

EXTERNAL COMPONENTS

Figure 2

Rear view of the MEDIVATOR[™] ISA[™]
Endoscope Reprocessor.



INTERNAL COMPONENTS

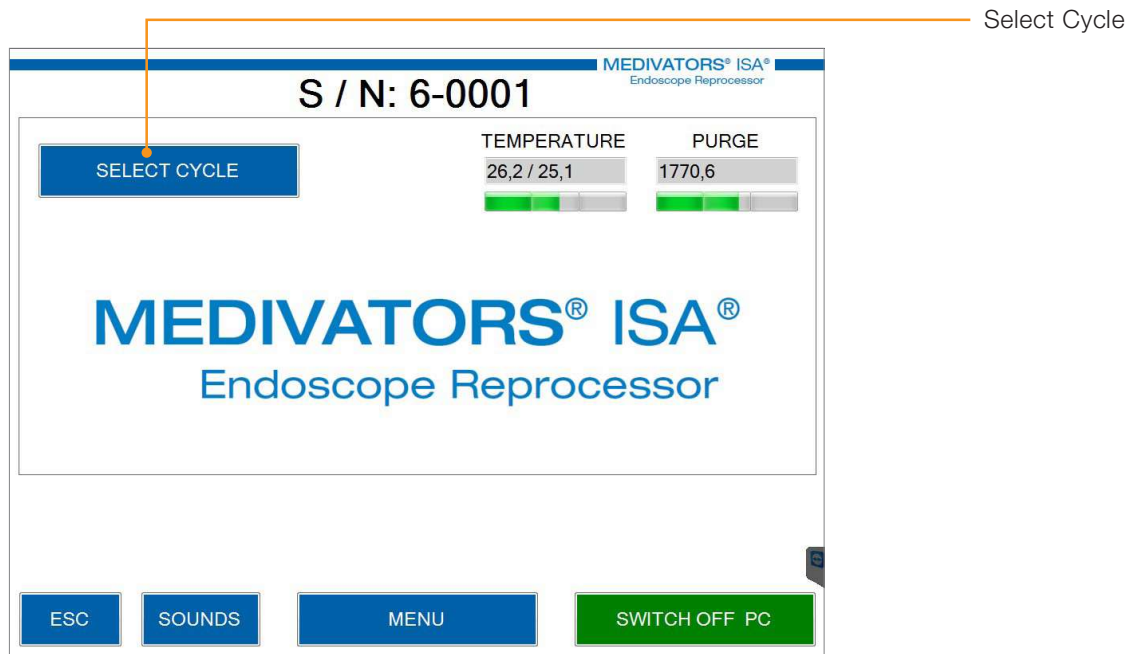
Figure 4

Chemical solutions and alcohol (optional) of the MEDIVATORS™ ISA™ Endoscope Reprocessor.

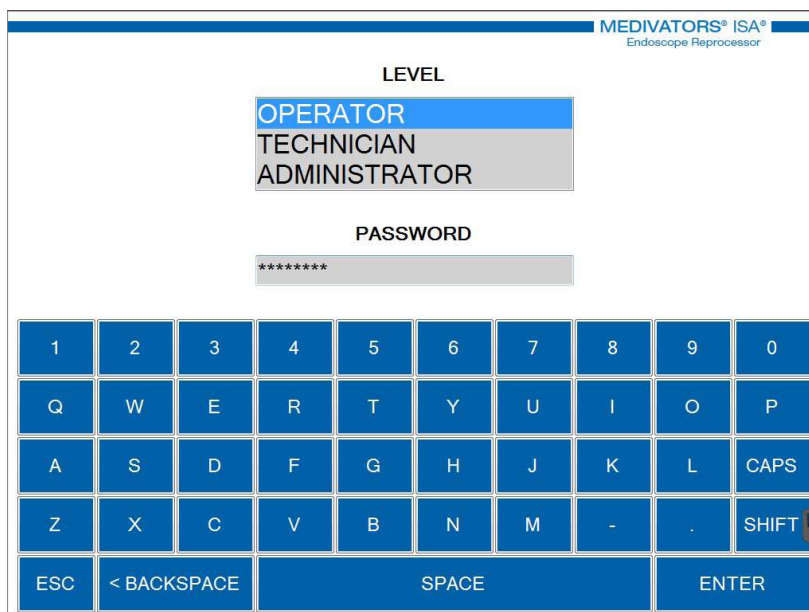


CYCLE START PROCEDURE

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:

INSTRUMENT

CATEGORY	MODEL	SERIAL NUMBER	ID
Sigmoidoscope	ES-3840	1	1
Gastroscope	GIF-Q165	A012345	1
Colonoscope	CF-100L	123	
Duodenoscope	JF-130	A123	
TEST		TEST	
	TESTER	A	
Duodenoscope	JF-130	t	1
Gastroscope	GIF-100	e	

CYCLE TYPE

CYCLE NAME

COMPLETE DISINFECTION

FAST DISINFECTION

PHYSICIAN

PATIENT

SELF-DISINFECTION

MENU

START

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.

STEPS IN THE “DISINFECTION CYCLE”

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

duration:
12 minutes



STEPS IN THE “SELF-DISINFECTION” CYCLE

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

duration:
20 minutes



STEPS IN THE “COMPLETE DISINFECTION” AUSTRIAN CYCLE

1. Initial leak test (with monitoring throughout the entire cycle)
2. Pre-wash
3. Water and detergent loading
4. Cleaning
5. Drain (instead of discharge)
6. Water loading
7. Rinsing
8. Water drain
9. Water loading
10. Rinsing
11. Water drain
12. Water loading
13. Rinsing
14. Water drain
15. Water and disinfectant solution loading

duration:
50 minutes



16. Disinfection
17. Solution discharge
18. Water loading
19. Rinsing
20. Water discharge
21. Endoscope channel drying

STEPS IN THE “COMPLETE DISINFECTION CYCLE”

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

duration:
20 minutes



STEPS IN THE “COMPLETE DOUBLE CLEAN DISINFECTION CYCLE”

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

duration:
25 minutes



TECHNICAL SPECIFICATIONS

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

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

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

DISPOSAL

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



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

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.

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):

S / N: 6-0001

MEDIVATORS® ISA®
Endoscope Reprocessor

STOP

TEMPERATURE
27.4 / 26

PURGE
1755

CYCLE TYPE
COMPLETE DISINFECTION

REMAINING TIME
2

INSTRUMENT
TEST / / TEST /

DOCTOR

PHASE
ALARMS.DRAIN

PATIENT

MAINTENANCE

ALARMS

ESC

SOUNDS

MENU

SWITCH OFF PC

STOP cycle button

Type of cycle in progress

Remaining cycle time

Endoscope identification

Cycle phase

Alarm button

Previous page

Reset acoustic signal

Warning button for expired maintenance

INTENDED PURPOSE

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

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

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

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

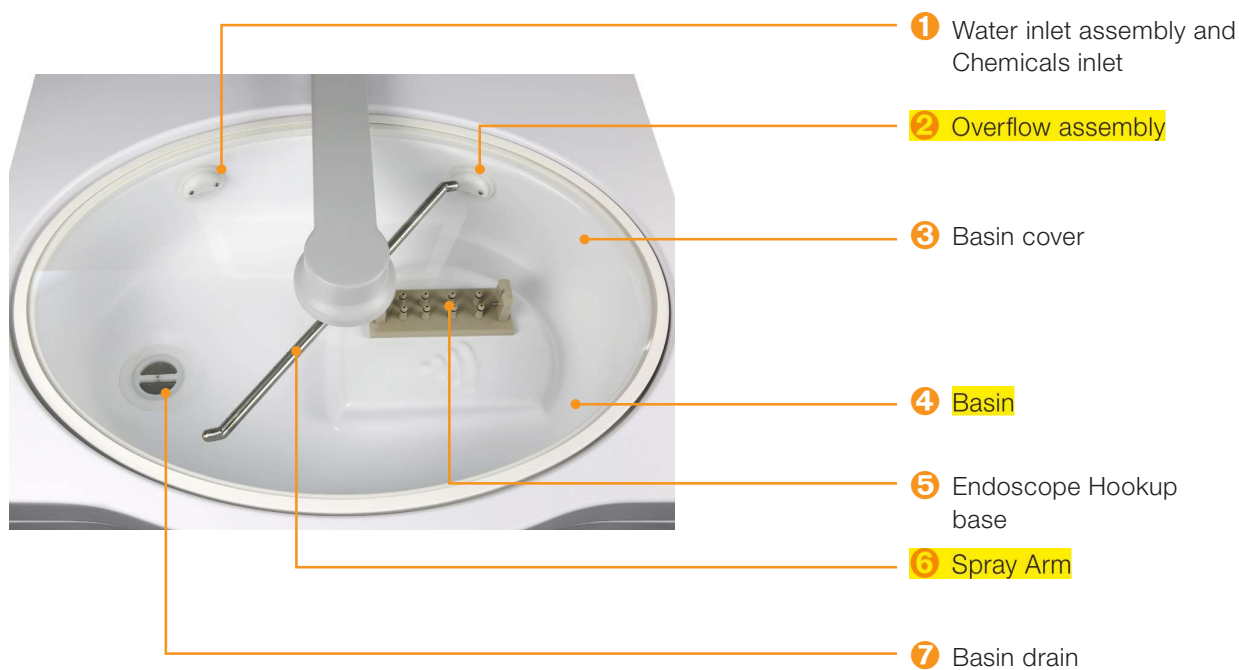


The equipment must only be used by qualified personnel and only after having attended a training course organized by the manufacturer or by personnel authorized by the manufacturer.

INTERNAL COMPONENTS

Figure 3

Viewed from above the basin of
the MEDIVATORS™ ISA™
Endoscope Reprocessor.



PRINTER

The MEDIVATORSM ISASM 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



IT REQUIREMENTS

IT Network Features and requirements

MEDIVATORS™ ISA™ Automated Endoscope Reprocessor can be connected to an IT network to provide optional features

Network features

1. Hospital Information System (HIS) output.
An HIS output file can be sent to a network share at the end of a cycle. This data can be used by Track and Trace systems to record cycle data.
2. Data backup
Machine data can be manually backed up to a mapped network drive or USB removable media.

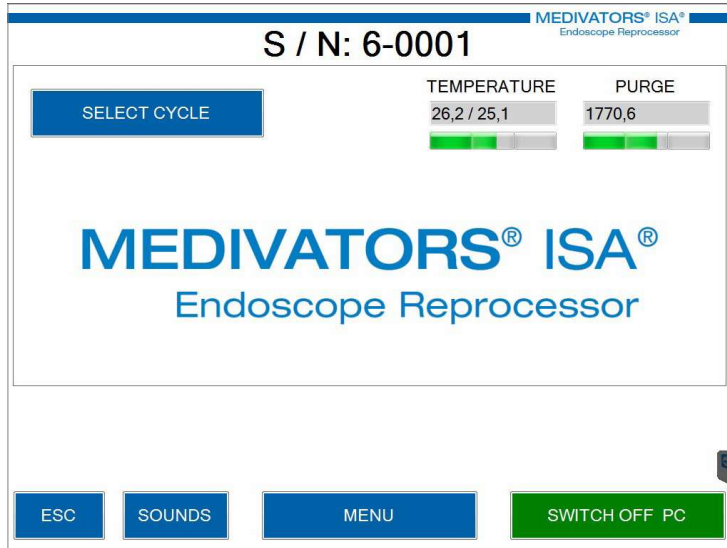
Operating environment requirements

1. MEDIVATORS™ ISA™ Automated Endoscope Reprocessor should be installed and operated in a controlled access environment.
2. MEDIVATORS™ ISA™ Automated Endoscope Reprocessor should be connected to a secure, controlled access IT network
3. Access should be restricted to authorized personnel only
4. Personnel should be provided the minimum access privileges required to perform their intended function.

For further information please contact Customer Services

- g. 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.



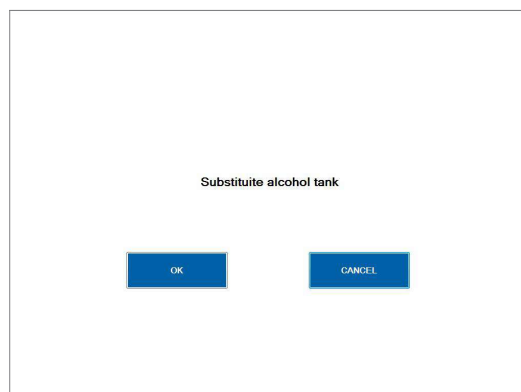
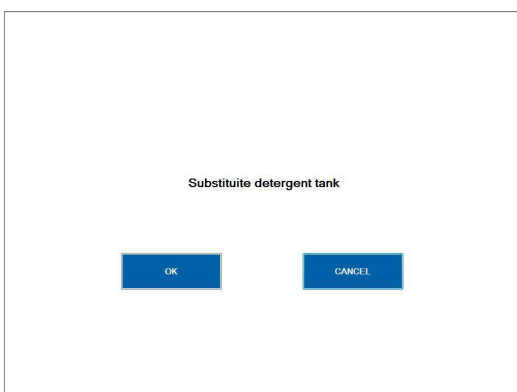
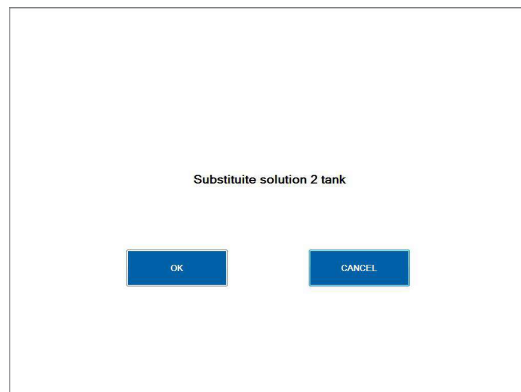
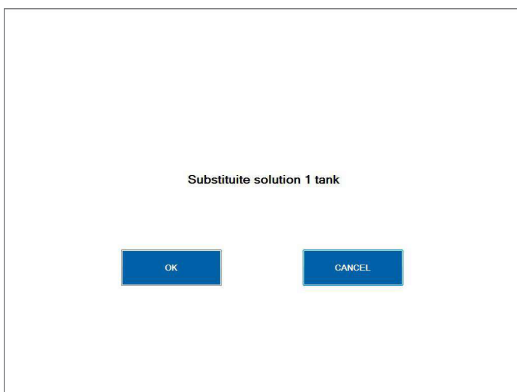
TANK REPLACEMENT PROCEDURE

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

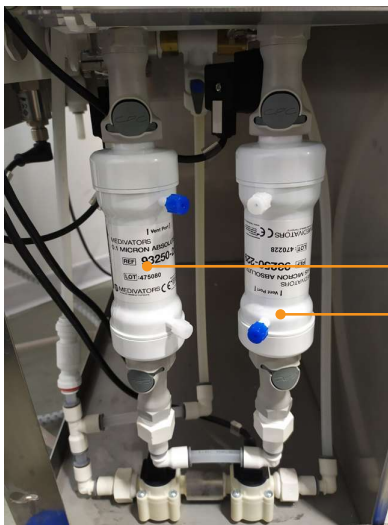
operator to be able to replace the corresponding product tank without the need to interrupt and restart the cycle from the start.

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



FILTRATION SYSTEMS

The MEDIVATOR™ ISA™ Endoscope Reprocessor is equipped with a water and air filtration system capable of Warranting the efficacy of the reprocessing cycles performed.



- 1 0.1 MICRON
- 2 0.45 MICRON

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 6 months.
- However, the lifespan of the water filters might be less than expected due to poor water quality at the installation site.

Code	Description
93250-222	Water Filter Kit Colder (0.1 µm + 0.45 µm)



Replacement of the water filters must be performed by qualified technical staff authorized by the manufacturer. Otherwise the efficacy of the washing and disinfection process is NOT warranted.

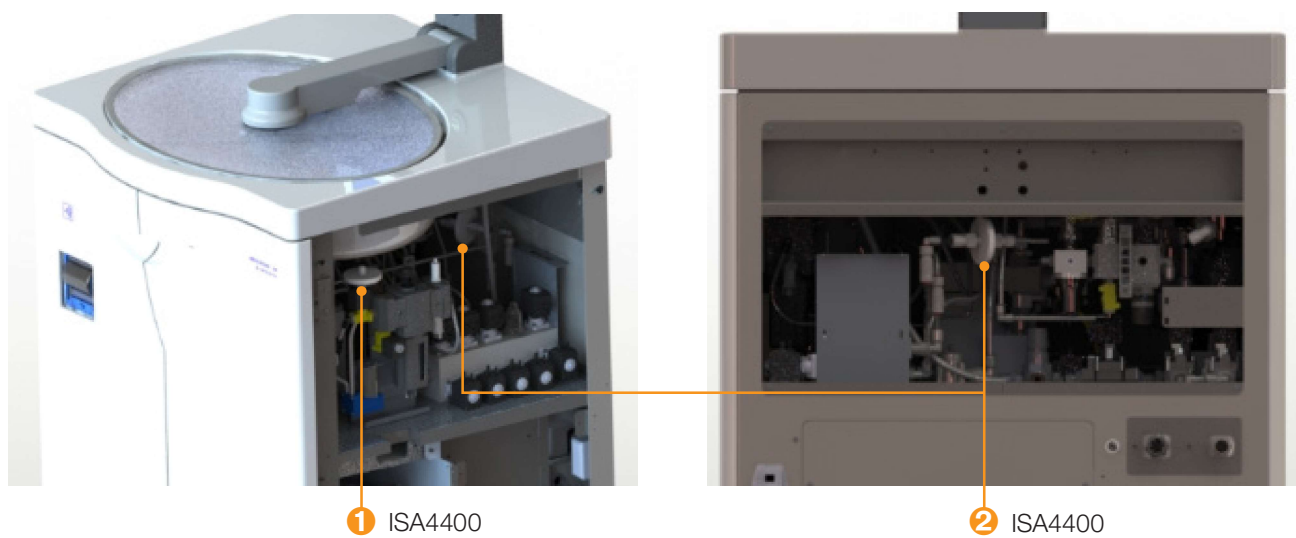
Any damage resulting from failure to replace the water filters and/or the use of NON ORIGINAL filters and/or operations performed by NON authorized personnel will invalidate any type of Warranty. The use of filters other than those indicated by the manufacturer does NOT Warranty the efficacy of the washing 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 6 months.



	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.