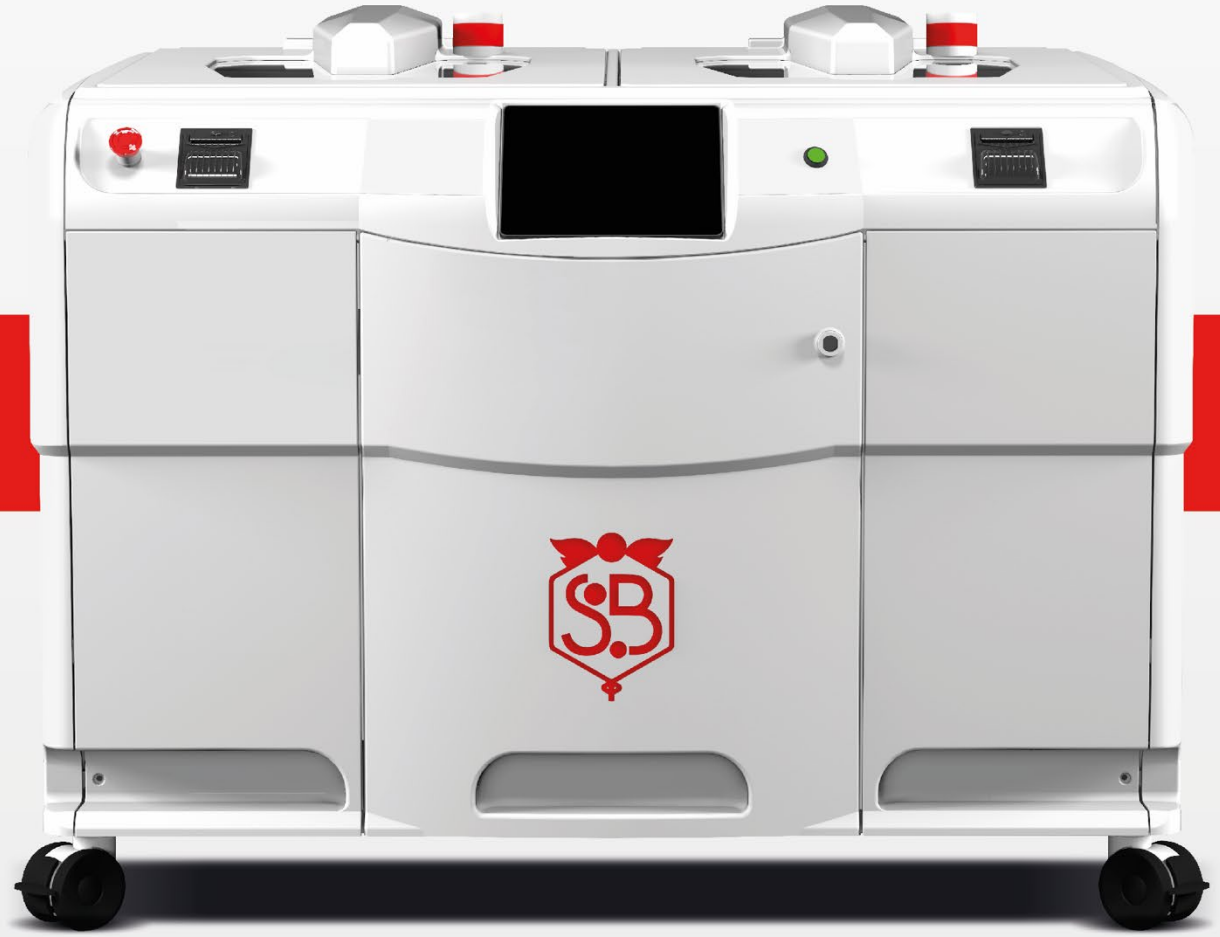
DATA SHEET

ENDOSCOPE WASHER MOD.

GANDY-90



CE 0476

SUMMARY

1. Introduction

1.1 Preliminary Information

MODEL	GANDY-90
Producer	NUOVA SB SYSTEMA S.R.L.
Manufacturer	Nuova SB System S.r.l.
CND	Z12011311 – STERILISERS FOR ENDOSCOPES
RDM	2168938
Designation of use	Washing, high-level disinfection and low-temperature chemical sterilization of thermolabile endoscopes.
Risk class	Class IIb

1.2. Certifications and Standards

CE CERTIFICATE	**CE Certificate - MED 31114 extended in the transitional period until the transition to the new medical device regulation MDR 2017/745 as specified in Art. 120.3c of the MDR as amended by Regulation (EU) 2023/607.**
REFERENCE STANDARDS	
UNI EN ISO 15883-1: 2014	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
UNI EN ISO 15883-4: 2019	Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors using chemical disinfection for thermolabile endoscopes
UNI EN ISO 15883-5: 2021	Washer-disinfectors - Part 5: Performance requirements and criteria for test methods to demonstrate cleaning effectiveness
UNI EN ISO 14937	Sterilization of medical products - General requirements for the characterization of a sterilizing agent and for the development, validation and systematic control of a sterilization process for medical devices.
IEC 61010-1:2010	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements.
IEC 61010-2-040: 2020	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washing machines used to process medical materials.
EN 61326-1: 2022	Electrical equipment for measurement, control and laboratory use - Electromagnetic compatibility requirements - Part 1: General requirements.
ISO 22196:2011	Measurement of antibacterial activity on plastics and other non-porous surfaces.
UNI EN ISO 13850:2015	Safety of machinery - Emergency stop function - design principles.
UNI CEI EN ISO 14971:2022	Medical devices - Application of risk management to medical devices.
COMPANY STANDARDS	
UNI EN ISO 9001:2015	Quality Management Systems - Requirements.
UNI CEI EN ISO 13485:2021	Medical devices - Quality management systems - Requirements for regulatory purposes.

1.3 Field of Application

The endoscope washing machine mod. GANDY-90 features two asynchronous washing tanks. The following table shows the types and number of endoscopes that can be reprocessed in each tank.

ENDOSCOPE TYPE	NUMBER OF REPROCESSABLE ENDOSCOPES PER SINGLE CYCLE
Flexible Endoscope	1
Bronchoscope	2
ENT without operative channels	4
ENT with one operative channel	2

2. Device features

2.1 Materials

The **materials** conceived and used for the design and workmanship of the mod. GANDY-90 washer-disinfectors are shown in the following table.

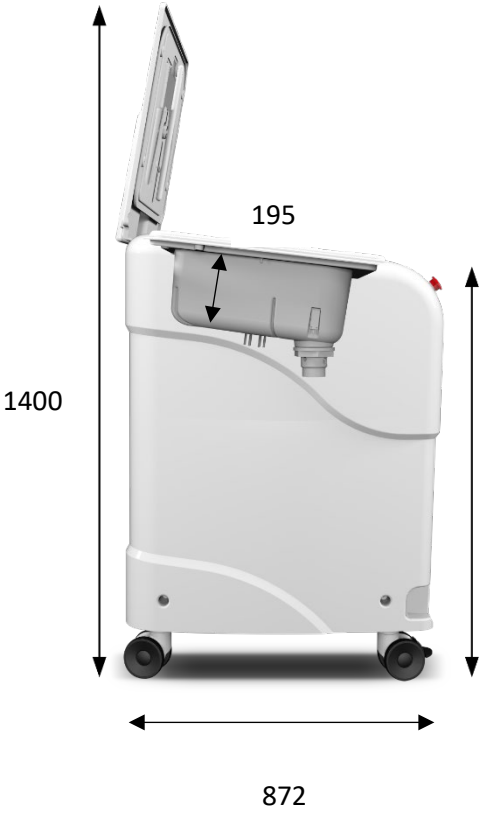
COMPONENT	MATERIAL
Metal structure	Stainless Steel 316
Fittings	Stainless Steel 316
Tank	PMMA
Machine structure	Polyurethane coated with antibacterial paint
Internal tubes	Silicone or polyurethane

This other table lists the general parameters of the equipment.

PARAMETER	VALUE
Average noise emission	60 db
Weight	234 Kg
Maximum power input	3.45 kW
Electrical safety class	I
Degree of electrical protection	IP45
Type of biomedical device	B

2.2 Dimensional parameters

Below there are the **views and relevant dimensional dimensions in millimeters** of the medical device mod. GANDY-90.



2.3 Structural features

Emergency button in accordance with ISO13850

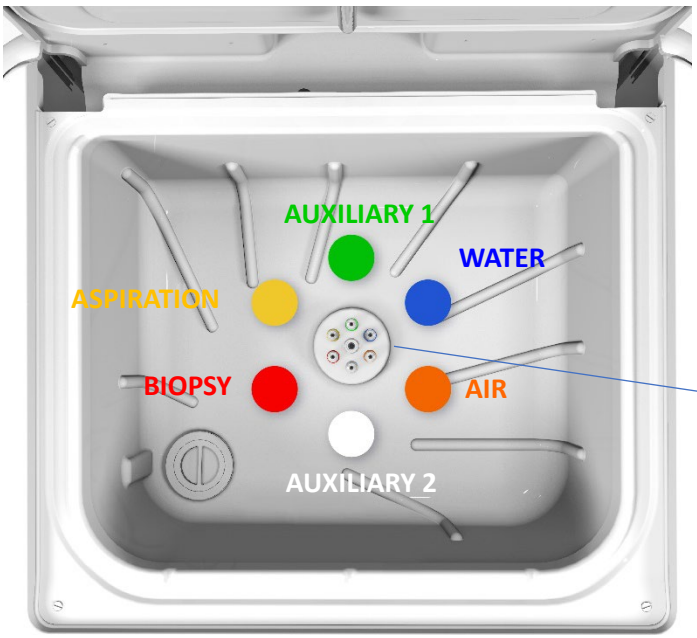
Integrated thermal printer

Ergonomic loading height for the operator

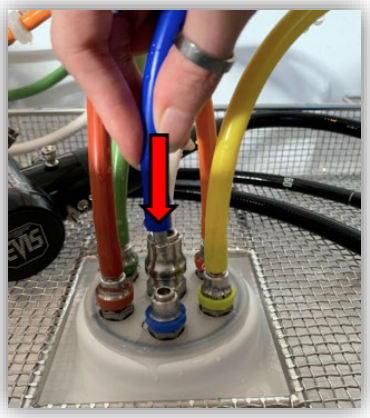
Wheels with brake

Chemical compartment easily accessible by the operator

Simple and intuitive 9.7'' touch-screen software interface



Different coloured connectors and tubes for each channel for easy identification

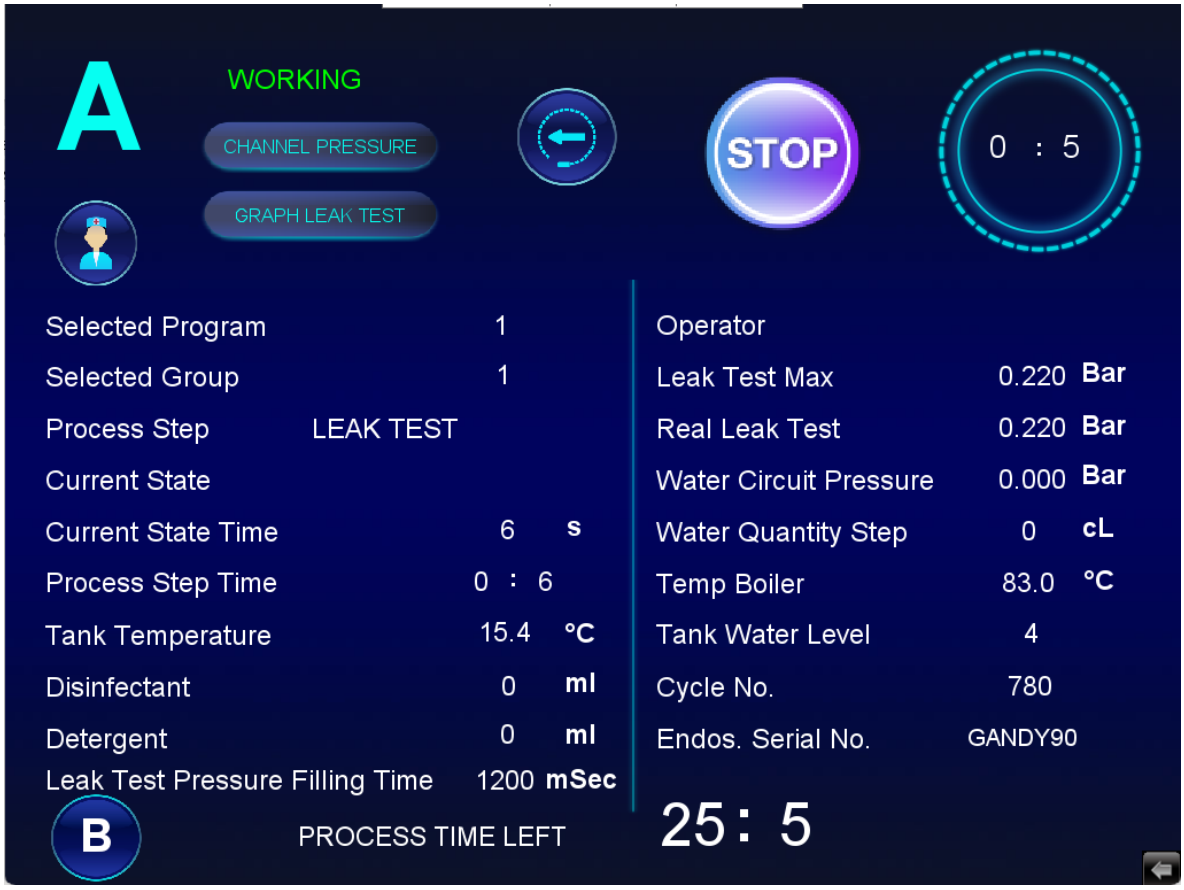


Easy-to-fit tube connectors

2.4 Functional features

The following table shows the **functional characteristics** guaranteed by the machine during the endoscope reprocessing operating cycles for each tank. The various programs, with their durations and water consumption for each phase, will be described later in section 2.5.

GUARANTEED FUNCTIONALITY DURING WASHING CYCLES
Leak test performed at the beginning of the cycle and throughout the duration of the cycle.
Automatic single-shot chemical dosing.
Individual channel monitoring throughout the cycle for obstructions or disconnections.
Pulsatile, unidirectional and self-regulating flow within each endoscope channel.
Possibility to cycle in 'fast' mode by framing the endoscope and operator barcode.
Possibility of programming self-disinfection cycles.
Integrated capacitive system that heats the water to a suitable temperature to ensure perfect hot water washing.
Possibility of discharging waste products into the sewage system.
Immersion and spray washing and disinfection process.
Automatic operator and endoscope recognition system via barcode gun.
Real-time monitoring on the large touch-screen of all detected parameters (see figure below).



The other table shows the **operating functions** that the GANDY-90 washer-disinfector is capable of performing in addition to those normally guaranteed during endoscope instrument reprocessing cycles.

EXTRA OPERATIONAL FEATURES
Three levels of accessibility: user, maintainer and admin.
Possibility of microbiological sampling directly from the wash tank.
Possibility to check the number of consumables in stock, with a warning message if stock is running low.
Monitoring the amount of chemical agent in the canisters.
Warning messages for filter change and routine maintenance.

2.5 Tracking

The following table shows the **tracking** characteristics of the mod. GANDY-90 washer.

TRACKING FEATURES
Complete tracking and recording of machine cycle data
Guaranteed paper tracking thanks to on-board thermal printer
The tracking of canisters and chemical agents used
Possibility of identifying whether a new canister you want to enter has already been used
Possibility of tracking thermal paper rolls
Operators, endoscopes and chemical agent canisters will be identified by their own barcode, which can be registered and identified on the equipment thanks to the barcode gun
Equipped with barcode gun.
Cycle traceability data can be exported via USB and Ethernet in .csv format.

The **information and data** in the reports printed on thermal paper for each cycle to ensure paper tracking are shown in the following table.

INFORMATION IN PAPER REPORTS
Hospital name.
Machine serial number.
Cycle number.
Selected washing program.
Date, time of loading, unloading of the instrument and total duration of the cycle.
Code of the responsible operator.
Endoscope serial number and its group.
Quantity of chemicals used and batch of canisters.
Phases of the cycle with relative duration.
Water circuit pressure and leak test.
Confirmation of cycle validation.
Possible red or orange alarm code with message of non-validation of the cycle.
Type of channels monitored.

2.6 Reconditioning programs

The following section will specifically describe the washing and disinfection features within each reprocessing program, as well as detailing the timing of each step and the water consumption required in each step.

2.6.1 Time and consumption of individual phases

High disinfection programs

	Program 1: Standard	Program 2: Standard double washing	Program 3: Advanced	Program 4: Disinfection phase	Program 6: Standard ENT	Program 9: Leak test repair
Leak test	20 s	20 s	20 s	20 s	20 s	20 s
Pre-washing	77 s	77 s	77 s		77 s	77 s
Washing 1	355 s Contact time:300 s	355 s Contact time:300 s	355 s Contact time:300 s		355 s Contact time:300 s	355 s Contact time: 300 s
Washing 2		355 s Contact time:300 s	355 s Contact time:300 s			
Rinse 1	95 s	75 s	95 s		95 s	95 s
Rinse 2		85 s				
Disinfection	355 s Contact time:300 s	355 s Contact time:300 s	505 s Contact time:450 s	355 s Contact time:300 s	355 s Contact time:300 s	355 s Contact time:300 s
Final Rinse 1	65 s	65 s	75 s	75 s	65 s	65 s
Final Rinse 2	65 s	65 s	65 s	65 s	65 s	65 s
Final Rinse 3	85 s	85 s	85 s	120 s	85 s	85 s
Drying	87 s	87 s	87 s	87 s		87 s
Total Time	20 minutes	27 minutes	28 minutes	13 minutes	16 minutes	19 minutes
Total water consumption	46 L	57 L	50 L	28 L	46 L	46 L

In addition, **the high disinfection program 11** is the one that allows for a fully **customizable cycle**.

Sterilization program

	Program 1: Standard
Leak test	20 s
Pre-washing	77 s
Washing 1	355 s Contact time: 300 s
Rinse 1	75 s

Rinse 2	85 s
Disinfection	655 s Contact time: 600 s
Final Rinse 1	65 s
Final Rinse 2	65 s
Final Rinse 3	85 s
Drying	87 s
Total time	26 minutes
Total water consumption	53 L

Other programs

	Program 5: Drying	Program 7: Chemical self-disinfection	Program 8: Thermal self-disinfection	Program 10: Leak test
Leak test				120 s
Pre-washing		175 s		
Disinfection		655 s Contact Time: 600 s	2230 s Temperature from 65 to 82°C Contact time: 2160 s	
Final Rinse 1		355 s	115 s	
Final Rinse 2		175 s	125 s	
Final Rinse 3		175 s		
Final Rinse 4		195 s		
Drying	200 s			
Total time	200 s	28 minutes	41 minutes	2 minutes
Total water consumption		42 L	21 L	

2.6.2 Washing and disinfection features

The following table lists the **chemical agents** manufactured and tested to ensure perfect disinfection of endoscopes in combination with the mod. GANDY-90 endoscope washer, including the **operating temperatures and mode of use.**

WASHING	
Chemical used	Eco Zyme, multienzymes cleanser and class I medical device
Washing phase temperature	Between 30 and 45°C
Modalities of use	1% dilution, 40 mL is dosed in 4 litres of water
DISINFECTION	
Chemical used	Ecosteril-F Plus, peracetic acid-based disinfectant and class IIb medical device
Washing phase temperature	<30°C, or at least the temperature of cold mains water
Modalities of use	1% dilution, 70 mL is dosed in 7 litres of water

2.7 Safety

The model GANDY 90 medical endoscope washer is equipped with all the necessary safety measures to guarantee the safety of the operator, endoscope, patient and machine itself, as well as to limit cross-contamination as much as possible. The following tables show the design solutions adopted to guarantee the safety of all those involved in the reprocessing cycle of flexible endoscopes.

2.7.1 General safety measures

Operator safety

OPERATOR SAFETY SYSTEMS
Anti-crushing sensor active when closing the doors.
Closed-loop system to prevent leakage of fumes and chemicals into the environment.
Presence of an active carbon filter for each tank to remove toxic fumes from the use of peracetic acid disinfectant.
Locking of the doors during the entire cycle, which can only be opened at the end of the reconditioning cycle.
Doors with watertight closure.
Wash tank vent filter with 0.01 µm porosity
Caps on the detergent and disinfectant canisters integrated in the suction lances to facilitate changing canisters if the chemical agent is exhausted.
Different colored canister caps to distinguish detergent and disinfectant.
Emergency discharge in case of alarm and non-validated cycle.
Emergency unloading also possible from the main menu.
Possibility of safety rinsing of the tank.

Safety for the endoscope

ENDOSCOPE SAFETY SYSTEMS
Watertight doors closure with soft silicone sleeve.
Temperature monitored throughout the reconditioning cycle by temperature sensor.
Maximum permitted temperature of 45°C
Acoustic and visual alarm system capable of signaling possible channel disconnections or obstructions.
Continuous monitoring and measurement of all pressures generated in each individual endoscope channel.

Safety for the machine

Safety systems dedicated to safeguarding the equipment, which then inevitably also affect endoscopes and operators, can be divided into **anti-corrosion and anti-contamination systems**.

MACHINE SAFETY SYSTEMS
ANTI-CORROSION SYSTEMS
Materials resistant to corrosion caused by peracetic acid disinfectant (See section 2.1).
Scheduled periodic replacement of the most delicate components subject to the corrosive action of the peracetic acid disinfectant.
Cold disinfection to limit the corrosive effect of the peracetic acid disinfectant.
ANTI-CONTAMINATION SYSTEMS
Chemical and thermal self-disinfection.
Presence of non-return valves.
Disconnected water loading and unloading system.
Smooth equipment surfaces that can be easily washed with any commercially available detergent.
Antimicrobial coating of the entire instrumentation, endoscope washer and barcode gun, containing bacteriostatic additive in accordance with ISO 22196.

General security systems

GENERAL SAFETY SYSTEMS
Emergency button in accordance with ISO 13850.
Presence of IOlink sensors for monitoring machine parameters and working conditions.
Possibility of remote technical support.

Limitation of cross-contamination

CONTAMINATION LIMITATION SYSTEMS
CROSS-CONTAMINATION SYSTEMS
Hands-free technology: presence of an infrared sensor that detects the operator's foot, allowing the door to be opened without contact with the device.
Equipped with a stainless-steel basket compatible with the disinfection processes of the GANDY 90 washer-disinfector.
CYCLE ANTI-CONTAMINATION SYSTEMS
Inlet water filtration with double membrane filter with 0.2+0.1 µm porosity.
Air filtration used for drying with 0.01 µm filter.

2.7.2 Alarms

The mod. GANDY-90 endoscope washer is equipped with **acoustic and visual** alarms capable of signaling to the operator any type of malfunction that may occur during the endoscope reprocessing cycle. The alarms are colour-coded according to the severity of the malfunction that occurs during the cycle.

WASHING	
ALARM COLOUR CODE	**SIGNIFICANCE**
	Visual warning only with message on the main page.
	Acoustic and visual alarm, with message, which does not interrupt the cycle.
	Acoustic and visual alarm, with message and error code, interrupting the cycle.
	Acoustic and visual alarm, with message and error code, interrupting the cycle.

3. Installation requirements

3.1. Electrical requirements

ELECTRICAL REQUIREMENTS	
Supply voltage	400V 3P + N
Power supply frequency	50 Hz
Input power	3.45 kW
Maximum amperage	10 A

3.2 Internet connection requirements

INTERNET CONNECTION REQUIREMENTS	
LAN socket	LAN socket RJ45
LAN socket data	IP address
	Subnet Mask
	DNS Address
	Gateway

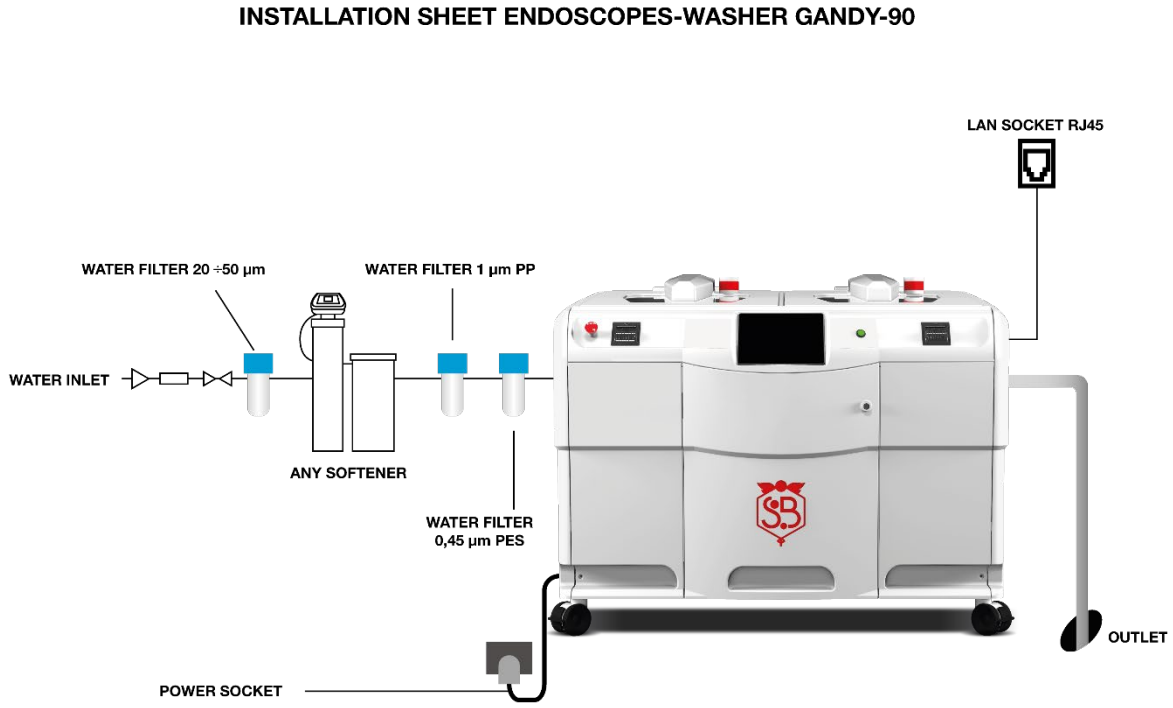
3.3. Water requirements

REQUIREMENTS FOR WATER CONNECTION	
Water connections	Cold water inlet
	Drainage
WATER CHARACTERISTICS	
Minimum flow rate	15 L/min
Hardness	< 120 mg/L of calcium carbonate (12°F) N.B.: In case of high-water hardness, with values above 12°F, the installation of a water softener is mandatory. For values close to, but below, 12°F, a water softener is strongly recommended.
Pressure	2-4 bar
Temperature	<40°C If the inlet water temperature is between 30 and 40°C, the appliance will not use the internal boiler to heat the water further.
pH	6.5-9
Conductivity	At least 10 µS

3.4 Environmental requirements

ENVIRONMENTAL REQUIREMENTS	
Room temperature	5-60°C
Relative humidity	<80%
Maximum horizontal inclination allowed	1°
Recommended ventilation frequency	> 10 Air change/h

3.5 Installation scheme



4. Consumables and accessories

4.1 Consumables

CONSUMABLE	CHARACTERISTICS
Ecosteril-F Plus	Peracetic acid disinfectant stored in 5-litre HDPE canister.
Eco Zyme	Multi-enzymatic cleaner stored in 5-litre HDPE canister.
Thermal paper KT 55 FA	Thermal paper with guaranteed 10-year stability.
Prefilter WFC-DPSHF4545	Water prefilter with 0.45 µm porosity.
Prefilter WFCC2-DPPD10100	Water prefilter with 1 µm porosity.
Filter WF4C2-DPSHF-2210	Water filter with double filter membrane and 0.2+0.1 µm porosity.
Filter WSF-GPFL-0001-05	Air filter with 0.01 µm porosity.
Filter M1000-8G-W	Leak test air filter with 0.01 µm filtration degree.
Filter 90DHV-PF0001EP	Tank vent air filter with 0.01 µm porosity.
Filter CamCarb CG ABS	Activated carbon filter.

4.2 Accessories

ACCESSORIES	CHARACTERISTICS
Connectors for endoscopes	Connectors are available for each channel of endoscopes of any model and brand, such as Pentax, Olympus, Fujinon, Storz, Wolf and others.
Stainless steel basket	Designed and manufactured to be contained within the wash tank, this basket can be used for handling endoscopes by limiting contact with them.