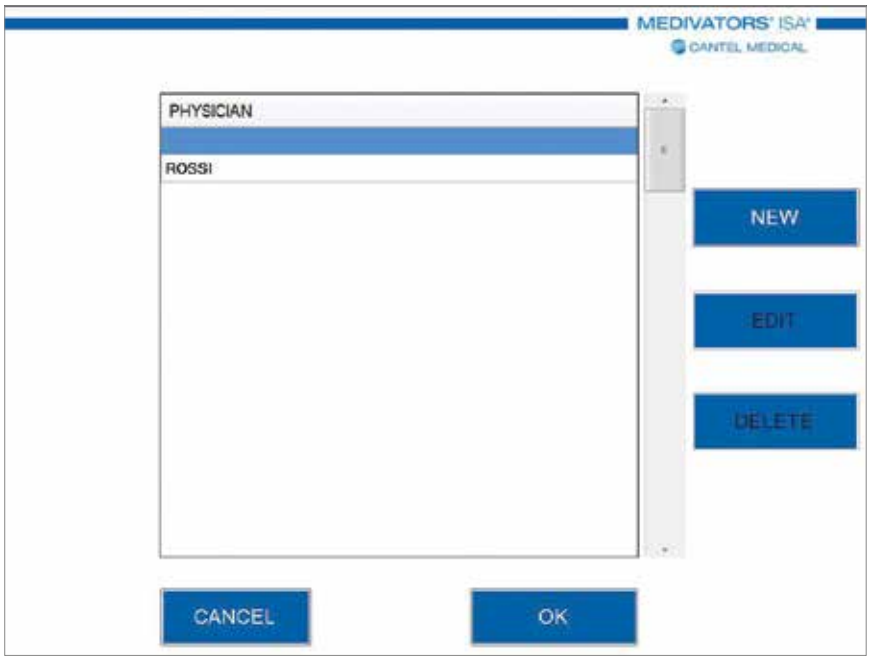




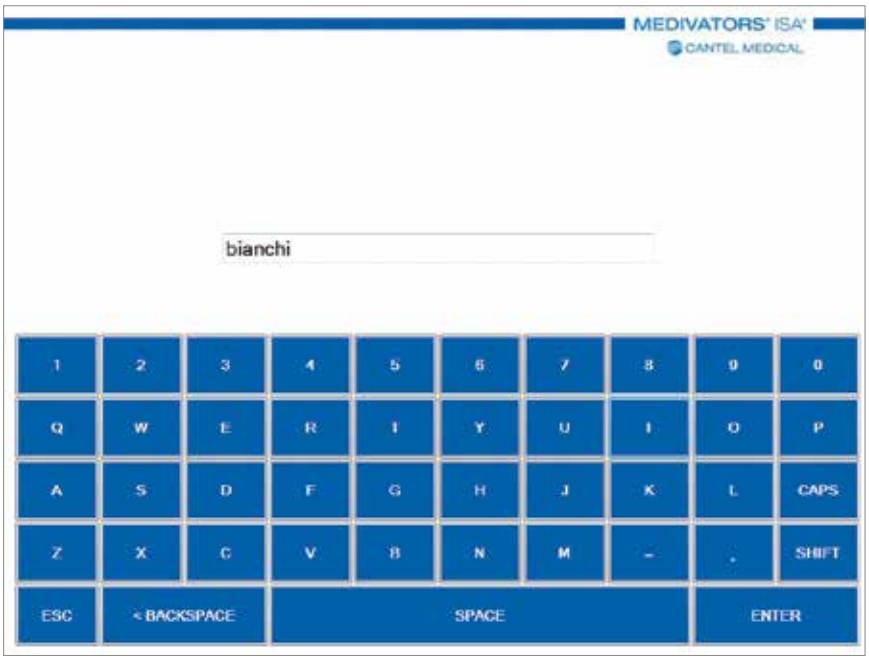
After having inserted the information, press ENTER:



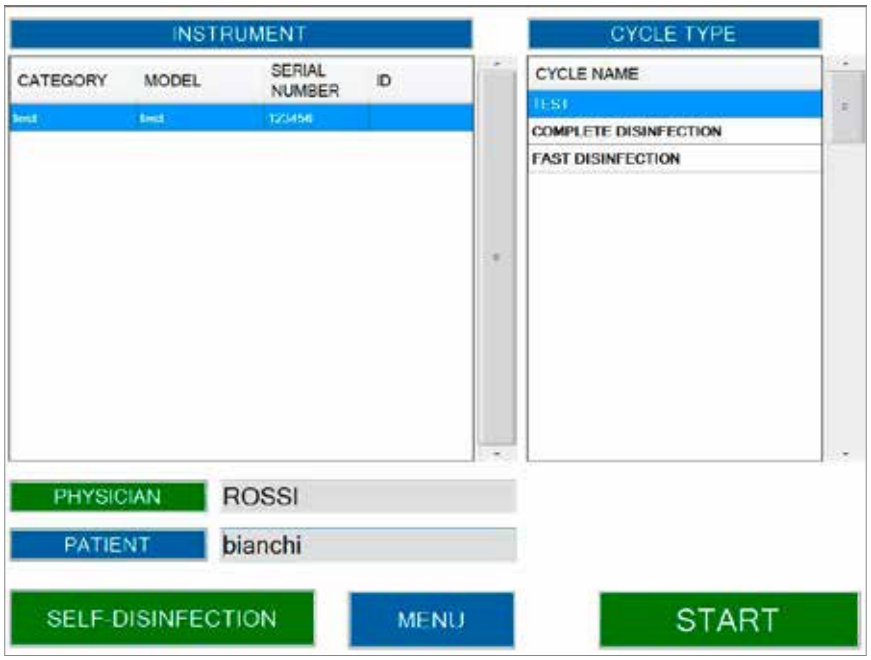
In the case of the information already being present in the list, simply select it from the list (the colour of the line changes to BLUE):



It is possible to enter patient ID information by clicking the white line to the right of the relevant PATIENT button, and once inserted, press the ENTER button:



On completion of data insertion, the cycle selection page is displayed thus:



Press the START button to start the cycle. The screen is updated as follows:

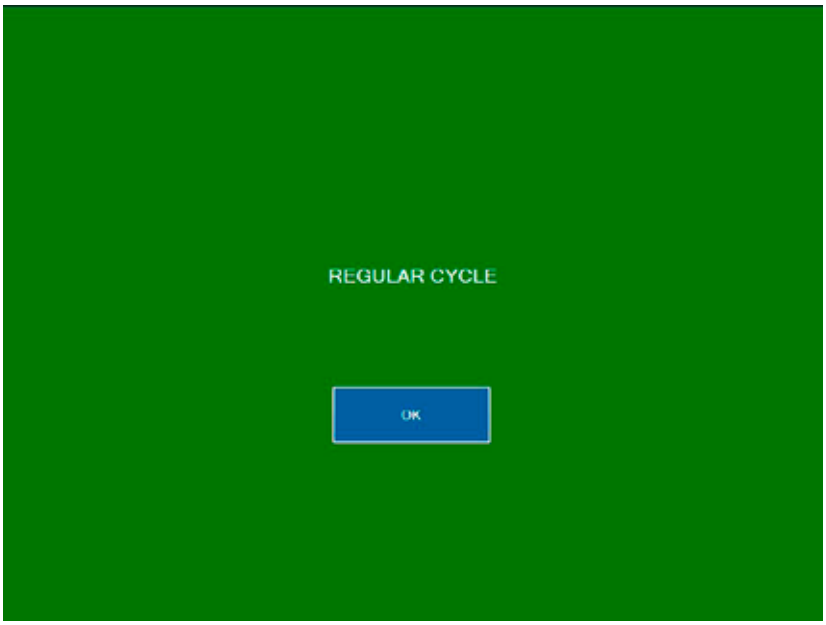
- The main page if accessing as the OPERATOR;
- A synoptic page if accessing as the TECHNICIAN or ADMINISTRATOR.

In addition, from the same page it is possible to run the auto-decontamination cycle by pressing the corresponding SELF-DISINFECTION button, and the cycle starts without the need for any further selection.

Pressing the MENU button or starting the cycle returns the system to the previous page.

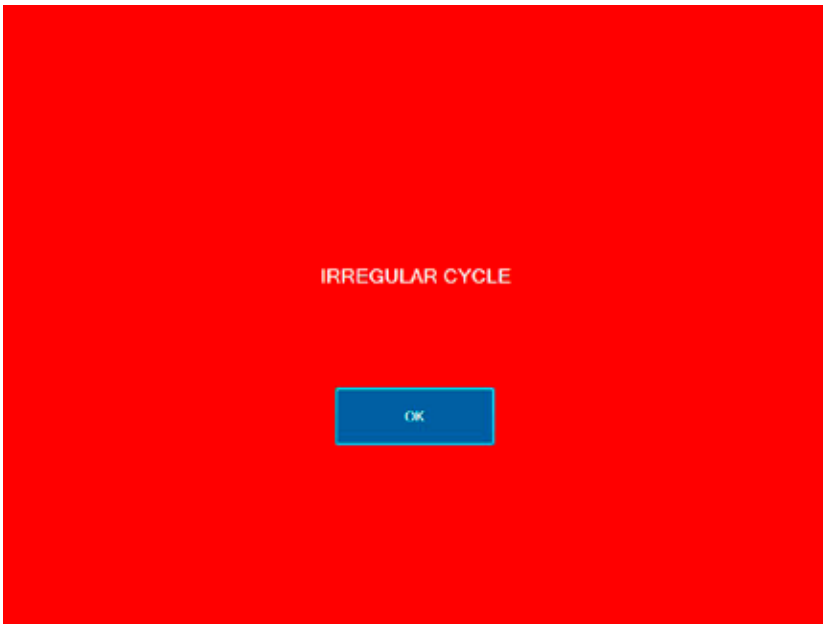
CYCLE END PROCEDURE

On completion of a cycle, it is not possible to open the cover until the OK button is pressed. In the case of a regularly completed cycle, the green "REGULAR CYCLE" screen appears, accompanied by an acoustic signal, indicating the correct conclusion:



In the case of an irregularly completed cycle, a red "IRREGULAR CYCLE" screen appears, accompanied by an acoustic signal, indicating the incorrect conclusion (this sound is different from that for a regular cycle):

Again in this case, it is not possible to remove the endoscope until the OK button is pressed.



END OF CYCLE REPORT - ARCHIVING PROCEDURES

The MEDIVATORS® ISA® system records all the information relating to the cycles performed on its own hard disk, creating an electronic archive that can be consulted at any time. It is also equipped with a built-in printer which automatically prints the cycle report on completion of the cycle. The report is a document that is essential for cycle validation and must always be filed.

Parameters included in the print-out:

- MEDIVATORS ISA serial number
- Cycle start date and time
- Instrument data (category-s/n)
- Physician (optional)
- Patient (optional)
- Operator
- Type of cycle performed
- Cycle progressive number
- Cycle steps with relevant contact times
- Cycle outcome

A sample report relating to a correctly concluded cycle is reported below:

```
        MEDIVATORS ISA
------------------------------
SERIAL NUMBER: 6-0006
CYCLE START: 03/12/2015 11:06:32
INSTRUMENT: GIF-Q165
CATEGORY: GASTROSCOPE
SERIAL NUMBER: A012345
OPERATOR: VERDI
PHYSICIAN: ROSSI
PATIENT: 12345
CYCLE TYPE: COMPLETE DISINFECTION
CYCLE NUMBER: 27
11:06:33 LEAK TEST
11:06:33 WATER LOAD
11:06:53 DETERGENT LOAD
11:07:10 CLEANING (120s,14°C)
11:09:16 DRAIN
11:10:41 WATER LOAD
11:11:16 RINSE
11:12:27 DRAIN
11:13:52 WATER LOAD
11:14:12 STERILANT 1 LOAD
11:15:15 DISINFECTION (180s,14°C)
11:18:21 DRAIN
11:19:46 WATER LOAD
11:20:21 RINSE
11:21:31 DRAIN
11:22:56 PURGE
11:24:04 CYCLE END

11:24:06 REGULAR CYCLE
```

In addition, if the requirement of identification for removal of the endoscope is set, the report also states the ID of the operator that performed the task.

In case of need, it is in any case possible to print any report performed and archived in the device database.

To perform this operation, proceed as indicated below:

Figure A
From the main screen, press the MENU button:

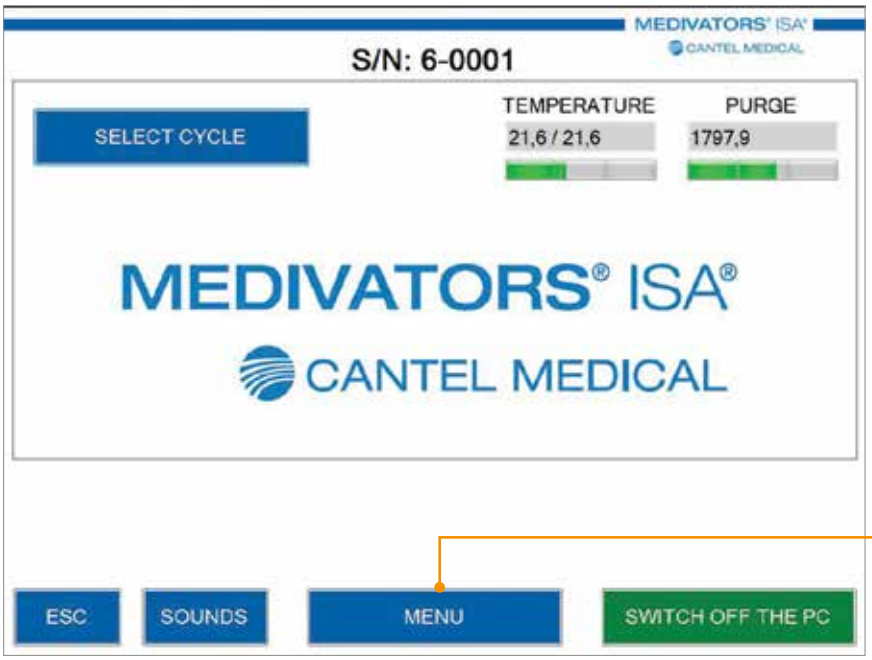


Figure B
Press the PRINT REPORTS button:

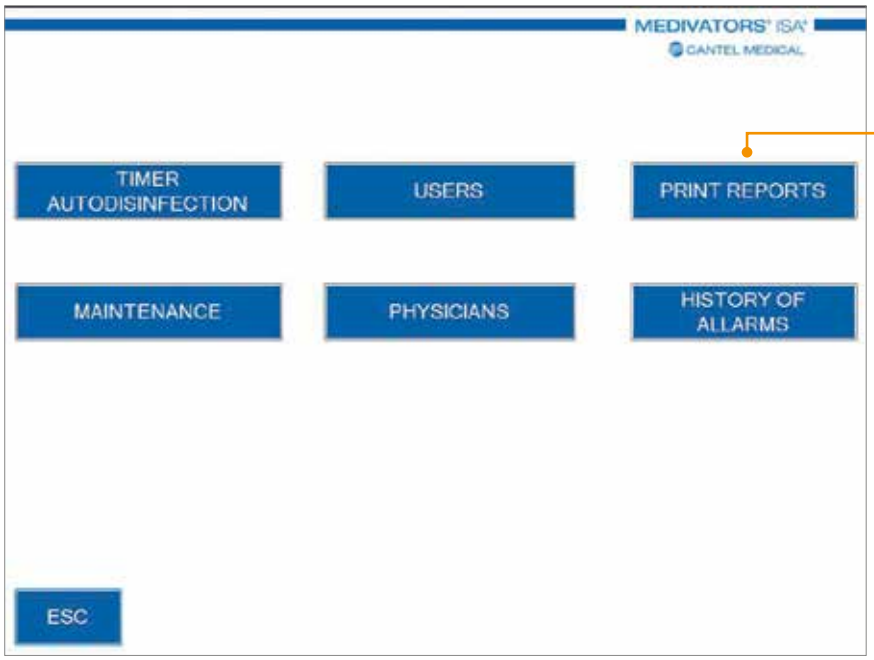
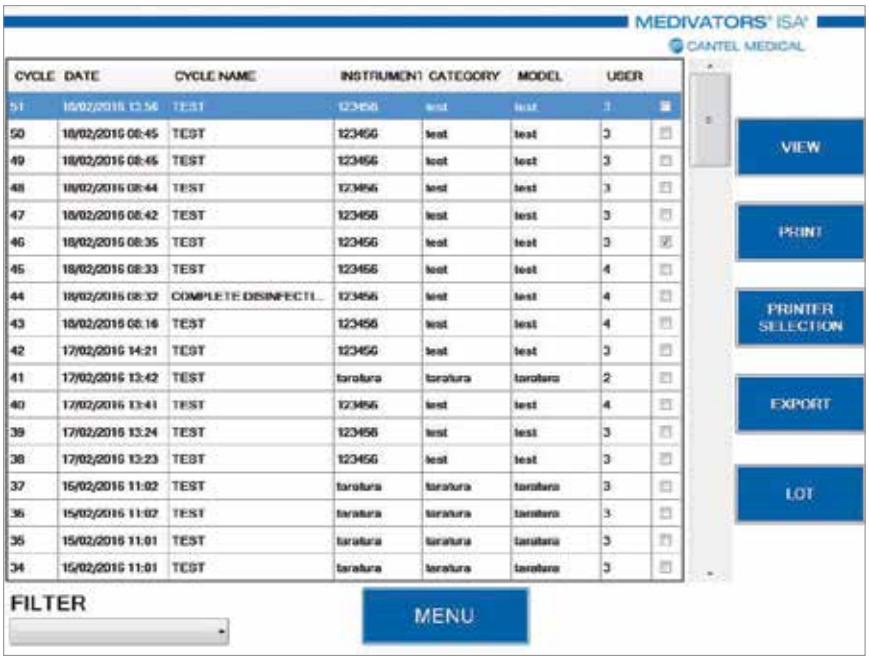


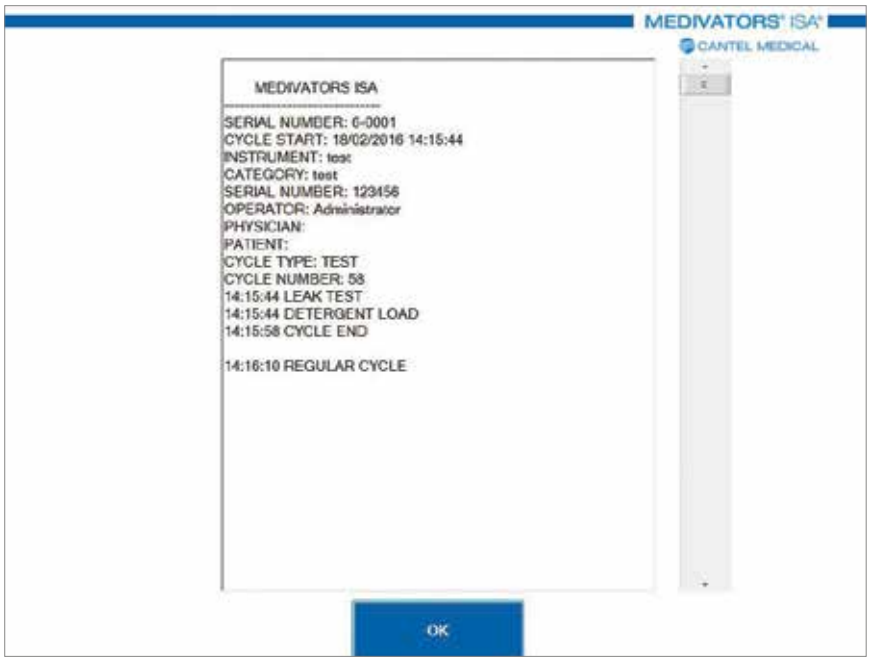
Figure C
The following screen is displayed:



The PRINT REPORTS screen displays all the reports for the cycles performed in chronological order, indicating the instrument used, the operator that performed the cycle, the cycle outcome and the batch numbers for the filters and products used, for each type of cycle performed.

Each cycle can be selected by pressing above the relevant line, which changes colour to blue.

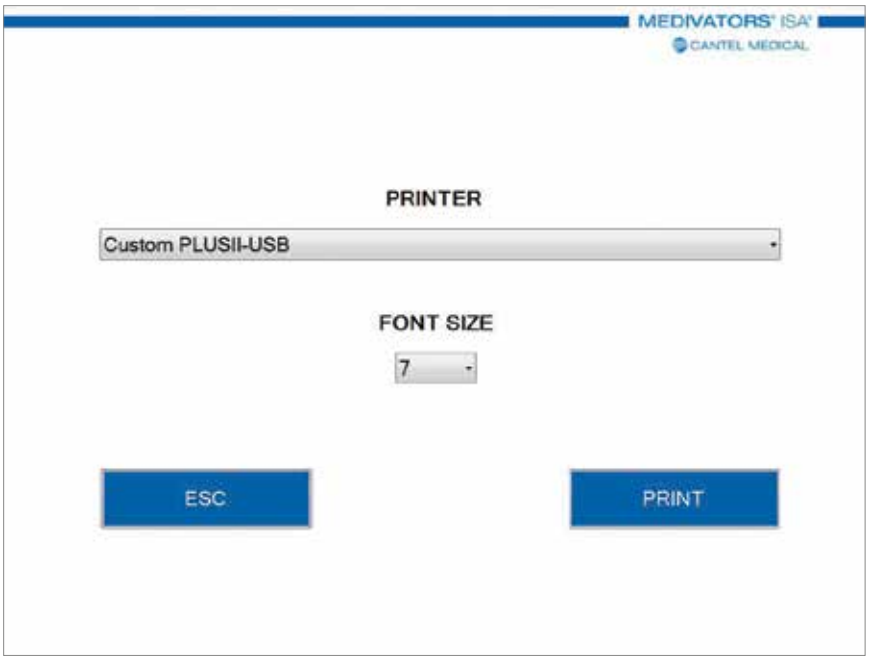
Figure D
Pressing the VIEW button opens the report screen for the cycle selected:



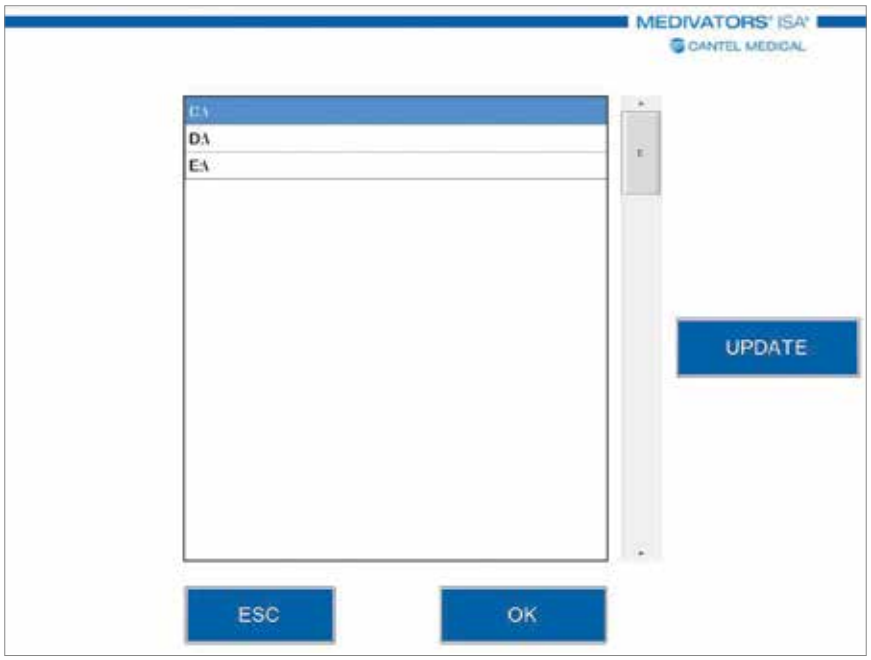
Press the OK button to return to the previous screen.

1. Press the PRINT button to start the process.
2. In the case of more than one printer being available, select the desired printer from the PRINTER SELECTION menu. It is also possible to select the FONT size:

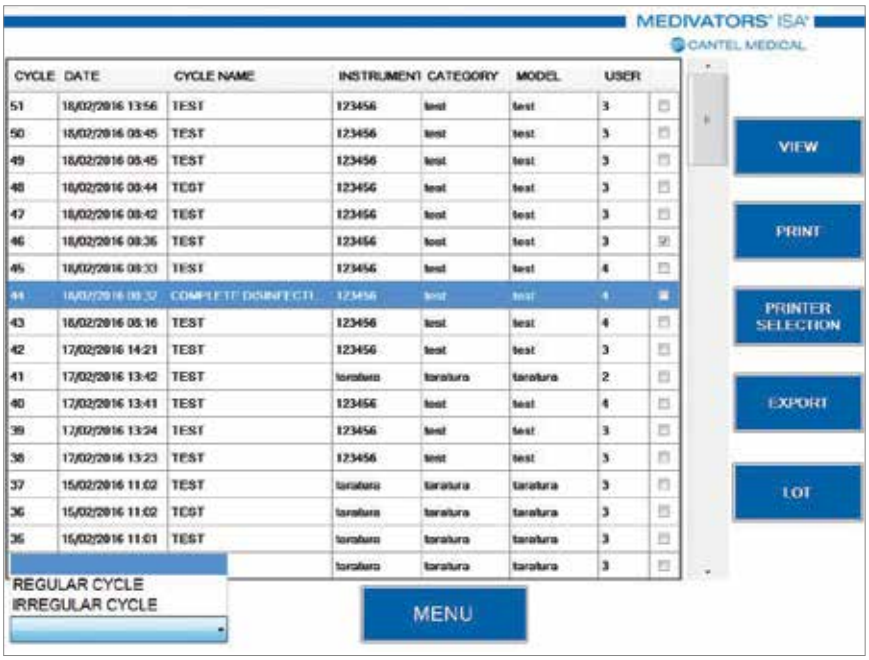
Figure E
Press the PRINT button to conclude the process.



Press the EXPORT button to copy the complete report database to the desired media. Press the UPDATE button to display all available connected media:

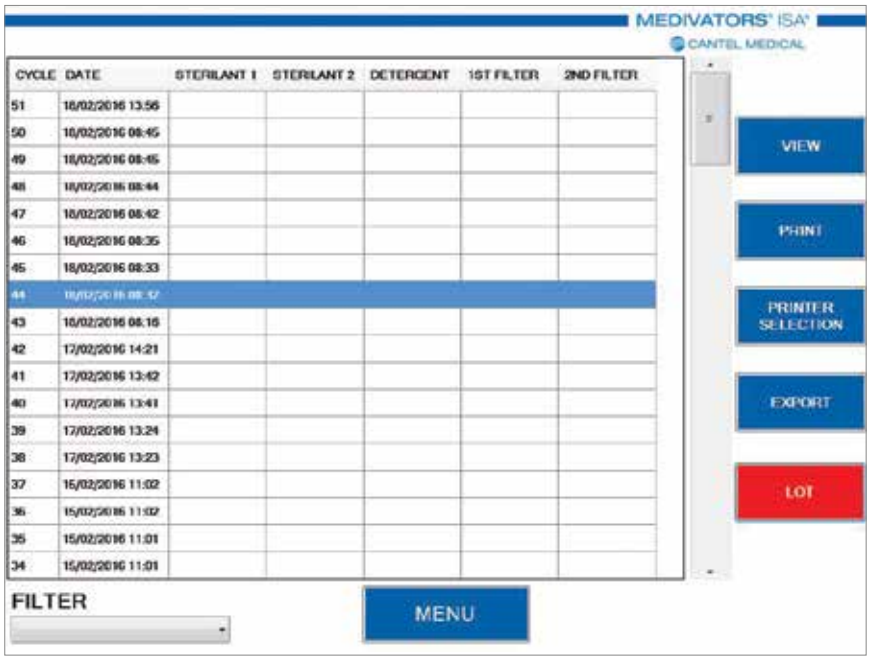


It is possible to apply filters to the select report page using flags and the drop-down menu located in the lower left of the page:

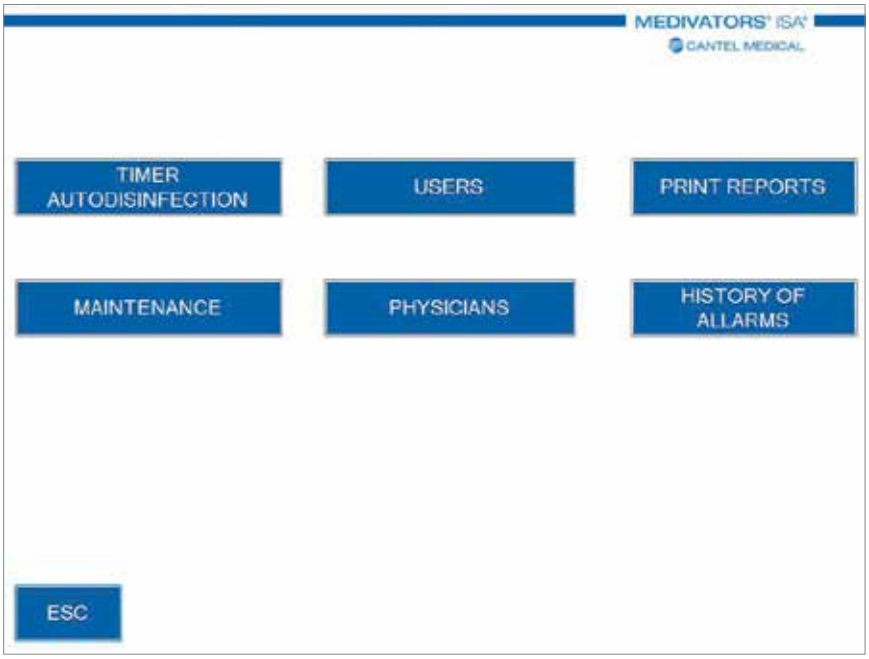


Select the REGULAR CYCLES filter to display only cycles that have concluded regularly. Select the IRREGULAR CYCLES filter to display only cycles that have concluded irregularly. Selecting nothing to display all cycles, independently of outcome.

In the case where a checkmark is applied to LOT, the lots of filters and chemical products used in the corresponding cycle will be displayed:

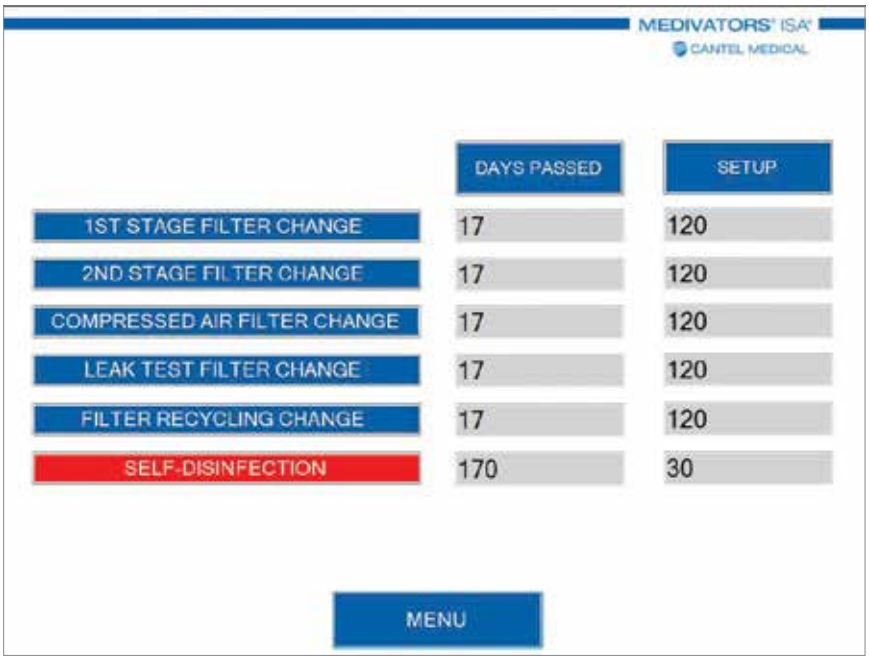


OTHER OPERATOR SOFTWARE FUNCTIONS



From the MENU screen, the user has access to other functions:

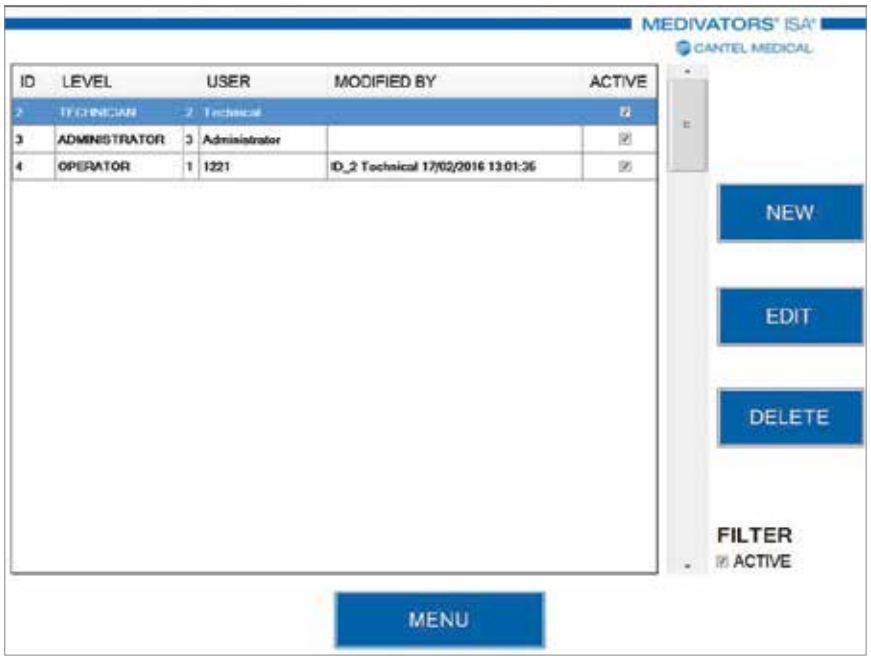
a. MAINTENANCE: press this button to display the status of routine maintenance for the equipment. It is possible to verify the SETUP (days scheduled between one maintenance operation and the next) and the number of days elapsed since the most recent maintenance operation:



Press the MENU button to return to the previous screen.

b. USERS: in this screen, the user can display the list of registered operators.

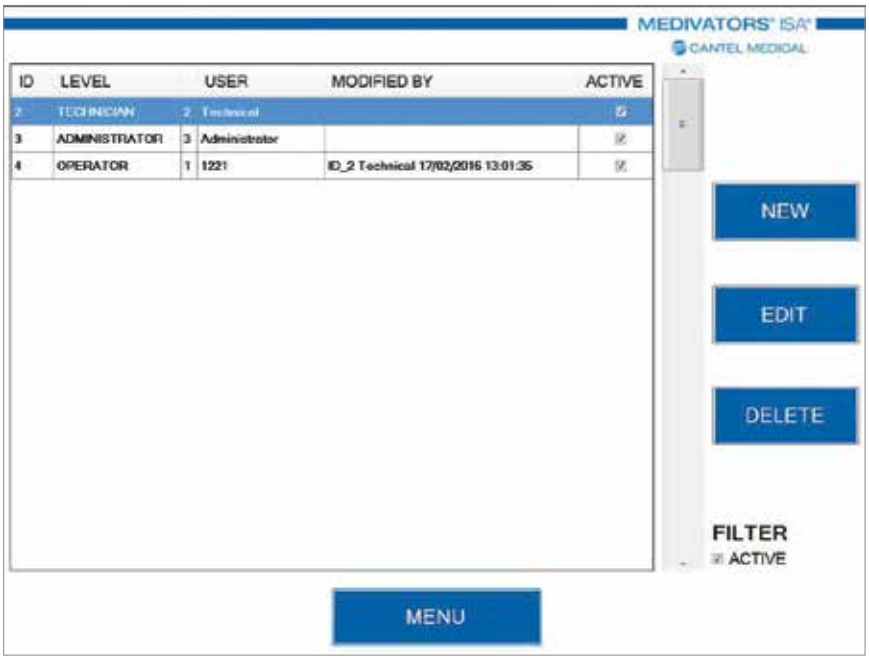
It is not possible to insert, modify or delete the users present in the list using the USERS user level.

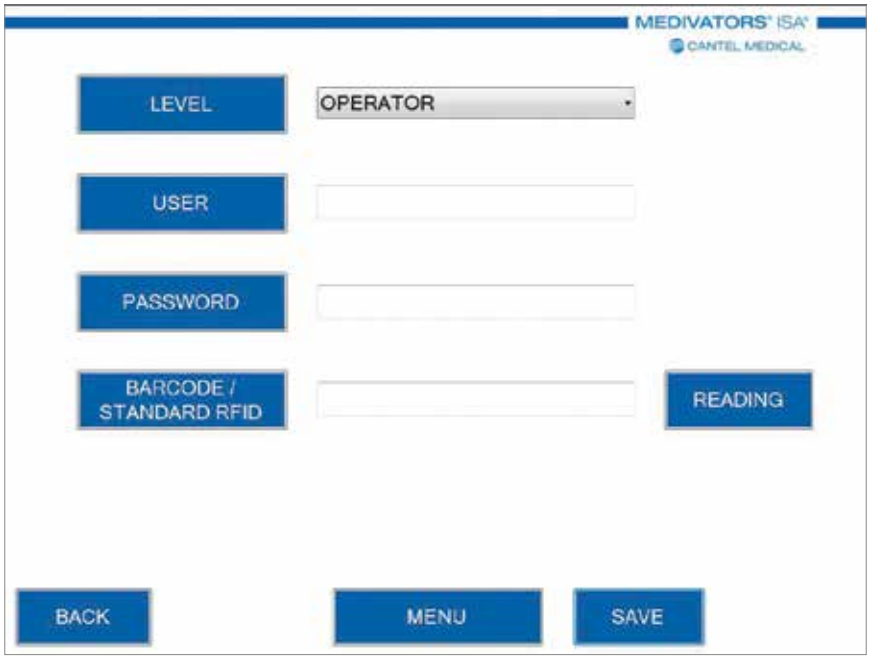


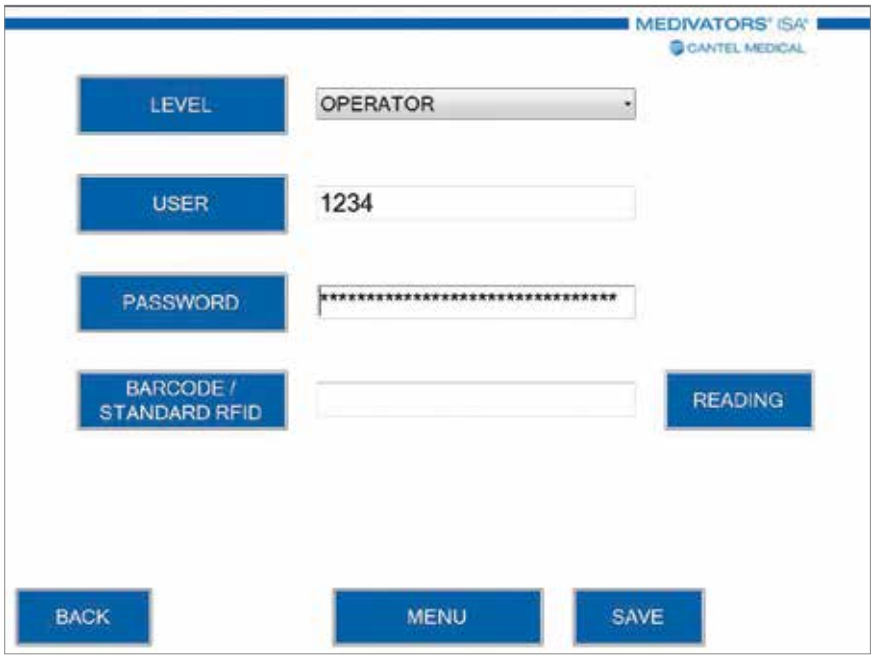
The insertion, modification and deletion of users can only be made at TECHNICIAN and/or ADMINISTRATOR level.

TECHNICIAN level can only insert, modify and delete up to technician level, on the other hand the ADMINISTRATOR can act at all levels.

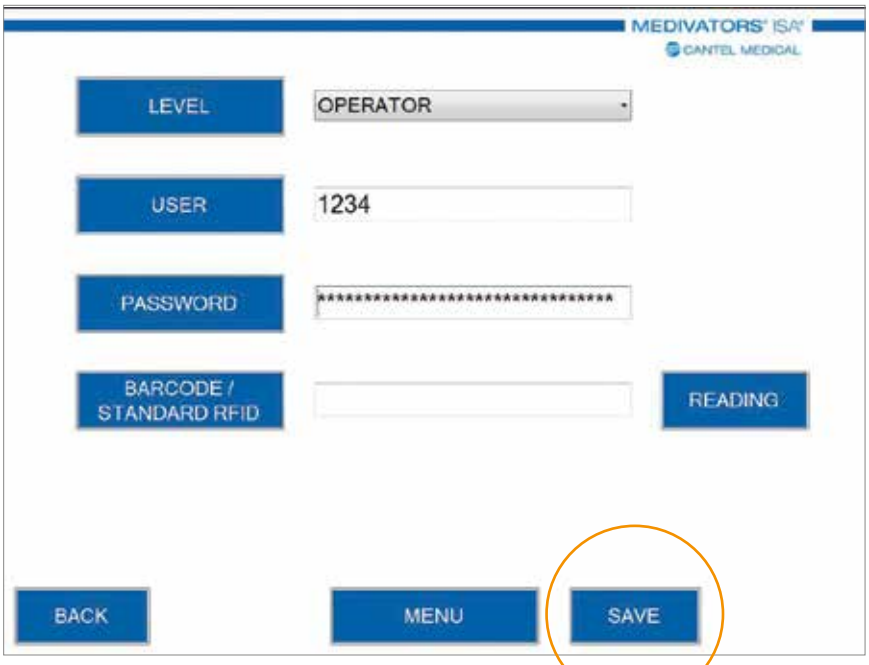
To insert and modify a new operator, select the level, insert the name and password, confirm the password and press the SAVE button.




MEDIVATORS® ISA®
CANTEL MEDICAL
LEVEL
OPERATOR
USER
PASSWORD
BARCODE / STANDARD RFID
READING
BACK
MENU
SAVE

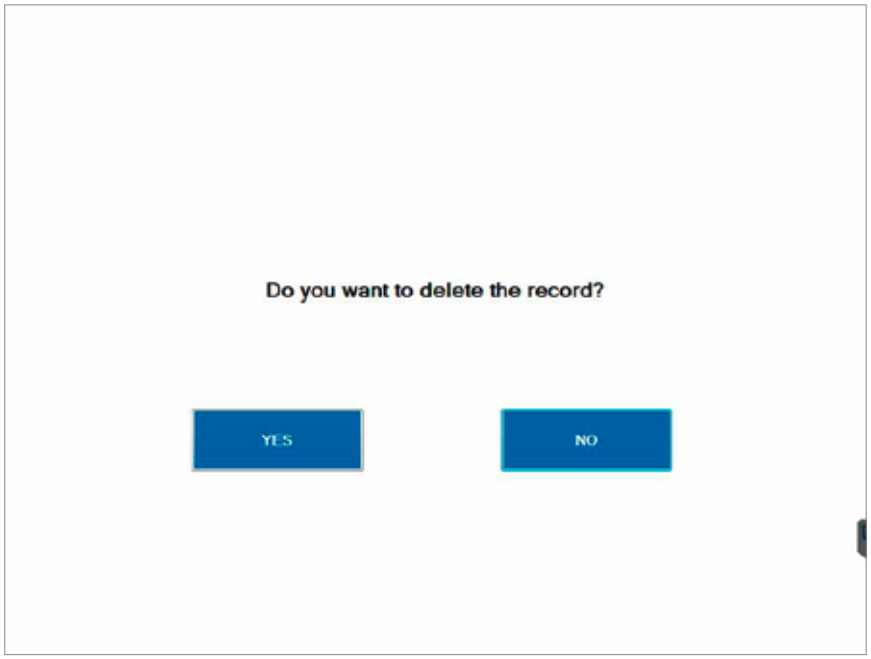

MEDIVATORS® ISA®
CANTEL MEDICAL
LEVEL
OPERATOR
USER
1234
PASSWORD
BARCODE / STANDARD RFID
READING
BACK
MENU
SAVE


Please enter the new password for confirmation
OK


MEDIVATORS ISA
CANTEL MEDICAL
LEVEL
OPERATOR
USER
1234
PASSWORD
BARCODE / STANDARD RFID
READING
BACK
MENU
SAVE

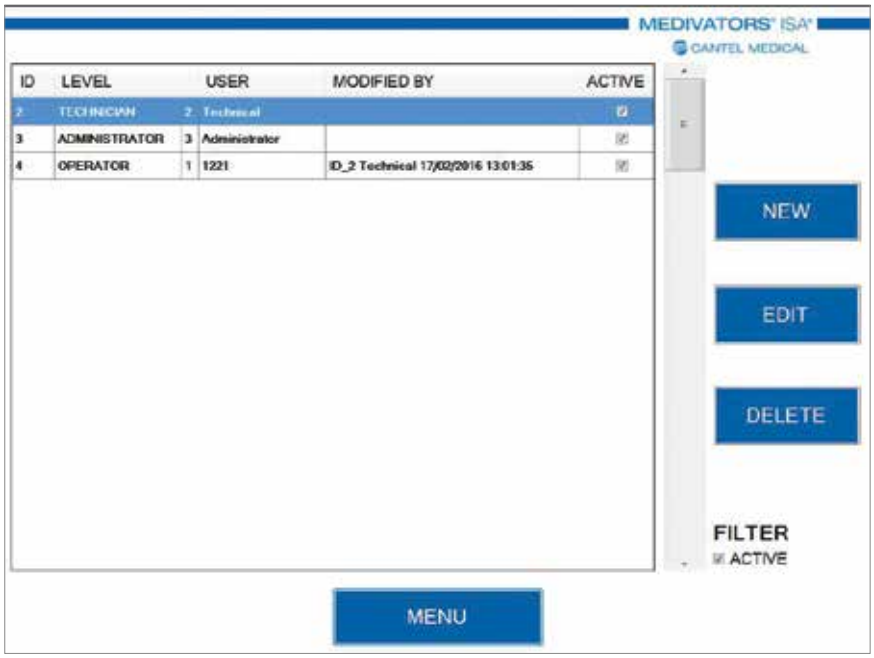
In the case where it is desired to delete a record present in the list, simply select the corresponding line and press the DELETE button.

Then confirm the operation by pressing the YES button:



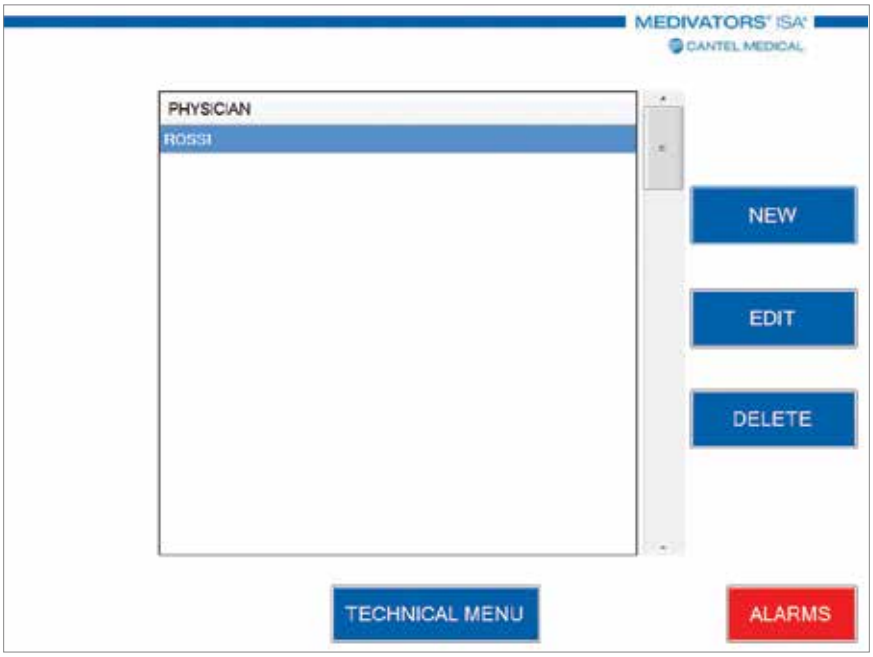
The report will be definitively deleted from the list. It is possible to insert the filter, present in the lower right of the screen (ACTIVE), to allow displaying of only active users.

Press the MENU button to return to the previous screen.



c. PHYSICIANS: in this screen, the user can display and add medical personnel, which can be included in the end of cycle report print-out, if selected.

It is not possible to insert, modify or delete physicians present in the list using USER level.

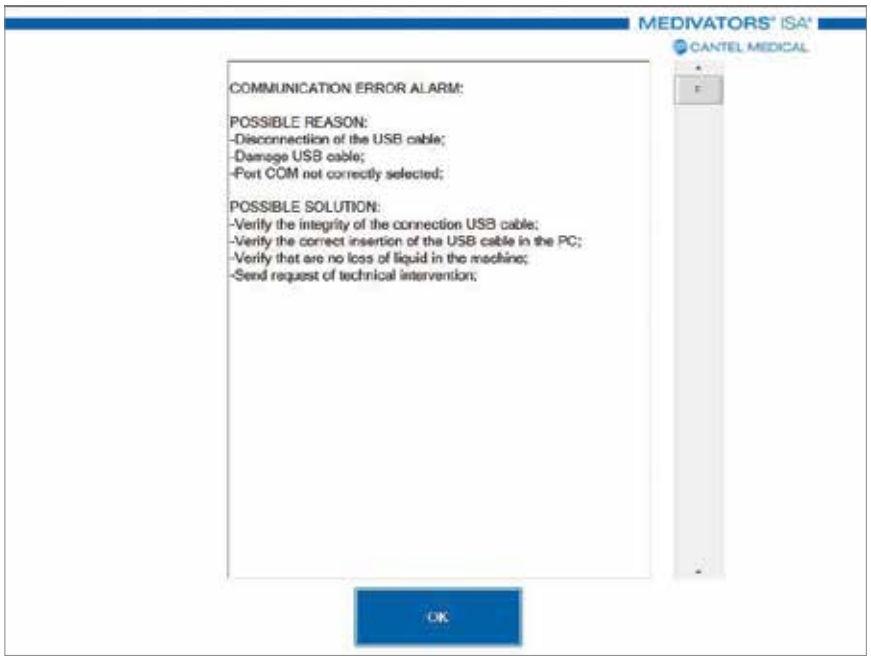


Modification and deletion operations can only be made at TECHNICIAN and/or ADMINISTRATOR level.

d. ALARM HISTORY: press this button to display the log of all alarm events:

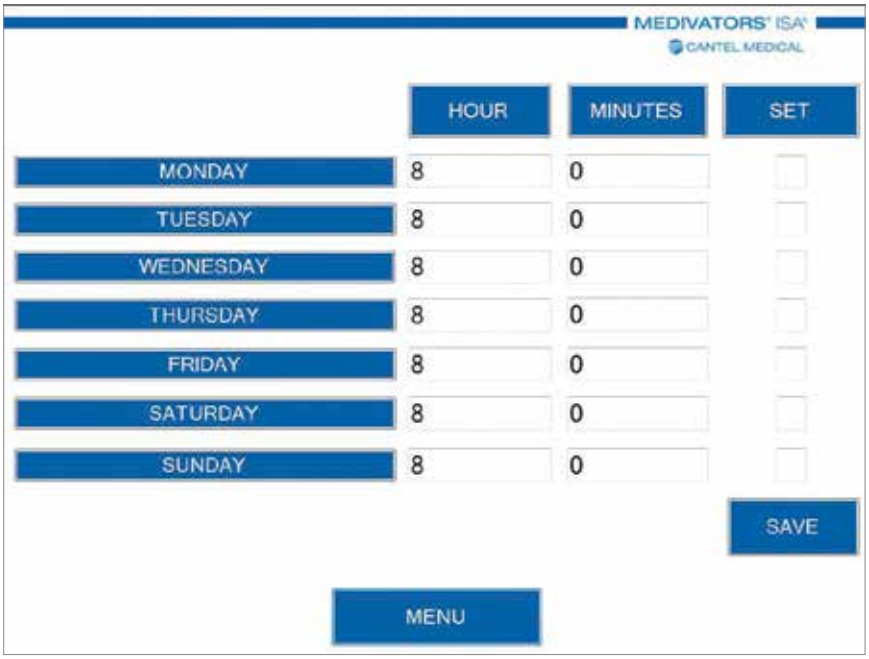
Press the desired line and then the INFORMATION button to display the information relating to the alarm:

Press the MENU button to return to the previous screen.



e. PROGRAMMED SELF-DISINFECTION (TIMER AUTODISINFECTION): from this screen it is possible to schedule self-disinfection, which will start automatically according to the programmed schedule.

To program this event, access the following page:



From which it is possible to set the days and insert an automatic cycle start time.

Cantel Medical recommends daily execution of the programmed self-disinfection cycle in order to sterilize the fluid circuit and to Warranty a higher level of safety with regard to infections.

The Self-disinfection cycle must be performed without endoscopes.

The basin must be empty, and must only be connected to the selfdisinfection connector.

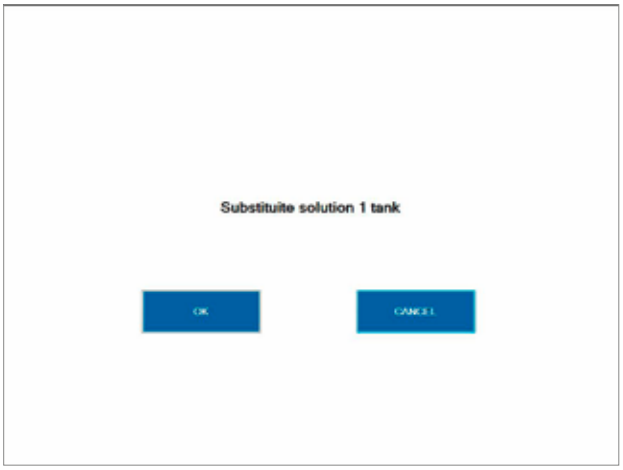
f. SWITCH OFF THE PC: it is obligatory that this button be used to shut-down the PC. **Any other PC shut-down procedure could cause damage to the PC itself, which DOES NOT fall within the scope of the manufacturer's Warranty.**

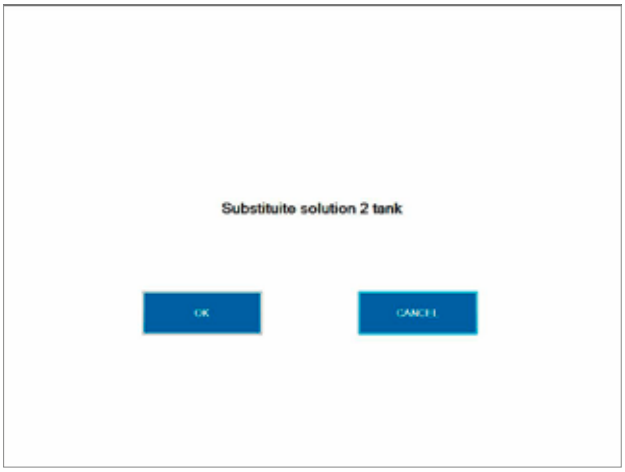
TANK REPLACEMENT PROCEDURE

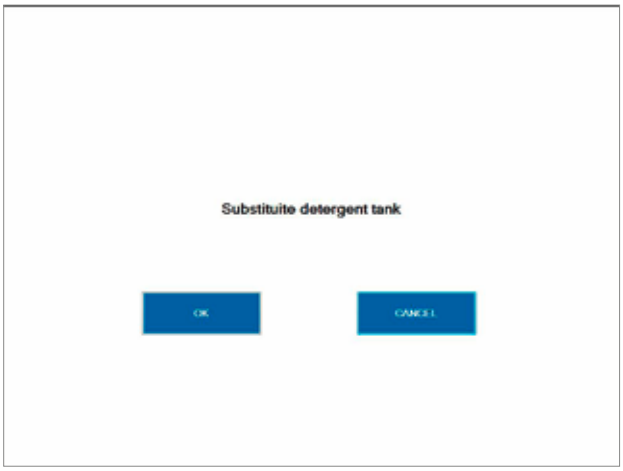
During the cycle, if the equipment detects a lack or partial load for one of the products, it informs the user of the need to replace the relevant tank by means of visual and acoustic messages.

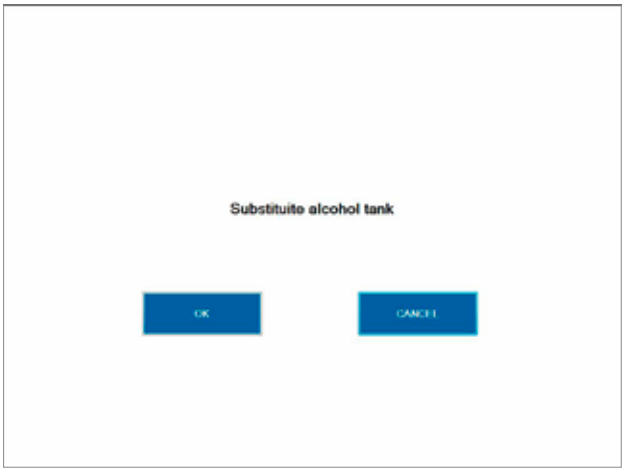
This warning is managed so as to allow the operator to be able to replace the corresponding product tank without the need to interrupt and restart the cycle from the start.

When an absence of product load is detected, the screen displays one of the following messages:









Having replaced the tank, press the OK button to restart the cycle.

This operation may be performed a maximum of 3 times, after which the cycle is interrupted and reset.

It is also possible to interrupt the cycle by pressing the CANCEL button on the warning screen.

The purpose is to establish a procedure to instruct personnel of the actions to be implemented for the correct replacement of MEDIVATORS® ISA® Endoscope Reprocessor tanks.

This procedure takes into account the chemical risks associated with the replacement actions, decontamination of the machine and disposal of the spent tanks.

APPLICABILITY

This procedure must be applied by staff members each time the MEDIVATORS ISA Endoscope Reprocessor chemical agents are correctly replaced.

RESPONSIBILITIES

Responsibility for the correct replacement of chemical agents and proper disposal of the empty tanks is entrusted to the operator performing said operation.

WARNING! When handling the solutions, adopt the protective measures present in the product material safety data sheets.

OPERATING CONDITIONS FOR SUBSTITUTION OF THE ISASPOR® SINGLE SHOT COLD STERILANT/DISINFECTANT (SOLUTION A) TANK

1. Wear PPE, including: face mask, gloves and eye protection.
2. Remove the seals from the cap on the full tank.
3. Place the full tank in front of the tank to be replaced.
4. Unscrew the cap on the tank to be replaced without removing it.
5. Unscrew and remove the cap from the full tank.
6. Extract the nozzle, together with the cap, from the spent tank.
7. Insert the extracted nozzle into the full tank and tighten the cap.
8. Seal the empty tank using the cap from the full tank.
9. Remove the empty tank and insert the full tank into the compartment.
10. Dispose of the tank in accordance with the applicable legislation and the provisions reported in the material safety data sheet.

OPERATING CONDITIONS FOR SUBSTITUTION OF THE ISASPOR SINGLE SHOT COLD STERILANT/DISINFECTANT (SOLUTION B) TANK

1. Wear PPE, including: face mask, gloves and eye protection (goggles/mask).
2. Remove the seals from the cap on the full tank.
3. Place the full tank in front of the tank to be replaced.
4. Unscrew the cap on the tank to be replaced without removing it.
5. Unscrew and remove the cap from the full tank.
6. Extract the nozzle, together with the cap, from the spent tank.
7. Insert the extracted nozzle into the full tank and tighten the cap.
8. Seal the empty tank using the cap from the full tank.
9. Remove the empty tank and insert the full tank into the compartment.
10. Dispose of the tank in accordance with the applicable legislation and the provisions reported in the material safety data sheet.

OPERATING CONDITIONS FOR SUBSTITUTION OF THE ISACLEAN TANK

1. Wear PPE, including: face mask, gloves and eye protection (goggles/mask).
2. Remove the seals from the cap on the full tank.
3. Place the full tank in front of the tank to be replaced.
4. Unscrew the cap on the tank to be replaced without removing it.
5. Unscrew and remove the cap from the full tank.
6. Extract the nozzle, together with the cap, from the spent tank.
7. Insert the extracted nozzle into the full tank and tighten the cap.
8. Seal the empty tank using the cap from the full tank.
9. Remove the empty tank and insert the full tank into the compartment.
10. Dispose of the tank in accordance with the applicable legislation and the provisions reported in the material safety data sheet.

CHAPTER 5

MAINTENANCE

This chapter describes the periodic maintenance that must be performed by the operator.

OPERATOR PERIODIC MAINTENANCE

With regard to periodic maintenance of the MEDIVATORS® ISA® Endoscope Reprocessor, the operator must verify that changing the water/air filters and the periodic checks are conducted regularly every 4 months and that they are documented by work reports suitably signed by staff, specialized and authorized by the equipment manufacturer.

CLEANING THE MEDIVATORS ISA ENDOSCOPE REPROCESSOR

For cleaning of the MEDIVATORS ISA Endoscope Reprocessor, use specific products according to surface type:

- Non-aggressive products for steel surfaces in the machine structure.
- Non-aggressive products for plastic and glass surfaces.
- Non-aggressive products for the PC.

WARNING! Make sure that no residues remain inside the basin.

WARNING! clean the pc after first having made sure that the electricity supply has been disconnected. Use specific products and do not leave any liquid residues that might damage the pc.

CHANGING TO STANDBY MODE DUE TO INACTIVITY

At the end of the day's activities, proceed as described below:

- Insert and connect the auto-decontamination connector to the basin.
- Close all the machine's feed inlets (water, compressed air, electricity).
- Remove the air and water filters from the machine.

WARNING! Filters must only be removed by technical staff that are specialized and/or authorized by the manufacturer.

WARNING! Do not leave endoscope connectors not connected to the related endoscope in the basin: any liquid present could infiltrate into the leak test connector and damage the endoscopes. In this case, the manufacturer is exonerated from all responsibility relating to damage to the endoscope.

CHAPTER 6

WARRANTY

This chapter describes the Warranty covering the MEDIVATORS® ISA® Endoscope Reprocessor and related parts.

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EXCLUSION OF RESPONSIBILITY

Cantel Medical (Italy) S.r.l. warranties the perfect operation of the MEDIVATORS® ISA® Endoscope Reprocessor and the attainment of washing and disinfection results for the endoscopes reprocessed only if:

- The equipment is used in compliance with the procedures described in this manual and in accordance with the instructions provided by the manufacturer.
- Technical servicing is performed by technical personnel authorized by Cantel Medical.
- Consumable products (filters, products, spare parts etc.) that are validated and supplied by the Manufacturer are used.

LIMITED WARRANTY

Cantel Medical (Italy) S.r.l. warranties that the MEDIVATORS ISA Endoscope Reprocessor complies with the specifications declared by Cantel Medical and is warranted to be free from material and processing defects during normal use and maintenance for a period of fifteen (15) months from the date of dispatch from Cantel Medical/ Medivators or one (1) year from the date of installation, depending on which of the two situations should occur first.

Independently of all provisions to the contrary contained in the present document, the warranty period for consumables and accessories supplied by Cantel, including by way of non-limiting example, endoscope connectors, filters, printers, printer spare parts, accessories, is ninety (90) days from the date of installation or 120 days from the date of dispatch, depending on which of the two situations should occur first.

The warranty only includes any faults or manufacturing defects.

The warranty does not cover, and the Company shall have no obligation of warranty regarding damages to the Product caused by or associated with: (i) external causes, including, without limitation, accidents, acts of vandalism, natural disasters, acts of God, loss of electricity supply or power surges, (ii) abuse, negligence or improper use of the product by the client or third parties, or the use of unauthorized third party filters or other consumables or accessories or chemical substances not validated by the Company, (iii) use not in compliance with the Product instructions, (iv) lack of preventive maintenance requested by the client, or (v) unauthorized support and repairs.

LIMITATION OF RESPONSIBILITIES

At the discretion of the Company, the SOLE RESPONSIBILITY of the Company, with regard to the warranty, shall be the repair or replacement of defective Product(s) or the reimbursement or the issuing of credit to the value of the purchase price. This shall be the sole solution for the client for a defect covered by the warranty.

To obtain compensation under warranty, the client should inform the Company of the defect (describing the problem in a reasonably detailed way) before the expiration of the warranty period and within thirty (30) days of discovery of the defect.

After having received the official „return merchandise authorization“ (RMA) from the Company, the client should return the defective product immediately to the company itself (or to the support centre indicated in the RMA), paying transport and insurance in advance. The Company shall not be responsible for any damages occurring during transport.

LIMITATION OF THE WARRANTY

The above Warranty represents the entirety of the Warranty obligations of the company‘ towards the product purchaser. The company expressly declines all other warranties and conditions, expressed or implied, statutory or of any other nature, including, without limitation, warranties or conditions of commerciability and suitability for a particular purpose, in addition to warranties resulting from execution of an agreement and from commercial uses; the company does not declare nor Warranty that the products satisfy the needs of the client.

Within the legally permitted limits, and except in the case of gross negligence or malicious behaviour by the company, the company shall not be responsible to the client for indirect or consequential damages or for damages or other costs or passivity (whether foreseeable or not), even if advised of the possibility of said damages, resulting from the warranty or from the contract, from negligence or other illegal acts of another nature, including, without limitation, foreseeable commercial losses, loss of profits, loss of contracts or commercial opportunities, and dependant damages.

This New Product Limited Warranty provides the Product client with specific legal rights; the client themselves can also benefit from other rights which vary from one jurisdiction to another.

Within legally permitted limits, the Company‘s responsibilities cannot exceed the original purchase price of the Product covered by the warranty.

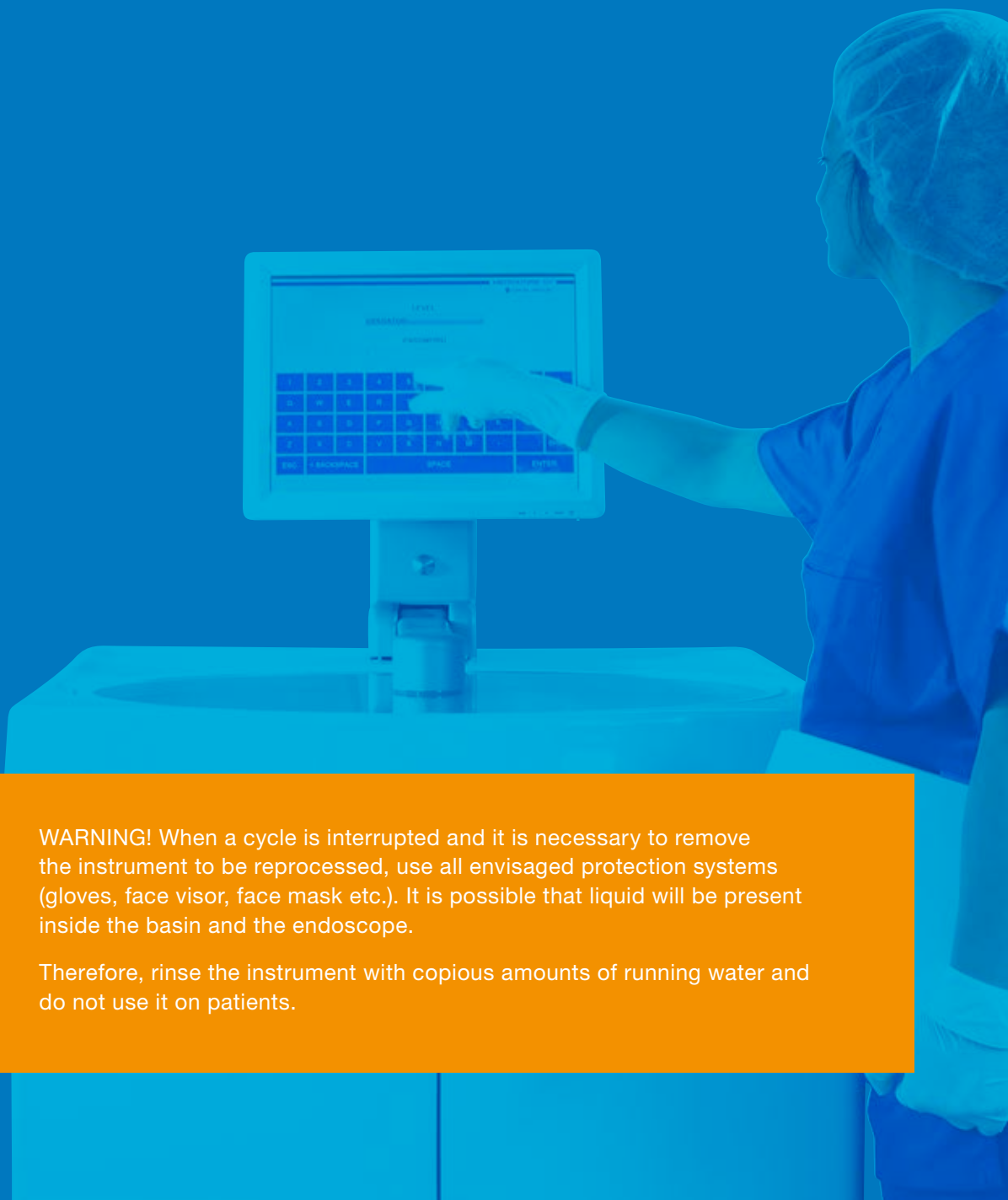
No Company representative or agent has the power to bind the Company to any other declaration or warranty with regard to the Products, and the client accepts that the Products are subject to all the aforementioned terms.

CHAPTER 7

RESOLUTION OF PROBLEMS

This chapter deals with the resolution of problems affecting the MEDIVATORS® ISA® Endoscope Reprocessor, with regard to alarms indicated by the equipment and the potential actions of healthcare workers for the resolution of said problems.

Any other operations for the restoration of equipment function must be performed by staff that are qualified and authorized by the Manufacturer.



WARNING! When a cycle is interrupted and it is necessary to remove the instrument to be reprocessed, use all envisaged protection systems (gloves, face visor, face mask etc.). It is possible that liquid will be present inside the basin and the endoscope.

Therefore, rinse the instrument with copious amounts of running water and do not use it on patients.

RESOLUTION OF PROBLEMS

Type of alarm	Cause	Solution
MINIMUM WATER PRESSURE	1. No mains water pressure 2. Failure in TP1	▶ Check the mains water supply is on. ▶ Check the inlet water pressure. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
MINIMUM AIR PRESSURE	1. No compressed air feed 2. Fault in R1 3. Fault in F4 4. Fault in TP4	▶ Check that the inlet air pressure is present and/or sufficient. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
MAXIMUM AIR PRESSURE	1. Fault in R1 2. Fault in TP4	▶ Check that the inlet air pressure is not too high. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISINFECTANT 1 LOADING TIME OUT ALARM	1. Component A tank empty 2. Aspiration nozzle not inserted in the tank or faulty 3. Fault in SL11 4. Fault in V11 5. Fault in V11a 6. Fault in V11b 7. Fault in V17 8. Fault in P1	▶ Replace the tank. ▶ Check that the cap is correctly inserted into the tank and that it is properly closed. ▶ Check that the nozzle tube is not kinked and is obstructing the passage of liquids. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISINFECTANT 2 LOADING TIME OUT	1. Component B tank empty 2. Aspiration nozzle not inserted in the tank 3. Fault in SL12 4. Fault in V12 5. Fault in V12a 6. Fault in V12b 7. Fault in V17 8. Fault in P1	▶ Replace the tank. ▶ Check that the cap is correctly inserted into the tank and that it is properly closed. ▶ Check that the nozzle tube is not kinked and obstructing the correct liquid flow. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
DETERGENT LOADING TIME OUT	1. Detergent tank empty 2. Aspiration nozzle not inserted in the tank 3. Fault in FT13 4. Fault in V13 5. Fault in P5	▶ Replace the tank. ▶ Check that the cap is correctly inserted into the tank and that it is properly closed. ▶ Check that the nozzle tube is not kinked and obstructing the correct liquid flow. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
ALCOHOL LOADING TIME OUT	1. Alcohol bottle empty. 2. Aspiration nozzle not inserted in the tank. 3. Fault in FT19 4. Fault in V19 5. Fault in P4	▶ Change the bottle. ▶ Check that the cap is correctly inserted into the tank and that it is properly closed. ▶ Check that the nozzle tube is not kinked and obstructing the correct liquid flow. ▶ Send technical intervention request.

RESOLUTION OF PROBLEMS

Type of alarm	Cause	Solution
DISINFECTANT 1 DISCHARGE TIME OUT	1. Fault in SL11 2. Fault in V11 3. Fault in V11a 4. Fault in V11b 5. Fault in V17 6. Fault in P1	▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISINFECTANT 2 DISCHARGE TIME OUT ALARM	1. Fault in SL12 2. Fault in V12 3. Fault in V12a 4. Fault in V12b 5. Fault in V17 6. Fault in P1	▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISINFECTANT 1 MAX LEVEL ALARM	1. Fault in SL11 2. Fault in V11 3. Fault in V11a 4. Fault in V11b 5. Fault in V17 6. Fault in P1	▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISINFECTANT 2 MAX DISCHARGE LEVEL ALARM	1. Fault in SL12 2. Fault in V12 3. Fault in V12a 4. Fault in V12b 5. Fault in V17 6. Fault in P1	▶ Send technical intervention request.

Type of alarm	Cause	Solution
COVER CLOSURE ALARM	1. Cover open 2. Fault in SW1	▶ Check that the cover of the basin is closed. ▶ Check that nothing is obstructing correct cover closure. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
SPRAY TURNING SENSOR	1. Erroneous endoscope positioning. 2. Fault in SGR	▶ Check that the cover of the basin is closed. ▶ Check that nothing is obstructing the proper movement of the spray arm. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
LEAK TEST ALARM	1. Endoscope selected incorrectly. 2. Interblock connector connected incorrectly. 3. Endoscope connected incorrectly. 4. Endoscope damaged. 5. Fault on P2 6. Fault on V4 7. Fault on V16 8. Fault on TP2	▶ Check correct endoscope selection. ▶ Check proper endoscope seal by manual testing. ▶ Check the interblock connector is connected properly. ▶ Check the endoscope is correctly connected to the interblock connector. ▶ Send technical intervention request.

RESOLUTION OF PROBLEMS

Type of alarm	Cause	Solution
LEAK TEST OVERPRESSURE ALARM	1. Endoscope selected incorrectly 2. Fault on V16 3. Fault on TP2	▶ Check correct endoscope selection. ▶ Check that the interblock connection leak test tube is positioned correctly. ▶ Check that the endoscope is correctly positioned inside the basin. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 1 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-5 7. Fault in V5 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 2 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-6 7. Fault in V6 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 3 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-7 7. Fault in V7 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 4 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-8 7. Fault in V8 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 5 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-9 7. Fault in V9 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

RESOLUTION OF PROBLEMS

Type of alarm	Cause	Solution
CHANNEL 6 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in FT-10 7. Fault in V10 8. Connector fault	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 7 BLOCKED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel blocked 3. Channel connector fault 4. Fault in P1 5. Fault in R2 6. Fault in TP7 7. Fault in VPP1	▶ Check correct endoscope selection. ▶ Check that the endoscope channel is not actually blocked. ▶ Check that the channel connector is connected correctly. ▶ Check that the interblock connector tube has no blockages. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 1 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2 5. Fault in FT-5	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 2 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2 5. Fault in FT-6	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 3 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2 5. Fault in FT-7	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 4 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2 5. Fault in FT-8	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

RESOLUTION OF PROBLEMS

Type of alarm	Cause	Solution
CHANNEL 5 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2; 5. Fault in FT-9;	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 6 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel disconnected 3. Endoscope connector fault 4. Fault in R2; 5. Fault in FT-10;	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
CHANNEL 7 DISCONNECTED ALARM	1. Endoscope selected incorrectly 2. Endoscope channel incorrectly connected 3. Endoscope channel connector fault 4. Fault in TP7 5. Fault in R2	▶ Check correct endoscope selection. ▶ Check the connector-channel connection is correct. ▶ Check the endoscope connector and replace if necessary. ▶ Check the correct insertion of the channel separator slide on the endoscope handle. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
MAXIMUM TEMPERATURE ALARM	1. Excessively high temperature 2. Fault in T1 and/or T2 3. Faulty connection in T1 and/or T2	▶ Check that the temperature is within the envisaged limits. ▶ Reduce the equipment inlet temperature. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
MINIMUM TEMPERATURE ALARM	1. Temperature not reached 2. Fault in T1 and/or T2 3. Faulty connection in T1 and/or T2	▶ Check that the temperature is within the envisaged limits. ▶ Reduce the equipment inlet temperature. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
WATER LOADING TIME OUT ALARM	1. No mains water supply 2. F1 filter fault 3. F2 filter fault 4. Basin water inlet connector fault 5. Fault in V1 6. Fault in V18 7. Fault in FT-1 and FT-2	▶ Check for water in the mains water feed. ▶ Check the water stopcock is opened correctly. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
WATER FLOW METER REDUNDANCY ALARM	1. Fault in FT-1 and/or FT-2;	▶ Send technical intervention request.

RESOLUTION OF PROBLEMS

Type of alarm	Cause	Solution
BASIN LEVEL ALARM	1. Excessive basin liquid level 2. Fault in SL1 3. Fault in P1 4. Fault in FT-1 and/or FT-2 5. Fault in V3 6. Fault in FT-3	▶ Close the water inlet stopcock. ▶ Send technical intervention request.

Type of alarm	Cause	Solution
DISCHARGE ALARM	1. Discharge pipe blocked 2. Fault in P1 3. Fault in V3	▶ Check that the basin discharge pipe is not blocked. ▶ Check the external waste water system is not blocked. ▶ Send technical intervention request

Type of alarm	Cause	Solution
COMMUNICATION ERROR	1. USB cable disconnected 2. USB cable faulty 3. Faulty circuit board	▶ Check and insert the USB cable into the PC if necessary. ▶ Turn the PC off then on again. ▶ Send technical intervention request.

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A Cantel Medical Company

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CERTIFICATO CE - SISTEMA COMPLETO DI GARANZIA DI QUALITÀ

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

APPROVAZIONE DEL SISTEMA DI QUALITÀ ATTUATO DA
APPROVAL OF THE QUALITY SYSTEM OPERATED BY

CANTEL MEDICAL (ITALY) S.R.L.

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

SITI / SITES

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

PER I SEGUENTI DISPOSITIVI O GRUPPI DI DISPOSITIVI / *FOR THE FOLLOWING DEVICES OR GROUPS OF DEVICES*

Disinfettanti per dispositivi medici

Disinfectants for medical devices

Certiquality S.r.l., Organismo Notificato n° 0546, certifica che il sistema di qualità
Certiquality S.r.l., Notified Body n°0546, certifies that the quality system

è conforme ai requisiti della Direttiva 93/42/CEE, Allegato II ad esclusione del punto 4
is in compliance with the requirements of Directive 93/42/EEC, Annex *excluding section 4*

RAPPORTO DI AUDIT N° / *AUDIT REPORT NO.* **24884**

CERTIFICATO N. / *CERTIFICATE N.* **24884**

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CONCESSIONE E IL MANTENIMENTO DELL'APPROVAZIONE DI SISTEMA QUALITA' AI SENSI DELLA DIRETTIVA 93/42/CEE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE REGULATIONS FOR AWARDING AND MAINTENANCE OF QUALITY SYSTEM APPROVAL IN ACCORDANCE WITH DIRECTIVE 93/42/EEC

Il SISTEMA QUALITÀ E' SOGGETTO A SORVEGLIANZA PERIODICA

THE QUALITY SYSTEM IS SUBJECT TO PERIODICAL SURVEILLANCE

LA VERIFICA DEL SISTEMA QUALITÀ E' LIMITATA AGLI ASPETTI DELLA FABBRICAZIONE CONCERNENTI LA CONFORMITÀ AI REQUISITI METROLOGICI PER I DISPOSITIVI DI CLASSE I CON FUNZIONE DI MISURA E AGLI ASPETTI DELLA FABBRICAZIONE CHE RIGUARDANO IL RAGGIUNGIMENTO E IL MANTENIMENTO DELLO STATO STERILE PER I DISPOSITIVI DI CLASSE I STERILE

THE AUDIT OF THE QUALITY SYSTEM IS RESTRICTED TO THE ASPECTS OF MANUFACTURE CONCERNED WITH THE CONFORMITY OF THE DEVICES WITH METROLOGICAL REQUIREMENTS FOR DEVICES IN CLASS I WITH MEASURING FUNCTION AND WITH SECURING AND MAINTAINING STERILE CONDITIONS FOR DEVICE IN CLASSE I IN STERILE CONDITION

IL PRESENTE CERTIFICATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO

THIS CERTIFICATE IS NOT VALID WITHOUT THE RELEVANT ANNEX

PRIMA EMISSIONE / *FIRST ISSUE* 08/04/1998

EMISSIONE CORRENTE / *CURRENT ISSUE* 12/07/2017

DATA DI SCADENZA / *EXPIRY DATE* 11/07/2022

CERTIQUALITY S.r.l.

Mod. 5.20 ED 06 260517

ORGANISMO NOTIFICATO N° 0546

NOTIFIED BODY N° 0546

ALLEGATO AL CERTIFICATO N. **24884**

ANNEX TO CERTIFICATE N.

CANTEL MEDICAL (ITALY) S.R.L.

SITI / *SITES*

IT - 00071 POMEZIA (RM) - VIA LAURENTINA 169

ELENCO PRODOTTI / *PRODUCT LIST*

ADASPOR, ADASPOR ERS, ADASPOR M, ADASPOR MONODIE, ADASPOR PENTADIE, ADASPOR SINGLE SHOT, PROLYSTICA AUTO PAA, BLUESTERIL ALCOLICO, BLUSTERIL FERRI CE, CLOREXAN FERRI, NEO PROTEOZIM PLUS 500, PROTEOZIM PLUS 400, PROTEOZIM PLUS 1000, PROTEAZONE,PROTEAZONE ERS, PROTEAZONE OD, SPOREX, SPOREX OPA, SPOREXIN PLUS DS, SPOREXIN PLUS OD, SPOREXIN PLUS SALVIETTE, SPOREXIN PLUS VACUUM, SPORIDOX, SPORIDOX PLUS, ISASPOR, ISASPOR MONODIE, ISASPOR SINGLE SHOT, ISACLEAN, BACTRYL SPRAY, BACTRYL WIPES, ADASPOR PLUS PRONTO, ADASPOR PLUS CONCENTRATO, ADASPOR PLUS MONODIE, ADASPOR PLUS SINGLE SHOT, ISASPOR M, ISASPOR PENTADIE, ISASPOR ERS, ADASPOR PLUS M, ADASPOR PLUS PENTADIE, ADASPOR PLUS ERS, ISACLEAN SPRAY, SPOREXIN SPRAY, SPOREXIN VACUUM, SPOREXIN WIPES

IL PRESENTE ALLEGATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO CERTIFICATO
THIS ANNEX IS NOT VALID WITHOUT THE RELEVANT CERTIFICATE

PRIMA EMISSIONE *FIRST ISSUE* 08/04/1998

EMISSIONE CORRENTE *CURRENT ISSUE* 12/07/2017

DATA DI SCADENZA *EXPIRY DATE* 11/07/2022

CERTIQUALITY S.r.l.

CERTIQUALITY S.r.l. ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
Via G. Giardino, 4 - 20123 Milano - Tel. 02/8069171 Fax. 02/86465295 certiquality@certiquality.it - www.certiquality.it

CERTIFICATO CE

Certificato n. 1812/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

mantiene negli stabilimenti di:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Lava disinfettatrice-sterilizzatrice chimica a freddo per endoscopi
Mod. MEDIVATORS ISA
Marca Cantel Medical (Italy) S.r.l.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II.

Riferimento pratiche IMQ:
DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i.
Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2015-07-20
Data di Aggiornamento:	2016-05-26
Sostituisce:	2015-12-17
Data Scadenza:	2021-05-25

cosign

IMQ

ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

EC CERTIFICATE

Certificate No 1812/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

CANTEL MEDICAL (ITALY) SRL

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

manages in the factories of:

00071 POMEZIA (RM) - VIA LAURENTINA 169 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Cold chemical washer disinfector and sterilizer for endoscopes
Type ref. MEDIVATORS ISA
Trade mark Cantel Medical (Italy) S.r.l.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II.

Reference to IMQ files Nos:
DM15A0449933-01; DM15E0572628-01; DM16A0607476-01; DM16-0000589.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version.
Notified Body notified to European Commission under number: 0051.

Date:	2015-07-20
Updated:	2016-05-26
Substitution Date:	2015-12-17
Expirying Date:	2021-05-25

IMQ

IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
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This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratia de conformitate CE
I.3. Certificatul CE	Certificat CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
		medivators				cantel				
DM000197378	REPROCESOR AUTOMAT PENTRU DEZINFECTARI ENDOSCOAPEL	MEDIVATORS® ISA®			Italia	CANTEL MEDICAL (ITALY) S.R.L.	DATACONTROL S.R.L.	A07.PS-01.Rg04-13	28-01-2019	

Содержит([Producatorul], 'cantel') И Содержит([NameMake], 'medivators') Очистить