User manual

COMPACT WASHER-DISINFECTOR-STERILIZER FOR ENDOSCOPE EQUIPMENT

EW 1

Serial N°:

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Date: 2023.01.05 02:43:05 EET
Reason: MoldSign Signature
Location: Moldova

CE 0051

Steelco Miele Group Member

Via Balegante, 27
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ITALY

Manufacturer:

STEELCO S.p.A.
Via Balegante, 27
31039 Riese Pio X (TV)
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CONTENTS

Thank you for purchasing this appliance.

The installation, maintenance and operating instructions given in the following pages have been prepared to ensure the long life and good performance of the appliance.

Following the instructions carefully.

The appliance was designed and constructed using the latest technological innovations available.
Please take good care of it.

Your satisfaction is our best reward.

WARNING:
NON OBSERVANCE, EVEN IN PART, OF THE RULES INDICATED IN THIS MANUAL WILL CAUSE THE PRODUCT GUARANTEE TO BECOME INVALID AND RELIEVES THE MANUFACTURER OF ANY RESPONSIBILITY.

THE MANUAL CONTAINS ALL THE OPTIONALS THE MACHINE CAN BE EQUIPPED WITH.

1. GENERAL RULES

1.1 Limits of manufacturer’s liability

The manufacturer shall not be held liable for failures or problems which arise due to tampering and/or incorrect applications and/or improper use of the machine.
The purchaser must comply with all instructions set forth in the user's manual, and he must in particular:

- Always work within the allowable limits for the use of the machine;
- Always carry out constant and diligent maintenance;
- Allow use of the machine by persons with proper skills and abilities for their role and purpose who have been properly trained and instructed;
- Use only manufacturer original spare parts.

Any modifications, adaptation or the like which may be made to machines which are subsequently placed on the market do not oblige the manufacturer to intervene on previously supplied machines, nor to consider the machine and the related user's manual lacking and inadequate.

The installation, maintenance and operating instructions given in the following pages have been prepared to ensure the long life and outstanding performance of the appliance.

For some especially demanding programming or maintenance operations, this manual serves as a memorandum of the main operations to be carried out.
Education on these topics can be obtained by attending training course held by the manufacturer.

The instructions in this manual do not replace but rather are in addition to employer requirements to adhere to current legislation on standards of prevention and safety.

The machine is guaranteed for 15 months as from the time of shipment.

1.2 Manual validity, contents and conservation

This manual reflects the state of the art at the moment of manufacture and delivery of the appliance and is valid for its entire life cycle.
The manufacturer is at clients' disposal for further information or to receive suggestions for making the manual more compliant with the needs for which it was prepared.
The translation of the contents into the client's language has been carefully prepared.
In order to prevent possible accidents to persons or property due to in correct translation of the instructions, the client must:

- Not perform operations or manoeuvres with the machine if there are any doubts or uncertainties about the operation to be performed;
- Ask technical service for clarification of the instruction.
- If lost, ask for a new copy from the manufacturer.

It is important to keep this instruction manual with the machine for future reference.
If the machine is sold or transferred, the manual must be handed over to the new owners or user in order for them to become acquainted with its functioning and the relative warnings.

Read the warnings carefully before installing and using the machine.

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

1.3 Regulations

The purpose of the warnings is to safeguard the user in compliance with following Regulations and “Technical Product Standards”:

EUROPE:

- 2006/42/CE (Machine directive);
- 93/42/EEC and s.m.i (Medical Devices Directive);
- 2014/35/EU (Low Voltage Directive);
- 2014/30/EU (EMC - Electromagnetic compatibility directive);
- 2014/68/EU (PED Directive);
- EN 61010-1 (Safety);
- EN 61010-2-040 (Safety);
- 2011/65/EC (RoHS II);
- 2012/19/EC (WEEE);

and recognized international standards:

- IEC 61000 (Electromagnetic compatibility);
- IEC 61326-1 (Electromagnetic compatibility);
- ISO 14971 (Medical devices risk analysis);
- ISO 15883-1 (General requirements, terms, definitions and tests);
- ISO 15883-4 (Requirements and tests for medical washer and disinfectors that carry out the chemical disinfection of flexible endoscopes);
- ISO/TS 15883-5 (Soil test – A soil test method to prove the effectiveness of cleaning activities);
- IEC 60529 (IP Grade);
- UNI EN ISO 14937 (Sterilization of healthcare products).

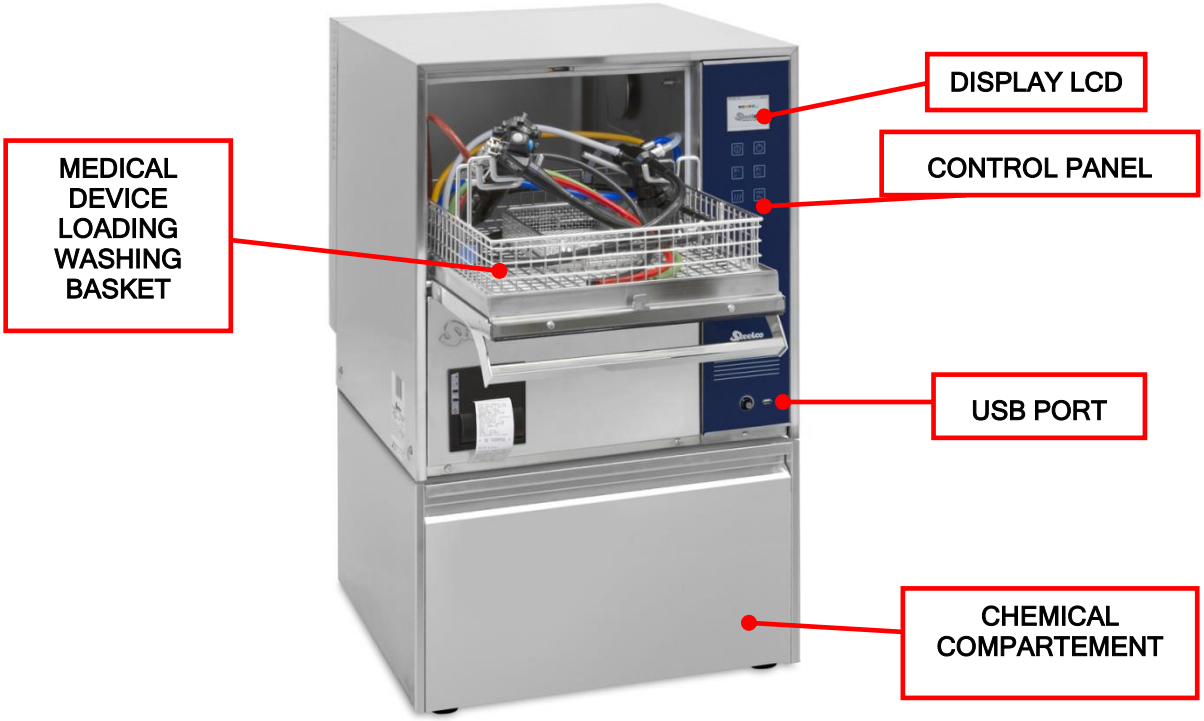
Steelco declares that this product, when it is equipped with a water steam version, is in accordance with PED 2014/68/UE directive art. 4 par. 3 and it has been designed and built in accordance with the correct building procedure.

2. SAFETY INFORMATION

Compliance with safety standards allow the operator to work productively and calmly, without the danger of harming himself or others.

Before starting work, the worker must be completely familiar with the functions and proper operation of the machine.
He must know the precise function of all command and control devices of the machine.

2.1 Machine components description



2.2 Intended use, improper use

INTENDED USE:

The use of this device is intended for washing, high level disinfection and/or sterilization of thermolabile endoscopes by using only chemical agents approved and validated by the device manufacturer.
This device is intended only and exclusively for the medical devices treatment.

2.2.1 Application fields

The use of this device is intended only and exclusively for the treatment of medical devices, such as:

- Flexible endoscopes
- Rigid endoscopes

2.2.2 Validated cycles

The cycles of high chemical disinfection and sterilization have been validated by the following chemical products:

HIGH-LEVEL DISINFECTION CYCLES	CHEMICALS
HYDROGEN PEROXIDE	SteelcoXide-DT (detergent)
	SteelcoXide-A (component A)
	SteelcoXide-B (component B)
PERACETIC ACID	Neodisher SC (detergent)
	Neodisher Septo PAC (paracetic acid)
GLUTARALDEHYDE	Neodisher SC
	Neodisher Septo GDA

STERILISATION CYCLES	CHEMICALS
HYDROGEN PEROXIDE	SteelcoXide-DT (detergent)
	SteelcoXide-A (component A)
	SteelcoXide-B (component B)

The improper use of this device is any use other than that for which the machine is intended.

The device has been validated to achieve high-level disinfection and liquid sterilization.

	WARNING
	**Any use other than the one intended is forbidden.**
	Improper use of this unit may be hazardous to the operator and may seriously damage the machine itself.
	If the appliance is used in a manner not specified by the manufacturer, protection of the appliance may be compromised.

2.3 Important warnings and suggestions

For proper use of the machine, and in order to safeguard employed staff, carefully comply with the following general and specific standards.

THE OPERATOR MUST:

- **Carefully adhere to the provisions and instructions** provided by the employer, managers and supervisors for individual and group safety.
- **Use safety devices appropriately and with care**, as well as group and individual safety gear provided by the employer.
- **Immediately inform the employer,** the manager and the supervisor of deficiencies in the aforementioned devices and means, as well as any hazardous conditions which he may become aware of, taking action directly in urgent cases within their scope of responsibilities and abilities to eliminate or reduce the deficiencies or hazards.

THE OPERATOR MUST NEVER:

- **Remove or modify, without authorization, the safety devices**, nor those for signalling and measuring, nor the individual and group safety gear.
- **Undertake on his own initiative operations or manoeuvres which are not his responsibility which** may compromise safety.
- **Insert foreign objects into the electrical parts.**
  Do not insert foreign bodies into the covers of the electrical motors or into the moving parts of the machine.
- **Provide power to the machine by tampering with the main switch and the safety devices.**

2.4 Safety recommendations

- If the new machine seems damaged, contact the retailer before using it.
- Any modification of electrical and hydraulic systems necessary to install the machine must be carried out by qualified, authorised persons only.
- This machine must be operated by trained persons only.
- This machine has been designed for the reprocessing of flexible and rigid endoscopes and the thermal disinfection of washing chambers;
- Any use other than that for which the machine was intended is forbidden.
- The user is forbidden to carry out any work or repairs on the machine.
- Technical Assistance for this machine should be carried out by qualified and authorised operators only.
- The equipment should be installed by authorised persons only.
- The electrical safety of machine is only guaranteed if it is connected to an efficient earth system.
- Take great care when handling detergents and additives: avoid contact, wear gloves, goggles and mask and act in compliance with the safety recommendations indicated by the manufacturer of the chemical products.
- Do not inhale the fumes produced by chemical products.

WARNING: The chemical products are an irritant for the eyes, in case of contact rinse thoroughly with plenty of water and consult a doctor.
If these products come into contact to the skin, rinse with plenty of water.

- The water in the tank is not drinking water.
- Do not lean on the door and do not use it as a step.
- Do not install the equipment in rooms where there is the risk of explosion (ATEX).
- Do not expose the equipment to intense cold.
- Do not wash the machine using high-pressure jets of water.
- The machine reaches a temperature of 80°C during the self-disinfection: take great care to avoid burns.
- Disconnect the machine from the electrical supply before carrying out maintenance work.
- The acoustic pressure of the machine is < 60 dB(A).
- The operator has always to verify before starting of the cycle the presence of the filters water in the sump and their correct positioning.

2.4.1 Inlet water

Physical Properties

Min. flow pressure	200 kPa (2,0 bar g)
Max. pressure	300 kPa (3,0 bar g)
Max. temperature	35° C
Max. hardness	7° f (70 ppm CaCO3)
Max. conductivity / Ph:	n.a. / 5…8 pH

Chemical Properties

Heavy metal ions	Iron	min 0 mg/l (ppm)	max 2 mg/l (ppm)
	Manganese	min 0 mg/l (ppm)	max 2* mg/l (ppm)
	Copper	min 0 mg/l (ppm)	max 2* mg/l (ppm)
	Total heavy metal ions	min 0 mg/l (ppm)	max 10 mg/l (ppm)
Halides	Chloride	min 0 mg/l (ppm)	max 50 mg/l (ppm)
Others ionic contaminants	Phosphates (P_2O_5)	min 0 mg/l (ppm)	max 0,2 mg/l (ppm)
	Nitrates (N_i)	min 0 mg/l (ppm)	max 20* mg/l (ppm)
	Silicates (S_iO_2)	min 0 mg/l (ppm)	max 2 mg/l (ppm)

Microbiological parameters

Parameter	Parametric Value
Escherichia coli	0/100 ml
Enterococci	0/100 ml
Pseudomonas aeruginosa	0/250 ml
Colony count 22 °C	100 CFU/ml
Colony count 37 °C	20 CFU/ml
Bacterial endotoxins	max 0,25 EU/ml

2.4.2 Rinse water

Physical Properties

Min. flow pressure	200 kPa (2,0 bar g)
Max. pressure	300 kPa (3,0 bar g)
Max. temperature	35° C max
Max. hardness	1,5° f (15 ppm CaCO3)
Max. conductivity / Ph:	30 µS/cm / 5…8 pH

Chemical Properties

Heavy metal ions	Iron	min 0 mg/l (ppm)	max 0,2 mg/l (ppm)
	Manganese	min 0 mg/l (ppm)	max 0,2* mg/l (ppm)
	Copper	min 0 mg/l (ppm)	max 0,2* mg/l (ppm)
	Total heavy metal ions	min 0 mg/l (ppm)	max 10 mg/l (ppm)
Halides	Chloride	min 0 mg/l (ppm)	max 10 mg/l (ppm)
Others ionic contaminants	Phosphates ($P_2O_{5)}$)	min 0 mg/l (ppm)	max 0,2 mg/l (ppm)
	Nitrates (N_i)	min 0 mg/l (ppm)	max 20* mg/l (ppm)
	Silicates (S_iO_2)	min 0 mg/l (ppm)	max 0,2 mg/l (ppm)

Microbiological parameters

Parameter	**Parametric Value**
Escherichia coli	0/100 ml
Enterococci	0/100 ml
Pseudomonas aeruginosa	0/100 ml
Mycobacterium Sp.	0/100 ml
Colony count	< 10 CFU/100 ml
Bacterial endotoxins	max 0,25 EU/ml

2.5 Recommendations to ensure high quality performance

- **The user must oversee the machine during the cycle.**
- **The injection tube for washing water must always be connected to the appropriated basket.**
- **When the machine is running do not interrupt the cycle since this jeopardises disinfection.**
- **Check periodically the correct disinfection with final rinse water checks.**
- **Use recommended detergents and chemical additives only.**
- **The use of other products may damage the machine.**
- **The use of opportune PPEs is compulsory, in order to avoid contact with infected material and to prevent contamination during the handling procedures of medical devices to be reprocessed.**
- **The chemical products recommended by the manufacturer are those that have been certified and validated by ISO 15883:4, 15883:5-TS and ISO 14937 standard.**
- **Check that type of chemical product is suitable for the specific washing program used.**
- **Comply with the instructions provided by the chemical product manufacturer.**
- **The machine was designed for use with water and chemical additives.**
  Do not use organic or other types of solvent as this may result in the risk of explosion or the rapid deterioration of certain machine parts.
- **Residues of solvents or acids, particularly "hydrochloric acid", can damage steel.**
- **Contact should be avoided.**
- **Repairs and servicing of this machine must be carried out by authorised persons only.**
- **Do never use soap powder.**
- **Do never use foaming detergent.**
- **Use original accessories only.**
- **Under no circumstances should the user attempt to carry out repairs.**
- **The machine is to be used only with the accessories provided by the manufacturer.**
- **Accessories which are not approved by the manufacturer may compromise the results achieved as well as user safety.**
- **Do never use chemical products based on chlorides (bleaches, sodium hypochlorite, hydrochloric acid and so on).**
- **These kinds of chemical detergents irreparably damage the machine and jeopardise the integrity of materials and objects treated.**
- **Check at every cycle the integrity of the connexions used to connect the endoscopes.**
- **Wet location.**
- **Mains supply voltage fluctuations: +/- 10%.**
- **Overvoltage category: II.**
- **Pollution degree: 2.**
- **IP:00.**

ATTENTION:

The taps of the water must be always turned off, as the safety and diagnosis system will be deactivated, in the following situations:

- **If the machine is left unused;**
- **If the machine is disconnected from the electrical connection.**

The Manufacturer cannot be held responsible for damage or injury caused by failure to observe the above rules.

The non-observance of these rules produces the total and prompt cancellation of the guarantee.

2.6 Residual risks

The appliance includes a series of fixed guards to prevent access to hazardous internal parts or zones.
It is however considered that the **EW 1** includes some residual risks.
Hereunder for each phase or significant work intervention are useful measures to be taken:

PHASE	BASKET LOADING
RISK	**Contusions and cuts to the upper limbs,** due to accidental contact with due to falling or striking against tools, objects and instruments, mainly while loading and handling the basket.
MEASURE	Assign staff that is instructed and equipped with work equipment (e.g. basket with protections, transport carts) and appropriate clothing and individual protection gear (e.g. shirts and protective gloves).

PHASE	OBTAINING DETERGENTS/CHEMICAL ADDITIVES
RISK	**Contact with body parts with chemical washing products.**
MEASURE	Assign staff that is instructed and equipped with appropriate clothing and individual protection gear. Wear clothing, gloves, goggles and mask and act in compliance with the safety recommendations indicated by the manufacturer of the chemical products.
FIRST AID MEASURE	• **Immediately take off/remove clothing which has been contaminated or soaked by the product.** • **If the substances come into contact with the skin, wash off affected skin areas immediately and rinse with water.**
RISK	**Inhalation of vapours of chemical wash products.**
MEASURE	Assign staff that is instructed and equipped with appropriate clothing and individual protection gear. Comply with the safety instructions provided by the manufacturer of the chemical products and if there are none, wear a mask for the protection of the respiratory airways.
RISK	**Accidental release of chemical wash product**
MEASURE	Do not flush concentrate into drains, surface or ground waters. Collect spillage with adsorbent material (e.g. sand, earth, vermiculite, diatomaceous earth). Flush away minor amounts with plenty of water.
	**IN CASE OF CONTACT WITH BODY OR RELEASE OF CHEMICAL PRODUCT LOOK ALWAYS AT THE SAFETY MEASURES INDICATED IN THE CHEMICAL TECHNICAL DATASHEET.**

PHASE	MAINTENANCE OF INTERNAL EQUIPMENT
RISK	**Burns of body parts by hot parts of the appliance.**
MEASURE	Allow maintenance to be performed only by trained personnel, equipped with appropriate clothing and individual protection gear. Wear suitable clothing and protective gloves.

PHASE	EMISSION OF HAZARDOUS GAS
RISK	**Inhalation of vapours of hazardous gas.**
MEASURE	With a correct installation, concurring with the manufacturer prescription, using the authorized chemical product and concurring with the rules in force in your country, the machine doesn't generate hazardous gas. However, the machine is supplied with vapours discharge, that have to be connected concurring with the instruction in chapter 3.

2.7 Safety signals used

To inform personnel operating on the machines of obligations of behaviour and residual risks, adequate safety signals (as set forth by 92/58 EEC) are applied to the machine and near the workplace.

GENERIC SAFETY SIGNALS:
In particular, labels with signals of obligation, prohibition and danger contained in this manual and pertinent to this machine and most commonly used are:

Electrical risk

Warning!
See annex documentation

Caution hot surface

INDIVIDUAL SAFETY WEAR:
The evaluation of risks for the health and safety of workers carried out in the workplace and on any equipment used, as well as the evaluation of residual risks as indicated, allow the employer to evaluate the need to adopt the individual protection gear which is most suitable and appropriate to be provided to workers.
Considering the type of machine, it is felt that the individual protection gear should be provided to staff.

2.8 Training

Instructions for use of the machine will be provided by the **STEELCO INSTALLATION TECHNICIAN** during the start-up phase to **MACHINE OPERATORS** and **MAINTENANCE TECHNICIANS** for their areas of responsibility, which will be thus instructed and trained. Moreover, an appropriate course certificate is issued (see Annex A).
It will be the duty of the **EMPLOYER** to check that the degree of staff training is suitable for assigned duties.

2.8.1 Staff qualification

Depending on the difficulty of certain installation operations, and of the operation and maintenance of the system, professional profiles are identified as follows:

IS ***INSTALLATION and REPAIR TECHNICIAN:***

Specialized installation and maintenance staff capable of carrying out all machine positioning and installation operations, connection of various systems and machine start-up at the client's place of business, as well as all routine and special maintenance operations.
This operator is responsible for training staff for machine operation and for testing the machine.

AS ***RESPONSIBLE AUTHORITY FOR THE MACHINE IN THE WORKPLACE:***

Specialized staff assigned to the verification of safety devices and procedures for proper use of the machine in complete absence or hazards.

The *responsible authority* is personally responsible for training courses for staff assigned to machine operation and maintenance.
He must ensure that staff assigned to operation has acquired all information required for use and routine maintenance of the machine, registering attendance and documenting comprehension tests.

The *responsible authority must* have a perfect understanding of all command, control and safety devices of the machine.
He must inform all personnel assigned to machine operation and maintenance of the instructions concerning *safety standards*, the *actions to be avoided* and the *first aid interventions* connected with use of the machine and the chemical wash agents it contains.

The *responsible authority* must be aware of all correct procedures for carrying out in absolute absence of danger all operation and maintenance of the machine, as well as all procedures for disposal of any residual pollutants and manufacturing wastes.
He must always be present during extraordinary or routine maintenance and give his *approval to proceed* to staff assigned to operation or to personnel assigned to routine or special maintenance.

The *responsible authority* will be responsible for operation of all command, control and safety devices in the machines of the system.
He shall carry out scheduled verification of those devices in order to ensure their continued operation over time.

AC ***MACHINE OPERATOR:***

Skilled personnel assigned to machine operation.
The *machine operator must* be perfectly aware of all of the machine's command and control devices.

Only after approval by the *safety supervisor, the machine operator* must be capable of using the assigned commands to do the following:

- Commissioning and start-up of the machine;
- Loading and unloading of material to be washed in the baskets;
- Operation of the machine in the various possible working modes, such as the start of various programmed wash cycles.
- Programming and setting data from the operator panel, adjustment of single control devices during working phases, starting or resetting of work functions.
- In addition, the *machine operator* must, by making use of all required individual protection gear and following adequate safety measures, be capable of performing some routine maintenance such as cleaning inside the machine, cleaning clogged filters, and disposing of pollutant waste materials produced during working.

2.9 Indication of sound level

The value shown refers to the measurement obtained on a machine of the same type as that covered herein and measured with an instrument at a height of 1,5 m at a distance of 1 m from the machine.

AVERAGE SOUND PRESSURE LEVEL: < 60 dB (A)

2.10 Transport and storage

Environment conditions:

- Temperature range +5 ... +50 °C;
- Relative Humidity range 20…90% without condensation;
- Ventilation: Air exchange not required (required only if chemical tanks are installed).

2.11 Chemical products connections

The chemical product dosing system consists of two different systems: one for aggressive chemical products (neutralizing detergent etc.) and another for disinfectants (peracetic acid, hydrogen peroxide, aldehydes):

- Dosing pump for chemical products.

- Presence sensor chemical product.

- The system can be equipped with meter quantity of dispensed product.

Further dosing pumps and accessories can be ordered as optional.
Each pump is combined with a corresponding type of chemical, according with the references on the table below.

PERACETIC		
PAA	DISINFECTANT	YELLOW
SC	DETERGENT	BLUE
3rd	CHEMICAL	BLACK

PEROXIDE		
XIDE B	YELLOW	DISINFECTANT
XIDE A	RED	DISINFECTANT
DT	BLUE	DETERGENT

	ATTENTION
	In order to guarantee the right treatment of the objects, we suggest the use of specific products. In the case of necessity, ask for advises to the seller or the producer.

2.11.1Presence sensor of chemical product

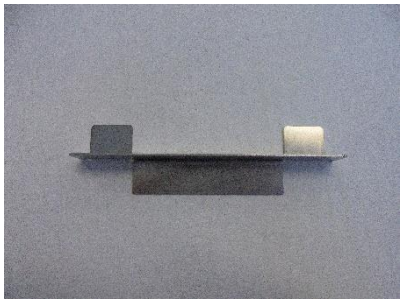
Each dosing pump is combined with a sensor that confirm the presence of chemical product inside the container. If the product is scarce, the electronic control system of the machine sends a message on video of lack of product.

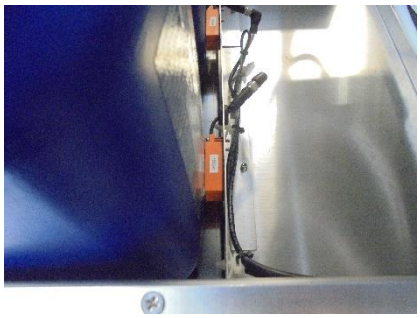
2.11.2Meter quantity of chemical product

Each individual pump is linked to two volumetric sensors in order to measure the quantity of chemical product dispensed. The dual PLC electronic control unit manages the value of the minimum quantity requested and, if necessary, it interrupts the cycle.

2.11.3Container block

Each container must be locked by the special bracket to ensure the correct data reading.





2.11.34Replacement of chemical product container

To replace the chemical product container perform the following procedure:

- Take the new product container.

- Open the chemical compartment.

- Replace the chemical product container removing the level sensor from the empty tank and put into the new one.

- Close the topper of the chemical product container and place it in the area for the storage of chemical substances.

- Close the chemical compartment.

	ATTENTION
	The used chemical product can be dangerous if touched or inhaled. Before the use, read carefully the safety information supplied by the manufacturer of the chemical product and the label on the package.
	During the operations of replacement of chemical product container, use the appropriate tools for individual protection (chemical protective gloves, face masks for breathing, etc.).
	The access to the technical compartment, where are located the chemical product containers, is permitted only with keys and to the authorized personal.
	If the chemical tank is in the vacuum or overpressure condition (tank deformation) use the PPE before doing every operation.

If the machine gave an alarm for chemical lack (Error 17-Error 18), after the replacement of the canister, the machine automatically proposes a special cycle for the circuit filling and for the chamber rinsing.
This cycle called **CHEMICAL LOAD** has to be started imperatively after this alarm: it will be not possible to select other cycles until the machine have filled the detergent circuit.
At the end of this cycle the machine will return on stand-by status waiting for a new command.

NB: the chemical loading cycle will not be saved on the historical and will not be printed.

2.12 Ambient ventilation requirements

During the normal operation, the machine warms up itself dispersing heat and hot air increasing the humidity value; in the drying phase, these events increase. Therefore, in order to guarantee a comfortable environment with good temperature and humidity for the operator, it is necessary to prepare an air conditioning or air circulation system capable to balance the emissions reported in the installation plan.
The machines with drying system are equipped with an exhaust which can be connected to an external extraction system.
As for machines designed to use Glutaraldehyde, connect the exhaust air connection to an external air evacuation system or put the machine under an extraction hood.

2.13 Table of symbols

Symbols installed on the machine:

	Electrical risk
	Warning - hot surface
	Manufacturer
	Manufacturing date
	Attention! See the enclosed documentation for important warnings, such as warnings and precautions.
	See instruction for use
	Protective conductor terminal
	EC Mark
	WEEE waste disposal
MD	Medical device indication
REF	It indicates the catalogue number of manufacturer.
REP	Authorized Local Representative.

3. USING THE MACHINE

3.1 Checks

Check the quantity of chemical additives present and replace if necessary, as described below:

- Obtain appropriate individual protection gear (gloves for protection from chemical substances, breathing protection masks, goggles etc.) and the new detergent container.
- Turn off the machine by pressing the OFF button.
- Follow the instruction on section 2.11.3.

ATTENTION:
The chemical product which is used may be hazardous if touched or inhaled.
Prior to use, carefully read the safety information provided by the detergent supplier and the label applied to the package.

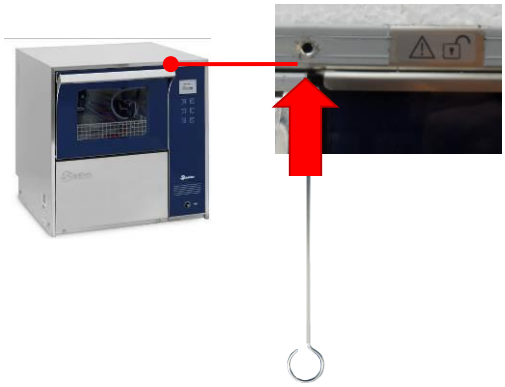
3.2 Opening and closing the door

- The machine is fitted with an electric door lock to prevent it being opened when the machine is running.
- To open the door during a wash cycle, interrupt the cycle and remember that:
  1. The items inside the machine may be very hot (**ONLY DURING THE SELF-DISINFECTION**).
  2. The objects inside the machine could be contaminated
  3. The entire wash cycle must be repeated.

3.2.1 Door unlocking

In case of power fail or malfunctioning of door lock, it is possible to unlock and open the door by follow the procedure:

1. Identify the hole between the door and the cover panel (see the picture).
2. Insert the dedicated instrument.
3. Keep pushing the dedicated instrument. In this moment the door is unlocked and it is possible to open it.
   To close the door, keep pushing the dedicate instrument as described on point 3.



	ATTENTION
	After performing the procedure described previously, remember that: • **The items inside the machine could be very hot and contaminated.** • **The entire treatment cycle must be repeat.** • **Material contaminated with peri acetic acid could be present inside the machine.**

3.3 Switching on

Turn on the machine following the procedure:

- Press the ON-OFF switch as shown below:

- The control panel starts automatically.
- Check that no alarm messages are present. In negative case remove it.

3.4 Preparation of the endoscopes

In order to be correctly reprocessed inside the EW 1 system, the endoscopes must undergo pre-cleaning and manual washing procedures.
Follow the current applicable National Guideline instructions as well as any internal protocols in force.
Some of the main currently available Guidelines are specified below:

COUNTRY		GUIDELINES
	**EUROPE**	*ESGE±ESGENA guideline: Cleaning and disinfection in gastrointestinal endoscopy Update 2008.*
	**ITALY**	*ANOTE-ANIGEA - Linee guida Pulizia e disinfezione in endoscopia - Update 2011*
	**FRANCE**	*Guide de Bonne Pratique de désinfection des dispositifs médicaux - obligatoire depuis le 14 juin 1998.* *Conseil Supérieur d'Hygiène Publique de France, section prophylaxie des maladies transmissibles.* *Comité Technique Nationale des Infections Nosocomiales.*
	**IRELAND**	*PART 4: RECOMMENDED PRACTICES FOR ENDOSCOPY UNITS* *Health Service Executive Code of Practice for Decontamination of Reusable Invasive Medical Devices - Review date August 2008.*
	**GERMANY**	*Recommendation of the Commission for Hospital Hygiene and Infection Pr evention at the Robert Koch Institute (RKI).* *Hygiene Requirements for Reprocessing Flexible Endoscopes and Additional Endoscopic Instrumentation - Published in the Federal Health Gazette in April 2002.*
	**GREAT BRITAIN**	*National Endoscopy Programme - Decontamination Standards for Flexible Endoscopes - Updated March 2009.*
	**UNITED STATES**	*SGNA Society of Gastroenterology Nurses and Associates, Inc.* *Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes - Revised in 2012.*

3.4.1 Check of endoscope instrument connectors

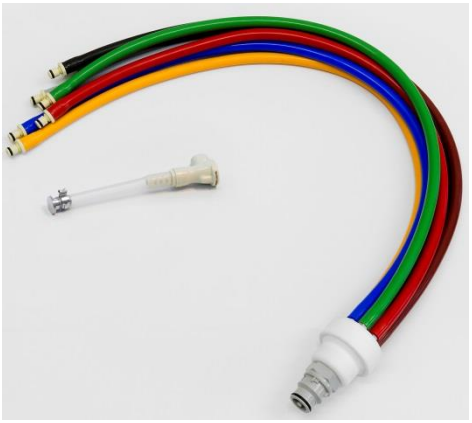
Connectors for the endoscope instruments supplied with the EW 1 machine must be checked daily by machine users and periodically by technicians in charge of maintenance.
The use of not original Steelco connectors or worn connectors can damage the endoscope instruments, activate machine alarms (ex. “channels disconnected”, “channel partially clogged” etc.) and most of all does not guarantee a correct disinfection process, endangering both patients’ and sanitary personnel’s wealth.

3.5 Thermal-disinfection cycle in conformity with EN ISO 15883:4

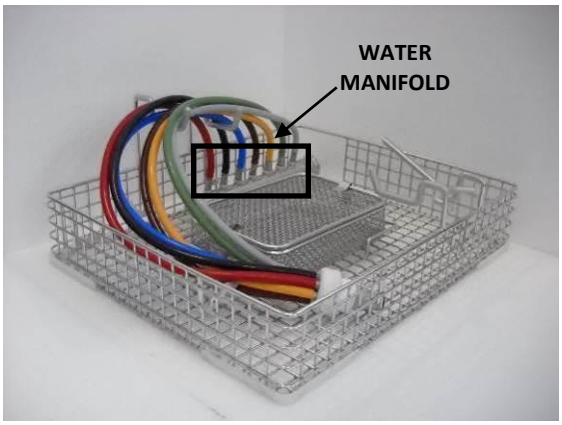
The Endoscope washer-disinfector must perform a daily thermal self-disinfection (regardless the chemical products used).
It is recommended to run the thermal self-disinfection program daily, to minimize contamination risk. This cycle can be performed automatically at a defined time: in case the endoscope washer-disinfector is not used during the weekend, make sure that the automatic self-disinfection is conducted.
If the endoscope washer-disinfector is not used for more than 24 hours, before restarting the operation:
1. Run 2 thermal self-disinfection processes.
2. Control the shelf life of the reprocessing chemicals and replace if expired.
3. Run 1 reprocessing program without endoscopes.

MACHINE WITH ONE DOOR

- Connect the CPC connections of the basket water manifold.



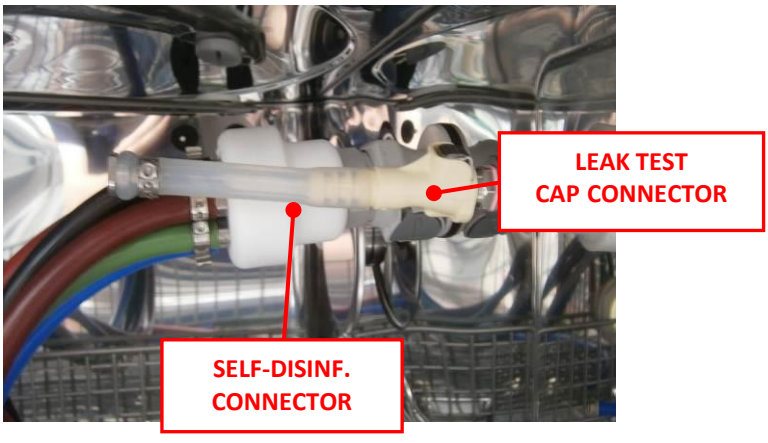
Connection with tubes for auto-disinfection (code 671511)



Basket

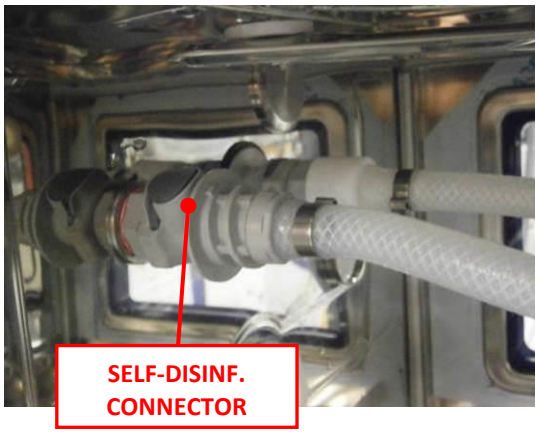
- Put the basket inside the machine and connect the connection with tubes for auto-disinfection to the relative connector. Then close the leak test inlet by means of the appropriate cap connector as shown in the illustration.

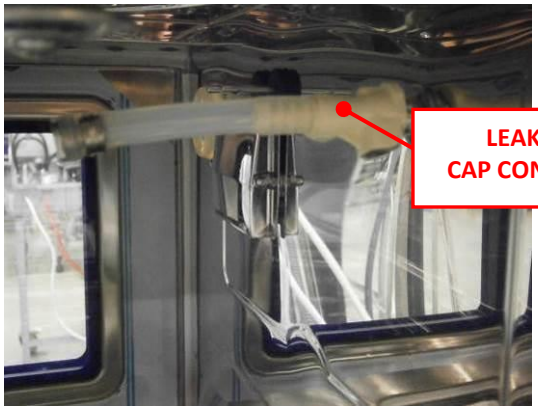
- The yellow tube must be connected to the basket and the opposite side must be free in order to drain the basket water manifold.



MACHINE WITH TWO DOORS

- Connect the connection for auto-disinfection inside the washing chamber.





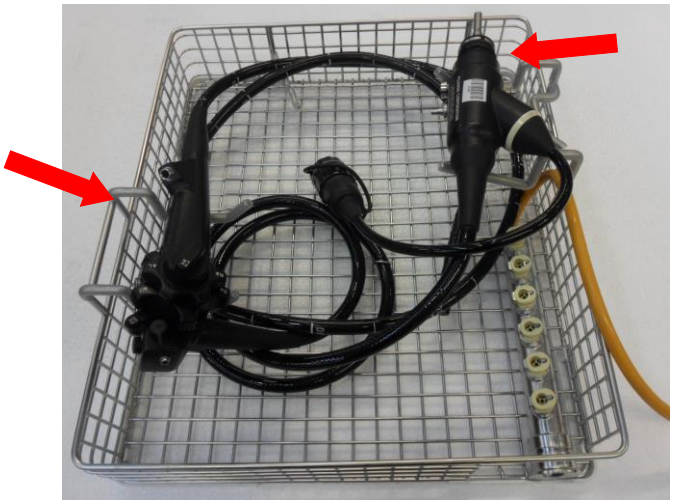
- Close the leak test inlet by means of the appropriate cap connector as shown in the illustration.

3.6 Load preparation

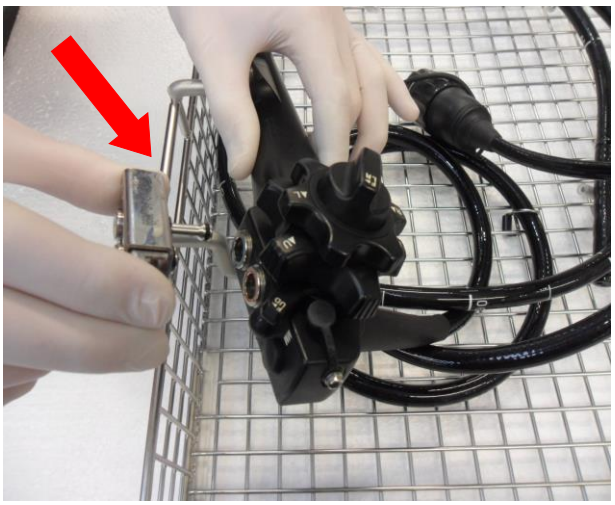
Once the thermal disinfection cycle has finished, remove the sanitation and leak test connectors and proceed with the loading of the endoscope into the basket by carrying out the following procedure:

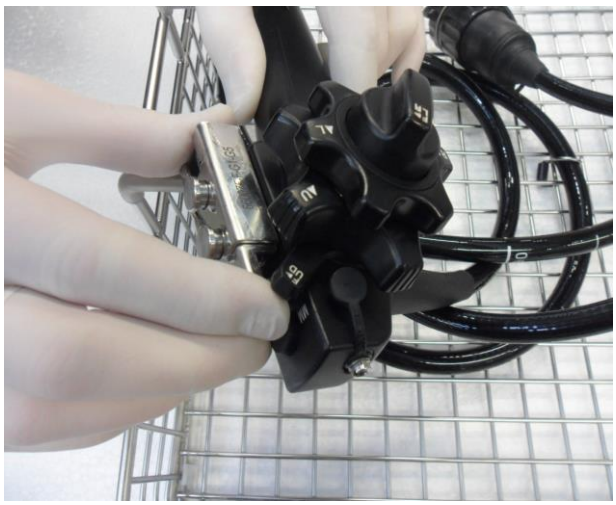
PUT THE ENDOSCOPE CAREFULLY INTO THE BASKET USING THE APPROPRIATE SUPPORTS

(SEE PHOTO);



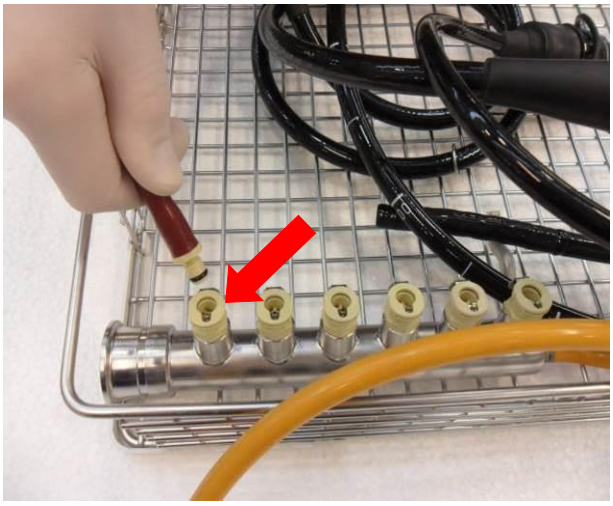
INSERT THE CHANNEL SEPARATOR, ACCORDING TO THE ENDOSCOPE TYPE (SEE PHOTO);

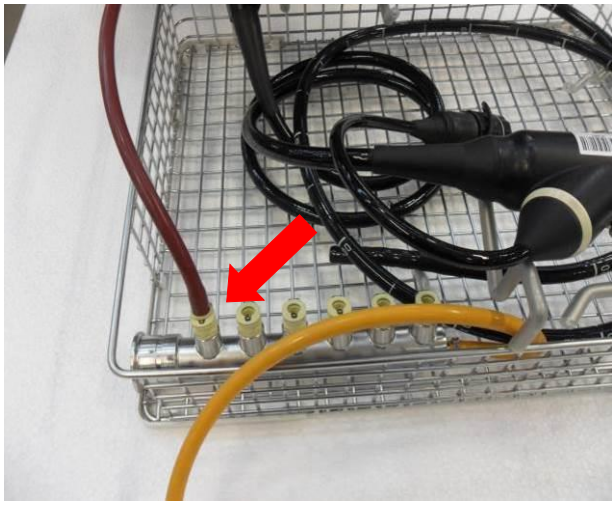


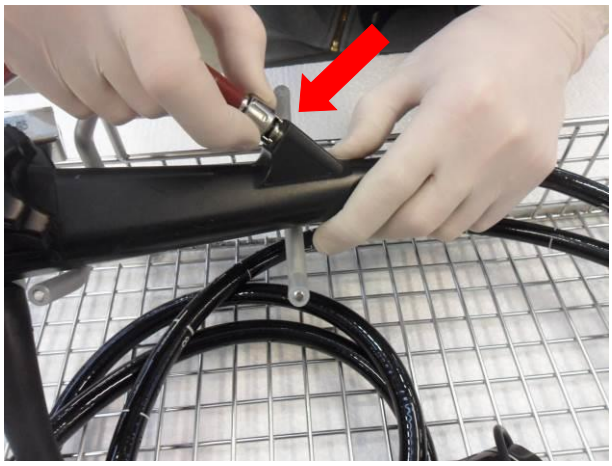


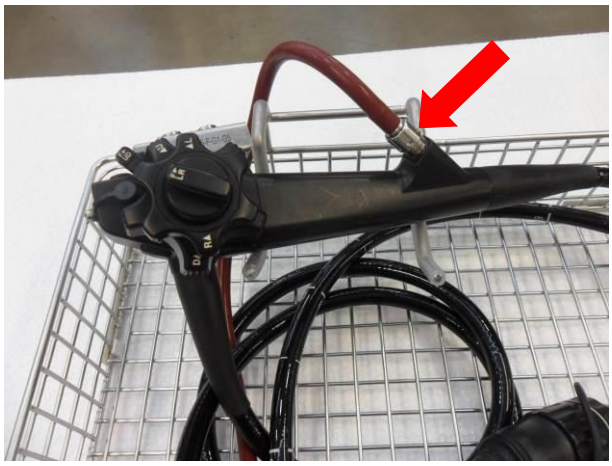
COUPLE THE CONNECTION PIPES TO BE USED FOR CONNECTION TO THE ENDOSCOPE WHICH ARE DIFFERENT DEPENDING ON THEIR BRAND AND MODEL (SEE PHOTO);

EXEMPLE OF BIOPSY CHANNEL CONNECTION;

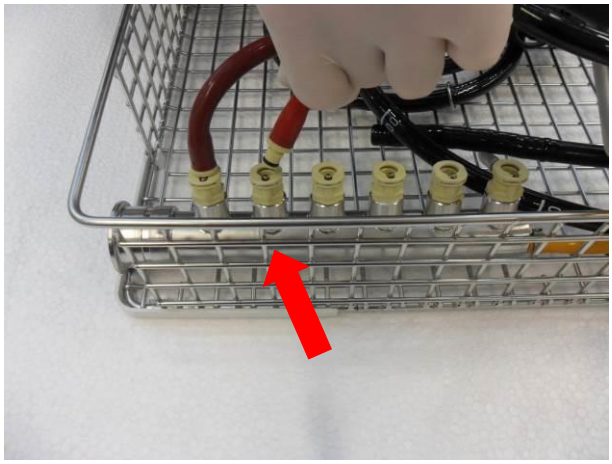


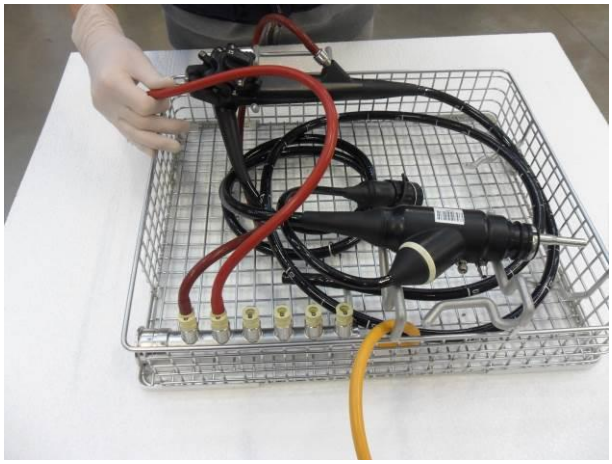


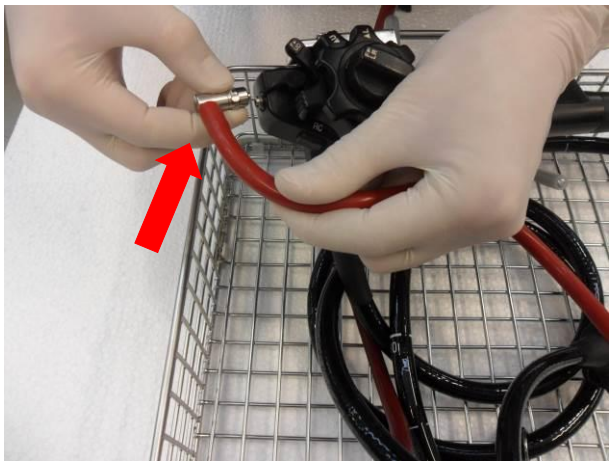




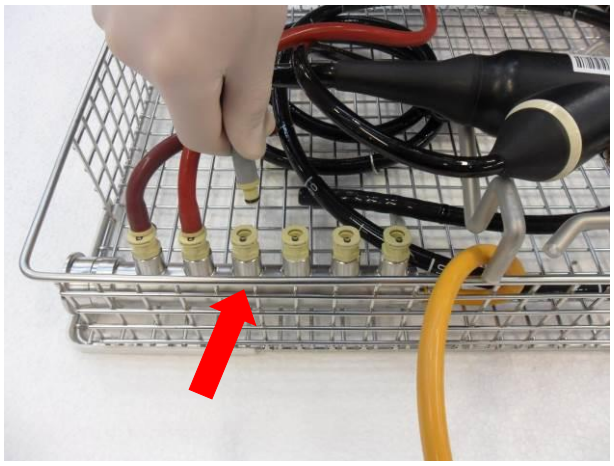
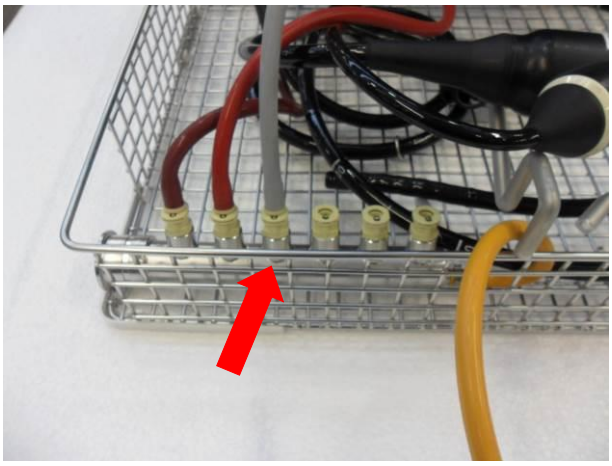
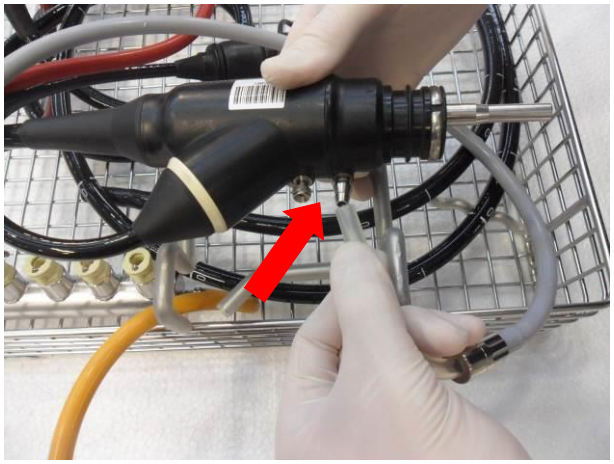
EXEMPLE OF “WATER JET” CHANNEL CONNECTION



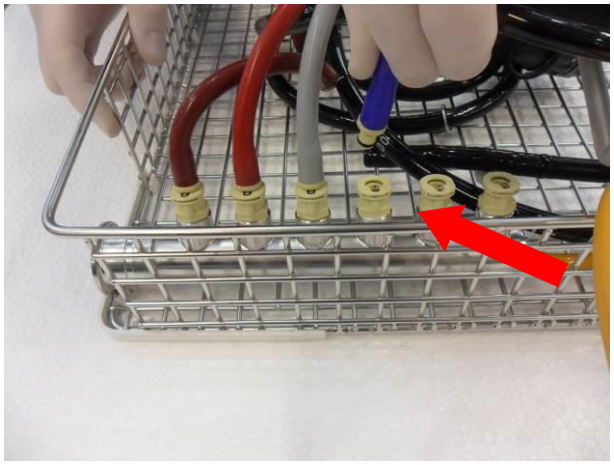




EXEMPLE OF SUCTION CHANNEL CONNECTION;

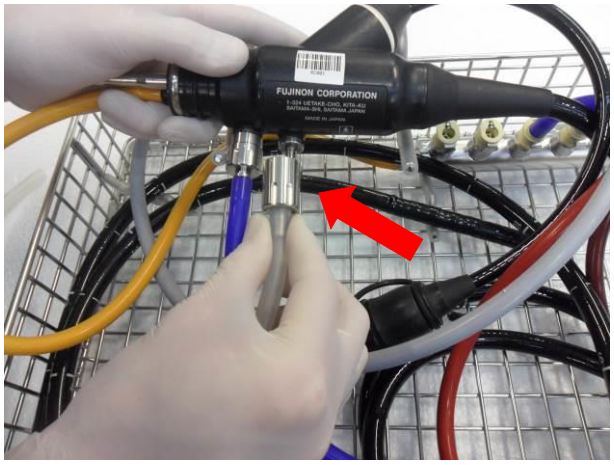





EXAMPLE OF A WATER CONNECTON POINT;

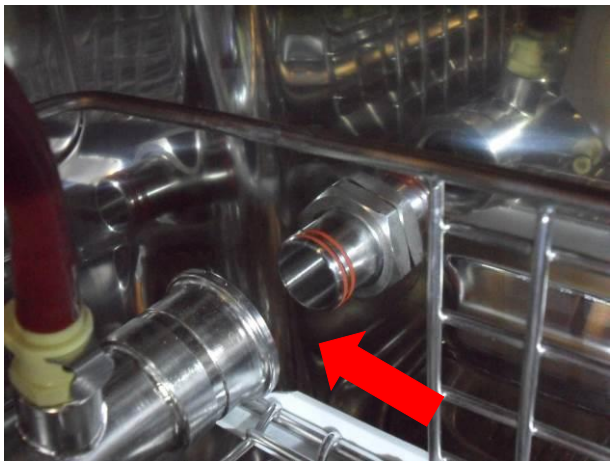



EXAMPLE OF AN AIR CONNECTION POINT

EXAMPLE OF A LEAK TEST CONECTION POINT



PUT THE BASKET INTO THE MACHINE, MAKING SURE THAT IT FITS INTO THE APPROPRIATE COUPLING;

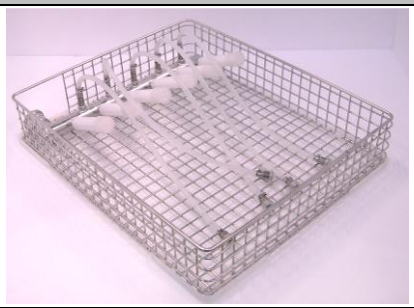


CONNECT THE CPC QUICK DISCONNECT LEAK TEST COUPLING TO THE MACHINE;

CLOSE THE DOOR AND START THE DISINFECTION CYCLE.

	ATTENTION
	• **If the endoscope has less than 7 channels, keep free the CPC connections of the basket water manifold.** • **During the wash the yellow tube must always be connected.** • **Verify that all channels are properly connected before starting the cycle and at the end, before unloading the endoscope from the basket.**

Below are shown some example of basket's type available for the machine:

AVAILABLE ONLY FOR MACHINE WITH ONE DOOR	
C566 - Flexible endoscopes	
	Maximum load for each cycle is 1 flexible endoscope.
C569 - Video bronchoscopes	
	Maximum load for each cycle is 2 video bronchoscopes or 3 fibrescopes.
C570 - Rigid endoscopes	
	Maximum load for each cycle is 10 rigid endoscopes.
C575 - Flexible endoscopes without support	
	Maximum load for each cycle is 1 flexible endoscope.

ATTENTION

- **Do never emptying any solid waste into the machine (excrement etc.). This will block the outlet system with pump and destroy the machine.**
- **The treatment cycle has to be activated only if the basket is present into the machine or if it is used a basket equipped with an injection system.**
- **Non observance, even in part, of the rule here indicated, can cause dangerous leakage of water from the door.**

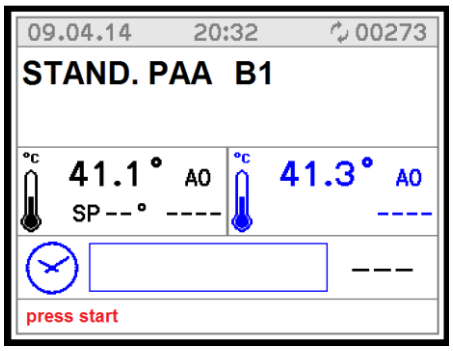
3.7 Start the washing cycle

To start the washing cycle follow the procedure:

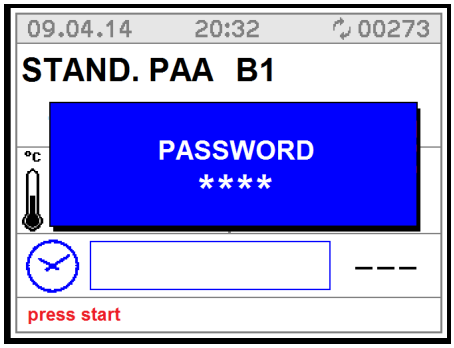
	**ATTENTION** **Before starting a cycle the operators and instruments lists must be uploaded.**

WITH KEYBOARD

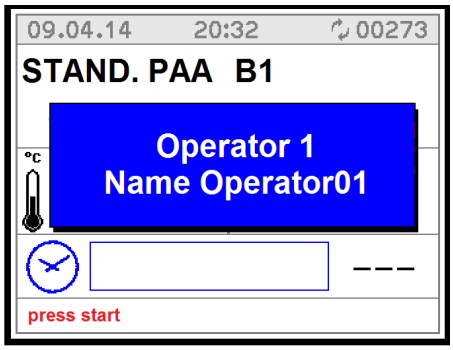
- Select the washing cycle and press **START**  button.



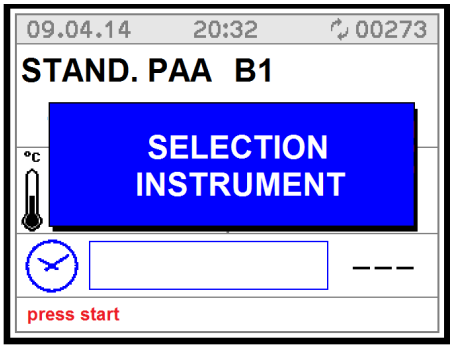
- The system requires the operator code (if it is activate). Enter the operator code (if the parameter P1.02=1).



- Confirm by pressing **START**  button.

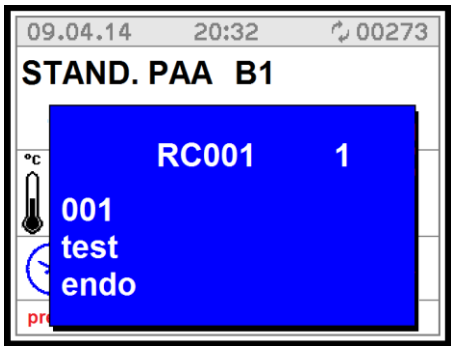


- The system requires the instrument code to be treated. Scroll the instrument list by using **P1**  and **P2**  buttons.

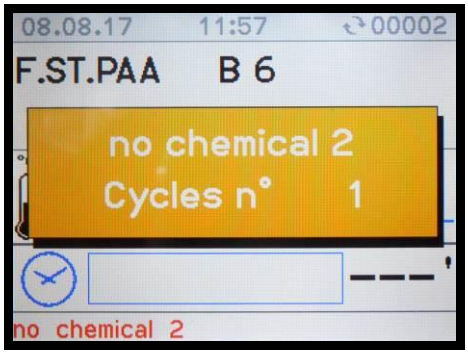


- Select the instrument or instruments by pressing PRG P+. Scrolling the instruments list, the LED PRG P+ button lights up only on the selected instruments.

  Press **START** button to start the washing cycle.

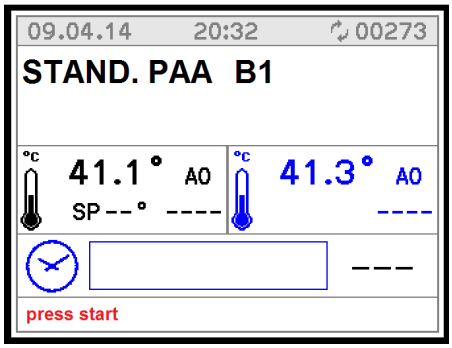


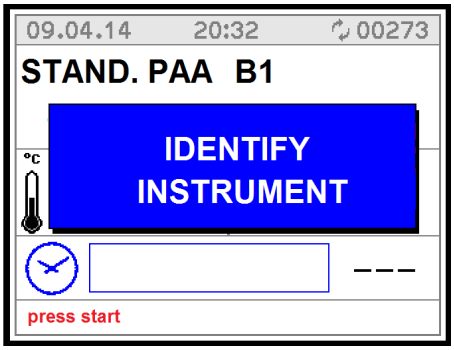
- If the chemical product is about to finish a pop-up appears as well as the number of cycles remaining.
  While the pop-up is still on the display, press the **START** button.



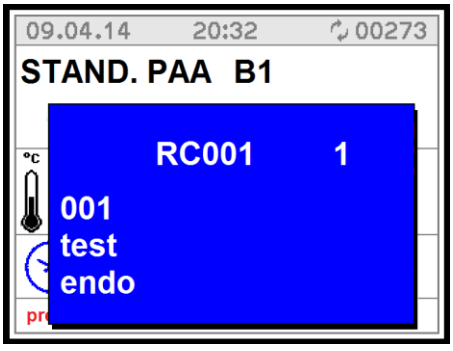
WITH BARCODE (Optional)

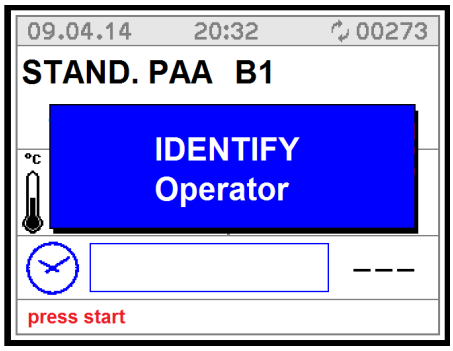
- Select the washing cycle and press **START** button.



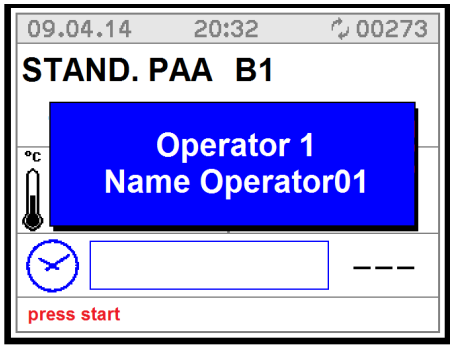


- Select the instruments by reading the instrument codes using the barcode reader. After completing this procedure, press the **START** button.

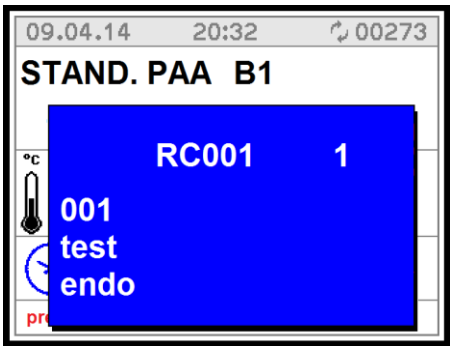




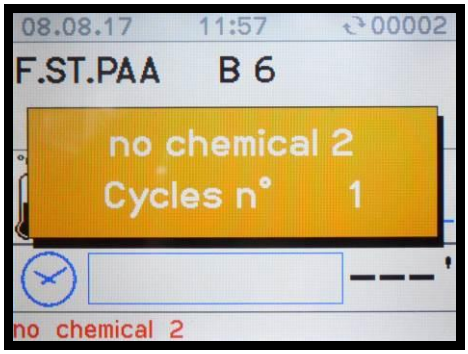
- Enter the operator code using the barcode reader and confirm this information by pressing the **START** button.



- The system shows the previously-entered data. Press the **START** button to start the washing cycle.



- If the chemical product is about to finish a pop-up appears as well as the number of cycles remaining.
  While the pop-up is still on the display, press the **START** button.



3.7.1 Endoscope requirements

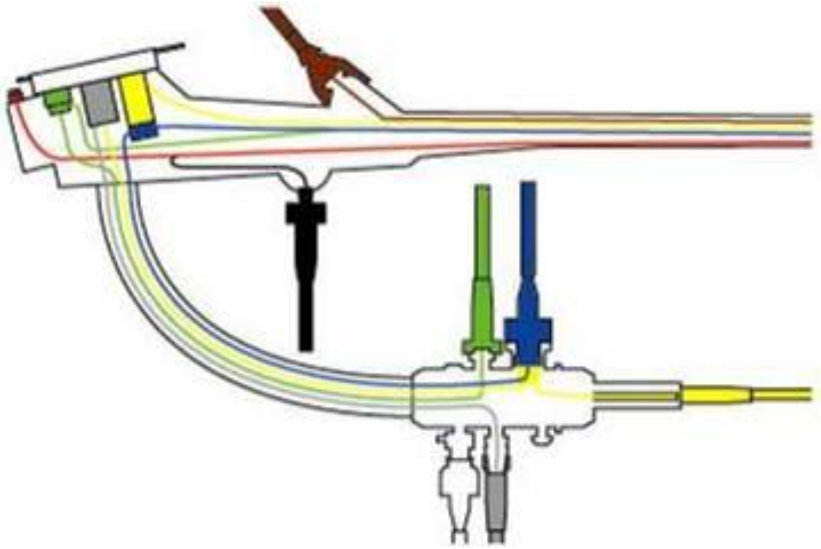
The flexible endoscopes treated in the EW 1 system must fulfil the following requirements:

- Resistance to a temperature between +10ºC and +60ºC;
- Resistance of the endoscope channels to a maximum pressure of 1.5 bar;
- Resistance to a pressure of max. 300 mbar during the leak test;
- Resistance to the detergents and disinfectants used;
- Presence of connections where to attach each of the endoscope channels;
- Waterproof with protection against the effects of immersion and, if applicable, equipped with parts that protect the endoscope from humidity.

In order to facilitate the connection of the endoscopes to the EW 1 system, all connections are identifiable in an unambiguous way by using a color coding system (see following figure).

ENDOSCOPE CHANNELS

- Brown: bioptic channel 1
- Green: bioptic channel 2
- Blue: water channel
- Yellow: air channel
- Grey: suction channel
- Red: auxiliary water channel
- Black: elevator wire channel
- Trasparent: leak test channel



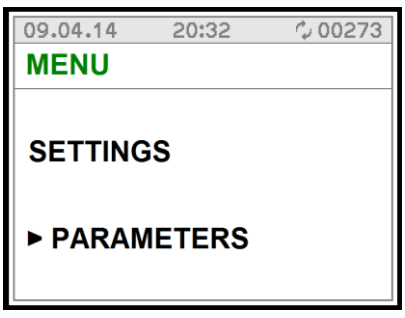
3.8 Instruction in case of 24h stop of the machine

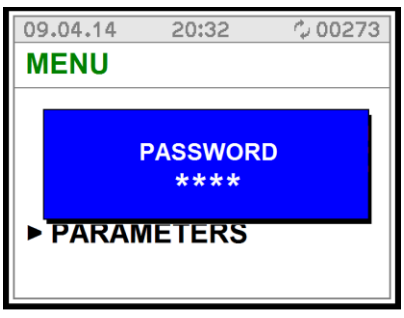
It is advisable to execute a sanitation cycle every day.

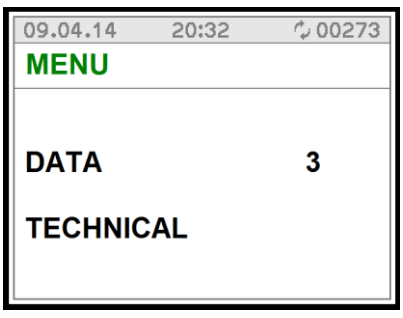
If the machine has not been used for more than 24 hours, it is advisable to carry out a sanitation cycle prior to using the machine.

Iti is possible to program on the machine an automatic sanitation cycle every day at the same time, that can be programmed by parameters P3.44 and P3.45. When this function is active (P3.43 = 1) the machine automatically start the sanitation cycle (B4) at the time set form the parameters.

WARNING: programming operations are to be performed by the maintenance technician.







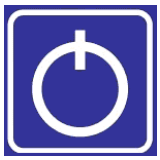
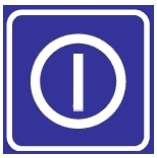
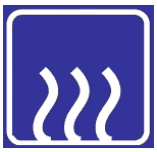
ATTENTION: it is important to follow these instruction to allow the correct execution of the self-disinfection procedure.

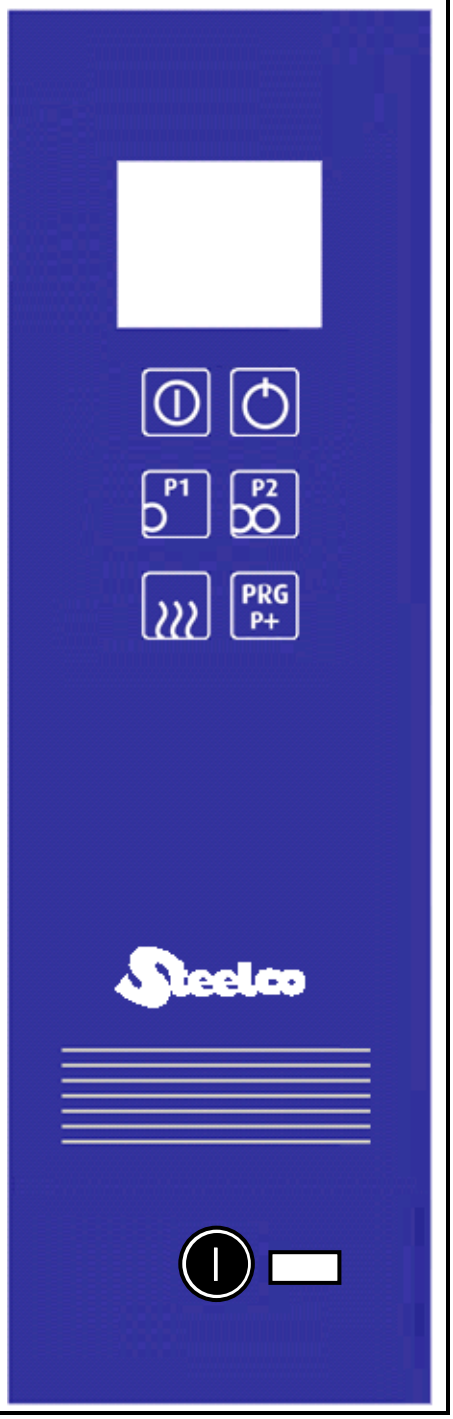
I. **The basket have to be connected to the sanitation circuit as explained on section 3.5.3.**
II. **The machine have to be left with the door shut.**

4. CONTROL PANEL AND SYMBOLS USED

4.1 Switches (loading side)

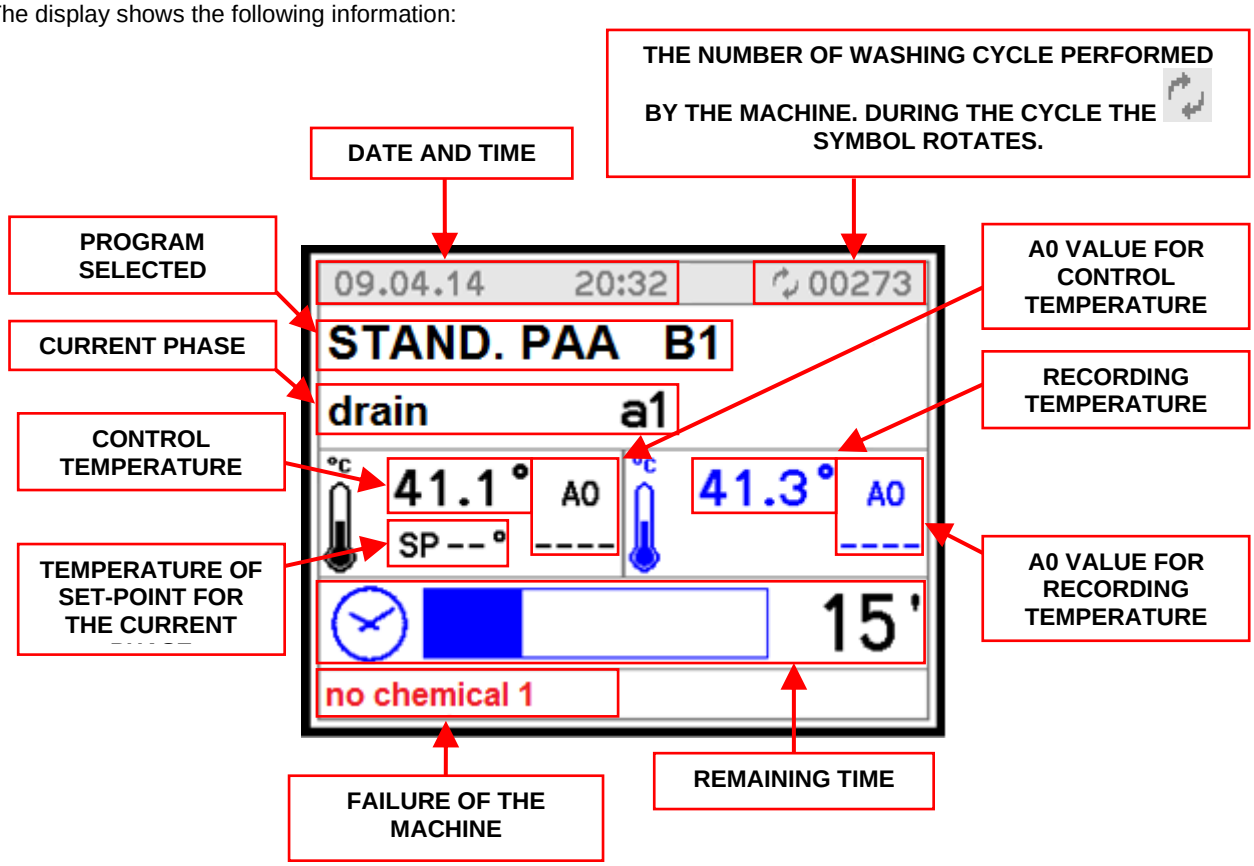
There are 6 switches with the following functions:

BUTTON	DESCRIPTION
	The switch **STOP** interrupts the cycle in progress, will be displayed a message indicating that disinfection did not take place, keeps the door locked and if necessary, indicates a high temperature inside the chamber. To return the machine to normal conditions wait the safety drain procedure and then press once more the button to unlock the door.
	After having selected the programme to be run, pressing the **START** button to start the cycle.
	Select **"STANDARD PAA"** cycle.
	Select **"SELF-DISINFECTION 80"** cycle.
	Pressing this button after having selected a programme and before starting it, it is possible to disable the forced air drying step (if selected by the parameter 3.20).
	Keep pressed for five seconds during Wait or Shutdown to display the Menu. Press once to display during the cycle information about the water and chemical quantity filled and information about the temperature and pressure measured by the transducers installed.
USB 	On the control panel board there is an USB port that allows the machine programming and data saving.



4.2 Control panel (loading side)

The display shows the following information:



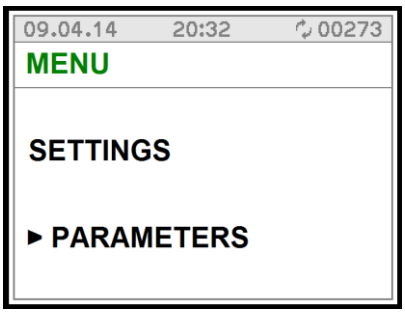
Initially, while the machine is in the stand-by status, it displays the type of program selected, the temperatures, date and time.
By pressing one of the programme switch (P1, P2, P+), the display shows the program selected at the top and at the bottom in red: "press start" or "door open" or any other warnings.
By pressing the switch “P+/PRG” it is possible to scroll all the programs available.

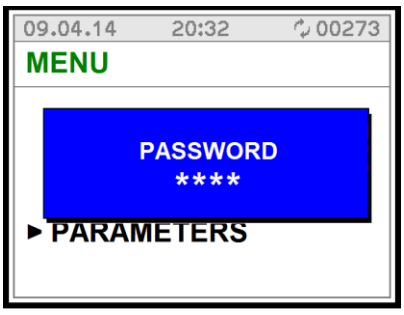
LED

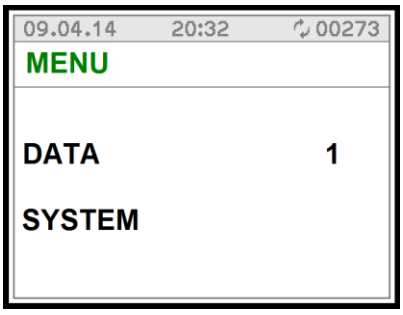
The keys of the glass display are touch-sensitive and backlit.

BUZZER

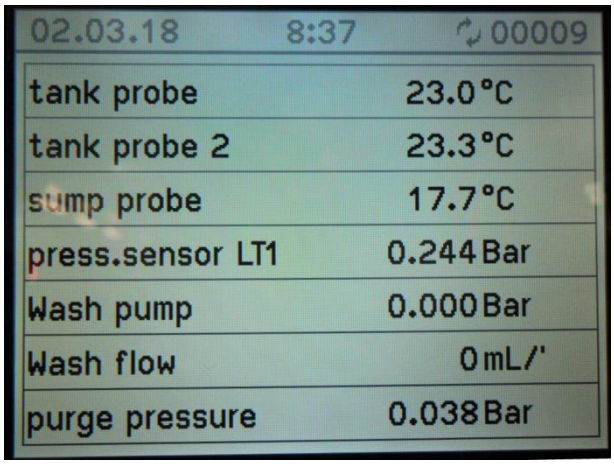
The buzzer sounds each time a key is pressed and intermittently in the case of a machine Shutdown, according to the setting of parameters **P1.7**, **P1.8**, **P1.9** through which is possible to set its volume.



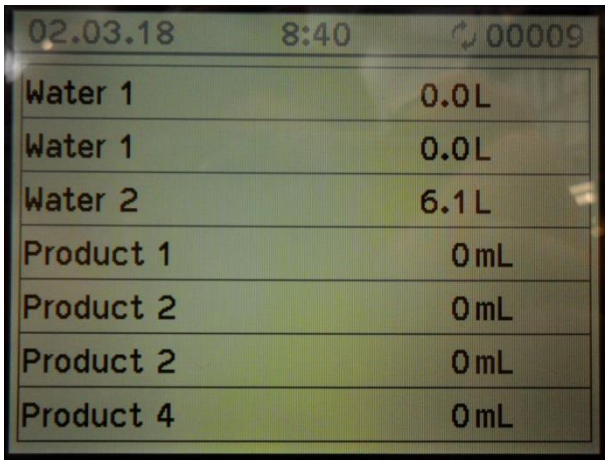


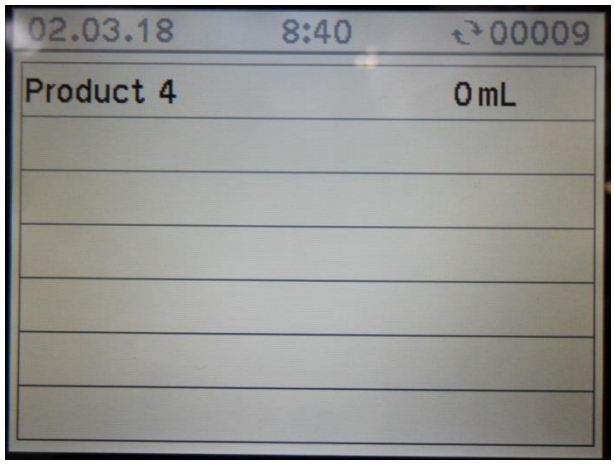


PIC. 2



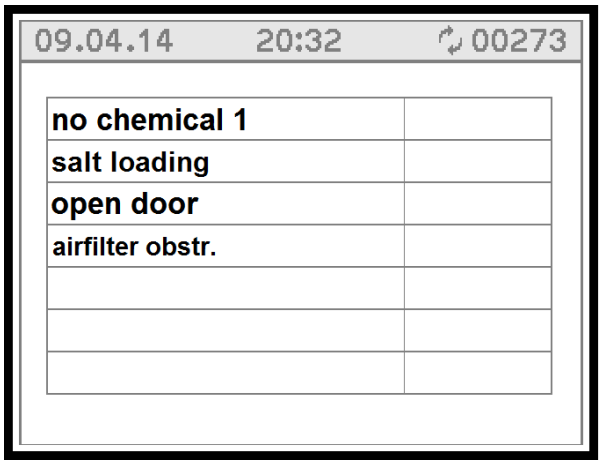
During the cycle, by pressing the switch **PRG** PRG P+ it will be displayed the various temperatures of the device and the values associated to the pressure transducers (Pic. 2).





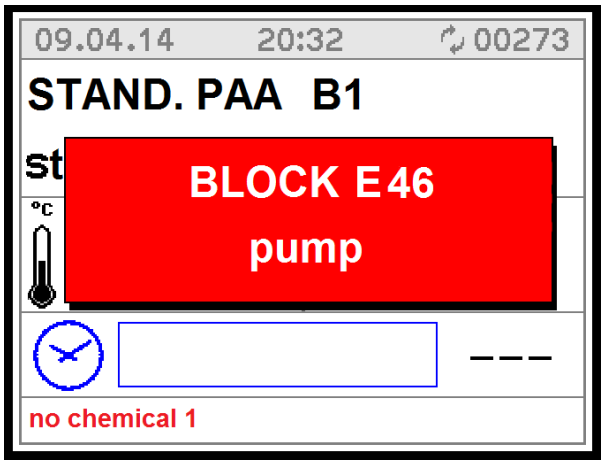
It will be displayed also the water quantity filled and the chemical product quantity for each phase, pressing twice the **PRG** PRG P+ switch.

PIC. 3

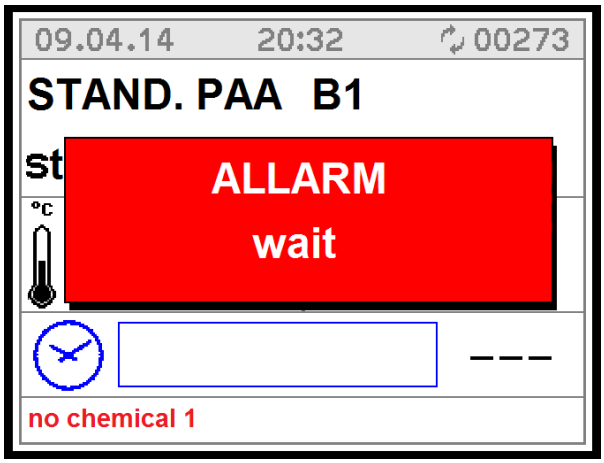


Pressing **PRG** PRG P+ a third time it display the screen with the list of alarms and warnings appears during the cycle (Pic.3).

PIC. 4

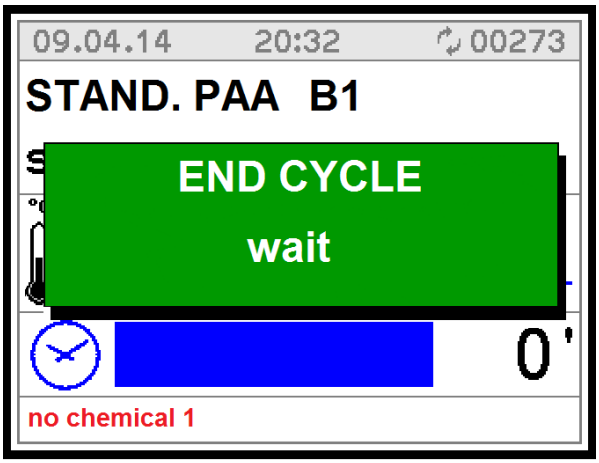
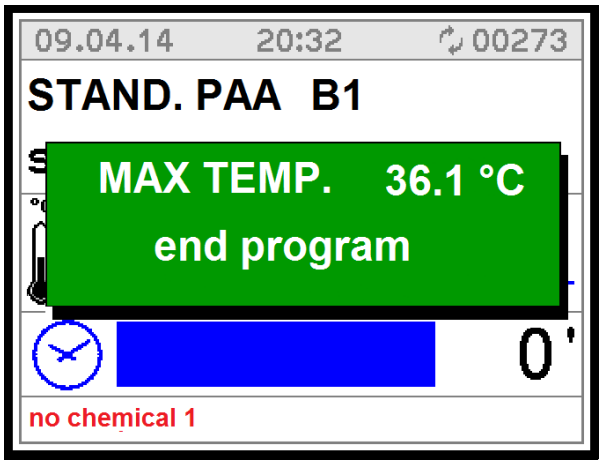


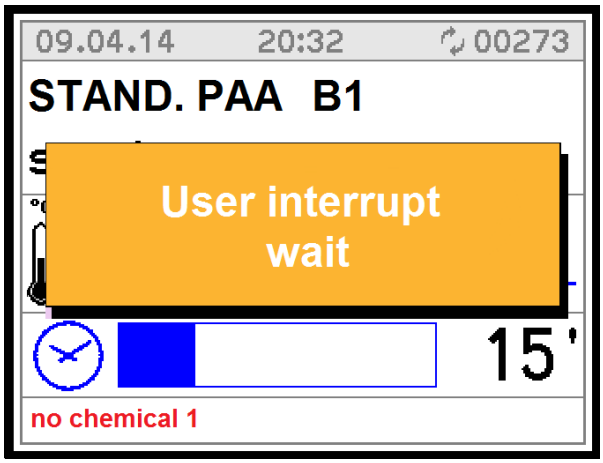
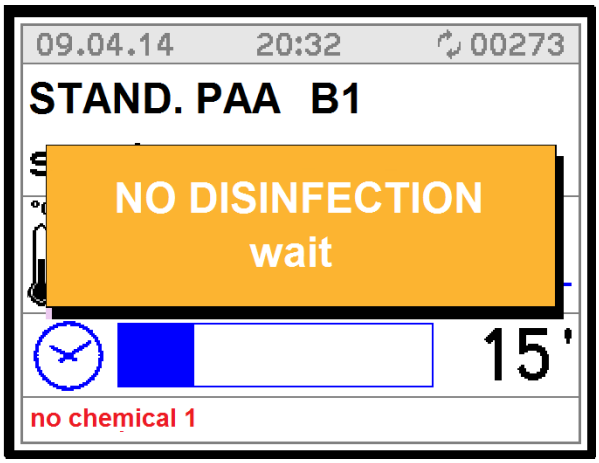
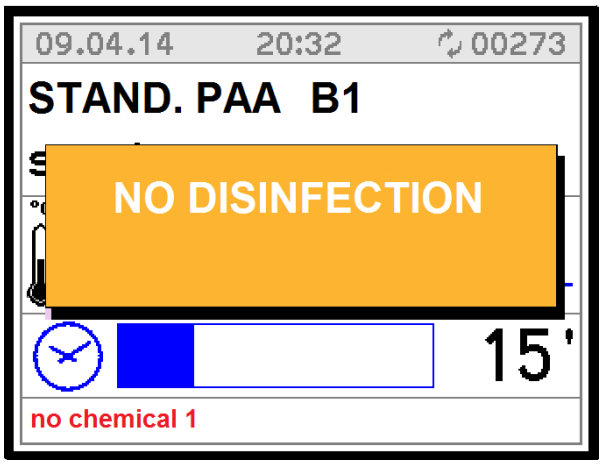
In case of alarm, a window appears which indicates the identification code and a brief description for the alarm as shown.



After the failure resolution and the reset procedure (see chap. 8.2), will be displayed the message shown on the picture and the machine will start the safety drain procedure.
After this, the machine will show the **ALARM** picture waiting for the manual door unlock: it is sufficient to press the **STOP** switch once. The picture on the side will be shown.
After the door unlocking the **ALARM** picture will be shown open the door and after few seconds the message will be re

In case of failure, which does not lead to a block, (lack of chemical) a message is shown at the bottom of the screen (Pic.1 point 11) or by pressing the **PRG** PRG P+ switch twice as shown in **Pic.3**.

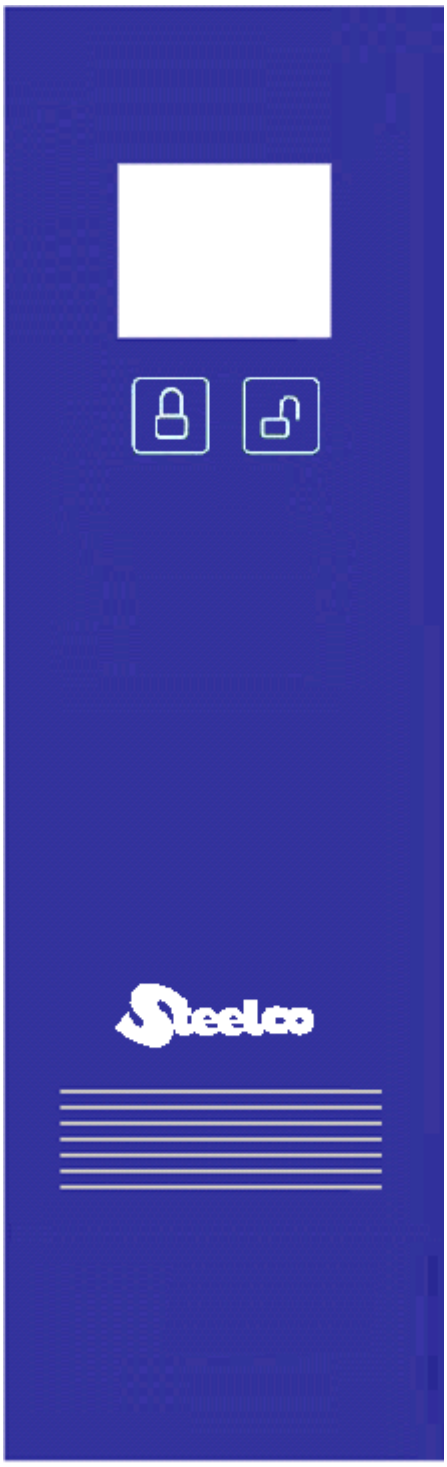
PIC. 5	
	At the end of the cycle, a special window appears as shown on the picture.
	After few seconds the final windows will be displayed. Now it is possbile to open the door.

PIC. 6	
	In case of manually stop of the cycle, the machine start the automatic safety drain and purge procedure showing a message as on the picture on the side. **NB**: if, on the phase stopped, where loaded a chemical product, the machine execute also a rinsing before the door unlocking.
	After the safety procedure will be displayed a message that warns about the disinfection lack.
	Pressing the **STOP**  switch it is possible to unlock the door. The message is still displayed and will be removed after the door opening.

4.3 Switches (unloading side – if present)

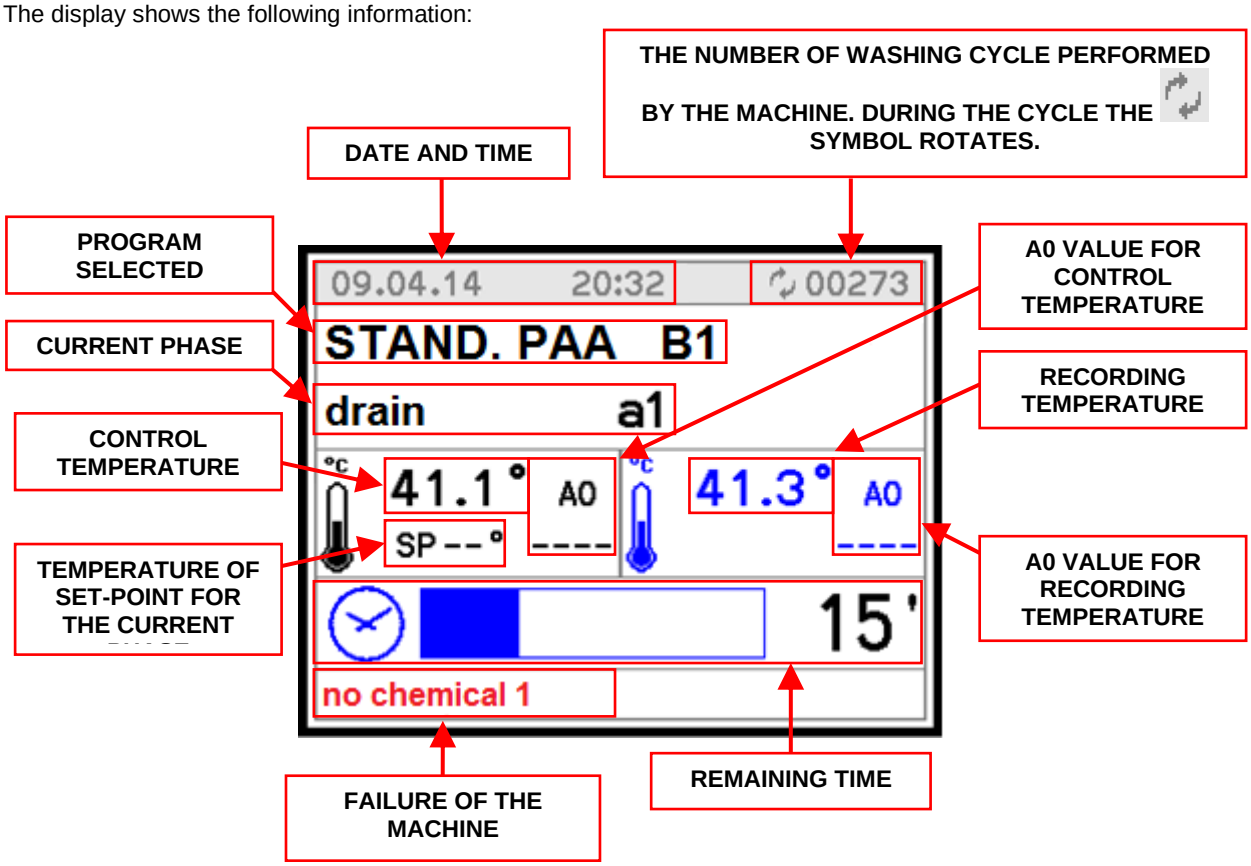
In case of machine with pass-through door, if the ID operator parameter is disabled (P1.23=0 or 1), at the end of the OK cycle, the unloading door opens automatically.

If this parameter is enabled, P1.23=2 (Ares) or=3 (Steelcodata not Ares with ID unloading machine operator), the ID unloading machine operator procedure at the end of the cycle is:
-at the end of the OK cycle "ended program" popup alternates with "Press start operator" popup;
-the operator must press one of the doors unloading or loading buttons, in order to enter the operator menu (he has to read alternatively "KEY START" or "KEY STOP" bar codes;
-it displays the "ID OPERATOR": the operator must read the operator bar code.
If it is uncorrect, it displays the timed failure message and it comes out the menu.
If it is correct, it displays the operator name and his list number: at that point he must confirm either with the door unloading button or either alternatively with "KEY START" bar code.
The door unlocks and the operator is registered into the supervisor.
-From the unloading machine operator menu, you can exit (return to the OK end cycle screen), by pressing the door locking button or with the "KEY STOP" bar code;
Anyway, you exit automatically by 60 sec. timeout.



4.4 Control panel (unloading side – if present)

The display shows the following information:

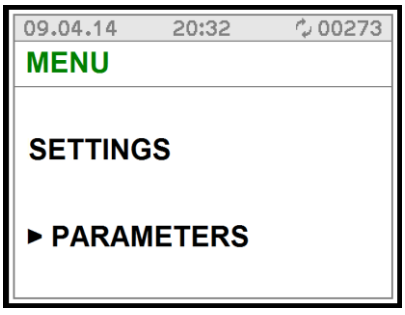


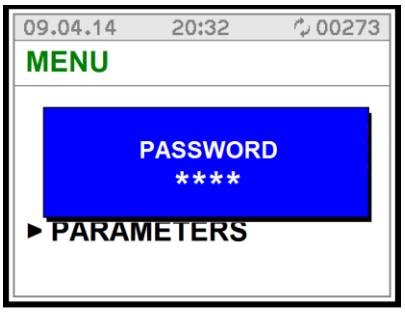
LED

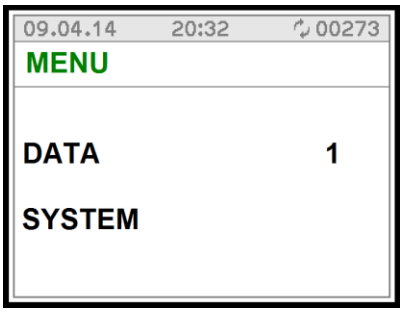
The keys of the glass display are touch-sensitive and backlit.

BUZZER

The buzzer sounds each time a key is pressed and intermittently in the case of a machine Shutdown, according to the setting of parameters **P1.10**, **P1.11**, **P1.12** through which is possible to set its volume.





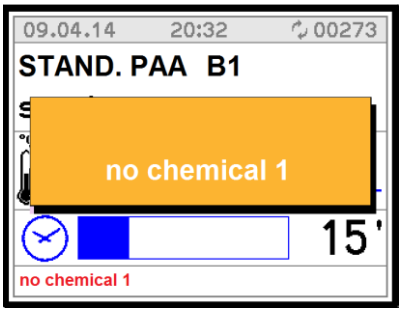


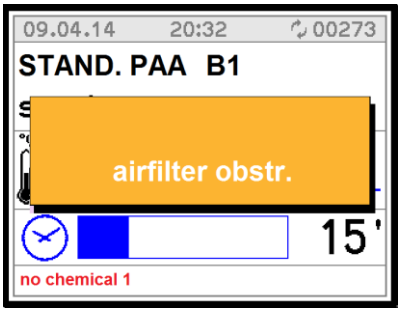
5. MACHINE CONDITIONS

The machine has three possible statuses.

5.1 Stand-by

The machine is ready to work.
The diagnostic is active.
There will be the possible indication of the door open or warnings: lack of chemical product, full memory (historical) or filter obstructed.

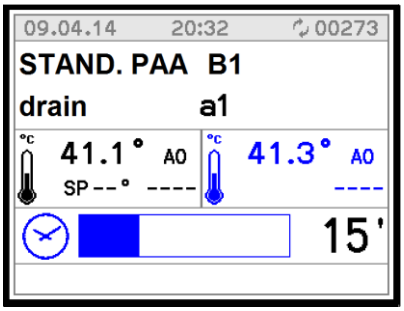




5.2 On cycle

You can reach this point in the procedure by selecting the desired cycle and by pressing the **START** key to start the machine up.
The cycle is running according to its phases.
The diagnostic and the regulators are active.

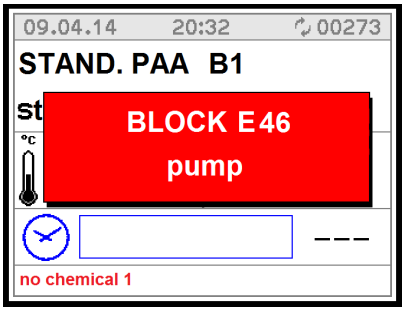
The user interface gives all indications about the different phases and about the chamber temperature.



5.3 Alarm

The diagnostic found an anomaly which cause a block, the cycle is interrupted keeping the door blocked.

The anomaly is shown on the display; after the failure solution is necessary to unlock the machine using the reset procedure (see chapter 6.2).



After that the machine start the safety drain procedure, the door is unlocked, and it is possible to start a new operation.

6. SPECIAL FEATURES

6.1 Power failure

In case of a power failure the machine will remember the state it had before the cut off.

6.1.1 Power failure during “WAIT” status

When tension is restored after a power failure during WAIT status the machine returns to the WAIT status waiting a command.

6.1.2 Power failure during a cycle or during an alarm

If the power failure occurs during a CYCLE or during an ALARM, after the restoration the machine will show an alarm (power fail): to return on the WAIT status is necessary to execute the reset procedure. The machine automatically starts the safety drain procedure and goes on the waiting state.

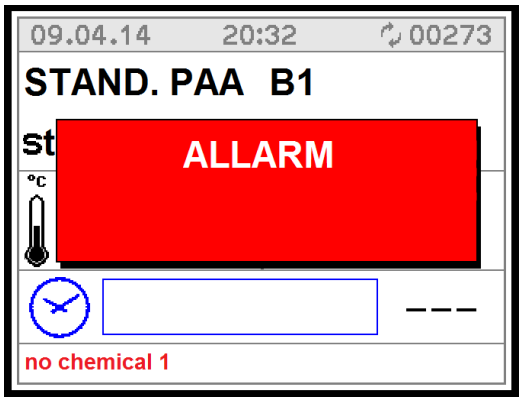
	ATTENTION
	After performing the procedure described previously, remember that: • **The items inside the machine could be very hot and contaminated.** • **The entire treatment cycle must be repeat.** • **Material contaminated with peri acetic acid could be present inside the machine.**

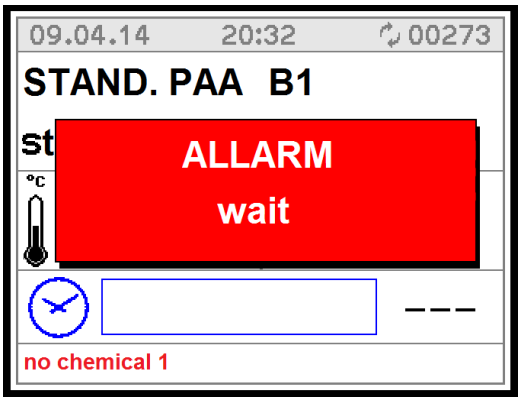
6.2 Reset procedure

In the event of a **POWER FAILURE** or an **ALARM**, the door remains locked.

To open the door, the reset procedure must be carried out from the keyboard as follows:

1. Press the  and  switch together and keep pressed for 5".
2. LCD display indicating “**switch procedure**”.
3. Press the  switch followed by the  switch.
4. The following screen will be shown: pressing  switch will be displayed the second screen: the machine is unlocking the door.





5. When the control panel shows the first picture again keep the door opened for 5 seconds and wait until the alarm is reset.
6. The machine returns to STAND-BY mode.

***NB**: if the alarm occurs during stand-by status, the procedures descripted on point 4 and 5 are not necessary. After the reset, the machine will automatically return on stand-by status.*

	ATTENTION
	**If the machine shutdown persists due to a fault in one of its components (e.g.: faulty probe, unsuitable levels, etc.), the door remain locked and the machine remains inactive.** **Seek technical assistance.** **Should it be necessary to remove the endoscope, switch the machine off and follow the procedure described in chapter 8.1.2.**

7. WORK PROCEDURES

7.1 Introduction

This machine has been designed only and exclusively for the reprocessing of flexible and rigid endoscopes and the thermal-disinfection of washing chambers. Therefore it is subject to continuous contact with aggressive detergents and contaminated instruments.
For this reason it is necessary to provide some useful instructions for the operators who will be using it.

7.2 Instructions to personnel

The machine operator, in normal operating conditions, is not subject to risks if he works safely using suitable means of protection.
In order to work safely the operator must:

- Carefully comply with the instructions set forth in this manual.
- Use safety devices appropriately and with care, as well as group and individual safety gear provided in the workplace.
- Personally take action, or inform appropriate persons in the event of deficiencies in the aforementioned devices and means, as well as any hazardous conditions which he may become aware of, taking action directly in urgent cases within their scope of responsibilities and abilities to eliminate or reduce the deficiencies or hazards.

The maintenance technicians, in normal operating conditions, are not subject to risks if they works safely using suitable means of protection.
In order to work safely the maintenance technician must:

- Carefully comply with the instructions set forth in this manual.
- Use safety devices appropriately and with care, as well as group and individual safety gear provided in the workplace.
- Use special care in making repairs or replacing mechanical parts (e.g. drain pump, etc.) on malfunctioning machines which have not completed the disinfection cycle.

7.3 Sterilization - Warnings (cycle validated in accordance with UNI EN ISO 14937 standards)

1. The cycle is valid only with the combination of the following chemicals:

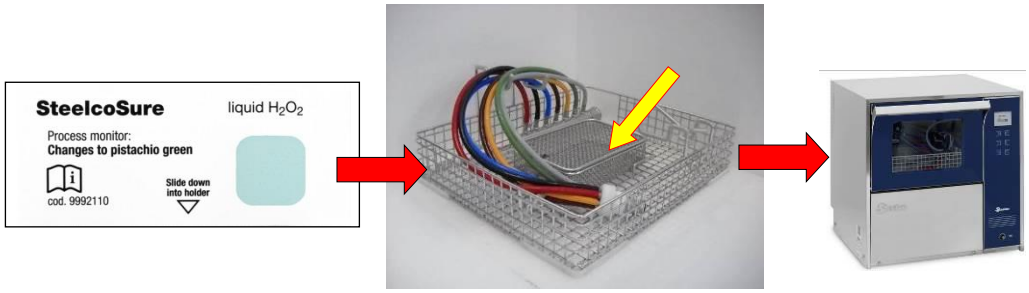
- SteelcoXide-DT
- SteelcoXide-A and SteelcoXide-B

2. At the end of the cycle the instrument is sterilized but not sterile, as it has no steril barrier system (SBS).

3.The material taken out of the sterilizing chamber must be used immediately and handled using sterile gloves and appropriate PPE.

4.LOAD VALIDATION

Chemical product presence indicators are available. The indicator has to be insered into the appropriate rack in order to check the right chemical dosing.
Once the cycle has finished, check the colour of the indicator (cod. 9992110):



(sea green) (pistachio green) (sea green)

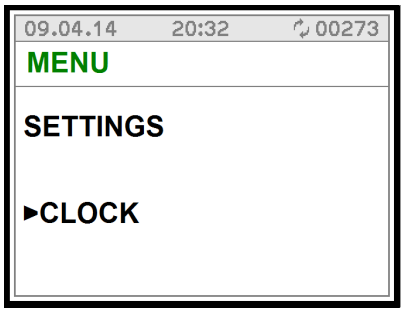
UNPROCESSED **PROCESSED - OK** **PRECOSSED - FAILED**

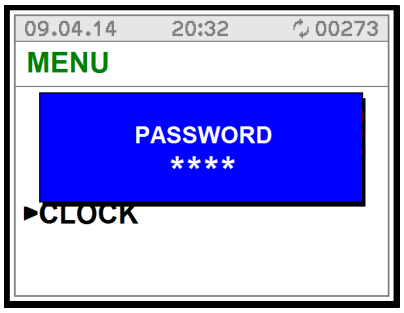
	WARNING
	IT IS NECESSARY TO REPEAT THE CYCLE IN THE EVENT THAT THE TEST RESULTS AS BEING PROCESSED YET IN REALITY IT HAS FAILED.

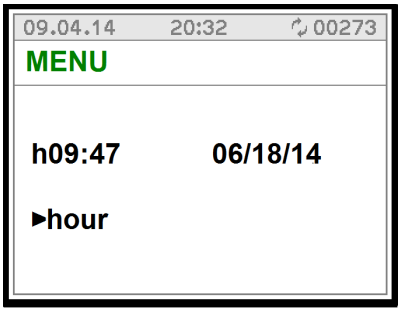
8. CLOCK

The main board is equipped with a real time watch. This clock can be set for the following menu:

SETTING → CLOCK → set date and hour.





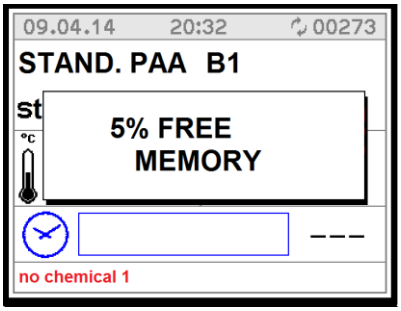


The time shown is also to qualify the events historical.

9. HISTORICAL DATA and PRINTOUT

During the working cycle, the machine memorizes on a RAM all the working data of the wash cycles that have been performed.
If a printer is installed the machine print step by step all the information shown on the example below.

The card is able to record the fields described below for up to a maximum of about 600 cycles in the permanent memory.
When 90% of the memory is full, a signalling pop-up with the message "5% FREE MEMORY" appears on the display.
Printing out the whole historical data, the message will be deleted.
The fields given in the example below are recorded for each cycle:




```
****************************************
            ****************
User              :  ****************
Model             :  EW 1
Machine           :  12001
Station           :      0
Software          :   7.00
Operator          :     13


INSTRUMENT 1      :   RC001
                      GD900123
                      GASTROSCOPE
                      STORZ
----------------------------------------
B 6 F. ST. PAA           Record:   00002
........................................
START:             07/06/14     h: 10:14

->  1: drain                    h: 10:14
     T1=  35.9°C  T2=  36.1°C

->  leak test                   h: 10:14

->  2: prewash                  h: 10:15
     T1=  35.4°C  T2=  35.3°C
                   programm.   executed
Water 2                 6 L        6 L
```

←Customer/distributor (value set by parameter P2.06)
←User name (value set by parameter P1.01)
←Machine model (value set by parameter P2.01)
←Machine serial number (value set by parameter P2.02)
←Station number (value set by parameter P2.05)
←SW version on main board
←Operator nr (or signature space in case of parameter P1.02=no)

←Endoscope information

←Cycle name and cycle number on historical

←Date and hour of cycle start ***(standard cycle 17 min)***

←Phase number, name and ending time
←Temperature chamber probe 1 e 2

```
->  3: drain                    h: 10:16
     T1=  35.4°C  T2=  35.4°C
     channel drying

->  4: treatment                h: 10:21
     T1=  37.2°C  T2=  37.1°C
                   programm.   executed
Water 2                6 L        6 L
Product 1= OK         30 mL      32 mL
     T>=  35°C   t=  300 s  t=  300 s
     (T1=  35.8°C) (T2=  35.8°C)

->  5: drain                    h: 10:22
     T1=  37.2°C  T2=  37.1°C
     channel drying

->  6: rinsing 1                h: 10:23
     T1=  36.4°C  T2=  36.4°C
                   programm.   executed
Water 2                6 L        6 L
     T>=   0°C   t=   20 s  t=   20 s
     (T1=  36.4°C) (T2=  36.4°C)

->  7: drain                    h: 10:24
     T1=  36.4°C  T2=  36.4°C
     channel drying

->  8: disinfect.               h: 10:29
     T1=  37.3°C  T2=  37.3°C
                   programm.   executed
Water 1                6 L        6 L
Product 2= OK         60 mL      61 mL
     T>=  35°C   t=  300 s  t=  300 s
     (T1=  35.9°C) (T2=  35.8°C)

->  9: drain                    h: 10:29
     T1=  37.3°C  T2=  37.3°C
     channel drying

-> 10: rinsing 4                h: 10:30
     T1=  36.4°C  T2=  36.4°C
                   programm.   executed
Water 1                6 L        6 L
     T>=   0°C   t=   20 s  t=   20 s
     (T1=  36.5°C) (T2=  36.4°C)

-> 11: drain                    h: 10:31
     T1=  36.4°C  T2=  36.4°C
     channel drying

end program:      07/06/14      h: 10:31

      <><><><><><><><><><><><><><><>
             END CYCLE OK
      <><><><><><><><><><><><><><><>

Doctor _____

Patient  _____

><- - - - - - - - - - - - - - - - ->
```

←Water consumption
←Chemical consumption
←Date and hour of the cycle end ***(standard cycle 17 min)***
←Alarm/warning description (if present)
←Doctor signature
←Patient signature

Repetition tickets header and cycle's result (this part of printout is controlled by parameter 1.19.)

```
**************************************
            ****************
User            :  ****************
Model           :  EW 1
Machine         :  12001
```

←Customer/distributor (value set by parameter P2.06)
←User name (value set by parameter P1.01)
←Machine model (value set by parameter P2.01)
←Machine serial number (value set by parameter P2.02)

```
Station          :      0
Software         :   7.00
Operator         :     13


INSTRUMENT 1     :   RC001
                     GD900123
                     GASTROSCOPE
                     STORZ
---------------------------------------
B 6 F. ST. PAA          Record:   00002
.......................................
START:            07/06/14     h: 10:14
end program:      07/06/14     h: 10:31
      <><><><><><><><><><><><><><><>
             END CYCLE OK
      <><><><><><><><><><><><><><><>

Doctor _____________________________

Patient  _____________________________

><- - - - - - - - - - - - - - - - - ->< 
```

←Station number (value set by parameter P2.05)
←SW version on main board
←Operator nr (or signature space in case of parameter P1.02=no)

←Endoscope information

←Cycle name and cycle number on historical

←Date and hour of cycle start ***(standard cycle 17 min)***
←Date and hour of the cycle end ***(standard cycle 17 min)***

←Alarm/warning description (if present)

←Doctor signature

←Patient signature

10. USB PORT

On the control panel board there is an USB port that allows the machine programming and data saving.
The card is able to record the fields described below for up to a maximum of about 600 cycles in the permanent memory.

10.1 Data saving

Insert the USB key on the dedicated port and enter the menu and select the USB menu.

It is possible to download from the machine the following information and files:

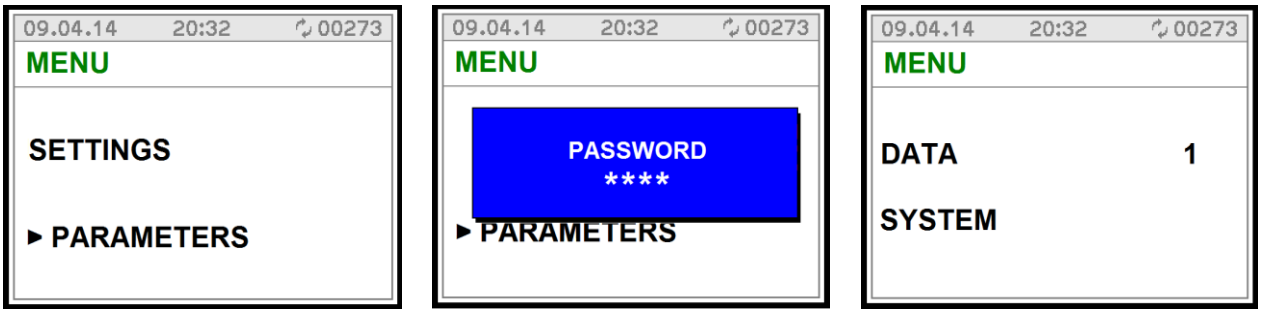
- Cycles
- Parameters
- Historical
- Maintenance historical

The cycle and parameter files can be used to program another machine or as back-up of the machine.

10.2 Data saving during the cycle

By means of the activation of the cycle save parameters required by the user and carried out by the (STEELCO) authorised installer/technician, it will be possible to save data at the end of each washing cycle by leaving the USB memory stick and by carrying out the following procedure:

- Set the parameters P1.04 at 3 and P1.05 to 1.



- Start the washing program;
- At the end of the cycle the machine creates the file with the samples of temperature and pressure probes with the information of every washing program phases.

To every washing program are associated two files which contain the data structured as below.

Errore. Non si possono creare oggetti dalla modifica di codici di

The file *****G.TXT contains:

N.B.: the *****G.TXT will be saved in automatically at the end of the washing program.

```
****************************************
                ****************
End user          :   ****************
Model             :   EW1
Machine           :   01234
Work station      :       0
Software          :    7.01
Operator          :

INSTRUMENT 1      :   TL001
                      Serial Number
                      Model
                      Brand

B 3 SoloDISINF    Record:    00028
.........................................
START:              19/07/13      h: 08:36

n°        mm:ss     °C(1)      °C(2)       Bar

0001       0:00      32.0       32.5       ----
0002       0:05      31.9       32.3       ----
0003       0:10      31.8       32.2       ----
0004       0:15      31.8       32.2       ----
0005       0:20      31.8       32.2       ----
0006       0:25      31.8       32.2       ----
```

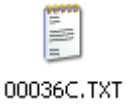
Information related to machine and operator.

Information related to washing program.

Data value to sampled data.

Number of samples.

Sampling time.



The file *****C.TXT contains:

N.B.: To save the *****C.TXT, insert the key in the dedicated port, enter the menu, select the USB menu and download from the machine the information of historical.

```
****************************************
                ****************
End user          :  ****************
Model             :  EW1
Machine           :  01234
Work station      :      0
Software          :   7.01
Operator          :

INSTRUMENT 1      :  TL001
                     Serial Number
                     Model
                     Brand
----------------------------------------
B1 STAND. PAA              Record:   00001
........................................
START:               01/01/12     h: 10:35

->  1: vidange                    h: 10:35
     T1=  18.2°C  T2=  18.3°C

->  2: prelavage                h: 10:38
     T1=  20.1°C  T2=  20.0°C
                    programm.   termine'
Eau 2                 6.0 L       6.1 L

->  3: vidange                    h: 10:39
     T1=  20.0°C  T2=  19.9°C

->  4: traitement                h: 10:46
     T1=  37.1°C  T2=  37.3°C
                    programm.   termine'
Eau 1                 6.0 L       6.1 L
Prodotto 2           60.1 mL     60.0 mL

->  5: vidange                    h: 10:47
     T1=  29.9°C  T2=  30.0°C

STOP:                01/01/12     h: 10:48
FIN DU CYCLE          FAIL 91
                User interrupt
```

Information related to machine and operator.

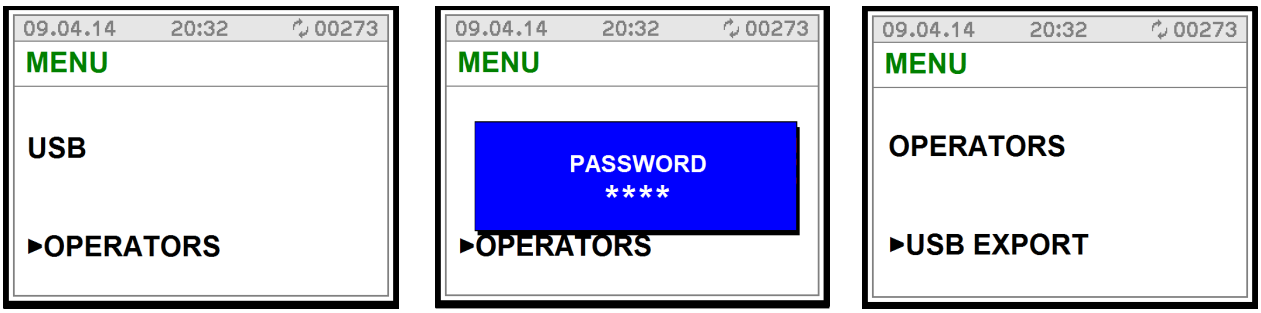
Information related to washing program.

Information related to every washing program phase.

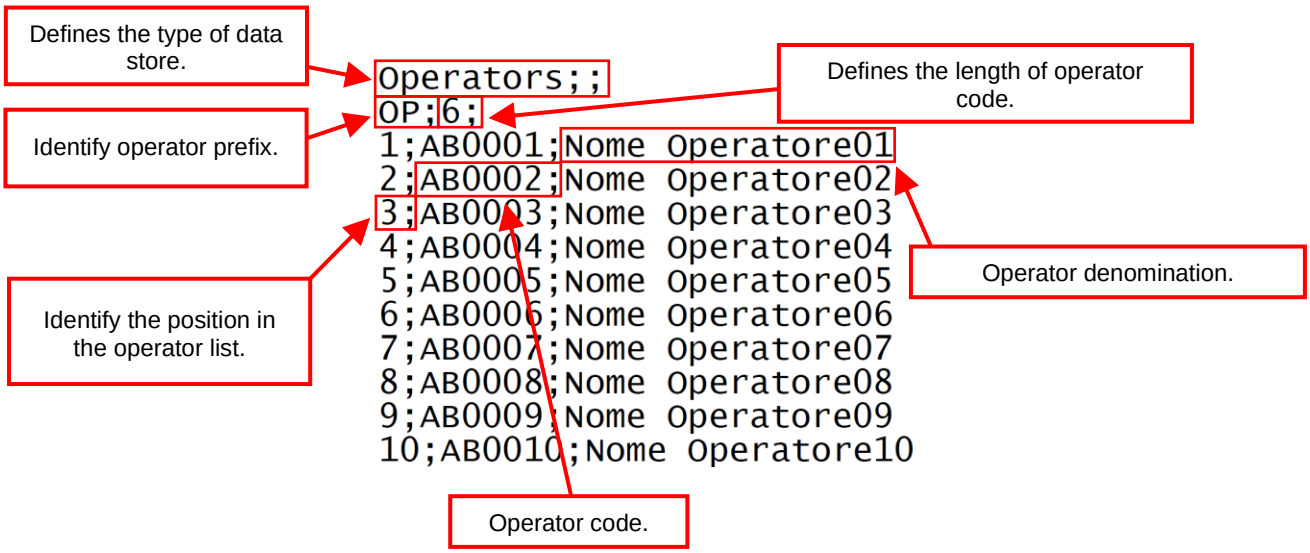
10.3 Operator archive management

By means of the activation of the cycle save parameters required by the user and carried out by the (STEELCO) authorised installer/technician, it will be possible to save the file archives of the operators present in the machine memory in a file by carrying out the following procedure:

- Insert the USB key into dedicated port.
- Enter menu: **USB → OPERATOR → Insert 3rd level password → USB EXPORT → Press START button.**

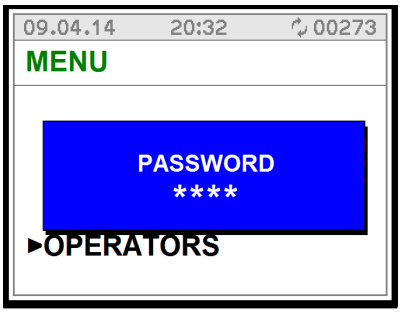


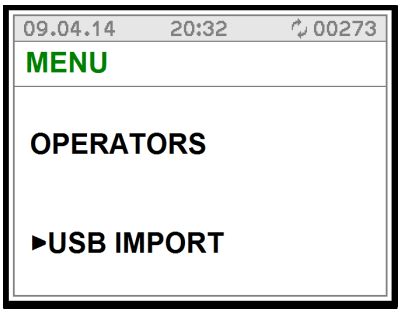
The name of file is "**OPERATxxxxx.CSV**", where "**xxxxx**" stands for an optional generic denomination and it contains the data structured as below:



FIELD	FIXED CHARACTERISTICS
Type of data store	Nothing
Operator prefix	Length = 2 Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-"minus sign, "." full stop. **ATTENTION:** set '**OP**' if it is used the barcode reader while set '**00**' if it is used the keyboard (operator identification).
Lenght of operator code	From 1 to 8
Position in the operator list	Progressive order (Maximum number of operators = 60)
Operator code	Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-"minus sign, "." full stop.
Operator denomination	Length ≤ 16 (can be empty) Allowable characters: 0…9 number digits, "A…Z" uppercase alphabet, "a..z" lowercase alphabet, " " space, "-"minus sign, "." full stop.

It is possible to upload the archive operators by insert the USB key into dedicated port and enter the menu: **USB → OPERATOR → Insert 3rd level password → USB IMPORT → Press START button.**





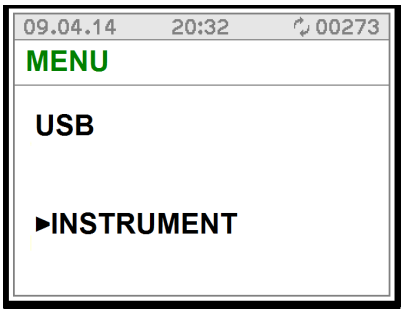
ATTENTION

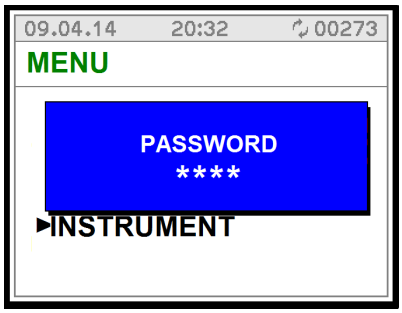
- To modify the operator archive file, it is recommended use a text editor (ex. Notepad).
- If the file contains an operator with the field "**OPERATOR CODE**" null (no character), the file is considered valid up to the previous operator. All subsequent elements are ignored.
- If the file contains values that do not comply with the constraints described above, the file is considered incorrect. During the upload it is displayed the first line where the error is present.

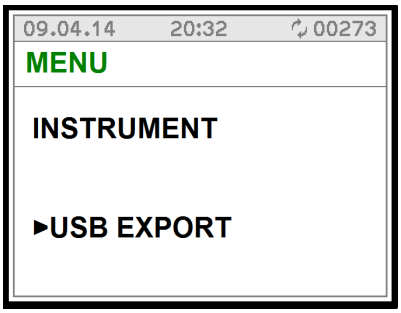
10.4 Instrument archive management

By means of the activation of the cycle save parameters required by the user and carried out by the (STEELCO) authorised installer/technician, it will be possible to save the file archives of the instruments present in the machine memory in a file by carrying out the following procedure:

- Insert the USB key into dedicated port;
- Enter menu: **USB → INSTRUMENT → Insert 3rd level password → USB EXPORT → Press START button.**







The name of file is "**INSTRUxxxxx.CSV**", where "**xxxxx**" stands for an optional generic denomination and it contains the data structured as below:

Instrument					CHANNELS				AUX. CHANNELS				
RC													
1	1	G120432	colonEC-380LKp	pentax	100	30000	10	2500	50	130	900	1100	1
2	2	G124804	gastroEG-290Kp	pentax	100	30000	10	2500	50	130	900	1100	1
3	3	G120387	colonEC-380LKp	pentax	100	30000	10	2500	50	130	900	1100	0
4	4	H122654	colonEC-380LKp	pentax	100	30000	10	2500	50	130	900	1100	0
5	5	generico	colon-gastro	pentax	100	30000	10	2500	50	130	900	1100	1
6	6	generico	colon-gastro	pentax	100	30000	10	2500	0	0	0	0	1
1	2	3	4	5	6	7	8	9	10	11	12	13	14

ATTENTION*

TABLE DESCRIPTION

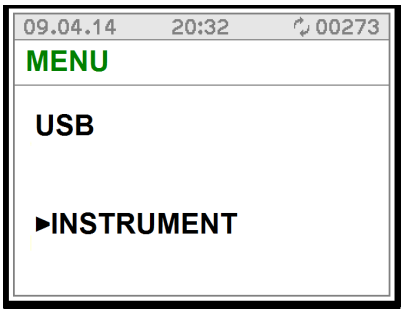
1. Identify the position in the instrument list
2. Instrument code
3. Serial number
4. Instrument denomination
5. Instrument manufacturer
6. Parameter value of endoscope lower washing water flow limit (ml/')
7. Parameter value of endoscope upper washing water flow limit (ml/')
8. Parameter value of endoscope lower limit for washing pressure (mb)
9. Parameter value of endoscope upper limit for washing pressure (mb)
10. Parameter value of aux. channel lower washing water flow limit (ml/')
11. Parameter value of aux. channel upper washing water flow limit (ml/')
12. Parameter value of aux. channel lower limit for washing pressure (mb)
13. Parameter value of aux. channel upper limit for washing pressure (mb)
14. Channels pump

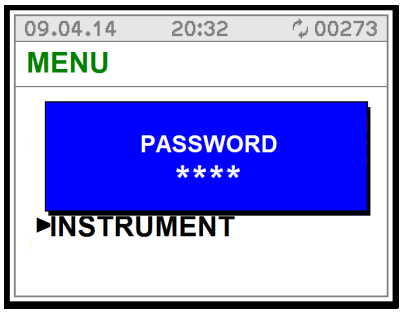
***ATTENTION:**
IF THE INSTRUMENT HAS NO AUX. CHANNEL, SET THE VALUES **10, 11, 12, 13** TO **0.**

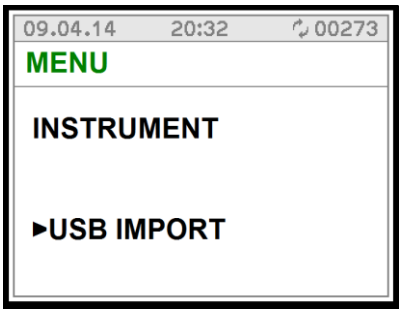
** Channels pump activation;
If it is set to 0=not activated channels pump (When there are small instruments);
If it is set to 1= activated channels pump.

FIELD	FIXED CHARACTERISTICS
Type of data store	Nothing
Instrument prefix	Length = 2 Allowable characters: 0…9 number digits, “A…Z” uppercase alphabet, “a..z” lowercase alphabet, “ “ space, “-“ minus sign, “.” full stop.
Position in the instrument list	Progressive order (Maximum number of instruments = 60)
Instrument code	1 ≤ Length ≤ 8 characters Allowable characters: 0…9 number digits, “A…Z” uppercase alphabet, “a..z” lowercase alphabet, “ “ space, “-“ minus sign, “.” full stop.
Serial number	Length ≤ 16 (can be empty) Allowable characters: 0…9 number digits, “A…Z” uppercase alphabet, “a..z” lowercase alphabet, “ “ space, “-“ minus sign, “.” full stop.
Instrument denomination	Length ≤ 16 (can be empty) Allowable characters: 0…9 number digits, “A…Z” uppercase alphabet, “a..z” lowercase alphabet, “ “ space, “-“ minus sign, “.” full stop.
Instrument manufacturer	Length ≤ 16 (can be empty) Allowable characters: 0…9 number digits, “A…Z” uppercase alphabet, “a..z” lowercase alphabet, “ “ space, “-“ minus sign, “.” full stop.
CHANNELS	
Parameter value of lower washing water flow limit of endoscope.	0 ≤ value ≤ 9999 Expressed ml (Es. 115 → 11.5 litres)
Parameter value of upper washing water flow limit of endoscope.	0 ≤ value ≤ 9999 Expressed ml (Es. 360 → 36.0 litres)
Parameter value of lower limit for washing pressure od endoscope.	-1000 ≤ value ≤ 2500 Expressed millibar (Es. 200 → 0.2 bar)
Parameter value of upper limit for washing pressure of endoscope.	-1000 ≤ value ≤ 2500 Expressed millibar (Es. 1500 → 1.5 bar)
Channels pump	If it has been setted to 0= no active channels pump (when small instruments are present);
AUX. CHANNELS	
Parameter value of lower washing water flow limit of endoscope.	0 ≤ value ≤ 9999 Expressed ml (Es. 115 → 11.5 litres)
Parameter value of upper washing water flow limit of endoscope.	0 ≤ value ≤ 9999 Expressed ml (Es. 360 → 36.0 litres)
Parameter value of lower limit for washing pressure of endoscope.	-1000 ≤ value ≤ 2500 Expressed millibar (Es. 200 → 0.2 bar)
Parameter value of upper limit for washing pressure of endoscope.	-1000 ≤ value ≤ 2500 Expressed millibar (Es. 1500 → 1.5 bar)
ATTENTION!	By setting these four values to zero, it means the instrument is without aux. channel.

It is possible to upload the archive instruments by insert the USB key into dedicated port and enter the menu: **USB → INSTRUMENT → Insert 3rd level password → USB IMPORT → Press START button.**







	ATTENTION
	• To modify the instrument archive file, it is recommended use a text editor (ex. Notepad). • If the file contains an instrument with the field "**INSTRUMENT CODE**" null (no character), the file is considered valid up to the previous instrument. All subsequent element are ignored. • If the file contains values that do not comply with the constraints described above, the file is considered incorrect. During the upload it is displayed the first line where the error is present..

11. ALARMS and EVENTS LIST

11.1 Logical description of alarm interventions

During machine operation, the operator is aided by **ALARMS** or **ALARM MESSAGES** which use visual signals on the display to advise him of possible anomalies in progress and machine alarms which have intervened.
Intervention of an ALARM during operation of the system is signalled by a message on the operator panel.
The alarm which appears on the panel remains active until the cause of intervention is removed, and the alarm reset.
The intervention of an alarm stops the wash cycle currently in progress.

11.2 List of alarm messages

The message includes the number of the alarm that has intervened and its name.

N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION
E 1	**power fail**	It shows power failure during cycle (Diagnostic is active if P3.04≠END CYCLE).
E 2	**open load. door**	Loading door open and/or unlocked during cycle.
E 3	**open unload.door**	Unloading door open and/or unlocked during cycle.
E 4	**load.door fail.**	Loading door locked but open (discrepancy).
E 5	**unload.door fail**	Unloading door blocked but open (discrepancy).
E 6	**doors problem**	Incorrect door position (both open or unblocked).
E 7	**unblock.door 1**	Loading door problems (loading side): a) Overtime lock door ref. P6.14 (problems on the door lock motor). b) During the door lock, the door has been opened.
E 8	**unblock.door 2**	Loading door problems: • Overtime lock door ref. P6.14 (problems on the door lock motor). • During block door, the door has been opened.
E 9	**unlocking 1fail.**	Overtime unlock loading door ref. P6.13.
E10	**unlocking 2fail.**	Overtime unlock unloading door ref. P6.13.
E11	**water 1 lack**	Interruption of water 1 filling (lack of new flowmeter impulse over P6.11). (Alarm for water dosing flowmeters (if P8.26=0)).
E12	**water 1**	Water 1 filling in the tank is not been completed within the maximum time P6.05. (Diagnostic is active if P6.05≠0)
E13	**water 1**	During water 1 filling in the tank, the water level is deactivated when the quantity measured by the flowmeter reaches or exceeds the parameter P7.09. (Diagnostic is active if P7.09≠0)

N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION
E14	**water 2 lack**	Interruption of water 2 filling (lack of new flowmeter impulse over P6.11)
E15	**water 2**	Water 2 filling in the tank is not been completed within the maximum time P6.05. (Diagnostic is active if P6.05≠0)
E16	**water 2**	During water 2 filling in the tank, the water level is deactivated when the quantity measured by the flowmeter reaches or exceeds the parameter P7.09. (Diagnostic is active if P7.09≠0)
E17	**no chemical 1**	Lack of chemical 1. No impulses within the time defined prom parameter (P6.12) with dosing pump active. (Diagnostic is active if P8.27<2)
E18	**no chemical 2**	Lack of chemical 2. No impulses within the time defined prom parameter (P6.12) with dosing pump active. (Diagnostic is active if P8.28<2)
E20	**no chemical 4**	Lack of chemical 4. No impulses within the time defined prom parameter (P6.12) with dosing pump active. (Diagnostic is active if P8.30<2)
E21	**heating element 1**	Discrepancy between the output control and the feedback input for the heating element (delay on the reading = P6.18)
E22	**no tank heating**	During the heating phase, the water in the tank is fallen below the level of heating ok.
E23	**drain problem**	The minimum chamber level during the drain has not been reached within the time defined from parameter P6.03 with drain valve open. (Diagnostic is active if P6.03≠0)
E24	**fan problem**	Diagnostic enabled if P6.19 ≠ 0, in this cases: - the fan pressure switch is open with the fan running at maximum speed - the fan pressure switch is closed with the fan off
E25	**drying min°C**	During the dryer the air temperature have not reach the temperature set at parameter P7.13, otherwise the temperature is under the set point if the set point is lower than parameter P7.13.
E26	**prewash max°C**	Tank temperature over maximum setup (P7.14) during prewashing.
E27	**tank probe lim°C**	Tank temperature over maximum value P7.31 during the working cycles, or P7.32 during sanitation cycle.
E28	**dryingprobelim°C**	Dryer temperature over maximum value P7.35.
E29	**drying max°C**	Tank temperature over maximum value P7.33 during the drying phase of working cycles, or P7.34 during sanitation cycle.
E30	**tank probe**	Tank temperature probe 1 failure.
E31	**tank probe 2**	Tank temperature probe 2 failure.
E32	**drying probe**	Dryer temperature probe 1 failure.
E33	**drying probe 2**	Dryer temperature probe 2 failure.
E34	**check temp.**	Appears when P3.02 = YES, only during the treatment phase and if all of these situations are occurred: a) Tank temperature over value P7.12. b) The temperature between the two probes has a difference higher than P7.11. c) The conditions a) and b) are present by over thirty seconds.
E35	**Serial connect.1**	No connection between main board and control panel board.
E36	**Serial connect.2**	No serial connection between expansion board to the keyboard (unloading side).
E37	**CAN serialconnec.**	No connection between main and slave board (can bus).
E38	**TIME**	During a treatment phase, the temperature after reaching the set point had a oscillation upon and under the set point. The delay on this reading is fixed at 30”. The alarm can be shown also with wrong setting of the chemical loading temperature: chemical loading temperature higher than the set point temperature.
E39	**no tank heating**	During tank heating phase, the temperature does not increase of 1°C into the time given by parameter P6.01.
E40	**chan.obstructed**	When the washing pump is ON, the water flowmeter (in the washing cycle with instruments) measure a flow lower than the minimum value defined than: • parameter for single instrument. • parameter P7.36 for selection of 2 instruments. • parameter P7.60 for selection of 3(+) instruments. (Diagnostic is active if P3.48≠0)

N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION
E41	chan.disconnect.	When the washing pump is ON, the water flowmeter (in the washing cycle with instruments) measure a flow higher than the maximum value defined than: • parameter for single instrument. • parameter P7.37 for selection of 2 instruments. • parameter P7.61 for selection of 3(+) instruments. (Diagnostic is active if P3.48≠0)
E44	instrum.leakage	During the cycle, activation number of leak valve (endoscope 1) has reached the maximum limit set by parameter P7.58. (it is excluded the first activation to put under pressure the instrument). (Diagnostic is active if P3.47≠0, P3.50=0 and P7.58>0)
E45	instrum.leakage	During the cycle, activation number of leak valve (endoscope 1) has reached the maximum limit set by parameter P7.58. (it is excluded the first activation to put under pressure the instrument). (Diagnostic is active if P3.47≠0, P3.50=0 and P7.58>0)
E46	washing flow	Failure of the flowmeter or washing pump: • When the washing pump is ON, the water flowmeter doesn't read a new impulse within P6.07. • When the washing pump is OFF, the water flowmeter read a number of impulses that exceed P7.20. (Diagnostic is active if P3.48≠0)
E47	flowmeter fail.1	The chemical flowmeter 1 had count an impulse number higher than set point + P7.21. (Diagnostic is active if P8.27<2)
E48	flowmeter fail.2	The chemical flowmeter 2 had count an impulse number higher than set point + P7.21. (Diagnostic is active if P8.27<2)
E50	flowmeter fail.4	The chemical flowmeter 4 had count an impulse number higher than set point + P7.21. (Diagnostic is active if P8.30<2)
E51	water 1 flowmeter	The water 1 flowmeter (control) had count an impulse number higher than set point + P7.20.
E52	water 1 flowmeter	The redundancy water flowmeter 1 had count an impulse number higher than set point + P7.20. (Diagnostic is active if P8.26=0)
E53	water 1 flowmeter	Discrepancy between control and redundancy flowmeters higher than P7.10. (Diagnostic is active if P8.26=0)
E54	Purge pressure	After the time set by P6.16 from the command to open the drain purge valve has been given (following the purge procedure pressurisation stage), the purge pressure has not dropped below the [P7.54 - P7.61] threshold or below the [P7.03 - P7.61] threshold. Active diagnostic if P3.39 is not =0 and P3.50=0.
E55	Conductivity probe	Fault in conductivity probe
E56	Conductivity	The conductivity value exceeds the maximum P7.60 threshold level, with a 5-second debounce
E57	flowmeter fail.1	Discrepancy between the measured value by time and by flowmeter higher than P7.10. (DETERGENT). (Diagnostic is active if P8.27=0)
E58	flowmeter fail.2	Discrepancy between the measured value by control flowmeter and redundancy flowmeter higher than P7.10. (DISINFECTANT). (Diagnostic is active if P8.28=0)
E60	flowmeter fail.4	Discrepancy between the measured value by control flowmeter and redundancy flowmeter higher than P7.10. (DISINFECTANT – bi-component). (Diagnostic is active if P8.30=0)
E61	no water 1	During water 1 filling in the break tank, the water level is not reaches level within time set by P6.06.
E62	break tank	Emergency level is active.
E63	break tank	Lower level is deactive when work level is active.
E64	drain problem	The minimum break tank level during the drain has not been reached within the time defined from parameter P6.04 with drain valve open.
E65	tank probe lim°C	The chamber temperature has exceeded of 5°C the set point during the treatment phase (controlled by the control probe), in case of: • Temperature set point ≠ 0. • Water filling completed;

N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION
E66	**dryingprobelim°C**	The air temperature has exceeded of 5°C the set point during the drying phase (controlled by the control drying probe), when the temperature set point ≠ 0.
E67	**check temp.**	Appears when P3.33=2, only during the drying phase and if all of these situations are occurred: a) Air temperature is over P7.06 value. b) Discrepancy between the two probes is over the P7.05 value. c) The conditions a) and b) are present by over thirty seconds.
E68	**chan.obstructed**	When the washing pump is ON, the water flowmeter (in the washing cycle without instrument) measure a flow lower than P7.44. (Diagnostic is active if P3.48≠0)
E69	**chan.disconnect.**	When the washing pump is ON, the water flowmeter (in the washing cycle without instrument) measure a flow higher than P7.45. (Diagnostic is active if P3.48≠0)
E70	**press.sensor LT1**	Failure on the leak test pressure transducer (instrument 1). (Diagnostic is active if P3.47≠0)
E71	**press.sensor LT2**	Failure on the leak test pressure transducer (instrument 2). (Diagnostic is active if P3.47≠0)
E72	**max pressure LT1**	The leak test pressure is higher than P7.38. (Diagnostic is active if P3.47≠0)
E73	**max pressure LT2**	The leak test pressure is higher than P7.38. (Diagnostic is active if P3.47≠0)
E74	**low pressure LT1**	During a cycle, the leak test pressure is lower than the minimum value, defined by one of the following conditions: • The set point P7.39 is not reached within P6.54 • Pressure lower than P7.39 – P.7.40 within P6.56 • Pressure lower than P7.39 –P.7.41 during the washing cycle. This alarm occurs also if the endoscope LT is failed, i.e. if the endoscope channel has a leakage. (Diagnostic is active if 3.47≠0)
E75	**low pressure LT2**	During a cycle, the leak test pressure is lower than the minimum value, defined by one of the following conditions: • The set point P7.39 is not reached within P6.54 • Pressure lower than P7.39 – P.7.40 within P6.56 • Pressure lower than P7.39 –P.7.41 during the washing cycle. This alarm occurs also if the endoscope LT is failed, i.e. if the endoscope channel hasa leakage. (Diagnostic is active if P3.47≠0)
E76	**LT1 drain failure**	The leak test pressure is not fallen under the max pressure value (P7.42) after the drain. (Diagnostic is active if P3.47≠0)
E77	**LT2 drain failure**	The leak test pressure is not fallen under the max pressure value (P7.42) after the drain. (Diagnostic is active if P3.47≠0)
E78	**water 2 flowmeter**	The water 2 flowmeter count a number of impulses that exceeds P7.20 with water filling solenoid valve OFF.
E79	**water 2 lack**	During water 2 filling in the break tank, the water level is not reached level within time set by P6.06.
E80	**washing pump**	Washing pump pressure transducer failure. (Diagnostic is active if P3.48≠0)
E81	**chan.obstructed**	When the washing pump is ON, the transducer measures a pressure higher than: • parameter for single instrument. • parameter P7.47 for selection of 2 instruments. • parameter P7.63 for selection of 3(+) instruments. (Diagnostic is active if P3.48≠0).
E82	**chan.disconnect.**	When the washing pump is ON, the transducer measures a pressure lower than: • parameter for single instrument. • parameter P7.46 for selection of 2 instruments. • parameter P7.62 for selection of 3(+) instruments. (Diagnostic is active if P3.48≠0)
E83	**chan.obstructed**	When the washing pump is ON, the transducer measures a pressure higher than P7.49. This alarm occurs during a treatment cycle or during a self-disinfection cycle. Check the filter and if necessary, replace. (Diagnostic is active if P3.48≠0).
E84	**chan.disconnect.**	When the washing pump is ON, the transducer measures a pressure lower than the P7.48. This alarm occurs during a treatment cycle or during a self-disinfection cycle. (Diagnostic is active if P3.48≠0)

N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION
E88	**lim °C sump probe**	Functional limit for the over temperature protection. The temperature measured form the sump probe is higher than the value of parameter P7.31 on working cycle and P7.32 on sanitation cycles. (Diagnostic is active if P3.49≠0)
E89	**Sump probe**	Failure on the sump probe. (Diagnostic is active if P3.49≠0)
E90	**lim °C sump probe**	The temperature measured from the sump probe is 5°C higher than the set point set for that phase (only if the set point is different form 0°C) (Diagnostic is active if P3.49≠0)
E91	**flowmeter fail.1**	The disinfectant redundancy flowmeter measures an excess of impulses higher than P7.21 with dosing pump OFF. (Diagnostic is active if P8.27≠0)
E92	**flowmeter fail.2**	The disinfectant redundancy flowmeter measures an excess of impulses higher than P7.21 with dosing pump OFF. (Diagnostic is active if P8.28≠0)
E94	**flowmeter fail.4**	The disinfectant redundancy flowmeter (for bi-component disinfectant) measure an excess of impulses higher than P7.21 with dosing pump OFF. (Diagnostic is active if P8.30≠0)
E95	**sanificat. Flow**	- The pressure switch of the sanitation circuit is OFF, but the sanitation valve is open and the pump is ON - The pressure switch of the sanitation circuit is ON, but the sanitation valve is OFF Delay on the pressure switch status reading = P6.52
E96	**purge pressure**	Failure on air pressure sensor for purge. (Diagnostic is active if P3.39≠0)
E97	**purge pressure**	The setpoint set by P7.54 is not reached within maximum time set by P6.59. (Diagnostic is active if P3.39≠0)
E98	**Max. air pressure**	The air pressure measured from the purge transducer (when the purge activity is in progress) has exceeds the maximum limit set by P7.57. (Diagnostic is active if P3.39≠0)
E99	**Min. air pressure**	The air pressure measured from the purge transducer (when the purge activity is in progress) has exceeds the minimum limit set by P7.59. (Diagnostic is active if P3.50=YES)
E100	**CAN serialconnec.**	(Diagnostic is active if P1.23≠0) No connection between main board and gateway (CAN/Ethernet) for interface the supervisor (Diagnostic is active when the machine is in wait mode).
E101	**AUX chan block**	(Diagnostics are enabled if p3.48 = 2) Possible damage has been caused to the flow meter or to the auxiliary instrument channel pump: - When the aux channel pump is active, the aux channel flow meter does not signal any new pulses beyond the time specified in p6.07; - When the aux channel pump is not in use, the aux channel flow meter signals an excessive amount of pulses exceeding the threshold specified in p7.20 (diagnostics are disabled during fan operation).
E102	**AUX press probe**	(Diagnostics are enabled if p3.48 = 2) Failure of the auxiliary instrument channel pump pressure sensor
E103	**AUX chan block**	(Diagnostics enabled if p3.48 = 2 and a single instrument is selected) - When the aux channel pump is active, the aux channel water circulation flow meter in cycles with instruments in the chamber has measured a flow rate lower than the min. threshold defined by the parameter of the instrument itself in the instrument file (blocked aux instrument channel) in the following conditions: - The calculation of the water flow rate is updated every 5 seconds while diagnostics are updated every 10 seconds after the first minute by the activation of the water circulation system; - An alarm is triggered if the flow rate remains continuously below the threshold for a period of time exceeding that specified in p6.26; - Diagnostics are disabled in case multiple instruments are selected.

N° AL.	DISPLAY MESSAGE	ALARM DESCRIPTION
E104	**AUX chan disc**	(Diagnostics are enabled if p3.48 = 2 and a single instrument is selected) - When the aux channel pump is active, the aux channel water circulation flow meter in cycles with instruments in the chamber has measured a flow rate exceeding the max. threshold defined by the parameter of the instrument itself in the instrument file (disconnected aux instrument channel) in the following conditions: - The calculation of the water flow rate is updated every 5 seconds while the diagnostics are updated every 10 seconds after the first minute by the activation of the water circulation system; - An alarm is triggered if the flow rate remains continuously above the threshold for a period of time exceeding that specified in p6.26; - Diagnostics are disabled in case multiple instruments are selected.
E105	**AUX chan block**	Diagnostics are enabled if p3.48 = 2 and a single instrument is selected) - When the aux channel pump is active, the aux channel pressure transducer in cycles with instruments in the chamber has measured pressure exceeding the max. threshold defined by the parameter of the instrument itself in the instrument file (blocked aux instrument channel) in the following conditions: - An alarm is triggered if the pressure remains continuously above the threshold for a period of time exceeding that specified in p6.27; - Diagnostics are enabled after the first minute by the activation of the water circulation system; - Diagnostics are disabled in case multiple instruments are selected.
E106	**AUX chan disc**	(Diagnostics are enabled if p3.48 = 2 and a single instrument is selected) - When the aux channel pump is active, the aux channel pump pressure transducer in cycles with instruments in the chamber has measured pressure lower than the min. threshold defined by the parameter of the instrument itself in the instrument file (disconnected aux instrument channel) in the following conditions: - An alarm is triggered if the pressure remains continuously below the threshold for a period of time exceeding that specified in p6.27; - Diagnostics are enabled after the first minute by the activation of the water circulation system; - Diagnostics are disabled in case multiple instruments are selected.
E107	**AUX press probe**	(Diagnostics are enabled if p3.48 = 2) When the water pressure of the aux instrument channel exceeds the maximum tolerance level of the instrument (2000 mbar). Diagnostics are enabled only when cycle is in progress (not while in stand-by status).
E108	**Sanif. flow**	With sanification valve open and washing pump activated, the water flow is not detected in the hydraulic field of the water flowmeters 1 (lack of new flowmeter pulse from beyond P6.11). Alarm active when for at least one of the two water dosing flowmeters this condition is verified (if P8.26=0).

11.3 List of warnings messages

DISPLAY MESSAGE	DESCRIPTION
press start	It is possible to start a cycle during a stand-by state.
no chemical 1	It informs that the product (DETERGENT) is: • run out if P8.27=2. • ending if P8.27<2.
no chemical 2	It informs that the product (DISINFECTANT) is: • run out if P8.28=2. • ending if P8.28<2.
no chemical 4	It informs that the product (DISINFECTANT – BI-COMPONENT) is: • run out if P8.30=2. • ending if P8.30<2.
salt loading	Warning to carry out loading procedure increases following the performance of a certain number of softener resin re-generations defined in p7.27 (as for configured regeneration, see p7.26 > 10).
- open door -	Inform that the door is open.
wait	Generic warn that inform to wait before to do a new action.
close door!	It warns to close the door open to allow proper initialization of the door.
ON PRINT	It appears when you try to start a cycle during the printing of the previous cycle.
UNBLOCKING wait	Automatic unlocking procedure after the unblock switch sequence after an alarm that interrupted a cycle.
ALARM	The safety procedure after an alarm is completed. It requests the manual unlock of the door pressing the STOP switch.
User interrupt wait	It warns that is in progress the safety procedure after a manual stop of working cycle.
NO DISINFECTION	Message shown at the end of the safety procedure after user interruption of the cycle. It requests the manual unlock of the door pressing the STOP switch.
END CYCLE	It is in progress the end cycle procedure after the last phase of cycle (the door remains locked).
airfilter obstr.	The air filter is obstructed.
Supervisor wait	It is in progress the data download of the performed cycle. It is necessary to wait to start new washing cycle.
NO Authorization	Response from Ares relating to denial of required instrument authorisation
Unidentified instrument	Response from Ares relating to required instrument not recognised by the supervisor's archive of reference
X REPETITION	(x = 1, 2, 3) states that repetition number "x" of the stage is in progress (as for stages which can be set with repetitions)

11.4 List of historical events

EVENT	DISPLAY MESSAGE	DESCRIPTION
FROM 1 TO 107	**SAME LIST OF ALARMS**	(SEE ALARMS LIST)
100	**OK**	CYCLE ENDS WITH SUCCESS
101	**NO DISINFECTION**	CYCLE HAS BEEN INTERRUPTED

12. INSTALLATION AND OPERATION

As highlighted in Annex A.3 of the ISO 15883:4 2009 standard, from the moment in which the EW 1 system has been installed on the site where it will subsequently be used, the customer/user shall be held responsible for its proper installation and operation.
This includes:

- Checks and installation tests;
- Operational tests;
- Performance qualification tests;
- Periodic tests;
- The use of process chemicals recommended by the manufacturer;
- The use of the EW 1 system in accordance with the manufacturer's instructions (by limiting the use of re-processable devices in the EW 1 system in favor of those recommended by the manufacturer).

13. RACK VERSION

The main device can be in vertical RACK configuration.
It refers to a configuration dealing with the disposing of two identical EW1, which are vertically placed, one on the machine top and the other one on the machine bottom.
Both these machines are equipped with:

- **2 screens (one corresponding to the machine top and the other one corresponding to the machine bottom);**
- **2 printers (one corresponding to the machine top and the other one corresponding to the machine bottom);**
- **a barcode reader system (one corresponding to the machine top and the other one corresponding to the machine bottom);**
- **a system of filters dedicated to each machine;**
- **a single chemical compartment in common for the two machines;**
- **a single electrical cabinet situated on the top of the machine.**
  That system has been designed, so that each machine is able to work on its own;

14. MAINTENANCE

14.1 General recommendations on maintenance

This machine has been designed only and exclusively for the reprocessing of flexible and rigid endoscopes and the thermal-disinfection of washing chambers. Therefore it is subject to continuous contact with aggressive detergents and contaminated instruments.
For this reason it is necessary to provide some useful instructions for the operators who will be performing maintenance on it.

The maintenance technicians, in normal operating conditions, are not subject to risks if they work safely using suitable means of protection.
In order to work safely the maintenance technician must:

- Carefully comply with the instructions set forth in this manual.
- Use safety devices appropriately and with care, as well as group and individual safety gear provided in the workplace.
- Use special care in making repairs or replacing mechanical parts (e.g. drain pump, etc.) on malfunctioning machines which have not completed the thermal disinfection cycle.

Maintenance operations for the machine described in this manual can be divided into "**Routine Maintenance**" and "**Special Maintenance**".

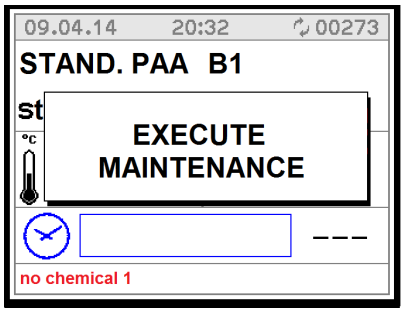
GENERAL GUIDELINES:

MACHINE STATUS
The machine must not be powered electrically and the dedicated safety device must be in the OFF position.
The person performing the task must ensure that there is no-one around the machine during this operation.

SAFETY SYSTEMS TO BE ADOPTED
The operation must be carried out in compliance with standards governing the use of disinfectant substances used (see technical information for the product being used), in compliance with standards concerning contact with parts of the machine which may be contaminated by pathogenic materials and with use of individual protection gear.

14.1.1 Maintenance request

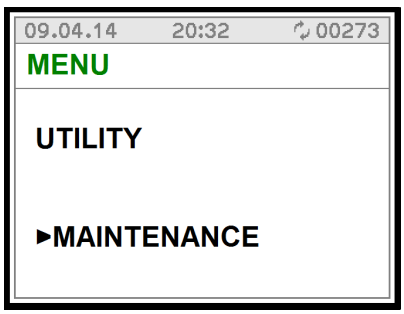
The machine displays the "**MAINTENANCE**" warning after a specified time or after a specified numbers of working hours according to parameter **P6.48**. This warning doesn't affect the normal use of machine. The service technician must do the maintenance operations in the shortest possible time.

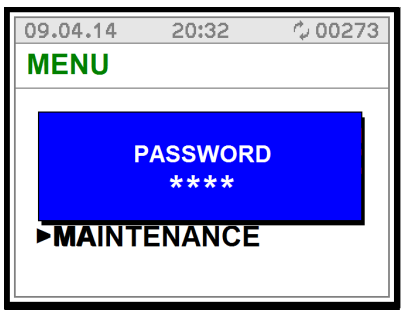


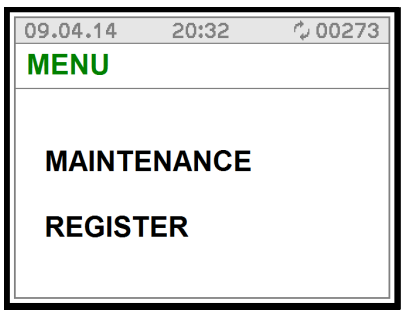
To clear the "**MAINTENANCE**" warning, follow the procedure:

1. Do the general maintenance of machine;
2. Enter the menu:

   UTILITY → MAINTENANCE → Insert 3rd level password → MAINTENANCE REGISTER → Press START button.







14.2 Table of routine maintenance

The following table shows the various routine maintenance tasks, their frequency, who is to perform them and the reference to the specific intervention form.
Each single task is more fully explained in the single reference forms.

Even if the water supply is relatively soft, the high temperature can cause the formation of residues which may create problems with the heating element, compromising the correct wash cycle and the reaching of the disinfection temperature.
For these reasons it is advisable to carry out regular cleaning as described below.

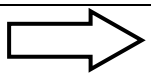
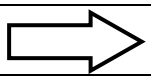
TABLE OF ROUTINE MAINTENANCE TASKS

ENDOSCOPES WASHER

Programmed maintenance scheme

Components	Step	months							Activity	TIME	RIFERENECE
	make every.....	3	6	9	12	15	18	24			
Chamber filters	make every day								Take off filters and cleaning.	10'	M1
Water solenoid filter	make every.....		x				x		Check, clean and if necessary replace.	10'	M4
Pre filter dryer F5	make every 100 hours								Replace.	2'	M5
Dryer HEPA filter	make every 300 hours								Replace.	2'	M5
Temperature probes	make every.....				x			x	During periodic validation, check the sensor status.	60'	M2
Safety thermostat	make every.....				x			x	Verify the sensor.	5'	
Chemical dosing pump	make every.....		x		x		x	x	Check the presence of leakage.	5'	
Chemical tank level sensor	make every.....		x		x		x	x	Check and clean the suction filter.	4'	
Connection pipe of dosing pump	make every.....		x		x		x	x	Check of crashing, any leakage or hardening.	10'	
Washing arms	every week								Check for free rotation. Open the cleaning caps and wash inside: check and in case cleaning the nozzle.	30'	M3
Door gasket	make every...		x		x		x	x	Verify the gasket and replace after 1000 cycles.	20'	
Washing pumps	make every...				x			x	Check for water leakage from the arm seal.	5'	
Water heating element	make every...				x			x	Check for water leakage fro the gasket.	1'	
Dryer heating elements (OPTIONAL)	none								Operation is checked by the control system.		
Water solenoid valves	make every...				x			x	Check for any leaks, if necessary remove and clean the membrane seat.	3'	
Drain pump	make every...				x			x	Check for any leaks, if necessary remove and clean the membrane seat.	3'	
Pressure switches	make every...				x			x	Operation is checked by the control system. In case of defect of control system of water levels, go on by empting the tank, blowing inside the black pipe connected to the pressure switch, in oder to free from obstructions.	10'	
Pipe of unloading water	make every...				x			x	Check the situation of pipe and the seal.	3'	
Pipes of loading water	make every...				x			x	Check the situation of pipe and the seal.	3'	

N.B.:
Routine maintenance tasks must be performed at the intervals set forth in the table.
It is however advisable to carry out single cleaning tasks anytime you feel they may be necessary.

In case the machine requires the replacement of one or more components, please refer to the manufacturer's spare part list.	
	**It is advisable to carry out a general check-up and to clean the appliance regularly, particularly if the supply water is very hard.**
	**Particular attention should be paid to heating element and the probe of thermostats.**

WARNING:

- **Do not clean the machine outside with high pressure water.**
- **Please contact the retailer that supplies your cleaning products for details of recommended methods and products for sanitizing the machine regularly.**
- **The machine has a safety thermostat that shuts down the power supply to the heating elements in the event of overheating.**
  To re-start the appliance the fault that caused overheating must be corrected.
- **Empty the tank of compressor before performing the maintenance.**

Every 12 months

- **Clean the diaphragms of solenoid valves and replace if necessary.**
- **Clean the thermostat probe.**

Even if the supply water is soft, the high working temperatures may cause limescale to build-up. Apart from damaging the resistors, limescale can also clog the nozzles in which case the correct tank temperature for thermodisinfection may not be reached.

ATTENTION

Before undertaking any sort of special maintenance or movement of machine, empty tanks and chemical dosing circuit from the chemical. It is advised to execute a treatment cycle without chemical.

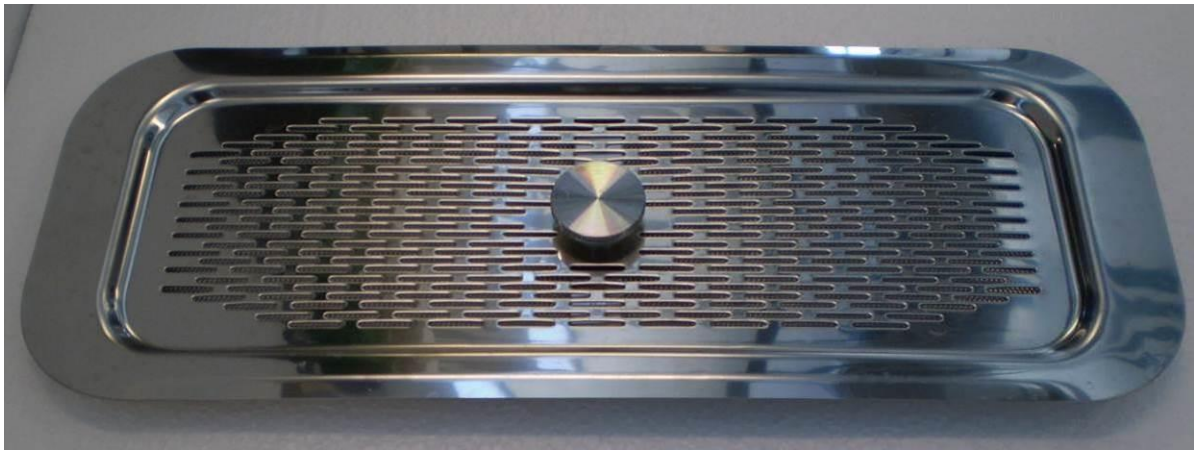
This procedure must be carried out in order to prevent contact of the chemical product with body parts and machine components that can be damage.

CLEANING OF WASHING CHAMBER DRAIN FILTERS

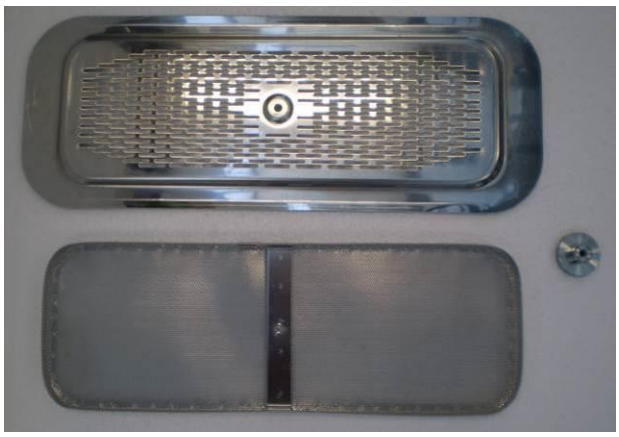
M1	Worker: **Ac**	Frequency of Intervention: **every day**

METHOD OF INTERVENTION: clean the washing chamber drain filters in the following manner:

- Open the washing chamber door and extract the basket.
- Extract the drain water filtering assembly from the chamber.



- Unscrew the threaded pin and remove the cover of the drain water filter basket.



- Clean the drain water filter basket. Remove residues deposited during various wash cycles.
- Remove and clean any deposits and incrustations from the wash chamber drain.
- Replace the clean filter on the wash chamber drain.
- Put the cover for the drain water filter back in place. Lock it in position with the threaded pin.
- Put the drain water filter group back in the washing chamber.

CLEANING OF WASHING CHAMBER TEMPERATURE PROBE		
M2	Worker: **Is**	Frequency of Intervention: **6 months**
METHOD OF INTERVENTION: clean the washing chamber temperature probe in the following manner:		
• Open the washing chamber door and extract the basket. • Check the washing chamber thermostat probe and clean it of any deposits or lime incrustations using a damp cloth and an appropriate detergent.		
Take care not to damage or move the probe		

CLEANING OF WASHING ARMS		
M3	Worker: **Ac**	Frequency of Intervention: **every week**
METHOD OF INTERVENTION: clean the washing arms as follows:		
• Open the washing chamber door and extract the basket.		

- Unscrew the fastening pin of the two rotors and extract them from the chamber.
- Unscrew the closure plug of the rear part of the nozzle and remove it.

- Carefully cleaned and remove any incrustations from the wash rotor nozzles using appropriate detergents.
- Put the plugs back in place at the ends of the wash arms. Make sure the gasket is properly positioned and in good condition. Replace it if necessary.
- Put the rotors back on the machine. Lock them in place with the previously removed fastening pin.

CHECK OF WASHING ARMS ROTATION		
	Worker: **Ac**	Frequency of Intervention: **every day**

METHOD OF INTERVENTION: check the washing arms rotation as follows:

- Open the washing chamber door and extract the basket.
- Check the free washing arm rotation for both upper and lower arms checking that no slowdown is shown from the washing arms.

CLEANING THE EXTERNAL BODY OF THE MACHINE		
	Worker: **Ac**	Frequency of Intervention: **every day**

METHOD OF CLEANING OUTER BODY

Use a damp cloth to clean the outer body of the machine.
Use only neutral detergents.
Do not use abrasive detergents or solvents and/or thinners of any kind.

METHOD OF CLEANING MARKING LABEL

Use a damp cloth to clean the marking label surface. Use only water or isopropyl alcohol.
Do not use abrasive detergents or solvents and/or thinners of any kind.

METHOD OF CLEANING CONTROL PANEL

Clean the control panel using only a soft cloth dampened with a product for the cleaning of plastic materials.

LIMESCALE REMOVAL TREATMENT		
	Worker: **Ac**	Frequency of Intervention: **whenever necessary**

METHOD OF INTERVENTION:

Use a descaling agent (we recommend vinegar) during an empty washing cycle with cold water (this is usually carried out every week unless the quality of the water requires a daily treatment in order to prevent the build-up of limescale and the blockage of the water jets).
As regards the quantity of the product to use, please comply with the instructions given on the technical data sheet of the product itself. In case vinegar is used, use 0.5 litres.
The descaling product must be poured into a container of the same size, positioned on an empty loading basket.
Use a washing programme with water at room temperature, without activating the drying cycle.

ATTENTION

Even if the feed water only contains a small amount of limescale, high temperatures can generate the formation of limescale residues. This, as well as problems that could be caused to the heating element, may cause the blockage of the nozzles, jeopardising the correct washing process and preventing the ideal disinfection temperature in the tank to be reached.

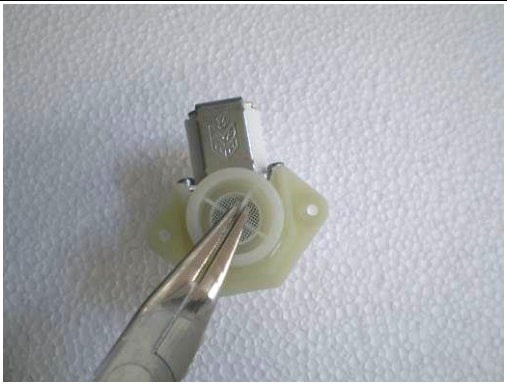
14.4 Procedure for special maintenance work

All special maintenance work is to be performed only by qualified, skilled personnel.
A table is shown below which includes possible special maintenance work that may be required.
If your machine should require special maintenance, please contact your retailer/distributor.

14.5 Table of special maintenance

See scheduled maintenance table.

CLEANING OF WATER SOLENOID VALVES INLET FILTERS		
M4	Worker: **Is**	Frequency of Intervention: **6 months or when necessary**
METHOD OF INTERVENTION: clean (or replace) the water solenoid valve filter as described below:		
• Close the water supply tap. • Loosen and completely unscrew the water supply pipe. • Remove the filter located inside the water supply pipe fitting and clean it, removing any incrustation or deposits by immersing it in a container of water, or in appropriate lime removal products if required.		

CLEANING OF DRYING PRE-FILTER

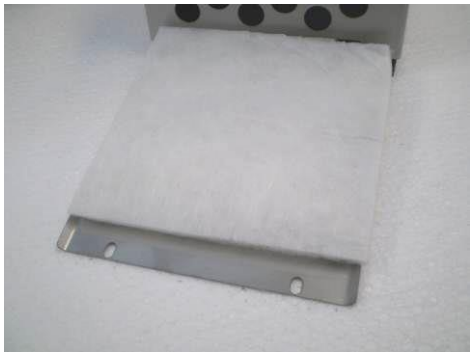
M5	Worker: **Is**	Frequency of Intervention: **100 hours**

METHOD OF INTERVENTION: clean (or replace) the drying system filter as described below:

- Remove the two screws from the drying system filter protective front panel and remove it from the machine.



- Extract the filter and clean it of any dust. If the filter is no longer usable, replace it with another filter of the same type.
- Carefully put the clean (or new) filter back in place. Use the screws to fasten the previously removed protective front panel.



CLEANING OF DRYING HEPA FILTER		
M6	Worker: **Is**	Frequency of Intervention: **300 hours**

METHOD OF INTERVENTION: clean (or replace) the drying system filter as described below:

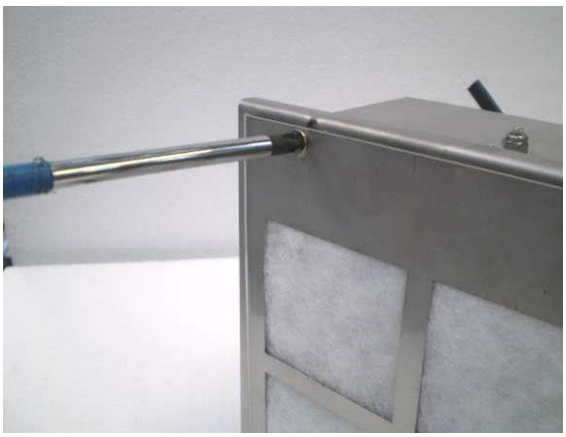
- Remove the two screws from the drying system filter protective front panel and remove it from the machine.



- Extract the pre-filter and than the HEPA filter: replace it with another filter of the same type.



- Carefully put the pre-filter back in place. Use the screws to fasten the previously removed protective front panel.

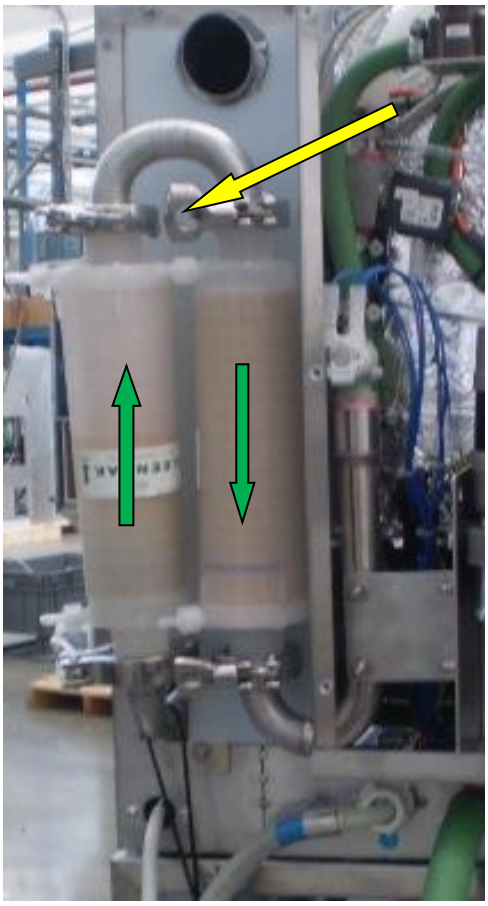



REPLACEMENT OF WATER FILTERS

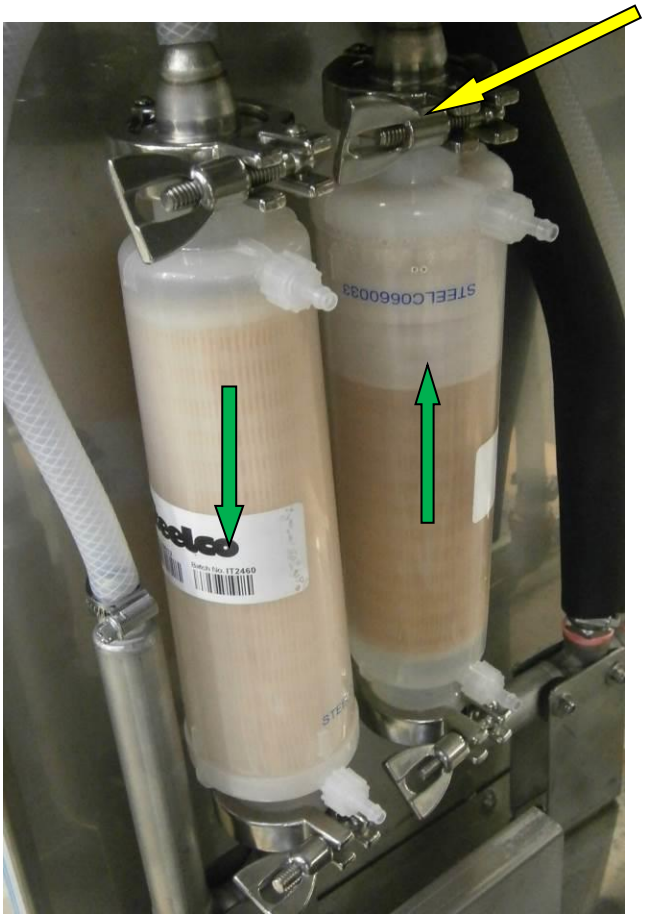
M7	Worker: **Is**	Frequency of Intervention: **every year**

METHOD OF INTERVENTION: replace water filters (0,1 micron and 0,45 micron) as described below:

- Remove water filters by unscrew pin of clamp (yellow arrow) and remove gasket between filters and machine pipe fitting.
- Replace water filters. Pay attention to flow direction (green arrow). Every filter has an arrow on the body to indicate the correct flow of water.
- Insert the gasket.
- Check the absence of leak.



MACHINE WITH ONE DOOR



MACHINE WITH TWO DOORS

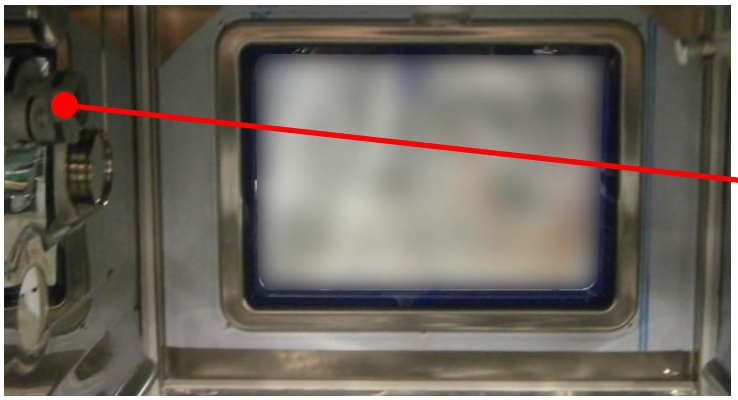
CHECKING OF SELF-DISINFECTION CONNECTOR

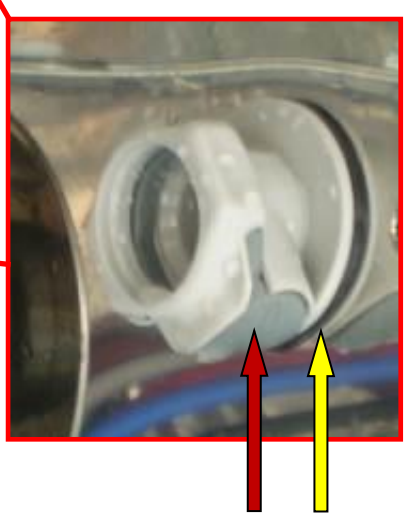
M8	Worker: **Is**	Frequency of Intervention: **every 3 months**

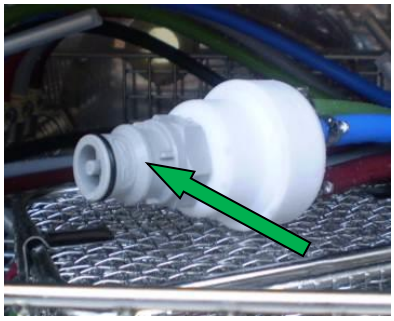
METHOD OF INTERVENTION: check the self-disinfection connector into the washing chamber as described below:

- Check that self-disinfection female connector (yellow arrow) is fixed in its place and that the gasket doesn't have leakage (check during self-disinfection cycle).
- Check that male connector (green arrow) can be freely connected/disconnected to/from female connector. To disconnect male connector, press grey button placed on female connector (red arrow).

ATTENTION:
Do not force the connection or disconnection of male connector when it is inserted to do not damage the gasket or the female connector.







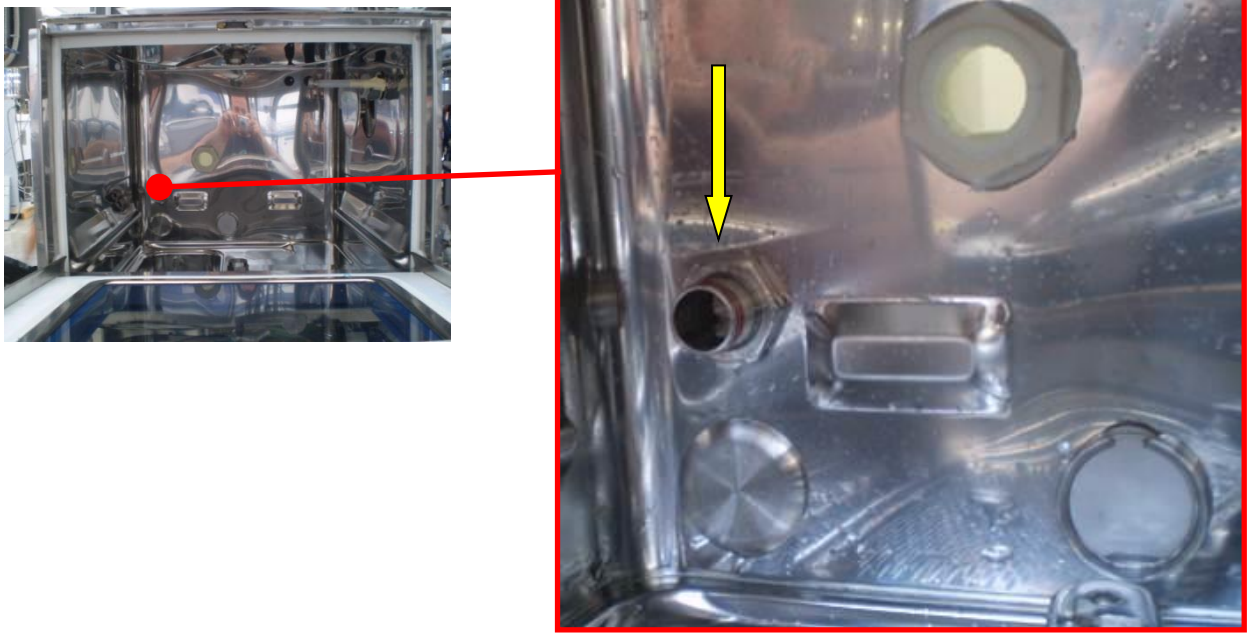
CHECKING/REPLACEMENT OF BASKET CONNECTION GASKET (only for one door version)

M9	Worker: **Is**	Frequency of Intervention: **every 3 months**

METHOD OF INTERVENTION: check of integrity of gasket for the connection between machine and basket, as described below:

- Check and/or replace the OR gasket on the connector machine and basket (yellow arrow).

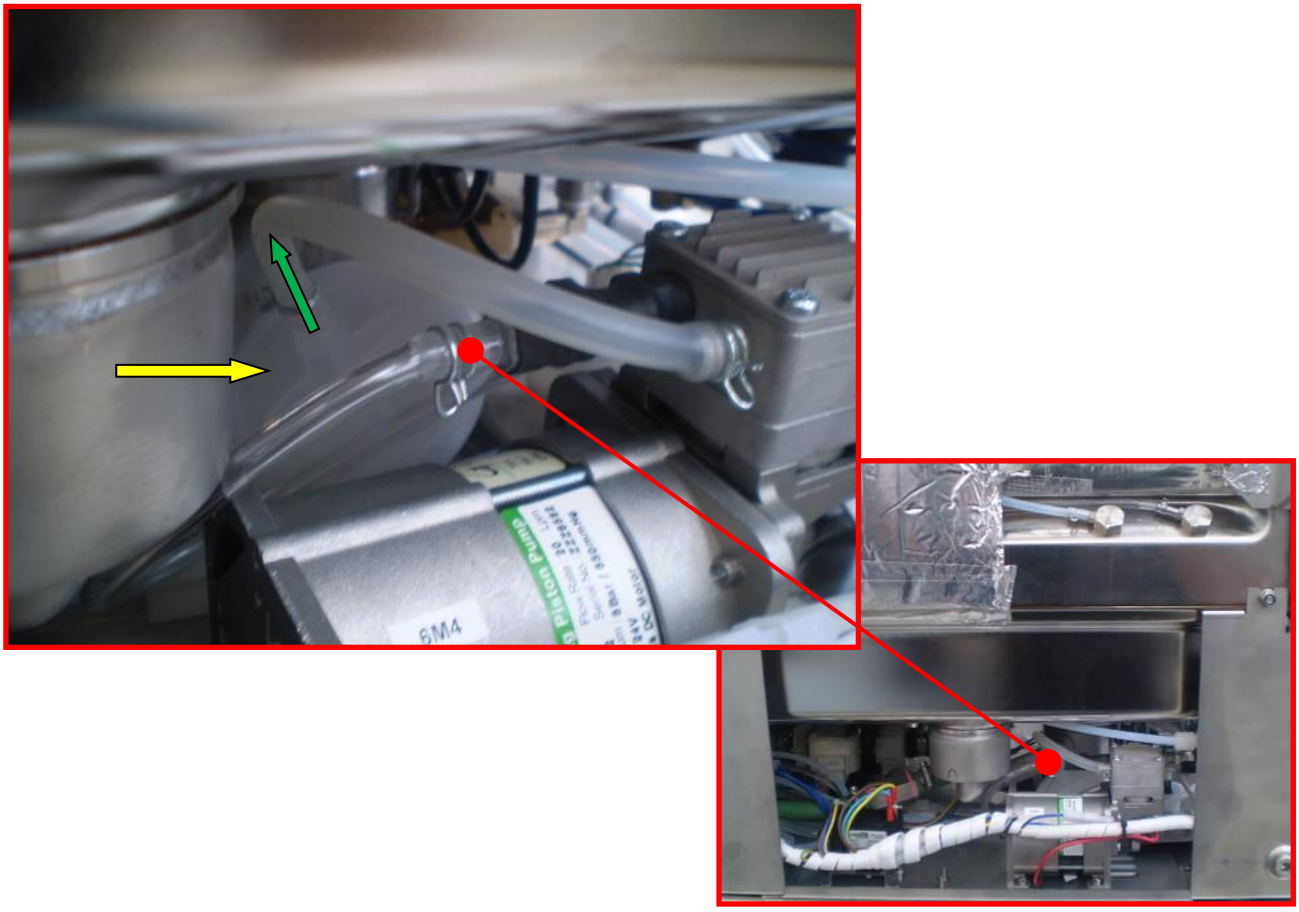
ATTENTION:
In case the OR-gasket is broken or too worn, the machine will show a disconnection alarm of endoscope channels.



REPLACEMENT OF AIR FILTER FOR LEAK TEST		
M10	Worker: **Is**	Frequency of Intervention: **every year**

METHOD OF INTERVENTION: replace leak test filter (0,2 micron) as described below:

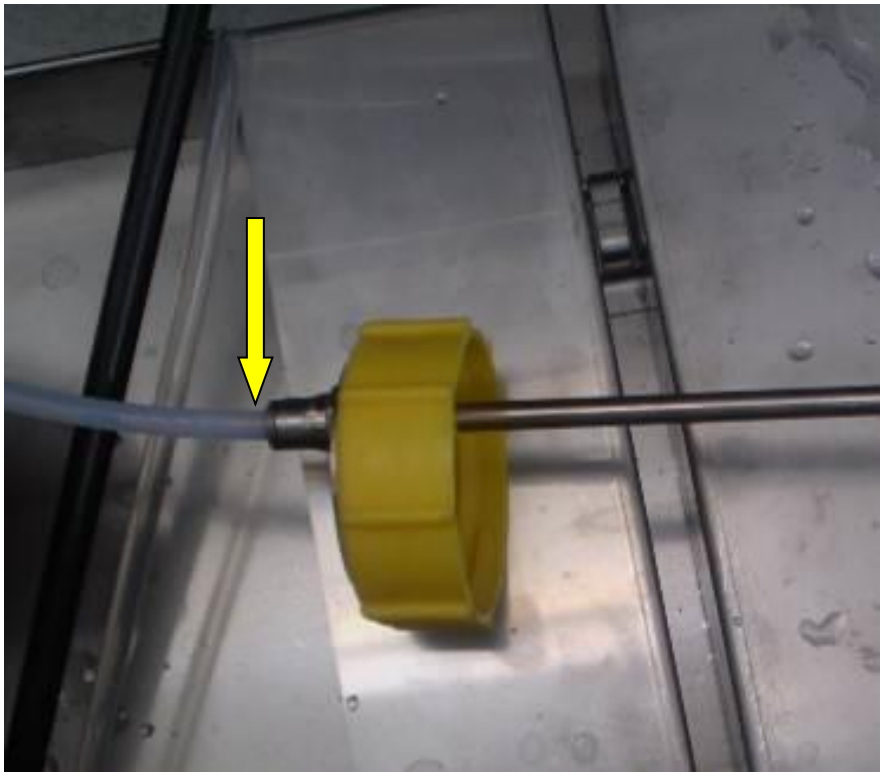
- Remove cover panels from the machine.
- The filter is placed on the left side of machine, looking from unloading side.
- Replace the filter (yellow arrow). Pay attention to the suction direction indicated on the filter body (green arrow).



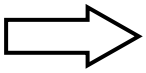
CHECKING THE SUCTION LANCE OF CHEMICAL PRODUCT 2 (DESINFECTANT)		
M11	Worker: **Is**	Frequency of Intervention: **every 3 months**

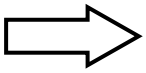
METHOD OF INTERVENTION: check the suction lance of chemical product 2 as described below:

- Check pipe integrity in the point indicated with yellow arrow, without remove the suction lance from container of chemical 2. In case the pipe is damaged or crushed, remove pipe from the connector (Inox fast coupling, rotating at 360°) and cut the damaged component.
- Check the suction pipe is not damaged throughout its length.



CLEANING OF SAFETY SIGNALS SURFACES		
	Worker: **Is**	Frequency of Intervention: **1 year**
METHOD OF INTERVENTION:		
Clean the safety signals surfaces with water or isopropyl alcohol, using a cloth.		

	**WARNING**
	Use a specific product to remove the lime scale. Avoid using products highly corrosive.

	**ASSISTANCE**
	Should your machine not work properly even after ordinary maintenance has been carried out, contact the Technical Support Centre of reference, describing the fault and giving the machine model and serial numbers.

15. PROBLEMS - CAUSES – SOLUTIONS

15.1 Introduction

This chapter includes possible problems which may occur during machine operation, along with their cause and solution. Should the inconveniences continue or take place frequently even after having carried out all the instructions stated in this chapter, please contact the Technical Support Centre of reference.

15.2 Problems - Causes - Solutions

P. MACHINE WILL NOT START:

C. Circuit breaker de-activated.

S. Place it in the "ON" working position.

C. Machine start switch de-activated.

S. Press the start button.

P. UPON GIVING START-UP COMMAND, WASHING CYCLE DOES NOT START:

C. The door is not correctly closed or locked.

S. Check door closure. Check that the door micro-switch is properly activated.

C. Micro-switch failure.

S. Check operation and replace as necessary.

C. No detergent in tank.

S. Turn the machine off and fill the tank.

P. MACHINE DOES NOT REACH THE SET TEMPERATURE FOR THE SELECTED WASHING CYCLE:

C. The thermostat probe of the washing chamber is dirty or covered with lime.

S. Clean the thermostat probe of the wash chamber, performing the routine maintenance described in chapter 13.

P. MACHINE DOES NOT PROPERLY RUN WASHING CYCLE:

C. The nozzles of the washing rotors are clogged by deposits or lime.

S. Clean the washing arms by carrying out the routine maintenance set forth in chapter 13.

C. The correct amount of water required for correct washing cycle does not arrive.

S. Ensure that the water is supplied at the correct pressure and that there are no obstructions.

C. The correct amount of water required for correct washing cycle does not arrive.

R. Completely close the tap for connection to the plumbing system located upstream from the machine and clean the filter as described in chapter 13.

P. DETERGENT FILLING PHASE DOES NOT OCCUR CORRECTLY:

C. Chemical dispensing pump not very efficient.

S. Perform the routine maintenance set forth in chapter 13.

C. Chemical dispensing pump failed.

S. Contact the Technical Support Centre of reference and ask for the assistance of an **authorized workshop technician** for the repair or replacement of the pump.

I. MACHINE DOES NOT PERFORM DRYING PHASE:

C. Air filter of drying system is dirty or clogged.

R. Clean the filter by carrying out the routine maintenance set forth in chapter 13.

C. The fan of the drying system does not work.

R. Check the electrical connections of the drying system.

R. Contact the Technical Support Centre of reference and ask for the assistance of an **authorized workshop technician** for the repair or replacement of the motor.

16. DECOMMISSIONING

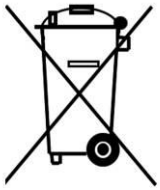
16.1 Instructions for disassembly of the machine

For demolition and subsequent disposal of your machine, proceed as follows:

- Disconnect the machine from the electrical power and water supply, and from the drain. With the machine disconnected, check that the water circuit is not pressurized.
- Contact the organization responsible for reporting and certifying machine demolition, in accordance with the laws in the country where the machine is installed.
- Carry out draining, storage and subsequent disposal of substances such as oils and grease which may be in the lubrication tanks in accordance with the law.
- When disassembling the machine, make sure to divide the materials it is made of according to their chemical makeup (iron, aluminium, bronze, plastic, etc.).
- Ensure that the floor where the machine or any parts of it are placed is made of washable materials, non-absorbent, and provided with adequate drainage to protect against accidental oil leaks or rust.
  These drains must carry any leakage to watertight collection containers.
- Cover the machine or parts of it with insulating covers to prevent rain or humidity from damaging the structure through oxidation or rust.

Following the legal requirements where the machine is installed and used, dispose of all materials and substances resulting from its disassembly.

16.2 Machine disposal



- For the dispose of the equipment get through to the manufacturer or distributor.
- Do not dispose of this equipment as miscellaneous solid municipal waste but arrange to have it collected separately.
- The re-use or correct recycling of the electronic and electrical equipment (EEE) is important in order to protect the environment and the well-being of humans.
- In accordance with European Directive WEEE 2012/19/EC, special collection points are available to which to deliver waste electrical and electronic equipment and the equipment can also be handed over to a distributor at the moment of purchasing a new equivalent type.
- The public administration and producers of electrical and electronic equipment are involved in facilitating the processes of the re-use and recovery of waste electrical and electronic equipment through the organisation of collection activities and the use of appropriate planning arrangements.
- Unauthorized disposal of waste electrical and electronic equipment is punishable by law with the appropriate penalties.

ANNEX A – TRAINING CERTIFICATE

devoted to hygiene

Certificate N° 569

Training Certificate

We certify that Mr. **XXXXXXXX** of the company **XXXXXXX** has attended the training course for

EW1

Riese Pio X, 17/10/2013

Person in charge for training

D. Alessi

Steelco S.p.A.

Via Balegante, 27 - 31039 - Riese Pio X (TV) - Italy
Tel. +39 0423.7561 Fax +39 0423.755528
Website: www.steelcospa.com

"For the Environmentally conscious"

MD 18#10 Rev.00

ANNEX B – WATER SAMPLING DURING THE FINAL RINSING CYCLE

Annex B provides both the instructions and the methods to take the microbiological sample by using the Steelco - Q water BSK (Professional Sampling Kit for Bacterial Check) as well as the relative key for the decoding and the reading of the results obtained.
In any case, please refer to current Legislation, National Guidelines and/or internal protocols.

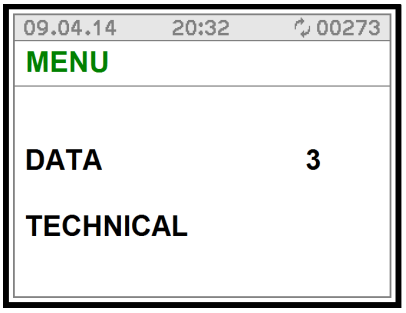
Q water BSK
Professional Sampling Kit for Bacterial Check
(code 99911268)

Endoscopes can be re-processed in the cycle dedicated to biological sampling. The only difference compared to a normal disinfection cycle refers to the interruptions during the final rinsing phase.

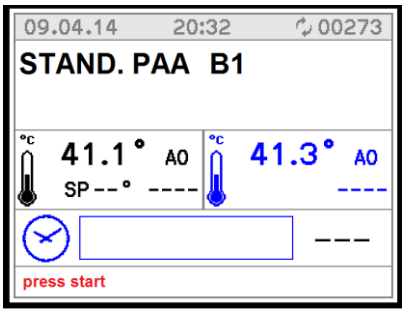
Water samples are taken during the final rinsing stage following the disinfection stage. The final rinsing cycle consists of two stages.
The sample must be taken during the final rinsing stage.

It is possible to take a water sample from the washing chamber by carrying out the following procedure:

- Set the parameter P3.42 = YES.
- Note: at the end of the water sample-taking cycle, restore the value to NO.



- Start the cycle to be tested.



- The machine will stop at the end of every stage and the door lock will be released.
- The **START** button will be flashing.
- Press the **START** button again to continue the cycle up to the desired point in order to take the water sample from the washing chamber.

- Open the door of the washing chamber and pick up the water sampling from the sump by using the Steelco - Q water BSK (Professional Sampling Kit for Bacterial Check). Be sure to perform the sampling in an aseptic way.

- Close the door and press the **START** button again to continue the cycle.

It is possible to activate the validation cycle by using the barcode reader, instead of changing the parameters.
The modification is valid for a cycle, then it will automatically reset.

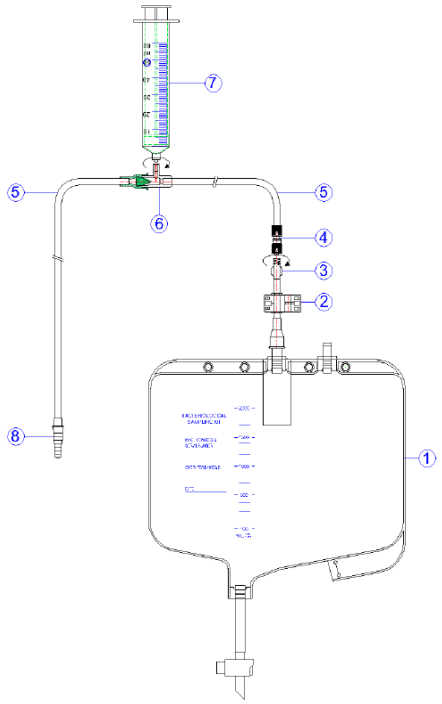
ENABLE C.V.T.

ATTENTION

- **Adequate measures must be implemented to avoid contamination of the sample during the water sample-taking stage. It is recommended to use the Steelco - Q water BSK (Professional Sampling Kit for Bacterial Check).**
- **The water samples for the microbiological test must be taken only during the final rinsing stage. Samples must not be taken during other stages of the process.**
- **Correct, periodic maintenance of the equipment prevents the risk of contamination. Follow the manufacturer's instructions as regards the replacement of bacteriological filters as well as any pre-filters.**
- **It is important to schedule appropriate thermal disinfection and chemical self-disinfection cycles in accordance with the manufacturer's instructions and internal protocols.**

SAMPLE TAKING

In order to take water samples during the final rinsing stage use the Steelco - Q water BSK (Professional Sampling Kit for Bacterial Check - code 99911268) and follow the instructions below:



1. Insert the 80 cm PVC pipe **(5)** into the sump of the washing chamber;
2. Suck the water from the washing chamber using the 60 ml syringe **(7)**;
3. Push the plunger of the syringe **(7)** to drain the water into the collection bag for biological fluids **(1)**;
4. Disconnect the collection bag for biological fluids **(3)** from the Kit and hand it to the microbiology laboratory quickly.
5. Compile the fields on the bag with the appropriate information:
   - Model and serial number of the machine;
   - Name and ID of the operator (that takes the water sampling);
   - Date.

REPROCESSING CYCLE EFFECTIVENESS TEST CARRIED OUT IN THE SUCTION CHANNEL

It is also possible to test the effectiveness of the entire re-conditioning cycle of the endoscope suction channel in the following way:

- Put 20 ml of sterile water in the suction channel (by using a sterile syringe) collecting it from a sterile container situated at the distal part of the tool;
- Clean the same channel using a special cleaning brush by cutting it directly inside the sterile water container. **WARNING:** the cleaning brush **MUST** be sterile.
- Remember to close all air and water channel valves before carrying out this procedure.
- Every single container must be accompanied not only by the request form but also by the endoscope type and serial number, the type of channel on which the brushing has been carried out, the name of the operator performing the sampling procedure as well as the report relating to the re-conditioning cycle carried out.

INTERPRETATION OF THE RESULTS

As for the interpretation of the results, please refer to the following table and criteria.

NUMBER OF COLONIES/100 ml	INTERPRETATION	ACTION
0	**SATISFACTORY**	---------
1-9 (carried out on a regular basis)	**ACCEPTABLE**	Count under reasonable control
10-100	**UNSATISFACTORY**	Investigate by implementing opportune thermal disinfection and chemical self-disinfection cycles
>100	**UNACCEPTABLE**	Stop the endoscope washer. Start two thermal disinfection and two chemical self-disinfection cycles. Repeat the test of control and take necessary actions as regards decontamination.

After interpreting the results, take opportune measures in accordance with the 2 attached tables.

NUMBER OF COLONIES (NOT PSEUDOMONAS)		
TVC LEVEL		**ACTION**
SATISFACTORY	**< 1cfu/100 ml**	• No action required.
ACCEPTABLE	**1 – 9 cfu/100 ml**	• The personnel must have carried out a self-disinfection cycle in the morning in accordance with the instructions provided by the endoscope washer manufacturer as well as internal protocols. • The carrying out of a daily self-disinfection cycle.
UNSATISFACTORY	**10 – 50 cfu/ ml**	• The personnel must carry out two thermal disinfection cycles (one after another - 80°C for 10 min) and a special chemical disinfection cycles (35°C for 10 min double chemical).
	51 – 100 cfu/ ml	• The personnel must carry out a special chemical disinfection cycle as well as a thermal disinfection cycle (one after another 80°C for 10 min one after another 55°C for 10 min double chemical). • Take another water sample.
UNACCEPTABLE	**> 100 cfu/100 ml**	**STOP USING THE ENDOSCOPE WASHER.** The person in charge of the endoscope washer must: • Carry out a special chemical disinfection cycle (55° double chemical for 10 min). • Carry out 2 thermal disinfections cycles (one after another to 80°C for 10 min). • Take another water sample. The personnel must: • Do not use the endoscope washer until it has been confirmed that the water sample has a contamination value of < 100 cfu/100 ml. • Continue to carry out a self-disinfection cycle on a daily basis. • Carry out a special thermal disinfection cycle on a daily basis. **Note: Advice will be obtained from the Lead Doctor for Infection Prevention and Control if there are recurring unacceptable TVC levels.**

NUMBER OF COLONIES (PSEUDOMONAS)		
TVC LEVEL		**ACTION**
SATISFACTORY	**< 1cfu/100 ml**	• No action required.
ACCEPTABLE	**1 – 9 cfu/100 ml**	• The personnel must have carried out a self-disinfection cycle in the morning in accordance with the instructions provided by the endoscope washer manufacturer as well as internal protocols. • The carrying out of a daily self-disinfection cycle. • Do not re-process endoscopes until it has been confirmed that the water sample has a contamination value of < 6 cfu/100 ml.
UNSATISFACTORY	**10 – 50 cfu/ ml**	• The personnel must carry out two thermal disinfection cycles (one after another - 80°C for 10 min) and a special chemical disinfection cycles (35°C for 10 min double chemical). • Do not re-process endoscopes until it has been confirmed that the water sample has a contamination value of < 6 cfu/100 ml. Do not re-process cystoscopes or bronchoscopes until it has been confirmed that water sample has a contamination value of < 10 cfu/100 ml.
	51 – 100 cfu/ ml	• The personnel must carry out two special chemical disinfection cycles (55°C for 10 min double chemical) and two thermal disinfection cycle (one after another 80°C for 10 min). • Take another water sample. • Do not re-process endoscopes until it has been confirmed that the water sample has a contamination value of < 6 cfu/100 ml. Do not re-process cystoscopes or bronchoscopes until it has been confirmed that water sample has a contamination value of < 10 cfu/100 ml. **Note: Advice will be obtained from the Lead Doctor for Infection Prevention and Control if there are recurring unacceptable TVC levels.**
UNACCEPTABLE	**> 100 cfu/100 ml**	**STOP USING THE ENDOSCOPE WASHER.** The person in charge of the endoscope washer must: • Replace all internal filters and clean the filter cases. Carry out 2 special chemical disinfection cycles (55° double chemical for 10 min). • Carry out 2 thermal disinfection cycles (one after another to 80°C for 10 min). • Take another water sample. The personnel must: • Do not use the endoscope washer until it has been confirmed that the water sample has a contamination value of < 100 cfu/100 ml. • Continue to carry out the thermal disinfection cycle on a daily basis. • Carry out a chemical self-disinfection cycle on a daily basis. • Do not re-process endoscopes until it has been confirmed that the water sample has a contamination value of < 6 cfu/100 ml. Do not re-process cystoscopes or bronchoscopes until it has been confirmed that water sample has a contamination value of < 10 cfu/100 ml. **Note: Advice will be obtained from the Lead Doctor for Infection Prevention and Control if there are recurring unacceptable TVC levels.**

ANNEX C – TEST PROCEDURE WHEN INSTALLING

ATTENTION

During the first installation of the equipment upon the site of use, with the aim of eliminating the risk of contamination of the endoscope washer, following maintenance operations that influence critical parts of the endoscope washer (wash pumps, etc.) or after transferring the endoscope washer to another operational centre, the following procedure **MUST** be carried out:

- 3 empty cycles carried out using only detergent;
- 2 complete cycles with detergent + disinfectant;
- 1 thermal disinfection cycle carried out at 80°C.

ATTENTION

USE ONLY CHEMICAL PRODUCTS THAT HAVE BEEN TESTED AND APPROVED BY THE MANUFACTURER AND IN USE WITH THIS SYSTEM.